S. HRG. 115–410

OVERSIGHT OF THE ENVIRONMENTAL PROTECTION AGENCY'S IMPLEMENTATION OF SOUND AND TRANSPARENT SCIENCE IN REGULATION

HEARING

BEFORE THE

SUBCOMMITTEE ON SUPERFUND, WASTE MANAGEMENT, AND REGULATORY OVERSIGHT

OF THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

OCTOBER 3, 2018

Printed for the use of the Committee on Environment and Public Works

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C O N T E N T S

OVERSIGHT OF THE ENVIRONMENTAL PROTECTION AGENCY'S IMPLEMENTATION OF SOUND AND TRANSPARENT SCIENCE IN REGULATION

WEDNESDAY, OCTOBER 3, 2018

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON SUPERFUND, WASTE MANAGEMENT,
AND REGULATORY OVERSIGHT,
Washington, DC.

The Committee met, pursuant to notice, at 2:20 p.m. in room 406, Dirksen Senate Office Building, Hon. Mike Rounds (Chairman of the Subcommittee) presiding.

Present: Senators Rounds, Booker, Barrasso, Carper, Ernst, Sullivan, Whitehouse, and Van Hollen.

OPENING STATEMENT OF HON. MIKE ROUNDS, U.S. SENATOR FROM THE STATE OF SOUTH DAKOTA

Senator ROUNDS. Good afternoon, everyone.

The Environment and Public Works Subcommittee on Superfund, Waste Management, and Regulatory Oversight is meeting today to conduct a hearing entitled Oversight of the Environmental Protection Agency's Implementation of Sound and Transparent Science in Regulation.

Today we will hear testimony from experts and members of the scientific community in order to explore opportunities for greater transparency and the use of the best available science at the EPA. Regulations created by the EPA help to protect the American people from tainted water, dirty air, and chemical exposure. The essential work completed by the EPA should always have as its basis protecting human health and the environment.

However, in the past, I have been concerned that the broad discretion and lack of transparency at the EPA has led the Agency to seek out the science that supports a predetermined policy outcome rather than relying upon the best available science before coming to conclusions. Failing to do so results in regulations that overly burden our economy without having a substantial impact on human health or environmental protection.

On April 30th, 2018, the EPA published a proposed rule entitled "Strengthening Transparency in Regulatory Science." This proposed rule would require the EPA to identify what science they used to come to regulatory decisions and to make those studies available to the public without compromising privacy protections.

The proposed rule would also require the EPA to take into account high quality studies that challenge current scientific assumptions. The proposal seeks to accomplish this without excluding historically relied upon studies by allowing the EPA Administrator to waive certain data access requirements on a case by case basis.

I thank the EPA for taking this important step, and I look forward to hearing from our witnesses today about the proposed rule.

In addition, on September 12th, 2017, I introduced S. 1794, the Honest and Open New EPA Science Treatment Act, commonly referred to as the HONEST Act. Companion legislation, H.R. 1430, was also introduced by Representative Lamar Smith. The HONEST Act passed the House of Representatives with bipartisan support on March 29th, 2017. Both bills have been referred to the Senate Committee on Environment and Public Works.

The HONEST Act would prohibit the EPA from proposing, finalizing, or disseminating regulations or guidance unless all scientific and technical information relied on to support those actions is based on the best available science. The bill also requires this information to be specifically identified and publicly available in a manner sufficient for independent analysis and substantial reproduction of research results. Finally, the HONEST Act requires the EPA to redact sensitive information such as personally identifiable information, trade secrets, or commercial or financial information.

It has been suggested by some that the EPA is incapable of providing greater scientific transparency because of privacy concerns. We have a responsibility to be sensitive to that issue, in part because we do not want to dissuade individuals from participating in environmental studies.

I believe the EPA should use, as a model, the privacy protections already used by other Federal agencies, including the de-identification protocols employed by the Department of Health and Human Services.

The EPA has a long history of creating burdensome, unnecessary regulations without giving the public an opportunity to fully vet the reasoning behind their decisions. We should all agree with providing greater transparency if it can be done without excluding legitimate scientific studies or compromising privacy. This is especially true if we can turn to other agencies, like the National Institutes of Health, for guidance on best practices.

Sound, reliable science is vital to helping us make important policy decisions that impact not just the health of American families, but their livelihoods. We should welcome vigorous debate on the science the EPA relies upon. Doing so will result in regulations that have the greatest benefit to human health and the environment, while doing the least harm to the economy. It will also result in regulations that can withstand legal challenges, providing industry with a level of certainty that allows them to make long-term investment decisions.

I would like to thank our witnesses for being here with us today, and I look forward to hearing your testimony.

At this time, I would like to recognize Senator Booker for a 5-minute opening statement.

Senator Booker.

OPENING STATEMENT OF HON. CORY A. BOOKER, U.S. SENATOR FROM THE STATE OF NEW JERSEY

Senator BOOKER. Mr. Chairman, I am really grateful. Thank you for this opportunity and for calling the hearing.

I just want to give a quick opening statement and will submit a lot more of my remarks for the record.

One thing the Chairman and I agree with is how important it is for our regulatory agencies, including the EPA, to use the best available science to inform their decisionmaking. That is why so many of their Federal environmental laws include a best available science requirement, including TSCA, something that all of us worked well together on, which members of this Committee spent lots of time working on and came to an incredible bipartisan consensus on.

I think we can also agree that transparency in agency decisionmaking is very important. So, I am glad to have the chance to have a discussion about the need for transparent, science based decisionmaking at the EPA.

Unfortunately, the policy proposals that are the subject of today's hearing include the EPA's proposed rule to purportedly strengthen transparency and regulatory science. This rule is far more likely to hinder science based regulation than help it. In fact, the EPA did not even consult with its own scientific advisory board, which is charged with determining whether the best available science is being used as a basis for EPA regulatory actions, regarding this public rule. Instead, it has chosen to ignore fundamental concerns raised by its own advisory board members.

I believe that the proposed rule put forth by the EPA and the legislation called the HONEST Act actually conflicts with the EPA's directive to use the best available science. Examples of this are common sense. If the EPA could not consider scientific studies unless the underlying data is made publicly available in a way that is sufficient for validation, the Agency would not be able to consider science gathered in the aftermath of environmental disasters, such as the Deepwater Horizon oil spill, which is not a scientifically replicable event.

The Agency would not be able to consider studies that rely on private medical information or confidential business information because that data could not be made publicly available. Obviously, it would be unethical for anyone to attempt to replicate public health analyses that used data gathered from different exposures to certain populations and communities, exposures to lead, to PCBs, to mercury, or other chemical contaminants. We would not want anybody to replicate those studies and that suffering.

For example, the EPA bases its standards for lead based paint hazards on long-term studies of children who were exposed to lead. Prohibiting the EPA from using these historical studies would cripple its ability to protect children and other vulnerable populations from lead, as one example.

I am looking forward to this afternoon's conversation, but I want to emphasize that if the EPA was truly concerned about transparency, there are actually meaningful actions the EPA could be immediately taking.

First, the EPA could release to the public the report that EPA completed more than 1 year ago regarding the cancer risks of formaldehyde, something we still have not released. Where is the transparency there?

Second, the EPA could convene an independent science advisory panel to recommend best practices for ensuring transparency in developing public health and environmental regulations, not ignore their own science based advisory board.

Finally, the EPA could immediately withdraw its May 2018 proposed rule to modify the Risk Management Program amendments where EPA is now proposing to restrict the public's access to information about what chemicals are being stored in facilities in their communities and neighborhoods. The public has a right to know about dangerous chemicals. Why is the EPA withholding that information from them?

So, I look forward to hearing from our witnesses. I will put more information for the record, but I again want to thank my colleague and friend for calling this important hearing having this discussion.

Senator ROUNDS. Thank you, Senator Booker.

Our witnesses joining us for today's hearing are Dr. Edward Calabrese, Professor, University of Massachusetts at Amherst School of Public Health and Health Sciences; Robert Hahn, Visiting Professor, Oxford University Smith School of Enterprise and the Environment; and Dr. Rush Holt, Chief Executive Officer, American Association for the Advancement of Science.

Welcome to all of you.

I would like to also, at this time, yield to Senator Booker to introduce Dr. Holt.

Senator BOOKER. I could not let this moment go, Chairman, without trying to make Dr. Holt blush a little bit, because he is nothing short of a New Jersey treasure. He served eight terms in the House of Representatives and was the Congress's only legitimate rocket scientist who was in Congress. He has had an extraordinary career of public service even beyond his eight terms as a House member.

Right now, he is a publisher of Science Family of Journals. In this role, Dr. Holt leads the largest multidisciplinary scientific and engineering membership organization. Prior to joining AAAS, Dr. Holt was not only a Congressperson, but he was probably one of the best well known leaders in his State of New Jersey because he was the most nerd-chic guy in our State.

Dr. Holt has been named one of Scientific American magazine's 50 national visionaries contributing to a brighter technological future and a champion of science by the Science Coalition. From 1989 to 1998 Dr. Holt was Assistant Director of the Princeton Plasma Physics Laboratory, and he previously taught physics and public policy at Swarthmore College.

And I just want to get rid of the rumor. In the TV show The Big Bang Theory, Sheldon's character was not based on Dr. Holt.

[Laughter.]

Senator VAN HOLLEN. Mr. Chairman, if I could just briefly add to that.

I want to welcome all the witnesses, but it is good to see my friend, Rush Holt. We served together for many years in the House,

and everything that the Ranking Member said is 100 percent true, but he left out a very important fact, which I believe you are the only Member of Congress who won Jeopardy or was a finalist on Jeopardy, as well.

I apologize because I am going to have to leave, and I am going to try and come back, but I appreciate the opportunity. Thanks.

Senator ROUNDS. Thank you.

Once again, thank you, Senator Booker.

Thank you to all of our witnesses for taking the time to participate today; we most certainly appreciate it.

We will now turn to our first witness, Dr. Calabrese, for 5 minutes.

I would share with you all your opening statements will all be included, without objection, for the record. We would ask if you could try to limit your opening remarks to about 5 minutes; that would be greatly appreciated by the Committee as well.

Dr. Calabrese, welcome, and you may begin.

STATEMENT OF EDWARD J. CALABRESE, PROFESSOR, UNIVERSITY OF MASSACHUSETTS AT AMHERST SCHOOL OF PUBLIC HEALTH AND HEALTH SCIENCES

Mr. CALABRESE. Thank you very much.

Good afternoon, Chairman Rounds, Ranking Member Booker, and distinguished members of the Committee. My name is Edward Calabrese, and I am a Professor of Toxicology at the University of Massachusetts School of Public Health, Amherst, Mass. I am pleased to share with you my views on the EPA risk assessment transparency proposal.

Briefly, I have been at UMass for 42 years, teaching and researching in the areas of toxicology and risk assessment. I have authored nearly 900 papers in the peer reviewed literature, about a dozen books, served on multiple National Academy committees such as the Safe Drinking Water Committee and the Air Cabin Safety Committee, which recommended to the FAA to eliminate smoking on commercial aircraft, a recommendation that was quickly adopted.

For the past 20 years, I have been funded by the Air Force Office of Scientific Research to assess the nature of the dose response of toxic substances in the low dose zone in order to protect the health and the well-being of Air Force personnel. These activities have led to a major dose response revolution in the area of biology, medicine, toxicology, and risk assessment.

The USEPA has proposed a general framework to strengthen its regulatory science procedures via enhancing transparency in multiple ways. I applaud EPA for this proposal as it is not only timely but requires scientific and administrative accountability. The proposal is broad, requiring the Agency to provide the scientific basis for proposed regulations, including underlying data. While this is an excellent start, the Agency should also commit to providing detailed explanations and public access to data that the Agency considered and decided not to use for regulation.

In addition, most EPA scientific decisions are based on multiple assumptions, some of which are frequently hidden, obscured, and often silent drivers of regulatory action; for example, the use of

highly susceptible and often poorly predictive animal models. These assumptions need to be fully described, documented, and justified. This process should also include the basis for why EPA chose not to adopt the use of other or different approaches and/or assumptions. Thus, EPA's transparency proposal is excellent as far as it goes, but it needs to be expanded; it also requires an explanation of what was considered, and why it was rejected.

Multiple high profile controversies exist over the lack of availability of data sets used by EPA for regulatory decisions. While I have not been involved in Agency disputes over such data bases, I would like to note two personal examples that speak to data sharing with EPA and the scientific community, and the value offered to the Agency and the public. For example, in the 1980s I developed a data base of 6,000 dose responses concerning whether carcinogens could cause cancer with but a single dose. I made many presentations on this topic across the country, including several NAS Committees concerned with acute/short term exposures to toxic and carcinogenic agents in the aftermath of the 1984 Bhopal, India, disaster. Following these presentations, EPA asked me to provide it with a copy of the single exposure carcinogen data base. These presentations and the shared data base were intended to assist the NAS in guidance to EPA.

Second, my group at the University of Massachusetts conducted multiple studies on soil ingestion in children and adults. Subsequently, EPA used these data for clean up standards of soil and dust contamination for the benefit of children and adults. Our group created a public Web site with all our data available for use by the EPA and the world, minus personal identifiers.

These are examples to enhance improved science and transparency in regulatory activities. The EPA transparency proposal is crucial to enhance public health and should have been adopted in some form 20 or more years ago.

With regards to risk assessment, "data transparency" should require the EPA to routinely receive and openly evaluate for accuracy any information that could significantly alter the key scientific assumptions underlying and dictating regulatory policy and practices. This current EPA proposal does just that by stating that EPA should no longer use the LNT, or linear non-threshold, model as the default in risk assessment.

Movement away from LNT as the accepted default model is long overdue. It is compellingly supported by many peer reviewed scientific and historical studies and is badly needed to advance toward a more science based approach in assessments of human and ecological risks.

Within this context, I have researched the nature of the dose response in the low dose zone for more than 30 years and have published about 500 papers on this topic in peer reviewed journals. I have organized and conducted international conferences on the topic for over 25 years and have created a professional journal called Dose Response, for which I am the editor in chief. I have also written chapters on dose response for some of the major textbooks.

More recently, in the past decade I have exhaustively researched the historical origins and scientific foundations of EPA's LNT model and have found it sorely wanting. LNT is important because

it is the model upon which all our cancer risk assessments and key health and ecological regulations are based. What I have learned was unexpected, and it has turned more than 30 years of my understanding of toxicology upside down. It has revealed that what I taught for so many years at UMass and have written about so ardently in my many articles and books was factually wrong. What I learned in this reevaluation of LNT was that the field of toxicology and our regulatory agencies, such as EPA, had made a serious error in their understanding of LNT and incorrectly applied it to the assessment of human and ecological risks.

During my research and publication over a dozen peer reviewed journal articles on the scientific origins of LNT, I learned that the LNT dose response model which drives cancer risk assessment was based on flawed science, on ideological biases by leading radiation geneticists, on scientific misconduct by National Academy of Sciences genetics panel during the atomic radiation scares of the 1950s, and on a 40-year mistaken assumption by yet another NAS committee.

I learned that these flaws, biases, misconducts, and mistakes ultimately gave rise to the EPA model and were perpetuated down to the present day by subsequent committees of the NAS and EPA. What began for me as a routine academic exercise to affirm the scientific origins and credibility of LNT ironically ended as a remarkable repudiation of its scientific adequacy, challenging both the old guard and an EPA risk assessment process that is in need of significant revision.

My findings show that the EPA adopted LNT for all the wrong reasons and built their flawed risk assessment edifice upon it, failing to perform due diligence expected by Congress and the public.

Senator ROUNDS. If I could ask you to perhaps wrap it up. Everything will be included in the record.

Mr. CALABRESE. It is one paragraph more, Senator.

Senator ROUNDS. Yes. Go ahead.

Mr. CALABRESE. Second, extensive research findings that contradict EPA's LNT model have now been documented in the scientific literature.

With so many failed LNT predictions, EPA must not continue to use LNT as its default. A crusading EPA was young, impressionable, inexperienced, and somewhat blinded, and it adopted the flawed LNT model, believing that it would save the world. Not only was it wrong scientifically; the LNT in many ways has damaged public health and the economy, the worst of both worlds.

The present EPA proposal to consider non-linear models for risk assessment is a critical, positive development. Thus, I believe that the EPA has made a bold and constructive proposal that is scientifically sound and should be strongly supported, approved, and implemented.

Thank you very much.

[The prepared statement of Mr. Calabrese follows:]

Dr. Edward J. Calabrese
Professor of Toxicology
University of Massachusetts, Amherst

Edward J. Calabrese is a Professor of Toxicology at the University of Massachusetts, School of Public Health and Health Sciences, Amherst. Dr. Calabrese has researched extensively in the area of host factors affecting susceptibility to pollutants, and is the author of over 850 papers in scholarly journals, as well as more than 10 books, including Principles of Animal Extrapolation; Nutrition and Environmental Health, Vols. I and II; Ecogenetics; Multiple Chemical Interaction; Air Toxics and Risk Assessment; and Biological Effects of Low Level Exposures to Chemical and Radiation. Along with Mark Mattson (NIH) he is a co-editor of the recently published book entitled Hormesis: A Revolution in Biology, Toxicology and Medicine. He has been a member of the U.S. National Academy of Sciences and NATO Countries Safe Drinking Water committees, and on the Board of Scientific Counselors for the Agency for Toxic Substances and Disease Registry (ATSDR). Dr. Calabrese also serves as Chairman of the Biological Effects of Low Level Exposures (BELLE) and as Director of the Northeast Regional Environmental Public Health Center at the University of Massachusetts. Dr. Calabrese was awarded the 2009 Marie Curie Prize for his body of work on hormesis. He was the recipient of the International Society for Cell Communication and Signaling-Springer award for 2010. He was awarded an Honorary Doctor of Science Degree from McMaster University in 2013. In 2014 he was awarded the Petr Beckmann Award from Doctors for Disaster Preparedness.

Over the past 25 years Professor Calabrese has redirected his research to understanding the nature of the dose response in the low dose zone and underlying adaptive explanatory mechanisms. Of particular note is that this research has led to important discoveries which indicate that the most fundamental dose response in toxicology and pharmacology is the hormetic-biphasic dose response relationship. These observations are leading to a major transformation in improving drug discovery, development, and in the efficiency of the clinical trial, as well as the scientific foundations for risk assessment and environmental regulation for radiation and chemicals.

October 3, 2018

Testimony of Edward J. Calabrese, Ph.D

Senate Environment and Public Works Subcommittee on Superfund, Waste Management and Regulatory Oversight

"Oversight of the Environmental Protection Agency's Implementation of Sound and Transparent Science in Regulation"

Good afternoon, Chairman Rounds, Ranking Member Booker, and distinguished members of the Committee. My name is Edward Calabrese, and I am a professor of toxicology at the University of Massachusetts, School of Public Health Sciences, Amherst, Massachusetts. I am pleased to share with you my views on the EPA Risk Assessment Transparency Proposal.

Briefly, I have been at UMass for 42 years, teaching and researching in the areas of toxicology and risk assessment. I have authored nearly 900 papers in the peer-reviewed literature, about a dozen books, served on multiple National Academy of Sciences (NAS) committees such as the Safe Drinking Water Committee and the Air Cabin Safety Committee, which recommended to the FAA to eliminate smoking on commercial aircraft, a recommendation that was quickly adopted. For the past 20 years I have been funded by the Air Force Office of Scientific Research to assess the nature of the dose response of toxic substances in the low dose zone in order to protect the health and wellbeing of Air Force

personnel. These activities have lead to a major dose-response revolution in biology, medicine, toxicology and risk assessment.

The U.S. EPA has proposed a general framework to strengthen its regulatory science procedures via enhancing transparency in multiple ways. I applaud EPA for this proposal as it is not only timely but requires scientific and administrative accountability. The proposal is broad, requiring that the Agency provide the scientific basis for proposed regulations, including underlying data. While this is an excellent start, the Agency should also commit to providing detailed explanations and public access to data that the Agency considered and decided not to use for regulation. In addition, most EPA scientific decisions are based on multiple assumptions, some of which are frequently hidden, obscured and often silent drivers of regulatory action. (e.g., the use of highly susceptible and often poorly predictive animal models). These assumptions need to be fully described, documented, and justified. This process should also include the basis for why EPA chose not to adopt the use of other/different approaches and/or assumptions. Thus, EPA's transparency proposal is excellent as far as it goes, but it needs to be expanded; it also requires explanation of what was considered and why it was rejected.

Multiple high profile controversies exist over the lack of availability of key data sets used by the EPA for regulatory decisions. While I have not been involved

in Agency disputes over such databases, I would like to note two personal examples that speak to data sharing with EPA and the scientific community and the value offered to the Agency and the public. In the 1980s I developed a database of 6,000 dose responses concerning whether carcinogens could cause cancer with but a single dose. I made many presentations on this topic across the country, including several to NAS Committees concerned with acute/short term exposures to toxic and carcinogenic agents in the aftermath of the 1984 Bhopal, India disaster. Following these presentations, EPA asked me to provide it with a copy of the single-exposure carcinogen database. These presentations and the shared database were intended to assist the NAS in guidance to EPA. Second, my group at the University of Massachusetts conducted multiple studies on soil ingestion in children and adults. EPA subsequently used these data for clean-up standards of soil/dust contamination for the benefit of children and adults. Our group created a public website with all our data available for use by the EPA and the world. These are examples to enhance improved science and transparency in regulatory activities. The EPA transparency proposal is crucial to enhance public health and should have been adopted 20 or more years ago.

With regard to risk assessment, "data transparency" should require the EPA to routinely receive and openly evaluate for accuracy any information that could significantly alter the key scientific assumptions underlying and dictating

regulatory policy and practices. This current EPA proposal does just that by stating that the EPA should no longer use the LNT (linear non-threshold) model as the default model in risk assessment. Movement away from LNT as the accepted default model is long overdue. It is compellingly supported by many peer-reviewed scientific and historical studies, and it is badly needed to advance toward a more science-based approach in the assessments of human and ecological risks.

Within this context I have researched the nature of the dose response in the low-dose zone for more than 30 years and have published about 500 articles on this topic in peer-reviewed journals. I have organized and conducted international conferences on the topic for over 25 years and created a professional journal called Dose Response, for which I am the editor in chief. I have also written chapters on dose response for some of the major toxicology textbooks. More recently in the past decade, I have exhaustively researched the historical origins and scientific foundations of the EPA's LNT model and have found it sorely wanting. LNT is important because it is the model upon which all our cancer risk assessments and key health and ecological regulations are based. What I have learned was unexpected and has turned more than 30 years of my understanding of toxicology upside down. It has revealed that what I had taught for so many years at UMass and had written about so ardently in my many articles and books was factually wrong. What I learned in this re-evaluation of LNT was that the field of

toxicology and our regulatory agencies, such as EPA, had made a serious error in their understanding of LNT and incorrectly applied it to the assessment of human and ecological risks.

During my research and publication of over a dozen peer-reviewed journal articles on the scientific origins of the LNT, I learned that the LNT dose-response model, which drives cancer risk assessment, was based on flawed science, on ideological biases by leading radiation geneticists, on scientific misconduct by an NAS Genetics Panel during the atomic radiation scares of the1950's, and on a 40-year mistaken assumption by yet another NAS Committee. I learned that these flaws, biases, misconducts and mistakes ultimately gave rise to the LNT model and were perpetuated down to the present day by subsequent Committees of the NAS and the EPA. What began for me as a routine academic exercise to affirm the scientific origins and credibility of LNT ironically ended as a remarkable repudiation of its scientific adequacy, challenging both the old guard and an EPA cancer-risk assessment process that is in need of significant revision.

My findings show that the EPA adopted the LNT for all the wrong reasons and built their flawed risk assessment edifice upon it—failing to perform the due diligence expected by Congress and the public. Secondly, extensive research findings that contradict the EPA's LNT model have now been documented in the scientific literature. With so many failed LNT predictions, EPA must not continue

to use the LNT model as its default. A crusading EPA that was young, impressionable, inexperienced and somewhat blinded adopted the flawed LNT model—believing it would save the world. Not only was it wrong scientifically, the LNT in many ways has damaged public health and the economy—the worst of both worlds. The present EPA proposal to consider non-linear models for risk assessment is a critical, positive development. Thus, I believe that EPA has made a bold and constructive proposal that is scientifically sound and should be strongly supported, approved, and implemented.

Senate Committee on Environment and Public Works
Subcommittee on Superfund, Waste Management, and Regulatory Oversight
Hearing entitled, *"Oversight of the Environmental Protection Agency's Implementation of Sound and Transparent Science in Regulation"*
October 3, 2018
Questions for the Record for Dr. Calabrese

Senator Markey:

Senator Markey: General Response Statement:

None of the questions provided by Senator Markey directly addressed subjects discussed in my prepared testimony for the Senate hearing of October 3, 2018. Only question #1 was related by way of a potential implication but still was beyond the scope of my testimony. Nonetheless, to the extent possible, I will attempt to address the questions asked.

1. Some of the important regulatory actions by EPA in the pesticide field, such as the suspension order that took aldrin/dieldrin off the market, were based on animal data, such as induction of cancer in mice. At the time there was no proof that aldrin/dieldrin caused cancer in humans, and no ethical way of establishing that by experimentations. Would that suspension be possible today, if the "sound and transparent science" proposal were enacted?

I don't think that there is a clear answer to this question since the EPA proposal is very open ended and non-prescribed for how cancer risk assessment would be undertaken. It appears that EPA is opting for more freedom for their scientists to judge risks and perform their assessment on a case-by-case basis. That is, I think that they want their scientists to have the flexibility to follow the data rather than be forced to follow a very prescribed default model approach, such as the LNT. I have submitted my comments into the record, offering a prescribed basis called model uncertainty. This process integrates optimal features of LNT, threshold, and hormesis in a straightforward fashion that could be used to inform and guide the risk assessment process for non-carcinogens and carcinogens.

2. You have stressed your past opposition to smoking on airplanes, yet the brochure of your 2004 Dose-Response conference shows contributions from R.J. Reynolds, Phillip Morris, Corillard, and British-American Tobacco. Can you see any possible circumstance under which tobacco in any form could be found to have a hormetic effect? If so, please describe it. If not, why do you think these companies thought it was in their interest to subsidize your conference?

The area of smoking and the possibility of hormesis could best be studied within an epidemiological framework. My area of expertise is as a toxicologist. Thus, whether hormetic effects could occur from exposures to tobacco products in humans would be an hypothesis that could be studied but it is outside of my area of expertise.

The question was raised as to why some tobacco companies provided support for a conference I directed in the early-mid 1990s. I suspect that they responded to my request

for financial support and someone in authority must have thought it was in their best interests. It should be noted that I requested permission from the University of Massachusetts to make such as request to Tobacco companies several years prior to that time. However, permission was not granted initially. The request was brought to the UMass Board of Trustees and eventually approved. My understanding is that all external sponsors must follow a set of prescribed UMass rules and groups such as Tobacco companies are not excluded as long as they follow all UMass sponsorship rules.

3. You have referred to yourself as being the author of "nearly 900 pages in the peer-reviewed literature." (Testimony 10/3/18, p 1). How many of those pages appeared exclusively in Dose-Response, the journal that you founded and are now the editor for?

The answer is 13. I might add that it is very common for editors to publish in their journals. Most editors I know do this modestly as would be the case with my history. Please note that I typically publish 20 or more papers per year. Thus, the proportion of my papers published in Dose Response is about 5% or possibly less.

4. In 2015, you published an article in the journal "Environmental Research" with the title, "On the origins of the linear no-threshold (LNT) dogma by means of untruths, artful dodges and blind faith." Later, solely on the basis of the publication of that article, you demanded that the editors of the magazine "Science" retract an article published in 1956. Did the editors of Science agree to that demand, and if not, how do you explain their refusal?

The editor did not agree with my request. As to why my request was denied, this would have to be addressed by the editor directly. I am attaching my published assessment of this situation.

5. In an article in Dose-Response entitled "Atomic Bomb Health Benefits," Dr. Thomas J. Luckey wrote, "One burst of low dose irradiation elicits a lifetime of improved health." Dose Response, 2008; 6(1): 97-112. Do you agree with respect to the health benefits of atomic bombs?

    a. In the same article, which as editor you presumably approved, Dr. Luckey suggested that survivors of a nuclear bomb blast should receive additional radiation. Do you agree?

I am not an expert on the effects of atomic bomb blasts on people. I have not studied this issue in a detailed manner.

The fact that a paper is published in the journal I edit has little to no relationship to my thoughts on the matter. I tend to follow the peer-review comments closely and almost never over turn a recommendation.

6. Dose-Response published Dr. Luckey's 2006 article, "Radiation Hormesis: The Good, the Bad, and the Ugly." (2006; 4(3): 169-190. In it he wrote: "Premature cancer deaths are caused by insufficient radiation… the United States has about 275,000 preventable premature cancer deaths each year. The cause is attributed to insufficient radiation… [W]e need radiation supplementation for more abundant health. Do you agree?

   b. In the same article, Dr. Luckey wrote that if EPA succeeded in reducing household radon exposures, the result would be to cause "many lung cancer deaths." Do you agree?

   c. In the same article, published by you, Dr. Luckey wrote, "Nuclear waste could provide safe radiation spas throughout the world." Do you agree?

These are research questions that could be tested. There are many studies of human populations where the radiation exposure is far higher than average. These might provide opportunities to evaluate questions relating to elevated human exposures to various types of ionizing radiation under differing environmental conditions and cultural circumstances. I would not speculate on the outcome of a study in advance. I am attaching an epidemiological study of radon exposure/lung cancer in Worcester County, Massachusetts that may provide some relevant insight to your question.

7. You have repeatedly declared that the Linear No-Dose Threshold Theory (LNT) was the product of scientific misconduct, originating with the Nobel Prize acceptance speech of Dr. Hermann Muller, who received the Nobel Prize in chemistry in 1946. (see http://www.21stcenturysciencetech.com/Articles_2011/Fall-2011/Interview_Calabrese.pdf). You seem to theorize that Dr. Muller deliberately lied, and that scientists and regulators have suppressed the truth about radiation ever since. Is it possible that there is an honest difference of opinion between you and the NAS, EPA, NRC, IAEA, ICRP, NCRP, etc.?

I am not sure to what extent my opinions differ with specific individuals or specific organizations. I do not know who represents EPA, NRC and the other groups listed. I do not know who in those groups have read any of my papers and what their understandings are.

8. In 2016, Dose-Response published a commentary by Dr. Carol S. Marcus ("Destroying the Linear No-Threshold Basis for Radiation Regulation," 2016 Oct-Dec; 14(4)), which described the regulation requiring licensees of nuclear facilities and materials to keep radiation doses to workers and the public "as low as reasonably achievable" (ALARA), as "nonsensical." She wrote: "What if large numbers of licensees went on an ALARA strike?" Do you agree that NRC licensees should consider this form of civil disobedience, by deliberately refusing to follow the ALARA regulation?

I do not have knowledge of NRC licenses duties and responsibilities. It not something that I have studied or worked on.

9. The same contributor, Dr. Carol S. Marcus, wrote in a 2015 rulemaking petition to the NRC that the thousands of thyroid cancers diagnosed in the former Soviet Union among children exposed to radiation from the Chernobyl accident were not in fact caused by radiation, as "the radiation doses were too low to have caused this." Do you agree?

I have not studied this question and do not have an opinion on it.

Senator Sanders:

10. As you know, medical studies with human subjects typically provide the basis for policies designed to protect public health. However, the individual health data of study subjects is required by federal law to remain confidential, which can make study results hard, if not impossible, to reproduce. If the EPA's proposed "Strengthening Transparency in Regulatory Science" rule (the rule) is implemented, these studies relying on human medical records may no longer be used. As you noted in your testimony, studies based on human medical records are superior to studies based on animal models, which tend to be, according to you "highly susceptible and often poorly predictive".

    During the hearing, you also used the term "secret science" to refer to scientific studies that deal with animal models rather than human populations, suggesting again that these animal model studies are inferior to those based on human subjects.

    Given that the rule would increase the EPA's reliance on this type of "secret science" you disavowed during the hearing, please describe your plan, including a timeline, for publicly opposing the rule and revising your testimony.

    Please explain how relying more heavily on these poorly predictive animal models advances the EPA's stated mission to "protect human health and the environment".

I re-read my prepared statement and did not find the term "secret science" mentioned. Senator Barrasso stated (page 42): Dr. Calabrese, your testimony also states that hidden assumptions in the EPA's secret science are often kind of silent drivers of regulatory action. Could you please deseribe how secret science can bias decisions made from a regulatory standpoint? My written testimony was mischaracterized by linking the concept of "hidden assumptions" in the risk assessment process to "hidden assumptions in the EPA's secret science"....I never linked hidden assumptions in risk assessment to "secret science".

The question posed does not relate to my comments or misunderstood my comments....I referred to the use of "multiple assumptions, some of which are frequently hidden, obscured and often silent drivers of regulatory action." I then gave the example of the use of highly susceptible animal models that do not predict human responses well.
I believe that the question posed by Senator Sanders misses the concept I was trying to convey. I did not disavow any type of study. I simply requested that EPA needs to fully describe/explain the assumptions relied upon when interpreting studies for human responses. Failure to describe the assumption relied upon can be problematic since one

cannot then fully understand the procedures used by the EPA in the risk assessment process.

11. Many epidemiological studies based on human subjects are only possible due to existing human exposure to toxic chemicals. These studies are obviously not reproducible because knowingly exposing human study subjects to toxic chemicals is unethical. These studies are extremely valuable in helping agencies like the EPA formulate effective policies to protect public health. If the rule is implemented, it would allow outside interests to "disprove" these irreproducible, yet scientifically sound, studies simply because those interests do not like the outcomes.

    Please describe the safeguards in the proposed rule to ensure that these types of scientifically sound, but ethically irreproducible, studies are not rejected by the EPA.

This area is outside of my expertise. However, I strongly support the use of all valid studies. Please note that it is very unlikely that any study perfectly replicates one another. There are always some differences. This is why each study tells something unique and should be used in the assessment process. It is also why I believe that a type of carefully described weight of evidence procedure should be developed, peer-reviewed, and used. EPA has used weight of evidence procedures in the past for cancer risk assessment guidelines. These could be updated, peer reviewed and employed to objectively guide Agency procedures.

Senator ROUNDS. Thank you, Mr. Calabrese.

Now we will turn to Mr. Robert Hahn for your opening statement.

STATEMENT OF ROBERT HAHN, VISITING PROFESSOR, OXFORD UNIVERSITY SMITH SCHOOL OF ENTERPRISE AND THE ENVIRONMENT

Mr. HAHN. Thank you, Chairman Rounds, Ranking Member Booker, and distinguished members of the Committee.

Most of you folks are probably old enough to remember the movie The Graduate with Dustin Hoffman. There was a scene early on in The Graduate where he is wandering around aimlessly by the swimming pool and a gentleman comes up to him and whispers the word plastics.

Well, the word I want to whisper to you today, and Senator Booker and Senator Rounds touched on this in their opening remarks, is the importance of evidence. There is a virtual explosion going on in the Academy in which I work as an economist in developing evidence based policy.

Just moving a little bit beyond the pros and cons of this legislation, which I will talk about in a minute and give my perspective on, I think there is a real opportunity politically to move forward in basing decisions that politicians and civil servants make about regulatory decisions and other programs, and basing them on evidence based policy, and that is where I would like to see us going. That is sort of my big ax to grind. So, if I run out of my 5 minutes, I have at least made my political statement, which is probably a good thing to do if I am going to run for President, which I am not.

I want to make a few points and conclude with a short plea for breaking the political logjam.

The first one is that I believe that the HONEST Act, as it is called, addresses a very important public policy issue, and it does so in a constructive way. That is not to say that it is perfect or can't be improved, but I am very sympathetic with the direction in which it and the EPA proposal is trying to move us.

The second point is why simply apply this to EPA? There are a lot of regulatory agencies and programmatic agencies in Washington, DC. We might want to think about expanding the kinds of ideas that Senator Rounds and Senator Booker talked about.

And the third point I want to make is the point I just made about better evidence decisionmaking related to a commission I served on that President Obama was instrumental in starting, along with Congressman Ryan and Senator Murray.

So, point No. 1. The HONEST Act addresses an important public policy concern. I am just going to give you one example, so it is proof by anecdote. I have about 3 minutes.

So, I ran a center for about 10 years between two think tanks in Washington, DC, the AEI Brookings Center on Regulatory Policy, or some such thing. I was doing a study with Ted Gayer, who is now at Brookings, trying to figure out what was going on with mercury emissions in a proposed regulation that EPA had on mercury emissions, and it took us a really long time to figure out what was going on because we didn't have easy access to the data or the models. We found, in our independent analysis, that that particular

rule, as it was tailored, probably wouldn't pass a benefit-cost test, and we published our findings in science. But that is of secondary importance.

What is of primary importance is the point that the Ranking Minority Member and the Chair pointed out, that we want to have these data made available and these models made available in a way that academics and other interested parties can check on the findings before they go into force.

Let me move on to a second point under this, and it relates to my specific views on the strengthening transparency and regulatory science proposal that EPA had.

There can be honest differences of opinion, but what would that proposal have done? It would have required the EPA to identify studies that are used in making regulatory decisions, it would have encouraged studies to be made publicly available to the extent practicable, and it would direct the EPA to clearly state and document assumptions made in regulatory analyses.

Now, if I were grading an exam, say, at the Kennedy School, where I was on the faculty many years ago, and a student didn't do that, they probably would have gotten a C or less. In other words, these are things that make common sense, at least from my point of view.

Here is what, in my view, the EPA rule wouldn't do: it wouldn't nullify existing environmental regs; it wouldn't disregard existing research, violate confidentiality protections, or jeopardize privacy.

Let me move on to my conclusion, which is repeating my opening introduction.

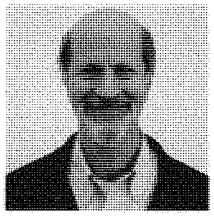
I think there is a real opportunity here for the Congress to move forward in promoting a new era in terms of getting people to acquire and use data more intelligently to improve decisions in government and in the private sector.

For the government, I believe there is an opportunity to move things forward by promoting, as I said before, evidence based policy. It is pretty hard for a politician or an individual of any political persuasion to object to the idea of evidence and using better evidence in decisionmaking. I think that is really important.

I think the HONEST Act represents a modest, albeit important, step in the direction of trying to move such policy, and I would urge legislators to move swiftly to consider this effort and other efforts that could vastly improve the quality of decisionmaking in government and thus improve the welfare of American citizens.

Thank you.

[The prepared statement of Mr. Hahn follows:]



Robert Hahn
Visiting Professor
Oxford University Smith School of Enterprise and the Environment

Bob Hahn is a visiting professor and former director of economics at the Smith School of Enterprise and the Environment, Oxford University, and a senior fellow at the Georgetown University Center for Business and Public Policy. He has served on the faculties of Harvard and Carnegie Mellon, and has also had senior appointments at the American Enterprise Institute (AEI) and Brookings. Mr. Hahn co-founded and directed the AEI-Brookings Joint Center for Regulatory Studies, a leader in policy research in law and economics, regulation, and antitrust. Previously, he worked for the U.S. President's Council of Economic Advisers and was the chief economist on the White House drafting team for the 1990 Clean Air Act Amendments. His responsibilities included helping to design the innovative cap-and-trade system for limiting smokestack sulfur emissions.

Mr. Hahn is currently conducting several economics experiments aimed at improving productivity, and promoting growth and sustainability. He also continues to do research on government regulation, competition policy, energy policy, Internet policy, environmental policy, and understanding the benefits of breakthrough innovations. He served as a commissioner on the U.S. Commission on Evidence-Based Policymaking and is currently working with key decision makers on ways to promote evidence-based policy.

Assessment of the Honest and Open New EPA Science Treatment Act of 2017 or the HONEST Act

Testimony before the Senate Committee on Environment and Public Works

Professor Robert Hahn*

October 3, 2018
Embargoed until the time of the hearing

*Visiting Professor, Smith School, Oxford University and Senior Policy Scholar, Georgetown Center for Business and Public Policy. The author would like to thank Nick Hart and Robert Shea for helpful conversations on this general topic and Jayani Chakravarti for excellent research assistance. The views in this testimony are those of the author, and do not necessarily reflect the views of the institutions with which he is affiliated.

Assessment of the Honest and Open New EPA Science Treatment Act of 2017 or the HONEST Act

Professor Robert Hahn

October 3, 2018

Good afternoon. My name is Robert Hahn. It is my pleasure to testify before the Senate Committee on Environment and Public Works on the HONEST Act.

I am a visiting professor at the Oxford University's Smith School and a senior policy scholar at the Georgetown University Center for Business and Public Policy. I have served on the faculties of Harvard University and Carnegie Mellon University and also held senior positions at AEI and Brookings. My bio is attached along with selected references that may be of interest to the Committee.

I wish to make three points and conclude with a plea for breaking the political logjam in this important area of policy. Here are the three points in a nutshell.

First, the HONEST Act addresses an important public policy issue in a constructive way. The use of sound science in a transparent manner in regulatory decision-making is critical for improving the welfare of Americans and consumers more generally.

Second, the issue of using sound and transparent science is one that is germane to many government agencies, and some of the ideas in this act could be usefully extended to other government agencies.

Third, there is a more fundamental issue of how to promote better evidence-based decision making in government. I will offer some ideas on that as well.

1. *The HONEST Act addresses an important public policy concern*

Having access to models and data are keys to being able to reproduce and extend results, which is important. I recall a research project I did with Ted Gayer on the regulation of mercury emissions from power plants. In that research, we reviewed EPA documents. It was challenging to replicate the findings of that analysis; and even though there was supposed to be a clear benefit-cost analysis, it was difficult to connect the dots. Once we connected the dots, we found that the regulation would not likely pass a benefit-cost test based on the government's data. It would have been very helpful in undertaking this research if we had easier access to the scientific models and data underlying that analysis.

A second strand of my research reinforced this finding. In work with Patrick Dudley, I found that environmental regulatory assessments for major regulations done by the U.S. Environmental Protection Agency were not always of high quality. For example, the agency often did not consider alternatives adequately, or consider a range of benefits and costs. In fairness, my understanding is that EPA has done much to improve the quality of their analysis since that study, but my understanding is that there are still significant issues with modelling and transparency.

Recently, I reviewed an EPA proposed rule on "Strengthening Transparency in Regulatory Science" (RIN 2080–AA14), which appears to have a similar goal to the HONEST Act. I published an editorial reflecting my views in the *Washington Post*. While many scientists argued that this proposal would likely stifle science in administrative rulemaking, I came to the opposite view.

Critics typically argued that the proposed regulation would suppress research that contains confidential records. A careful reading of the rule suggests that it would:

> require the EPA to identify studies that are used in making regulatory decisions; ... encourage studies to be made publicly available "to the extent practicable"... and it would direct the EPA to clearly state and document assumptions made in regulatory analyses.
>
> Here's what the EPA's rule wouldn't do: nullify existing environmental regulations, disregard existing research, violate confidentiality protections, jeopardize privacy or undermine the peer-review process."[1]

The EPA regulations likely have costs and benefits in the billions in the aggregate (using OMB's estimates). It is for that reason that I argued that its proposed rule was worth considering, and that it should be evaluated on an ongoing basis.

2. *Congress should consider something like the Honest Act for other government agencies.*

Greater transparency and accountability for decision making are critical not just for the EPA, but for virtually all government agencies that use models and data to design programs and regulations. Thus, I believe something like the HONEST Act should be considered for most other government agencies -- especially those involved with designing and evaluating programs, policies and regulations.

3. *Congress should promote better evidence-based decision making in government.*

"Taking steps to increase access to data, with strong privacy protections, is how society will continue to make scientific and economic progress and ensure that evidence in rule-making is sound." The EPA's proposed rule and the HONEST Act follow principles laid out in 2017 by the bipartisan Commission on Evidence-Based Policymaking — humility, transparency, privacy, capacity and rigor — and moves us toward providing greater access to scientific data while protecting individual privacy. Congress should consider adopting the recommendations in this report that would improve the basis for making informed government decisions.

[1] Quotations are taken from my Washington Post oped referenced at the end of the testimony.

In addition, Congress should consider legislation that requires all agencies to develop programs and regulations that are likely to pass a broadly defined benefit-cost test. This legislation could be patterned after executive orders that all presidents have used since President Ronald Reagan (e.g., Executive Order 12291). In addition, Congress should provide funding to evaluate and improve programs and regulations on an *ongoing* basis.

4. The Political Opportunity

We may be at the dawn of a new era in terms of acquiring and using data more intelligently to improve decisions in government and in the private sector. For government decision making, I believe there is an opportunity to move things forward by promoting "evidence-based policy". This is something that I believe all elected representatives should support, regardless of their ideological preferences or party affiliation.

The HONEST Act represents a modest, albeit important, step in the direction of trying to improve evidence-based policy. I would urge legislators to move swiftly to consider this effort and other efforts that could vastly improve the quality of decision making in government, and thus improve the welfare of American citizens.

Appendix: Selected References and Bio for Robert Hahn

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Bio for Professor Robert Hahn

Robert Hahn is a visiting professor and former director of economics at the Smith School of Enterprise and the Environment, Oxford University, and a senior policy scholar at the Georgetown University Center for Business and Public Policy. He is also co-founder of The Behavioralist and Signol, two companies that use behavioral economics and evidence-based policy making to promote the social good. Bob has served on the faculties of Harvard and Carnegie Mellon, and has also had senior appointments at AEI and Brookings. Bob co-founded and directed the AEI-Brookings Joint Center for Regulatory Studies, a leader in policy research in law and economics, regulation, and antitrust. Previously, he worked for the U.S. President's Council of Economic Advisers and was the chief economist on the White House drafting team for the 1990 Clean Air Act Amendments. His responsibilities included helping to design the innovative cap-and-trade system for limiting smokestack sulfur emissions.

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Senate Committee on Environment and Public Works
Subcommittee on Superfund, Waste Management, and Regulatory Oversight
Hearing entitled, *"Oversight of the Environmental Protection Agency's Implementation of Sound and Transparent Science in Regulation"*
October 3, 2018
Questions for the Record for Mr. Hahn

Senator Sanders:

1. You testified in the hearing that the EPA's proposed "Strengthening Transparency in Regulatory Science" rule (the rule) would not "disregard existing research" nor "jeopardize privacy". However, medical studies with human subjects typically provide the basis for policies designed to protect public health. Additionally, the individual health data of study subjects is required by federal law to remain confidential, which can make study results hard, if not impossible, to reproduce. If the rule is implemented, these studies relying on human medical records may no longer be used, which will lead to some existing research to be disregarded. Using individual health data of study subjects will jeopardize their privacy. Please explain how the EPA will be able to implement the rule without disregarding existing research or jeopardizing patients' privacy.

   Answer: The proposed rule says: "Nothing in the proposed rule compels the disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections."

2. Many epidemiological studies based on human subjects are only possible due to existing human exposure to toxic chemicals. These studies are obviously not reproducible because knowingly exposing human study subjects to toxic chemicals is unethical. These studies are extremely valuable in helping agencies like the EPA formulate effective policies to protect public health. If the rule is implemented, it would allow outside interests to "disprove" these irreproducible, yet scientifically sound, studies simply because those interests do not like the outcomes.

   Please describe the provisions in the proposed rule that would ensure these types of scientifically sound, but ethically irreproducible, studies are not rejected by the EPA.

   Answer: See answer to 1. I also quote the proposed rule: "The best available science must serve as the foundation of EPA's regulatory actions." Taken together, I believe a reasonable interpretation of the rule is that EPA should consider such studies.

3. The EPA estimates that the HONEST Act would cost $250 million a year to enforce, with one of the major costs being the process of redacting private information from studies. Yet, the HONEST Act would only authorize a total of $1 million each year for enforcement. Do you believe this insufficient funding would impede the EPA's ability to enforce the rule and protect confidential health data? If not, please describe how the EPA can effectively protect patients' privacy with 0.4 percent of the necessary budget to do so?

Answer: EPA cost estimates are often highly uncertain. I cannot comment on the validity of this particular cost estimate. I believe the benefits of this proposed rule should be weighed against the costs. Based on my experience I believe there are substantial advantages to sharing data and models on which important policy decisions are based with appropriate researchers. My testimony before the committee makes this clear. Thus, I would urge the Congress to encourage EPA and other agencies to move in this direction. This argument is consistent with many of the recommendations adopted by the U.S. Commission on Evidence-Based Policymaking, on which I served.

Senator ROUNDS. Thank you for your testimony, Mr. Hahn.

We will now turn to our third witness, Dr. Holt.

Dr. Holt, you may begin.

STATEMENT OF RUSH D. HOLT, CHIEF EXECUTIVE OFFICER, AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE

Mr. HOLT. Thank you. And I do hope to stick to the evidence and to the topic at hand. Thank you.

Chairman Rounds, Senator Booker, I appreciate the opportunity to testify before you today on behalf of the American Association for the Advancement of Science.

The AAAS is the world's largest general scientific membership organization publisher of Science magazine, among other things, and our mission is to advance science, engineering, and innovation throughout the world for the benefit of all people. We also represent 250 affiliated societies.

The transparency rule that you are considering is opposed by many, I think most, scientists and scientific organizations because, contrary to the stated purpose of the rule, the rule would result in the exclusion of valid and important scientific findings from the regulatory process, as Senator Booker has said.

Transparency, openness, and peer review and regulatory science are essential ingredients of science, as espoused by AAAS since the founding in 1948. However, the so called transparency rule is an insidious dodge.

Those who want to overturn the EPA procedures with this rule provide no good evidence that there is any deficiency in the scientific research that has been used up until now. Excluding the kinds of peer reviewed research that has been used is not justified.

To put it bluntly, the initiative you consider today is not about transparency or sound science; it apparently is about reducing regulations. We know this because the architects and proponents present their proposals as part of a deregulatory agenda.

But most important, whatever the ulterior purpose may or may not be, the effect of the rule would be a significant reduction in good, relevant science that could be used by EPA, and the change would likely result in harm to people and the environment.

The proposed rule and its strict application would allow only research that is made completely public, and this demonstrates either a deep misunderstanding of how science works, and should work, or an intention to cherry pick evidence in the name of transparency.

There are numerous examples of excellent peer reviewed research where some data cannot be published openly or where the experiment cannot be precisely repeated, and where redaction and anonymizing won't work. The most obvious examples are research projects that study human illness resulting from pollutants, for example.

There are accepted procedures for testing results and verifying outcomes with methodologies that do not require access to all the raw data, so it doesn't need to be fixed. That is my point there.

The U.S. Department of Defense has said the EPA transparency rule would be problematic. EPA's own Science Advisory Board

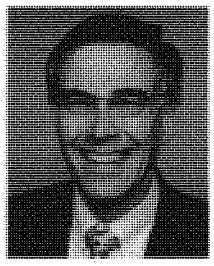
questioned whether it would be possible to implement the rule as proposed. The current Deputy Assistant Administrator of EPA's Chemicals Office stated that "such a requirement would be incredibly burdensome, not practical," and could justify all TSCA risk evaluations; not to mention the many, many scientists and scientific societies who see this rule as damaging.

The proponents of the rule want to eliminate secret science. There is no secret science here. The only secret that I see is the deficiency that the authors of the transparency rule see in the existing research used by EPA. The open secret is that the proponents of the rule are not seeking a better scientific process; they appear to be seeking a way to cherry pick research in order to loosen regulations.

So, I recommend that you scrap these initiatives and work with the science community and other stakeholders to increase the use of science in the regulatory process, not to find ways to decrease the science that can be used.

I thank you for your time, and I will be happy to take any questions.

[The prepared statement of Mr. Holt follows:]



Rush D. Holt
Chief Executive Officer
American Association for the Advancement of Science

Rush D. Holt, Ph.D., became the chief executive officer of the American Association for the Advancement of Science (AAAS) and executive publisher of the Science family of journals in February 2015. In this role, Holt leads the world's largest multi-disciplinary scientific and engineering membership organization.

Over his career, Dr. Holt has held positions as a teacher, scientist, administrator, and policymaker. From 1989 to 1998, Holt was assistant director of the Princeton Plasma Physics Laboratory (PPPL), a Department of Energy national lab, which is the largest research facility of Princeton University and one of the largest alternative energy research facilities in the country. At PPPL, Holt helped establish the lab's nationally renowned science education program. From 1980 to 1988, Holt was on the faculty of Swarthmore College, where he taught courses in physics and public policy. In 1982, he took leave from Swarthmore to serve as an AAAS/American Physical Society Science and Technology Policy Fellow on Capitol Hill. From 1987 to 1989, Holt served as an arms control expert at the U.S. State Department, where he monitored the nuclear programs of countries such as Iraq, Iran, North Korea, and the former Soviet Union.

Before coming to AAAS, Holt served for 16 years as a member of the U.S. House of Representatives, representing New Jersey's 12th Congressional District. In Congress, Holt served as a member of the Committee on Natural Resources and the Committee on Education and the Workforce. He served on the National Commission on the Teaching of Mathematics and Science (known as the Glenn Commission), founded the Congressional Research and Development Caucus, and served as a co-chair of the Biomedical Research Caucus. Holt served eight years on the Permanent Select Committee on Intelligence and, from 2007 to 2010, chaired the Select Intelligence Oversight Panel, which worked to strengthen legislative oversight of the intelligence community. His legislative work earned him numerous accolades, including being named one of Scientific American magazine's "50 National Visionaries Contributing to a Brighter Technological Future" and a "Champion of Science" by the Science Coalition. He has also received awards from the American Chemical Society, the American Association of University Professors, the National Association of Graduate-Professional Students, the American Institute for Medical and Biological Engineering, the Council of Scientific Society Presidents, the American Geophysical Union, and the Biotechnology Industry Organization. Holt is a past recipient of two of AAAS' highest honors: the William D. Carey Lectureship Award (2005) and the Philip Hauge Abelson Award (2010).

Holt is a Phi Beta Kappa graduate of Carleton College in Northfield, Minnesota, and he holds M.A. and Ph.D. degrees in physics from New York University. He is married to Margaret Lancefield, a physician, and they have three children and seven grandchildren.

Testimony before the
Senate Energy and Public Works Committee
Subcommittee on Superfund, Waste Management, and Regulatory Oversight
by
Dr. Rush D. Holt
American Association for the Advancement of Science
October 3, 2018

Chairman Rounds, Ranking Member Booker, and esteemed committee members, thank you for the opportunity to testify before you today on behalf of the American Association for the Advancement of Science, or AAAS. AAAS is the largest general scientific membership society in the world, and publisher of the journal *Science*. Our mission is to advance science, engineering, and innovation throughout the world for the benefit of all people.

You are considering the science that goes into EPA regulations. EPA is legally required to base its work on current scientific research. For almost a half century the Environmental Protection Agency has implemented legislation written to protect the health of people and their environment, saving countless lives. The Transparency Rule that you are considering is opposed by many — I think, most — scientists and scientific organizations because, contrary to the stated purpose of the rule, the rule would result in the exclusion of valid and important scientific findings from the regulatory process.

Of course, everyone wants transparency, openness, and peer review in regulatory science. These are essential ingredients of science espoused by AAAS since its

founding in 1848. However, this so-called Transparency Rule is an insidious dodge. There is no good evidence provided by those who want to overturn the successful procedures of EPA that there is any deficiency in the scientific research that has been used until now. Excluding the kinds of peer reviewed research that has been used is not justified.

To put it bluntly, the initiative you consider today – the Secret Science Act of some years ago, which became the HONEST Act, and then turned into the Transparency Rule – is not about transparency or sound science. It is about reducing regulations. We know this because the architects and proponents present these proposals as part of a deregulatory agenda. Most important, whatever the ulterior purpose may or may not be, the effect of the rule would be a significant reduction in good, relevant science that could be used by EPA. This change would likely result in harm to people and their environment.

The proposed rule says that only research about which every detail is made completely public could be used in regulatory decision making because the research must be subject to exact replication. That demonstrates either a deep misunderstanding of how science works (and should work) or an intention to cherry-pick the evidence in the name of transparency.

There are numerous examples of excellent, peer-reviewed research where some data cannot be published openly or where the experiment cannot be precisely repeated. The most obvious such examples are research projects that study human illness resulting from pollutants. You do not need to know the names of the victims who breathe dirty air or drink tainted water to know the science is done right. There are accepted procedures for testing results and verifying outcomes with methodologies that do not require access to raw data. Furthermore, using only studies that can be repeated precisely would eliminate, for example, studies of emissions of smelting plants that no longer exist or studies of a natural disaster that can shed light on continuing environmental insults.

The U.S. Department of Defense said the EPA transparency rule was problematic. The EPA's own Science Advisory Board questioned whether it would be possible to implement the rule as proposed. The current deputy assistant administrator of EPA's chemicals office stated when first reviewing the proposed rule internally, "such a requirement would be incredibly burdensome, not practical" and could jeopardize all TSCA risk evaluations because proprietary chemical process information would not be made public.

The proponents of the rule say they want to eliminate "secret science." There is no secret science. The only secret is the deficiency that the authors of this Transparency Rule see in existing research used by EPA. The open secret is that the proponents

of the rule are not seeking a better scientific process. They appear to be seeking a way to cherry pick research in order to loosen regulations.

I urge you to scrap these initiatives and work with the scientific community and other stakeholders to increase – not decrease – the use of science in the regulatory process.

Thank you for your time and for allowing me to testify, and I would be happy to answer any of your questions.

Senate Committee on Environment and Public Works
Subcommittee on Superfund, Waste Management, and Regulatory Oversight
Hearing entitled, *"Oversight of the Environmental Protection Agency's Implementation of Sound and Transparent Science in Regulation"*
October 3, 2018
Questions for the Record for Dr. Holt

Senator Markey:

1. How important do you think considering the science and evidence is for meeting the obligation of supporting "best available science" required by the Clean Air Act and many other EPA regulations?

   Regulations and agency actions do indeed need to be informed by the best available science and a rigorous scientific process free from political interference. It is for this reason that AAAS opposes issuing a rule that would restrict the ability of a federal agency to utilize rigorous science as it establishes policies and that could have long-term, negative consequences to public health and the environment for all Americans.

   Science, and the evidence that supports that science, are key to any interpretation of the notion of "best available science." The best available science should be science that continually reexamines previous findings and further advances the field of knowledge so regulations are updated with the latest information that science produces – not the kind that politicians would select to achieve a specific end.

2. In general, do you think the proposed secret science rule is more likely to increase or decrease the amount of peer-reviewed science being considered in regulations?

   As we stated in our comments to the *Federal Register*, AAAS is very concerned that EPA's proposed rule will prevent the use of the best available scientific studies in setting critical public health and environmental policies in cases where the underlying data cannot or should not be made publicly available. If put into practice, the proposed rule will prohibit the agency from using a wide swath of high-quality, past and present scientific research. Requiring all raw data to be made publicly available before a study can be utilized in EPA decision-making will cut off EPA from foundational research that has informed EPA's work since the inception of the agency and may violate Federal laws and directives already in place.

   a. Some of the important regulatory actions by EPA in the pesticide field, such as the suspension order that took aldrin/dieldrin off the market, were based on animal data, such as induction of cancer in mice. At the time there was no proof that aldrin/dieldrin caused cancer in humans, and no ethical way of establishing that by experimentations. How confident are you that this suspension would be possible today, if the "sound and transparent science" proposal were enacted?

      While animal studies do not contain protected health data of human research subject, they do often contain propriety or confidential business information.

Companies who produce substances like aldrin/dieldrin often submit their proprietary data to EPA with the explicit understanding it will not be publicly released. Industry, alongside the scientific community, has expressed concern that that the proposed transparency rule would negatively impact their ability to work with the EPA if all data were to be made public.

b. Safe Drinking Water Act Regulation for radionuclides relied on epidemiological studies of survivors from the Hiroshima and Nagasaki atomic bomb attacks. Would studies like these be considered by the EPA under this new science rule?

AAAS believes that many epidemiological studies will be prohibited from use by the EPA in setting regulatory decisions under the new transparency rule as they contain private health information of research participants that cannot be made publicly available. In addition, AAAS is concerned that for studies like the one mentioned above, which only happen once and cannot nor should not be repeated, that overly narrow prescriptions of how studies should be verified could prohibit research or data on singular events from being used. It is vital, as AAAS has repeatedly stated in comments to both the legislation and proposed rule, that the scientific process be freed from political influence or exacting guidelines that would hinder the advancement of new science.

c. Are there any other existing regulations you would like to note as being particularly at risk if the "secret science" proposal is enacted?

Regulations that use science as the foundation for their actions, like the Clean Air Act and Clean Water Act, would be at risk if the transparency rule is enacted. While the rule, and legislation like the Secret Science Act, are specific to EPA we have expressed concern that if enacted it could be used as a justification to implement similar policies at other agencies. This would in turn place any regulation at risk that uses science as major contributor to the justification for new regulations.

3. A brochure for the 2004 International Dose-Response Society conference shows contributions from R.J. Reynolds, Phillip Morris, Corillard, and British-American Tobacco. Why do you think these companies would subsidize this kind of scientific conference?

AAAS believes in the practice, use and promotion of sound science, regardless of funding sources. While many have cast science funded or conducted by corporate entities as tainted, we believe good science is science that is performed with integrity, adheres to the scientific method, and holds up to scrutiny. If research is funded by a corporation and still meets the high standards of good science, then it is still good science. However, if concerns exist that a funding source places a bias in the research or researchers, federal agencies should utilize their scientific integrity policies to protect against such biases.

4. In 2015, Dr. Edward Calabrese published an article in the journal "Environmental Research" with the title, "On the origins of the linear no-threshold (LNT) dogma by means of untruths, artful dodges and blind faith." Later, solely on the basis of the publication of that article, he demanded that the editors of your journal, "Science," retract an article published in 1956. How did you and your editors respond to that demand and why?

   The editors of *Science* did respond to Dr. Calabrese and his colleagues on their 2015 request to retract a 1956 article based on alleged scientific misconduct. The response was that in cases of scientific misconduct, which involves either plagiarism or the falsification or fabrication of data, it is the responsibility of the institution where the research was conducted to investigate such misconduct and to decipher whether the accusation has merit. Journals do not have the resources to conduct such an investigation. It was also noted that in this case it would be difficult to fully investigate misconduct as the original researchers are deceased. Lastly, the response also referenced that the 1956 paper in question was one of hundreds over the past half century on this broad topic, and the use of the LNT model is now based on more than the National Research Council's report in question and Dr. Mueller's work. Based on these factors *Science* did not consider retracting the paper.

Senator ROUNDS. Dr. Holt, thank you for coming and testifying today.

Each of the Senators now has the opportunity for a 5-minute Q&A with you, and I will begin at this time.

I would like to start with Mr. Hahn. I would just like to ask over a multi-period of time you have written extensively on the need for greater scientific transparency with regard to regulations that have an enormous impact on the economy and the quality of life for the American people. What do you believe has been the primary motivating factor behind not pursuing greater transparency prior to the current Administration?

Mr. HAHN. I am not sure I have a 1-minute answer to that question, but I guess I think about it on a couple levels. Sometimes there is raw politics involved in particular issues where Congress may feel strongly about doing something, and it may not be in its own interest to necessarily get to the heart of the scientific matter.

I think partly it is a matter that agencies don't always adapt to the latest technology, so we have the Internet now, we have easy ways of sharing things. It is worth, in my view, putting some resources into some of the issues that Dr. Calabrese mentioned earlier so that people can have access to the kinds of data bases that he developed, but I am thinking of the government, the models on which they are building things.

So, for example, when we were writing the Administration's version of the Clean Air Act, EPA used a consultant that didn't share its model, and a lot of the Clean Air Act was being driven by the results of this model, in my opinion, and I don't think that was an appropriate way to conduct the development of that very important piece of legislation.

Senator ROUNDS. Thank you.

Dr. Calabrese, as a scientist, can you speak to the value of studies that can be replicated?

Mr. CALABRESE. Replication is a pretty complicated question because it is really—in many ways, replication is the gold standard, especially when you are dealing with low dose exposures. High dose exposures is one thing, where you kind of overwhelm systems with massive exposures, and you can see effects, but human exposures are going to be at much lower levels, and you really want to see if there are adverse effects that you are trying to prevent and you think might be occurring, then you want to be able—in your experimental systems, you want to be able to see if these findings are reproduceable or not.

The problem with these types of things is that, especially with regards to epidemiologic data and to somewhat minor effects, a lot of times a study comes out positive in one and then can't be replicated in many other studies. So the gold standard is that we really have to hold the scientific researchers accountable for essentially providing reliable information to regulatory agencies and to society to give us confidence that the findings are sustainable and are believable, and this doesn't have to necessarily involve an exact replication, but would have to involve some type of confirmatory reliability that is substantial, that adds strong weight of evidence to any conclusion.

Senator ROUNDS. Thank you.

Dr. Holt, I am just curious. It would seem to me that for those of us that have to make decisions based upon recommendations from any type of an agency, in this case either Republican or Democrat, it seems to me the most data that we can get, and that which can be identified as being scientifically and peer reviewed, would be welcome by the scientific community, but you have expressed a real doubt about the intent of moving forward with that, and I am just curious. It seems as though the movement toward using sound science and one with as much transparency as possible would be a positive thing, and I am just curious.

I have heard your opening statement, but I am kind of surprised that there wouldn't be more of a welcoming to a peer reviewed discussion with a number of different points of view that would be brought in, and I am missing something, I think, on it. Could you maybe elaborate a little bit, please?

Mr. HOLT. Yes, thank you. Surely, you do want verification. EPA is required to base their work on science, actually different from most regulatory agencies. It is written into the laws. In other words, you should be using current science. And the science is not just the collection of data; it is collection of data in a way that removes bias; it is assembly of the data that—I mean, it has to be empirical, based on experiment, observation, and then it has to be verified, and that is the key word.

It is really a red herring to say replication is what is necessary. The verification can come in various ways: through repeating the experiment, if it is an experiment. But even most experiments are hard to repeat exactly, and certainly natural disasters. Senator Booker referred to the Gulf oil discharge. Let's hope that isn't repeatable. There are many circumstances where it can't be repeated in exactly the same way.

But it can be verified through peer review, through independent verification, through confirmation of the studies by putting them in the context of other studies. That is the way science works. And it is science, this whole process that you want to be maximized in the regulatory process.

Senator ROUNDS. Thank you.

Senator Booker.

Senator BOOKER. I am going to defer to my colleague and friend, Senator Carper.

Senator ROUNDS. Senator Carper.

Senator CARPER. Thank you so much for deferring.

A quick question of you, Dr. Holt. I am not going to ask a yes or no question of you, but anything that the other two witnesses said that you would say, yes, that is right, I agree with that? Have they said anything that you agree with?

Mr. HOLT. Well, yes. I mean, certainly that we need——

Senator CARPER. Briefly mention one of the things that you may heard.

Mr. HOLT. Yes. More evidence. Clearly, we always want more evidence in this day and age, when evidence, opinion, and ideology are considered interchangeable.

Senator CARPER. Good.

Same question, Dr. Calabrese, of you and Mr. Hahn. Anything that Rush said that you agree with even a little bit?

Mr. CALABRESE. I would have to say I agree only a little bit with a couple of points that he made, and that is in many ways, I agree, the Agency is directed toward science based regulation. But the problems with science based regulation are the assumptions upon which the science essentially feeds into, and that is that we have national toxicology program studies that use very high doses, three doses at extremely high doses that may be 100,000-fold more than what people may be exposed to, and we have unverified——

Senator CARPER. I am going to stop right there. Thank you. We will ask you to continue to respond for the record, if you will. I have little time.

Mr. Hahn, anything that he said that you actually agree with? If you could be very brief in stating.

Mr. HAHN. The answer is yes, and I think we all agree that agencies should use the best science, and they should have a transparent process so people and experts can understand what we are getting. I think the point of disagreement is about whether the proposals before us, the proposed rule and the HONEST Act, whether they move the ball forward or whether they don't, and my reading is that they do move the ball forward.

Senator CARPER. OK. Thank you.

A question, if I could, of Dr. Holt. I think it was in May of this year we learned that political appointees within EPA have stalled the release of EPA's formaldehyde risk assessment. The risk assessment reportedly concludes that formaldehyde causes cancer and leukemia. This health assessment has been years in the making and is ready to be peer reviewed, but EPA's political folks are insisting on keeping it under lock and key in response to industry pressure.

My question of you, Dr. Holt, is how would you respond to the concern that EPA is keeping its own formaldehyde science secret, while simultaneously claiming that it needs a new rule to "strengthen the transparency of EPA's regulatory science"?

Mr. HOLT. Senator Booker pointed out the irony in this. There does seem to a double standard there. I am not expert on the formaldehyde study per se, and in fact, much of it is not available for examination.

Senator CARPER. All right.

Let me try another question, if I could, Dr. Holt. EPA's 23 Federal advisory committees were established, I believe, to advise the Agency on environmental science, on public health safety, and other subjects that are central and critical to EPA's work.

Last year EPA announced that it would prohibit scientists who receive EPA grants from serving on its Federal advisory committees. In 1999 a Federal appellate court rejected a nearly identical approach at HHS, reasoning that members of these committees are "selected because they are experts in that field" and therefore, it is not surprising that HHS would also fund their research.

My question: Given that EPA's advisory committees should include the best scientists, shouldn't EPA eliminate its seemingly unlawful effort to exclude anyone with an EPA grant from serving on them?

Mr. HOLT. Senator, I would refer you to a statement that we made, our organization made some months ago. I won't take much

time from this hearing because that is somewhat apart from the subject of this hearing, but in EPA in particular, the science advisory process is essential. And I don't want to get into how much or if it is being degraded, but it is important to defend that scientific advisory process in the EPA.

Senator CARPER. All right.

One last question, Dr. Holt. Given that the rulemaking process, rewriting a rule or litigating a rule, are costly endeavors, shouldn't EPA either withdraw the rule entirely or perhaps remedy all the problems before finalizing it?

Mr. HOLT. That is what I was trying to get at when I said I don't see the reason to change this. If there is deficiency in how it has worked up to now, then we can talk about what changes might be needed. But I don't see the deficiencies.

Now, some people have said, for example, the six cities Harvard study that found deadly effects of small particulates was a flawed study, but most people don't think it was a flawed study, and in fact, it has been verified in a variety of ways. And yet that has been the example that has been used for why we need a change in transparency, a change in procedures at EPA.

So, unless I am convinced that what has been done is wrong and needs to be changed, I don't see why we should have this or any variation on it.

Senator CARPER. Mr. Chairman, thanks for allowing Dr. Holt to answer that question, and my thanks to Senator Booker for yielding his time to me. Thank you.

Senator ROUNDS. Thank you, sir.

At this time, I will turn to the full Committee Chairman, Senator Barrasso.

Senator BARRASSO. Thank you, Senator Rounds. Thanks for holding this important hearing.

Mr. Hahn, I was wondering. President Obama issued an executive order 7, 8 years ago, I think 2011, stating, he said regulations "must be based on the best available science." Does the EPA's current proposed rule to strengthen the transparency of the Agency's use of regulatory science, does this align with what President Obama asked for in 2011?

Mr. HAHN. I don't know exactly the text of what President Obama said, but to me, we all agree, there is consensus, that rules should be based on the best available science. And I would even go further and say we should roll rules out slowly so we can learn about what works and what doesn't work, and do pilot studies and feed that back into our knowledge.

The real issue is what is happening on the ground at agencies like EPA, HHS, independent agencies like the Federal Communications Commission, and that is kind of my wheelhouse, where we do benefit-cost analyses. We see that some of the regulations that come out of these agencies are incredibly beneficial, like seatbelt regulations, like the smoking regulation you talked about earlier, and some of them are not so beneficial, they are very expensive and actually don't improve overall consumer welfare.

So the short answer is yes, this rule, in my view, promotes the best available science, but I would like to see Congress more generally pushing in the direction of promoting evidence based policy.

Senator BARRASSO. Dr. Calabrese, your testimony notes a lot of health models currently used to inform regulatory decisions are based on data gathered 60 years ago. These models also use scientific assumption developed during that era.

How have the advances in science and technology improved the scientific community's ability to produce more accurate results and research?

Mr. CALABRESE. There has been a wealth of scientific development since the first proposal for the use of LNT for cancer risk assessment back in 1956, and essentially what we have had since the 1950s to the present time is really policy driving science. But we have such substantial scientific development that really has to be switched around, and science has to now drive policy. And my understanding of the dose response relationships in great detail is that the simplistic linearized model of the 1950s did not take into account the plethora of biology that we have today, and the regulatory agencies need to be flexible to the science and let science drive policy, rather than the other way around.

Senator BARRASSO. Mr. Hahn, EPA's proposal allows the Administrator to grant case by case waivers to use scientific studies which may not be able to meet the new transparency studies. Do you believe that the proposal's waiver is an appropriate method to provide flexibility, while maintaining the strong transparency standards that we are looking for?

Mr. HAHN. The short answer to your question is yes, but I haven't thought carefully about other ways of doing that that could potentially be better.

Senator BARRASSO. Dr. Calabrese, your testimony also states that hidden assumptions in the EPA's secret science are often kind of silent drivers of regulatory action. Could you please describe how secret science can bias decisions made from a regulatory standpoint?

Mr. CALABRESE. Yes. The so called what I call the secret type sciences is essentially you might have really excellent studies that deal with an animal model that has very little relevance to a human population, yet we assume that the human population is responding exactly like the information provided by the animal. So, the science can be great, but the relevance of a human population can be pretty much nil, and yet that is what the belief systems are based on, and regulations are based on, and there are a whole series of other specific examples like that.

Senator BARRASSO. Thank you very much.

Thank you, Mr. Chairman.

Senator ROUNDS. Senator Booker.

Senator BOOKER. I just want you to know, Mr. Chairman, I am not intimidated at all by going after the Chairman. He and I have a lot in common. He has a degree in science, biology, chemistry. I have a degree in science as well, political science.

[Laughter.]

Senator BARRASSO. And we are both left handed, as are several of the panelists today. It is a big day.

Senator BOOKER. Yes.

Senator BARRASSO. What about you, Carper? We have three left handers here and a couple left handers there.

Senator BOOKER. That is pretty good. That is pretty good.

Dr. Holt, Mr. Hahn used a football analogy which was an appeal to my more baser qualifications for the job I am in, as a former football player, where he talked about moving the ball up the field or not. He said that is what this is about.

Clearly, you want transparency. Clearly, you have talked about the urgency for transparency, the urgency for good science. But I just don't think what is being clearly stated is that this very great tune of saying, hey, we want more transparency actually doesn't move the ball forward; it actually is going to move the ball back and hurt, potentially, the health and well-being of folks.

Could you succinctly explain one more time why such a proposed rule and the legislation actually could devastatingly hurt the safety and security of the American public?

Mr. HOLT. The rule excludes the use of some kinds of research, and there are long lists of actual research or potentially relevant research that would be eliminated by any likely interpretation or application of this rule. I would direct the Senators to a letter I believe is available to you, I can certainly make it available to you, from the Emmett Environmental Law and Policy Clinic at Harvard Law School about the transparency rule. It is signed by presidents of hospitals and universities. They have a long list of valid research that they believe by any reasonable interpretation of this rule would be unusable in making regulatory policy.

And as I said in my prepared remarks, if you don't use all the good relevant science, people will be hurt.

Senator BOOKER. Right. And so the fact that the majority of your membership organization has spoken out against this; the EPA's own Science Advisory Board has spoken out against this; you have universities and other science folks saying don't do this because you are going to exclude relevant science, you are going to undermine the safety of individuals because much of this is not replicable; all these things should scream to us that there is something wrong, even though the buzz words sound really good.

I want to bring your attention to a strategy that was used by those industries that were trying to prevent health and safety standards that we take for example, cigarette smoking has been brought up. The EPA's proposed rule sounds so much similar. This secret science rhetoric that was used by the tobacco industry is the same rhetoric that is being used right now.

At the time, the tobacco industry lobbyists sought to create process based hurdles that would make it harder for agencies to establish guidelines and safeguards for secondhand smoke exposure. Rumored proposals would have prohibited the EPA from using a study unless it was considered replicable and all the underlying data in that study was released to the public.

This is déjà vu all over again, as another New Jerseyan once said.

So here is industry—and this is the irony of this moment for me—is that you have industry working really hard to stop the transparency on things like the methane rule, on what we are seeing right now with the methylene chloride, and then on other areas they are trying to stop us regulating things just like we did with the tobacco industry.

You have been, obviously, down here for 16 years of your career. Do you see this double standard and hypocrisy being used to try to do things that hurt the public health when it benefits industry, and doing things that undermine science?

Mr. HOLT. Well, in my testimony I talked about a likely motivation of the people who are proposing this because they are proposing it as part of a deregulatory regime, but I wanted to get beyond that because really what I wanted to talk about is not whether it is a double standard and what the motivation is, but what would the effect be. And this is not just me saying this; I mentioned this Environmental Law Clinic, but the Thoracic Medical Society, the American Geophysical Union, the American Chemical Society; many, many organizations and even far more individual scientists are saying the effect would be that science that we know to be good science would likely be excluded.

Senator BOOKER. And just to make this last comment, exactly what you said is the issue with the methylene chloride, which people are dying from in the United States of America. It has been responsible for dozens of deaths. Under the TSCA law, bipartisan TSCA law, the EPA proposed a ban on methylene chloride in paint strippers in 2017, and in 2018 the Agency said it would finalize a rule, yet they haven't acted. The scientific basis for the proposed ban on methylene chloride comes from an Agency risk assessment that received extensive interagency review and external peer review by independent scientists and relied on high quality studies but—and the point of here—the underlying case studies are not publicly available because of protecting information.

So this is an example of what you are saying of how this would stop the banning of this chemical, which we know now needs to be banned; other nations have done it.

So I would just like to submit for the record, Mr. Chairman, if I can ask unanimous consent to submit for the record comments and letters from the Boston University School of Public Health, the California Environmental Protection Agency, the Project on Government Oversight, the Environmental Defense Fund, the Natural Resource Defense Council, all demanding that the rule be withdrawn immediately, and the Ecological Society of America, which opposes the EPA's rule.

Senator ROUNDS. Without objection.

[The referenced information follows:]

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August 15, 2018

By Electronic Submission to www.regulations.gov

Acting Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Docket ID No. EPA-HQ-OA-2018-0259

Re: COMMENTS ON PROPOSED RULE, STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE, 83 FED. REG. 18,768 (Apr. 30, 2018)

Dear Acting Administrator Wheeler:

We are submitting this letter to express our strong opposition to the proposed rule and to request that EPA withdraw it in its entirety. The authors and signatories of this letter are four members of the National Research Council (NRC) Committee on Improving Risk Analysis Approaches Used by the U.S. Environmental Protection Agency (EPA). This committee authored the report titled "Science and Decisions: Advancing Risk Assessment" [1]. We had the mandate to broadly consider how the EPA conducts risk assessment, including the questions of how dose response modeling should ideally be done, how uncertainty should be dealt with, and the scientific bases for and alternatives to default assumption choices in areas of uncertainty. Beyond our roles on the NRC committee, the authors have worked in academia, state government, and federal government, and collectively have substantial experience addressing the topics within this proposed rule.

While we have objections to a number of elements of the proposed rule, many of which have been articulated in other letters [e.g., comments submitted by the International Society of Environmental Epidemiology (ID: EPA-HQ-OA-2018-0259-1973) and by Wendy Jacobs on behalf of signatories from Harvard (ID: EPA-HQ-OA-2018-0259-5418)], within this letter we are focusing specifically on the paragraph that relates to transparency of the assumptions underlying dose response modeling.

We have 4 primary objections related to this paragraph:

1) The statement that "there is growing empirical evidence of non-linearity in the concentration response function for specific pollutants and health effects" is vague, incorrect, and not supported by scientific evidence.

2) The statement that "the use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions" is incomplete, poorly defined, and does not reflect the necessity to make decisions based on uncertain information.
3) The proposed rule is overly prescriptive regarding the modeling approaches that should be applied, demonstrates misunderstanding of the concept of model uncertainty, and is vague about the responsible parties and implications of the rule.
4) Setting aside the merits (or lack thereof) of the content within the paragraph, the proposed rule is not the appropriate mechanism to effect change in risk assessment modeling practice at the Agency.

We expand upon each of these points below.

1. **The statement that "there is growing empirical evidence of non-linearity in the concentration response function for specific pollutants and health effects" is vague, incorrect, and not supported by scientific evidence.**

   In Chapter 5 of "Science and Decisions", the committee directly confronted the issue of dose response or concentration response modeling and how to address vexing challenges related to linear or non-linear associations. However, upon careful review of the literature and developing a theoretical framework for dose response modeling, the committee reached the opposite conclusion – there is growing empirical evidence of low-dose linearity. For example, many studies of fine particulate matter ($PM_{2.5}$) health effects displayed linearity at low concentrations at the time "Science and Decisions" was published [2-4], and the empirical evidence has grown substantially since that time [5-10]. There is analogous literature showing low-dose non-cancer health effects of lead [11-13], ozone [7, 8, 14], and arsenic [15-17], among other pollutants. In fact, for multiple pollutants and health outcomes, evidence indicates that the slope at low dose may be greater than the slope at high dose – a so-called "supralinear" concentration response function [18]. The proposed rule uses the phrase "non-linearity", but without any further explanation, it is not clear if that is solely intended to indicate evidence of thresholds below which no health effects would be seen, or to also incorporate other non-linear concentration response functions (whether supralinear, sublinear but where health effects are seen at low concentrations, or other non-monotonic forms).

   A major conclusion of "Science and Decisions" was that people are exposed to numerous background processes and exposures that would tend to lead to low-dose linearity for many chemicals in question. In other words, people may be exposed to pharmaceuticals, food, endogenous chemicals, and other exposures that all operate similarly in the body as a given chemical. Furthermore, people vary greatly in their vulnerability to chemical exposures for a variety of reasons. If a single person were exposed to a chemical in isolation, there could be a level below which no health effects would be exhibited. But if many people were exposed to that chemical, and a host of other substances, it would be likely that population-level health effects would be seen at low concentrations.

The aforementioned statement in the proposed rule, which was provided without any footnotes or references from the scientific literature, is therefore unsubstantiated by empirical evidence and directly contradicted by the conclusions from an expert committee specifically convened by EPA to address this question.

2. **The statement that "the use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions" is incomplete, poorly defined, and does not reflect the necessity to make decisions based on uncertain information.**

It is important to recognize at the outset that default models are intrinsic to risk assessment. Starting with the 1983 Red Book [19], which established the foundations of risk assessment, federal agencies were recommended to develop uniform inference guidelines to avoid the possibility of manipulation of risk assessment outcomes and to help to standardize risk assessment across chemicals, sites, and scenarios. These so-called "defaults" were intended to be the best choice in the absence of data to the contrary, based on a strong scientific foundation but ultimately requiring some science policy judgments. "Default" should therefore not be used as a pejorative term – it simply reflects the best current scientific understanding at a time when a decision needs to be made, for an Agency facing many similar decisions on a regular basis. New scientific understanding will lead to methods that deviate from the defaults and may, in fact, lead to new defaults.

"Science and Decisions" included specific discussion of the topic of defaults. The committee concurred with the challenges and complications related to the use of defaults, including the fact that ultimately any choice of defaults reflects a value judgment made by the Agency (i.e., regarding the degree to which the Agency balances errors of underestimation vs. errors of overestimation of risk).

That said, the "default models" statement within the proposed rule is incomplete, not reflective of current EPA practice, and not reflective of the need for the Agency to regularly make decisions. First, default models are based on current scientific understanding – far from obscuring the scientific justification for decisions, they illuminate them. For example, EPA has a default scaling factor to go from animal to human doses, which is based on our understanding of allometric variation of physiological factors across mammals as well as empirical evidence [20]. Similarly, use of linear extrapolation in cancer risk assessment reflects scientific insight about the mode of action of the compound.

Further, the current process as articulated by EPA [20] is ample to cover this concern, as it calls for a full evaluation of the available scientific data prior to invoking defaults. Therefore, risk assessments typically involve a comprehensive discussion of the available evidence, for compounds under study and others with similar attributes, with default models and methods used in situations when decisions must be made in the face of inadequate data. Default methods and default assumptions provide a bridge from available data that may not support more complicated analyses to decisions that need to be made in a timely manner.

Risk assessments are continually striving for increased transparency so that the uncertainties are understood by all parties, but this does not require engaging in a range of alternative approaches for which there is no obvious preference or scientific support. Default models and assumptions, where necessary, provide risk assessments with a uniform approach in the face of uncertainty rather than having to deal with many competing risk assessments on the same topic. How does this obscure the scientific justification for action?

In fact, presenting numerous alternative models, without some logical and consistent rationale for choosing among them, would obscure the ability to compare risk assessments and keep the Agency from making even the most basic decisions. The "Science and Decisions" committee grappled with this question and concluded that "the goal is not to present the multitude of possible risk estimates exhaustively but to present a small number of exemplar, plausible cases to provide the risk manager a context for understanding additional uncertainty contributed by considering assumptions other than the default" [1]. The proposed rule as written does not reflect this measured perspective.

3. **The proposed rule is overly prescriptive regarding the modeling approaches that should be applied, demonstrates misunderstanding of the concept of model uncertainty, and is vague about the responsible parties and implications of the rule.**

The proposed rule is quite specific about the concentration response modeling approaches that should be applied, including "a broad class of parametric concentration response models with a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the exposure range; and spatial heterogeneity". While it is not directly stated, this component of the proposed rule relates to epidemiological studies, and more specifically, appears to target air pollution epidemiology.

As articulated elsewhere [e.g., comments submitted by the International Society of Environmental Epidemiology (ID: EPA-HQ-OA-2018-0259-1973)], this prescriptive modeling approach is not reflective of best scientific practice. By following this approach, EPA would place greater weight on studies that force the data into shapes that may not be indicated by the data (i.e., by using defined parametric models and threshold models). This might potentially prioritize studies which report a range of statistical approaches even if they yield poorly fitting curves, as compared to a study which uses a widely-accepted non-parametric modeling approach that performs well. This is a far cry from "transparency".

Similarly, the call to consider spatial heterogeneity is largely pertinent to only national-scale air pollution epidemiology, and does not consider whether such an analysis is indicated by the study design and available data. More broadly, it is not clear what is meant by "should give appropriate consideration" – does this mean EPA should not use studies lacking these attributes when making regulatory decisions? Given that most journal articles would not include such a wide range of models, is EPA proposing that individual researchers should produce additional models and provide them to EPA, or that EPA plans to reanalyze studies to fit these specific criteria?

Similarly, fitting numerous specified curves to toxicological study data ("including linear, threshold, and U-shaped, J-shaped, and bell-shaped models") does not represent best scientific practice. Fitting major competing models where mechanistic model forms are suggested by the underlying data or understanding of chemical action is reasonable and supported by "Science and Decisions". However, while one can fit many curves to a set of data and show that the resulting risk estimates differ, this is not necessarily reflective of the true level of uncertainty and would thus further obscure the assessment and impede decision-making. There are two major issues. First, most available toxicological data sets do not have the resolution to differentiate among many different model forms that can have extremely different low-dose extrapolations. Many parametric model forms would fit the data equally well but result in a wide range of estimated risks. Second, where the data allow for such differentiation, those models that do not fit the data well should be down-weighted, and those models that are not mechanistically supported should not even be considered. Best scientific practice involves using model averaging, wherein numerous mechanistically justified models are fit and the better-fitting models receive a higher weight than more poorly-fitting models.

While we are supportive of the concept of incorporating model uncertainty, simply fitting a prescribed list of models to a small number of observations just provides a list of varying risk numbers without any strong scientific basis or ability to move forward. This reflects a fundamental misunderstanding of the concept of model uncertainty, ignoring the fact that some models are better justified than others, either based on scientific theory or empirical evidence related to curve-fitting. The text is confusingly written and not well thought through, and would leave the Agency ill-prepared to conduct risk assessments.

4. **Setting aside the merits (or lack thereof) of the content within the paragraph, this proposed rule is not the appropriate mechanism to effect change in risk assessment modeling practice at the Agency.**

The science associated with dose response modeling within risk assessment, ranging from better understanding of biological mechanisms to statistical modeling and risk estimation methods, continues to evolve. Because of the complexity of risk assessment and the fact that it operates at the science-policy interface, EPA regularly seeks guidance from the National Academies on where the field is and where it is going [1, 19, 21, 22]. EPA also has the Risk Assessment Forum, where senior scientists grapple with difficult issues related to risk assessment to allow for consistent implementation across the Agency, as well as periodic reports and guidance documents that provide best practices for cancer and non-cancer risk assessment (e.g., https://www.epa.gov/risk/risk-assessment-guidelines). These all represent deliberative processes that carefully examine the state of the science and offer conclusions regarding best practices. In contrast, this paragraph within the proposed rule is highly prescriptive in a manner that would add very little that is constructive and would most serve to lengthen and delay the risk assessment process. If the Agency wishes to re-examine questions related to how uncertainty is best characterized in dose response modeling, there are ample mechanisms to do so beyond a short paragraph with no citations tucked into a proposed "transparency" rule.

Conclusions

Broadly, the "Science and Decisions" committee was clear that EPA's approach to dose response modeling needed to be changed to reflect growing scientific knowledge and the evolving needs of decision makers. But this section of the proposed rule does not reflect the conclusions from the NRC committee (or other standard mechanisms by which changes in modeling and risk assessment practice are typically promulgated), and instead proposes prescriptive steps that, if taken in aggregate, would delay the risk assessment process and confuse risk managers, ultimately leading to paralysis by analysis.

The signatories of this letter affirm the value of transparency and agree that the question of how epidemiological or toxicological information is used by EPA risk assessors to inform decisions is an important and challenging one. But, an overly prescriptive and poorly defined list of modeling approaches will not either decrease or illuminate uncertainty, and will not provide the basis for the specific decisions that confront the Agency. It appears that the treatment of uncertainty here is meant specifically to undermine the basis for public health protective measures, rather than to better represent the information available. They are merely a recipe for obfuscation and delay.

We would ask that the proposed rule be withdrawn.

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CalEPA
California Environmental Protection Agency

Edmund G. Brown Jr.
Governor
Matthew Rodriquez
Secretary for Environmental Protection

August 16, 2018

Submitted Electronically

Andrew Wheeler, Acting Administrator
United States Environmental Protection Agency
1555 15th Street, NW
Washington D.C. 20005

Re: U.S. EPA Strengthening Transparency in Regulatory Science Proposal
Docket No. EPA-HQ-OA-2018-0259

Dear Acting Administrator Wheeler:

The California Environmental Protection Agency (CalEPA) submits the attached comments on the United States Environmental Protection Agency's (EPA) proposed "Strengthening Transparency in Regulatory Science" rule. (83 FR 18768 (April 30, 2018).) CalEPA submits these comments on its own behalf and on behalf of the following California environmental protection agencies: the California Air Resources Board, the Office of Environmental Health Hazard Assessment, the Department of Toxic Substances Control, the Department of Pesticide Regulation and the State Water Resources Control Board.

The proposed rule will not serve its purported purpose of guaranteeing that EPA relies on the best available science for its regulatory action. Instead, its requirement that all research data, methods and models for "pivotal" regulatory science must be made available to the public is unnecessary, impractical and will prevent EPA from considering the best available science in carrying out its mission to protect public health and the environment. CalEPA and its constituent agencies urge EPA to abandon the proposed rule.

Thank you for your consideration of the attached comments.

Sincerely,

Matthew Rodriquez
Secretary of California EPA

COMMENTS OF CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY, CALIFORNIA AIR RESOURCES BOARD, OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSEMENT, DEPARTMENT OF TOXIC SUBSTANCES CONTROL, DEPARTMENT OF PESTICIDE REGULATION AND STATE WATER RESOURCES CONTROL BOARD ON PROPOSED STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE RULE

DOCKET No. EPA-HQ-OA-2018-0259

INTRODUCTION

The California Environmental Protection Agency (CalEPA) submits the comments below on the proposed rule entitled "Strengthening Transparency in Regulatory Science" (83 Fed.Reg. 18768 (April 30, 2018). CalEPA submits these comments on its own behalf and on behalf of the following California environmental protection agencies: the California Air Resources Board (CARB), the Office of Environmental Health Hazard Assessment, the Department of Toxic Substances Control, the Department of Pesticide Regulation and the State Water Resources Control Board.

The proposed rule purports to be directed toward enhancing the transparency and validity of the scientific information relied upon by the U.S. Environmental Protections Agency (EPA) in order to strengthen the integrity of EPA's regulatory actions. (83 Fed. Reg. 18768.) The mechanism proposed to achieve this purported goal is to require that data and models underlying scientific studies that are "pivotal" to regulatory action must be made available to the public. (83 Fed. Reg. 18769.)

High quality science is critical to EPA's mission to protect human health and the environment. EPA must rely on science to understand the nature and relative risks of threats to human health and the environment, including the populations likely to be affected by any threats, the circumstances and levels of exposure to risks at which harm to human health or the environment have occurred or are likely to occur, and the methods and techniques that can be used to reduce or eliminate harm to human health or the environment.

However, the proposed rule would prevent EPA's consideration of relevant, high quality, important science and appears to be directed to that end. It is based on a fundamentally flawed assumption: that a threshold criterion for determining the merit of scientific research is that all raw data and research methods are made available to the public. The proposed rule does not explain why this criterion should take precedence over all other criteria that are used in the scientific community to evaluate the merit of scientific research, and it ignores well-established reasons that some high quality scientific data and research methods cannot be made available to the public. It also fails to explain why the consistent use of existing methods for evaluating scientific

research, including peer review and EPA's scientific advisory panels, is insufficient to ensure that EPA relies on the best available science for its regulatory actions.

There is no reason to codify the proposed rule's exclusionary regulatory requirement. If adopted, the proposed rule would only endanger and impede EPA's mission to protect public health and the environment. EPA should abandon the proposed rule.

I. The Proposed Rule is Based on a Faulty Premise Regarding the Determinants of Research Quality.

We agree that scientific research should be transparent regarding methods used to collect, analyze and interpret data, and transparent regarding the results and conclusions derived from analysis and interpretation of date. Indeed, scientists are trained in assessing research according to all of these criteria.[1] The proposed rule deviates from accepted standards used by the scientific community to assess the validity of research. The scientific community applies *all* of these criteria, and applies them even when not all data can be made publically available for a variety of reasons. These reasons include but are not limited to the confidential nature of personal health information, the confidential nature of business information, and the confidential nature of proprietary intellectual property. Notwithstanding these well-established protections for some raw data and research methods, the scientific community regularly assesses the merits of scientific research. The proposed rule advances no reason why the accepted methods used in the scientific community to evaluate scientific research should be replaced with the single, threshold requirement in the proposed rule.

The proposed rule also deviates from accepted practices that EPA routinely uses, and is required to use, to evaluate science it relies on for regulatory decisions. EPA has long recognized that proprietary "confidential business information" submitted to it cannot be shared with the public, yet it routinely relies on that information, including scientific studies and other scientific information, as the foundation for important regulatory decisions. (*See, e.g.*, confidential business information protection provisions in the Toxic Substances Control Act at 15 U.S.C. § 2613, subd. (c), and in the Federal Insecticide, Fungicide and Rodenticide Act at 7 U.S.C. 136h, subd. (b).) EPA also adheres to specific Congressional directives regarding the science it should consider for regulatory action, including directives to consider whether the scientific information is reasonable, clear, complete and whether it has been peer reviewed. (*See, e.g.*, the Toxic Substances Control Act at 15 U.S.C. § 2625, subds. (h) and (i), requiring EPA to consider several factors to evaluate science relating to toxic chemicals and requiring that decisions be based on "the weight of the scientific evidence," and the Clean Air Act at 42 U.S.C. § 7408, subd. (a)(2), requiring EPA to rely on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices.")

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[1] J. Berg, P. Campbell, V. Keirmer, N. Raikhel, D. Sweet, "Joint Statement on EPA Proposed Rule and Public Availability of Data," Science, April 30, 2018.

The fact that the proposed rule is at odds with the manner in which the scientific community evaluates research—underscored by the large number of comments submitted in opposition to the rule by scientists, scientific organizations, and scientific journals—and also at odds with methods EPA uses and is required to use to evaluate scientific information suggests that the proposed rule's true purpose is other than to ensure that EPA relies on the "best available science." Instead, the true purpose appears to be to exclude from EPA's consideration scientific research that might support a need for rigorous regulatory action. That purpose is unacceptable, unlawful, and contrary to EPA's mission and duty to protect human health and the environment. EPA should continue to use of the comprehensive criteria used by the scientific community (and historically used by EPA) to evaluate scientific research.

II. The Proposed Rule is Unnecessary Because Existing Procedures Assure that EPA's Regulatory Actions are Based on the Best Available Science.

The proposed rule does not contain an explanation of the necessity for the rule. There are no references to regulations adopted by EPA where a subsequent review of the data or models used in scientific research has revealed that they did not support the regulatory action or were falsified. Neither is there any suggestion that EPA has relied on flawed scientific methods as the basis for regulatory action, or that public unavailability of data or research methods has resulted in irrational or arbitrary regulations.

The lack of any explanation for a need for the proposed rule is doubtless because procedures are already in place that assure use of the best available science for EPA's regulatory activity. These procedures include the Scientific Advisory Board established by Congress in 1978 to advise on scientific matters (42 U.S.C. § 4365.), existing independent peer review of much of the scientific research relied on for regulatory action, and legal requirements that prohibit EPA's adoption of regulations that are arbitrary, capricious or unsupported by substantial evidence (*e.g.* 5 U.S.C. §. 706). When consistently implemented, these procedures and requirements, among others, assure that EPA's regulatory actions are based on the best available science and cast substantial doubt that the true purpose of this rulemaking has anything to do with strengthening the validity of regulatory science.

Congress created the Scientific Advisory Board (SAB) to provide the Administrator with scientific advice. (42 U.S.C. § 4365.) The SAB is required by its authorizing legislation to make every effort to maximize public participation and transparency, "including making the scientific and technical advice of the [SAB] and any investigative panels . . . publically available in electronic form on the website of the Environmental Protection Agency." (*Ibid.*) The proposed rule does not mention the SAB, or its important function in providing expert assessments of whether scientific research offered as the basis for regulatory action is, in fact, the best available science. In another telling signal about the proposed rule's true purpose, EPA did not even

consult with the SAB—its own scientific experts—regarding the proposed rule's provisions and has ignored the SAB's objections to the proposal.[2]

The proposed rule also ignores that much of the scientific research considered in the regulatory context, and all research published in reputable journals, has already been subject to extensive peer review. While the proposed rule would place judgments regarding the science that EPA may use in the hands of political appointees—with its suggestion of an ad hoc mechanism for making exceptions to the rule's limitations—the method that is accepted in the scientific community for assessment of the strength of scientific research is peer review. The fact that scientific studies are regularly peer reviewed, including peer review by expert panels such as the SAB, renders the proposed rule unnecessary.

The process for establishing National Ambient Air Quality Standards (NAAQS) illustrates the scientific review procedures that are already in place for EPA's regulatory actions. In the NAAQS process, the research results that are given the most weight are from the peer-reviewed literature. After EPA staff and their contractors review the literature, the Clean Air Scientific Advisory Committee of the SAB, which consists of internationally recognized experts in their scientific disciplines, reviews the EPA staff reports. The Committee provides advice to the Administrator regarding the adequacy of current standards and recommendations for revisions, if necessary for the protection of public health. The EPA staff reports also receive public comment, including from independent and industry scientists, and the Committee review includes consideration of those public comments. EPA NAAQS documents typically receive multiple rounds of expert scientific review before they are finalized.

The ultimate safeguard to assure that EPA regulatory action is based on high-quality science is the fact that EPA's regulatory action is subject to the notice and comment requirements of the Administrative Procedure Act (APA, 5 U.S.C. § 553) and ultimately to judicial review. To the extent that scientific information proposed as a basis for regulatory action falls short, the APA provides members of the public, regulated businesses and other scientists an opportunity to comment to the agency about those shortcomings and to submit contrary studies and information for agency consideration. (*Ibid.*) Following adoption of a regulation, interested parties may seek judicial review to determine whether it is arbitrary, capricious or lacking in evidentiary support. (5 U.S.C. § 706.) The APA requirements, and the opportunity for judicial review of EPA's regulatory action, protect against the adoption of regulations that lack high-quality scientific support. An additional rule is not required.

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[2] *See* Letter from Michael Honeycutt, Chair, Science Advisory Board, et al., to Scott Pruitt, Administrator, U.S. EPA (June 28, 2018), *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/LoopupWedReportsLastonthBOARD/4ECB44CA28936083852582BB004ADE54/$File/EPA-SAB-18-003+Unsigned.pdf

III. The Proposed Rule Would Eliminate Important Scientific Research from EPA's Consideration to the Detriment of Effective Protection of Human Health and The Environment and Establish a Disincentive for Innovative Research.

As set forth above, the apparent purpose of the proposed rule is to exclude high-quality scientific research from being considered by EPA, because it might point to the need for regulatory action. The examples below highlight research that EPA would likely not be required or permitted to consider if the proposed rule is adopted.[3]

A. The proposed rule would exclude vital epidemiological studies from EPA's consideration.

Many of the key studies likely to be affected by the proposed rule, if finalized, are long-term cohort epidemiological studies that have been integral to setting standards that protect public health and the environment, but for which raw data cannot legally or ethically be published. This prominently includes the NAAQS, particularly given the iterative nature of NAAQS administrative record reviews and EPA's specific solicitation of comment about retrospective application of the proposed rule to these reviews (83 Fed.Reg. at 18772).

EPA assesses the potential for adverse health impacts associated with air pollutants as part of setting NAAQS. Epidemiological studies reveal the links between pollutant exposure and adverse health effects. The Harvard Six Cities study of over 8,000 people[4] and the American Cancer Society study of over 500,000 people,[5] in particular, have demonstrated the association between particulate matter (less than 2.5 microns) exposures and premature mortality. A more recent study of 61 million Medicate recipients found adverse health effects associated with particulate exposure below the current standard.[6] These studies rely on confidential information about each

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[3] As discussed below, the proposed regulatory text would allow the Administrator to exempt studies from the rule "if he or she determines that compliance is impracticable because: (a) It is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security[.]" 83 FR at 18774. However, this exemption seems designed to allow EPA to avoid publishing dose response data and models on which the agency's "pivotal regulatory science" has already relied, rather than allowing EPA to base regulatory decisions on data that cannot be made publicly available.

[4] Johanna Lepeule, Francine Laden, Douglas Dockery, and Joel Schwartz. Chronic Exposure to Fine Particles and Mortality: An Extended Follow-up of the Harvard Six Cities Study from 1974 to 2009. Environmental Health Perspectives 2012. 120(7): 965-970.

[5] C. Arden Pope, III, PhD, Richard T. Burnett, PhD, Michael J. Thun, MD, Eugenia E. Calle, PhD, Daniel Krewski, PhD, Kazuhiko Ito, PhD, and George D. Thurston, ScD. Lung Cancer, Cardiopulmonary Mortality, and Long-term Exposure to Fine Particulate Air Pollution. JAMA. 2002 Mar 6; 287(9): 1132–1141.

[6] Qian Di, M.S., Yan Wang, M.S., Antonella Zanobetti, Ph.D., Yan Wang, Ph.D., Petros Koutrakis, Ph.D., Christine Choirat, Ph.D., Fransecsa Dominci, Ph.D. and Joel Schwartz, Ph.D.,

person in the cohort. This information includes employment history, medical history, and alcohol and drug use. Validation of the study's conclusions would require re-linking of data sets containing individually identifiable health information. For example, residence data needs to be paired with birth and death dates, and related health condition or lifestyle data (e.g. smoking habits) to isolate the effect of air pollution levels on the mortality rates of populations in different cities. Insisting such data be "publically available" is a violation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The proposed rule would either require publishing data so thoroughly redacted as to be effectively useless for validation, or, more likely and more in keeping with the rule's apparent actual purpose, preclude EPA from considering these studies and others like them in the NAAQS standard-setting process. EPA's failure to consider individual health data—because it cannot be made public—would miss important data regarding particularly vulnerable populations that the NAAQS were developed to protect. The ultimate result would be weakened NAAQS standards that would not rely on the best available science.

The proposed rule would also imperil vital health protections that relate to ensuring clean water. Epidemiological studies that EPA could not consider under the proposed rule include studies related to fecal indicator bacteria concentrations and water-content recreation at ocean and freshwater beaches. These studies of people swimming, wading, surfing and contacting water at beaches include individual participant enrollment in the studies and follow-up to gather private medical data to estimate dose-related responses. This type of epidemiological data was used in EPA's Clean Water Act section 304(a) criteria (33 U.S.C. § 1314(a)), including EPA's 2012 *Recreation Water Quality Criteria*,[7] which is a foundation document for the California State Water Board's proposed bacterial water quality objectives.

The proposed rule would also likely prevent EPA from considering epidemiological studies of children exposed in utero to mercury through maternal consumption of mercury-contaminated fish or marine animals because individual health data could not be made public. EPA used these epidemiological studies in its 2001 report, *Water Criterion for the Protection of Human Health: Methylmercury*,[8] which served as a basis for the California State Water Board's recently adopted mercury water quality objectives.

Other examples of vital research that would likely be excluded from consideration by the proposed rule include toxicity criteria for lead, arsenic and vinyl chloride, amongst other chemical agents, as well as biomonitoring studies that identify the presence of

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Air pollution and Mortality in the Medicare Population, New England Journal of Medicine 2017, 376 (26) 2513-2522.

[7] No. EPA-820-F-12-058, *available at* https://www.epa.gov/sites/productions/files/2015-10/documents/rwqc2012.df

[8] No. EPA-823-R-01-001, *available at* https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=20003UU4.TXT

chemicals in human subjects. All of this research is based on personal raw data that cannot be provided to the public,

Protection of public health and the environment requires that EPA not adopt an unnecessary regulatory requirement that would prevent its consideration of vital epidemiological studies.

B. The proposed rule would exclude large amounts of animal studies from EPA's consideration and important data regarding chemical exposures.

A large toxicological literature based on animal studies has accrued over the past 60 years that underlies the establishment of advisory levels and standards for hundreds of chemicals, including drinking water maximum contaminant levels, soil clean-up targets, hazardous air pollutants reference levels, water quality levels for establishing permits, pesticide registration decisions. In the scientific studies relied on for establishing these levels, data are generally provided in aggregated form due to journal page count limitations. Certain raw study data are available at an individual animal level (e.g., pathology data) online and from animal study reports performed by the National Toxicology Program (NTP), but such data are not included in study reports published by academic and industry researchers in peer-reviewed journals.

The proposed regulation would preclude EPA from considering a large number of these important, peer-reviewed animal studies — studies that should serve as a foundation for regulatory action – merely because of the unavailability of the raw data underlying the studies or the time and expense that would be required to obtain the raw data and provide it to the public. Further, a requirement to obtain an ad hoc exception to the proposed rule's requirements for large numbers of animal studies would be wholly unworkable. Again, the ultimate result of the proposed rule's requirements as applied to animal studies would be that EPA would not consider peer-reviewed, high-quality research that has been accepted in the scientific community.

C. The proposed rule would exclude innovative academic research from EPA's consideration.

For scientists at academic and research institutions, intellectual property protections for innovative analytical tools, models, and computer code are vital to scientific achievement and career advancement. Section 30.5(c) of the proposed rule, however, would require the publication of all details of such original models and code. Moreover , intellectual property is absent from the list of potential exceptions to the data publication requirements in proposed section 30.5 and bases for exemptions in proposed section 30.9, both of which suggest (without any detail) protections only for privacy, confidentiality, confidential business information, and national and homeland security.

This lack of protection for intellectual property would thwart innovation and/or prevent the consideration of newer tools and models in EPA's regulatory decision-making.

Additionally, industry research might still be protected as confidential business information, while academic or public interest research would not be entitled to rely on intellectual property protections. The absence of publication exceptions or exemptions for protected intellectual property makes it far more likely that industry research, rather than academic or public interest research, would form the basis of regulatory decision-making. This could build an industry preference into EPA's regulatory process.

D. The proposed rule would exclude high-quality meta-analyses from EPA's consideration.

The proposed rule would also substantially affect EPA's ability to consider high quality meta-analyses. Meta-analyses incorporate the results from multiple studies on the same topic, and can be most informative when using data sets with information at the individual level. If studies using individual data are excluded because of confidentiality and disclosure concerns, there will be concern for the validity of high quality meta-analyses that incorporate data from individual studies.

E. The proposed rule is likely to exclude high-quality CARB-funded research from EPA's consideration.

Over the past two decades, CARB has funded more than 460 research contracts, which have resulted in a similar number of peer-reviewed, highly cited publications in high-impact journals. On average, other articles cite these CARB-funded publications about 82 times each, and approximately 80 percent are published in the top quartile of journals in terms of scientific impact, which compares favorably to publications funded by other organizations such as the EPA and the Health Effects Institute. Publications on health and exposure, atmospheric science, and emissions monitoring and control have received the most citations, and reflect CARB's long-standing research strengths. CARB research also has been cited in reviews of the NAAQS and in dozens of CARB regulatory documents. Publications resulting from CARB research contracts have won multiple Haagen-Smit Prizes for outstanding papers published in the journal *Atmospheric Environment*, the John Johnson award for outstanding research in diesel engines from the *SAE International Journal of Engines*, and the Arthur C. Stern Distinguished Paper award from the *Journal of the Air and Waste Management Association*.[9]

A significant number of the studies that CARB supports are epidemiological/cohort studies that the proposed rule is likely to preclude from EPA consideration in its regulatory decision making for the reasons discussed above. These likely include:

[9] CARB 2018. Proposed Triennial Strategic Research Plan Fiscal Years 2018-2021, https://ww2.arb.ca.gov/sites/default/files/2018-04/FY2018-21_Triennial_Research_Plan-2018-04-24.pdf , p. 9.

- The 10-year Children's Health Study (CHS) initiated in 1993, which was the first major study to assess the impacts of long-term air pollution exposure on the respiratory health of California's children.[10] Following 5,500 students in 12 southern California communities from fourth grade through high school, this study revealed the extent to which ozone, nitrogen dioxide, acid vapors consisting of nitric acid and hydrogen chloride, and particulate matter affect children's lung development. The results of this study are evidence for classifying children as sensitive receptors to air pollution and have influenced research since and shaped California legislation addressing children's microenvironments.[11]
- The Los Angeles Family and Neighborhood Survey (LAFANS), a study of families in different neighborhoods in Los Angeles County.[12] The researchers found that children more highly exposed to traffic pollution were 30-40 percent more likely to report wheeze symptoms.[13]

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[10] Peters, J.M., et al. (1999) "A study of twelve Southern California communities with differing levels and types of air pollution. II. Effects on pulmonary function," American Journal of Respiratory and Critical Care Medicine. 159: 768-775; Avol, E.L., et al. (2001) "Respiratory effects of relocating to areas of differing air pollution levels," American Journal of Respiratory and Critical Care Medicine, 164: 2067-2072; Gauderman, W.J., et al. (2002) "Association between air pollution and lung function growth in Southern California children: Results from a second cohort," American Journal of Respiratory and Critical Care Medicine, 166(1): 74-84; McConnell, R., et al. (2002) "Asthma in exercising children exposed to ozone: A cohort study," Lancet, 359: 386–391; Gauderman, W.J., et al. (2004) "The effect of air pollution on lung development from 10 to 18 years of age," New England Journal of Medicine 351(11): 1057-1067; Gauderman, W. J., et al. (2005) "Childhood asthma and exposure to traffic and nitrogen dioxide," Epidemiology 16:737-743; McConnell, R., et al. (2006) "Traffic, susceptibility, and childhood asthma," Environmental Health Perspectives 114:766-772; Gauderman, W. J., et al. (2007) "Effect of exposure to traffic on lung development from 10 to 18 years of age: a cohort study," Lancet 369:571-577; Gauderman, W.J., et al. (2015) "Association of improved air quality with lung development in children" New England Journal of Medicine 372(10):905-913; Berhane, K. et al. (2016) "Association of changes in air quality with bronchitic symptoms in children in California, 1993-2012", Journal of the American Medical Association, 315(14):1491-1501.

[11] CARB 2018. Proposed Triennial Strategic Research Plan Fiscal Years 2018-2021, https://ww2.arb.ca.gov/sites/default/files/2018-04/FY2018-21_Triennial_Research_Plan-2018-04-24.pdf , pp. 6, 15.

[12] Ritz, B et al. (2009) "Traffic-Related Air Pollution and Asthma in Economically Disadvantaged and High Traffic Density Neighborhoods in Los Angeles County, California" Final Report ARB Contract No. 04-323 Prepared for the California Air Resources Board and California Environmental Protection Agency Sacramento, CA.

[13] CARB 2018. Proposed Triennial Strategic Research Plan Fiscal Years 2018-2021, https://ww2.arb.ca.gov/sites/default/files/2018-04/FY2018-21_Triennial_Research_Plan-2018-04-24.pdf , p. 15.

- The East Bay Kids Study[14] and the California Health Interview Survey (CHIS),[15] which sought to determine impacts of pollution levels and greater sensitivity in low-income neighborhoods on asthma, including in the CHIS study, on whether the asthma burden disparity is due to exposure to higher levels of air pollutants, greater vulnerability, or both. Findings from these studies have helped to inform policy decisions on motor vehicle emissions control and enforcement, and asthma prevention, control, and education in low socioeconomic status populations.[16]

IV. There are No Provisions That Could be Included in the Proposed Rule that Would Make it Workable or Effective to Assure that EPA Relies on the Best Available Science.

EPA's notice of the proposed rule solicits comments on which criteria it should base exceptions to the rule, including whether case-by-case exceptions to the rule may be appropriate. Because the underlying premise of the rule is flawed and the rule is unnecessary, unlawful, arbitrary, and harmful, we decline to provide suggestions for methods to determine exceptions to the rule. There are no criteria or ad hoc methods for making exceptions to the rule that would not pose an unnecessary risk of constraining use of the best available science to make regulatory decisions, particularly where political appointees rather than expert scientific panels, such as the SAB, would apply the criteria or make the ad hoc determinations.

Additionally there are no criteria or ad hoc methods that would prevent stalling vital decisions to protect public health and the environment by "analysis paralysis." The proposed rule, if adopted, would inevitably delay setting protective standards through prolonged evaluation of the sufficiency of the public availability of research data and methods, rather than evaluation of the actual quality and import of scientific research. A related likely consequence of the proposed rule, even if it contains ad hoc mechanisms for exceptions, is a reduction in EPA's ability to respond quickly to emerging challenges, when data and models take time to be made publicly available and/or redacted and otherwise prepared in a format appropriate for public review.

EPA suggests the following methods to protect privacy, confidentiality, security, and other necessary interests: "simple data masking, coding, and de-identification techniques"; "[r]equiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure

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[14] Kim, J., et al. (2008) "Residential Traffic and Children's Respiratory Health." *Environmental Health Perspectives* 116.9 (2008): 1274-1279.
[15] Meng, Y-Y., et al. (2012) "Is Disparity in Asthma among Californians due to Higher Pollution Exposures, Greater Vulnerability, or Both?" Final Report ARB Contract No: 07-309 Prepared for the California Air Resources Board and the California Environmental Protection Agency.
[16] CARB 2018. Proposed Triennial Strategic Research Plan Fiscal Years 2018-2021, https://ww2.arb.ca.gov/sites/default/files/2018-04/FY2018-21_Triennial_Research_Plan-2018-04-24.pdf , p. 22.

agreements." (83 Fed.Reg. at 18771.) Each of these proposed strategies is insufficient to protect privacy and confidentiality, and also a waste of time and resources because the underlying proposed rule is unnecessary in the first place. Further, these suggestions presume resources that EPA does not commit. EPA's failure to prepare a Regulatory Impact Analysis, or attempt to estimate the significant expenses that would be required to prepare, redact, and make public vast amounts of data—as it would have to do in order to actually base regulatory decisions on the best available science—suggests that EPA does not intend to take on any burdens associated with the proposed rule, including burdens attendant to data masking, coding and de-identification techniques.[17] The lack of any commitment to fund implementation of procedures to protect privacy, confidentiality, security and other interests would privilege industry science, where funds would be available to comply with the proposed rule's requirements, and would exclude robust academic and other science from EPA's consideration only because of insufficient funds to comply with the proposed rule's onerous and unnecessary requirements.

Data masking, coding, and other procedures suggested to protect privacy, particularly in the context of epidemiological research, also would not work. Even when medical data is masked or coded, subjects can be identified if the sample size is small enough, the characteristics described are rare enough, and/or the data includes, for example, subjects' family structure, geographic location, dates of birth, sex/gender, medical conditions, occupations, and/or dates and causes of death. The fact that the public would be able to de-anonymize much epidemiological data, after de-identification processes have been applied, would almost certainly have a chilling effect on voluntary public participation in important research. It would also prevent EPA from relying on the "best available science" in carrying out its work.

V. The Proposed Rule Undermines Established Principles and Practices in its Approach to Dose Response Modeling, and Would Result in Delays in Completion of Risk Assessments.

The proposed rule includes particular focus on dose response models and default assumptions used in those models. The need for default approaches in risk assessments has long been recognized as necessary to select among inference options in the presence of uncertainty. It has also been long recognized that there can be compelling scientific evidence for taking an alternative approach to a default in a

[17] U.S. EPA does not acknowledge or attempt to justify its failure to prepare a Regulatory Impact Analysis or otherwise estimate the benefits and burdens of the proposal, saying only: "One recent analysis found that: 'Improvements in reproducibility can be thought of as increasing the net benefits of regulation because they would avoid situations in which costs or benefits are wrongly estimated to occur or in which regulatory costs are imposed without corresponding benefits. . . .' They concluded that 'an increase in existing net benefits from greater reproducibility, which, if it occurred, would cover the costs of obtaining the data and making the data available.'" 83 Fed.Reg. at 18772, citing https://www.mercatus.org/system/files/ Mercatus-Lutter-Public-Access-Data-v3.pdf.Security.

scientific analysis. The National Academy of Sciences has reviewed this approach to defaults throughout the years,[18] and the need for default approaches to perform assessments absent compelling science to the contrary has been established. EPA has therefore developed a series of practices, handbooks and guidance documents over the years that guide the development of risk assessments. Further, as the science has developed, these practice and guidance documents have been updated following lengthy review and discussion. Individual EPA documents also undergo extensive internal and external scientific peer review. The result is a canon that guides the development of analyses and against which the analyses are judged.

In this context, we make the following observations about the proposed rule's provisions regarding dose response modeling data:

- Requiring justification for all default assumptions ignores establishment of defaults through prior public processes and external public peer reviews. Requiring EPA to justify the use of default assumptions for every toxicity health factor derivation ignores the detailed development process of those default assumptions. Those default assumptions were developed in several EPA documents (including the 2005 Guidelines for Carcinogen Risk Assessment[19]), which received public comment and extensive external peer-review. Requiring EPA to rejustify those default assumptions every time they are used, as the proposed rule suggests, would serve no purpose other than to add unnecessary delay to risk assessments and regulatory action.

- The approach to non-linear cancer dose-response modeling suggested by the proposed rule is inconsistent with scientific guidance for determining when defaults can be replaced by alternative modeling approaches that are backed by chemical-specific data.

- The requirement for sensitivity analysis for all alternative-modeling assumptions does not require an evaluation of the scientific validity of those models. The proposed rule's requirement that dose-response modeling include a sensitivity analysis including all alternative modeling assumptions does not make any

[18] National Academy of Sciences, National Research Council (2009) Science and Decisions: Advancing Risk Assessment, Washington DC, National Academy Press, *available at* https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment; National Academy of Sciences, National Research Council (1994). Science and Judgment in Risk Assessment. Washington DC National Academy Press;
National Academy of Sciences, National Research Council (1983). Risk Assessment in the Federal Government; Managing the Process, Washington DC National Academy Press

[19] No. EPA/630/P-03/001F, *available at* https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

mention of how those assumptions would be scientifically justified. This lack of scientific justification criteria would invite the submission of models that would not have biological relevance for inclusion in the sensitivity analysis. This would result in a process that would make EPA risk assessment documents unwieldy, unmanageable and unreliable.

- The proposed rule gives obvious preference to specific dose-response models (e.g., various cancer threshold models) over current EPA modeling practice. This preference is problematic. As an example, EPA cancer modeling generally assumes that no exposure threshold exists for carcinogenesis unless data to the contrary exist. This assumption includes the recognition of the study design of most cancer bioassays, which use a relatively small sample size, resulting in a low detection power. This low detection power often makes it difficult or impossible to determine the existence of a threshold for carcinogenicity for a specific chemical.

  This current EPA cancer modeling practice was developed in documents that received public comment and peer-review. That review process included consideration of the assumptions noted above. EPA non-cancer modeling practice documents also received public comment and peer-review.
  In contrast, the proposed rule's requirement for re-justification of established and accepted modeling practices has not undergone any scientific peer review, including peer review by EPA's own SAB, lacks scientific consensus, and is not scientifically justified in the rule.

- The proposed rule does not address guidance for evaluating the scientific plausibility and usefulness of alternative dose-response models. The proposed rule generally does not provide any guidance or direction on how alternatives to current EPA dose-response modeling practice would be evaluated for their scientific plausibility and usefulness.

  For instance, the preamble to the proposed rule states, "EPA should give appropriate consideration to high quality studies that explore...nonparametric models that incorporate fewer assumptions". (83 Fed.Reg at 18770.) Unfortunately, nonparametric dose-response models lacking a biological background can be manipulated to result in output that does not correspond to the biological reality. The proposed rule does not compel such models to be consistent with biology and to be evaluated for biological plausibility.

  Additionally, the statement in the proposed rule that "EPA should also

incorporate the concept of model uncertainty when needed as a default to optimize low dose risk estimation based on major competing models" (83 Fed.Reg. at 18770) is completely unclear.

CONCLUSION

The proposed rule, if adopted, would not strengthen the validity of regulatory science that serves as the basis for EPA regulatory action. Instead, it would exclude vital science from consideration, delay important regulatory action and interfere with the agency's ability to respond to environmental and public health emergencies, all for no discernable reason. The proposed rule is unnecessary to ensure that EPA relies on high quality science for regulatory action and is instead a dangerous and transparent attempt by EPA to limit its consideration of important and valid science that might impel action to protect human health and the environment. EPA should abandon the proposed rule.

PROJECT ON GOVERNMENT OVERSIGHT
Exposing Corruption. Exploring Solutions.

August 16, 2018

Acting Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Submitted to: http://www.regulations.gov

Subject: Comments on Proposed Rule, "Strengthening Transparency in Regulatory Science," 83 Fed. Reg. 18768 (April 30, 2018), Docket ID No. EPA-HQ-OA-2018-0259

Dear Acting Administrator Wheeler:

The Project On Government Oversight (POGO) provides the following public comment about the Environmental Protection Agency's (EPA) proposed rule, "Strengthening Transparency in Regulatory Science," published on April 30, 2018.[1] As an independent nonprofit organization committed to achieving a more effective, ethical, and accountable federal government, POGO has an interest in ensuring that the EPA follows its legal obligations for the use of scientific evidence in rulemaking, adheres to all appropriate steps of the rulemaking process, and continues to issue and strengthen sound public protections under its statutory obligations. Because this rule fails in each of these regards and would cause the EPA to fail in many future rulemakings going forward if put into effect, POGO expresses its strong objections to the proposed rule and urges the EPA to withdraw it.

The proposed rule notes that "the best available science must serve as the foundation of EPA's regulatory actions" and uses the words "transparency" and "reproducibility" to project lofty goals. But, instead of making scientific evidence more available or easier to use, the rule will often mean the best available science is off limits to the Agency. Its real effect will be to undermine the way that the EPA is able to rely on and even-handedly assess scientific studies for use in the rulemaking process.

The rule lacks a purpose and scientific basis

This proposed rule presents no clear explanation or examples of the types of problems it is seeking to solve

This rule lacks a fundamental statement of its purpose or of the problems that it purports to address, the central element of any proposed rule. In addition to offering no clear explanation of

[1] 83 Fed. Reg. 18768, April 30, 2018. https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0001

any problem, the proposal provides no supporting evidence, no studies establishing that the EPA has an information problem, nor any citations that the proposed standard has ever been used before or that the EPA understands what its impact will be when implemented. This lack of a statement of purpose reflects the wholly insufficient development process that produced this rule, which, as is described below, originated without input from key stakeholders inside and outside of the EPA.

If the EPA does believe there is a real problem, it should be able to provide some example of a scientific study that has been used during rulemaking that does somehow substantively lack transparency or fails some standard for reliability. Inclusion of such examples are necessary in a proposed rule so that commenters can debate those examples. By failing to include any past or present cases that might necessitate its proposed rule, we are left to conclude that there is no clear purpose for the EPA's proposal.

There is no systematic analysis of the use of scientific studies in rulemaking that provides a basis for this rule

Proposing a rule that will fundamentally change what information can be used in future rulemakings is a major undertaking and requires a great deal of certainty and evidence. Given the complete lack of evidence provided in this case, this proposed rule is premature even if the Agency truly believes there is some deficiency in the policies and procedures governing use of information in rulemakings. Before proposing any rule, but especially one that is this foundational to future rulemaking, the Agency should start by conducting studies to better understand the scope of the problem, if there is one, and the best way to improve its use of scientific studies. Without such a study, the EPA has provided no evidence to support the claim that there is an issue with the "transparency of EPA regulatory science" or that there is a need for the public to be able to "replicate findings," as the rule suggests.

This type of study should go hand-in-hand with an evaluation of the rule and its supporting evidence by the EPA's Science Advisory Board (SAB). In this case, to appropriately assess the scientific claims being made, the SAB should be allowed to fully investigate and offer specific recommendations on the rule. In fact, the SAB itself has said that the rule "deals with a myriad of scientific issues for which the Agency should seek expert advice from the Science Advisory Board."[2]

In fact, scientific studies are already thoroughly evaluated under the current rulemaking process

As is described below, this rule's implementation will place large portions of scientific research off-limits during EPA rulemaking. Instead of arbitrarily excluding broad types of studies from

[2] Memorandum from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science to Members of the Chartered SAB and SAB Liaisons, regarding Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14), May 12, 2018.
https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf

being cited in rulemaking, why not continue to give Agency scientists the ability, as they have had for decades, to comprehensively assess and compare the scientific evidence presented in a study and give weight to each study as a result of careful deliberation?

During the rulemaking process, EPA officials already decide if studies are unreliable or flawed based on the studies' own merits—and sometimes even flawed studies can offer important insights that the EPA should benefit from. For each rule, the Agency is already required to fully explain its reasoning and the studies relied on, offer dockets of supporting information, and have a public comment period. This notice-and-comment process already allows outside stakeholders to raise concerns or problems with the science used or offer alternative studies. The Agency has to consider and respond to those comments, which commonly occurs in the form of an extensive explanation that accompanies the final rule in the Federal Register.

A letter from the chief editors of six of the major scientific journals explains this process of evaluating studies, even when data cannot be made public:

> "The merits of studies relying on data that cannot be made publicly available can still be judged. Reviewers can have confidential access to key data and as a core skill, scientists are trained in assessing research publications by judging the articulation and logic of the research design, the clarity of the description of the methods used for data collection and analysis, and appropriate citation of previous results."[3]

The rule fails to explain its two key requirements for the use of studies in rulemaking

The rule fails to properly define the two key requirements that will have a major impact on how it is implemented: 1) how to anonymize sensitive data for public release and 2) the distinction between replicability and reproducibility and how either precisely applies to scientific studies.

Without knowing the details of how these transparency and replicability provisions, central to the rule, will be implemented, commenters can't even begin to assess the wide-ranging outcomes of this rule. Even ignoring the fact that this rule provides no statement of purpose, as described above, or that it was created with significant procedural shortcomings, as described below, the fact alone that it is impossible to provide substantive comment is sufficient reason for this rule to be withdrawn.

The rule provides only a vague description of how to anonymize data

First, the rule states that data relied on in making regulations must be made publically available, but there are a variety of valid reasons researchers don't publish all the underlying data—personally identifiable information and confidential business information being among the biggest concerns.

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[3] Jeremy Berg, *et al.*, "Joint statement on EPA proposed rule and public availability of data," *Science*, April 30, 2018. http://science.sciencemag.org/content/early/2018/04/30/science.aau0116

The scientific community itself acknowledges that not all data can be made public. The letter from the six chief editors explains the sharp limits on transparency, stating that "in not every case can all data be fully shared. Exceptional circumstances, where data cannot be shared openly with all, include data sets featuring personal identifiers."[4]

Given the range of studies and information that would be affected by the proposed rule, the Agency would need numerous and complicated processes to ensure that data was properly anonymized. The EPA's proposed rule claims there are ways to mask data to ensure privacy is protected, but fails to provide any details or specifics for how such a process would be implemented—this is not a simple issue of redacting a few data fields. But instead of providing specific steps for how this process would be handled so that commenters could provide input, the rule is all but silent on this issue.

Some scholars have explored ways to better anonymize data in scientific studies, but those efforts are not foolproof. Even when personal identifying information is removed from data, it can be possible to identify individuals in the right circumstances from a combination of simple data points.[5] The most effective way to protect personal privacy, then, is to not publish the detailed data underlying these studies at all. In these cases, even though the studies have been conducted by reputable researchers at academic institutions, and peer reviewed to ensure validity, they would ultimately be unavailable to Agency officials as evidence in rulemakings.

The rule fails to differentiate meaningfully between reproducibility and replicability

The second key consideration that the proposed rule fails to address is a concrete definition for what it means for information that "includes the information necessary for the public to understand, assess, and replicate findings," which is the standard the rule attempts to establish for information that is considered "publicly available in a manner sufficient for independent validation." Besides a vague list containing items that may be included in this type of publically available and replicable information ("data," "associated protocols," "computer codes and models involved in the creation and analysis of such information," "recorded factual materials," and "detailed descriptions of how to access and use such information,"), no further description of what it means to "replicate findings" is given.

Confounding matters, while the statement of the rule itself refers to replicability of scientific findings, the background information supporting the rule focuses on scientific studies' "reproducibility," which has a wholly different meaning in a scientific context. While the definitions of these terms continue to be debated by scientists, which further demonstrates the difficulty in how the EPA has used them, there is broad consensus:[6] a study is commonly defined by scientists as replicable if its findings can be obtained again through conducting a new,

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[4] Jeremy Berg, *et al.*, "Joint statement on EPA proposed rule and public availability of data," *Science*, April 30, 2018. http://science.sciencemag.org/content/early/2018/04/30/science.aau0116

[5] Mark van Rijmenam, "The Re-Identification Of Anonymous People With Big Data," *Datafloq*, February 10, 2018. https://datafloq.com/read/re-identifying-anonymous-people-with-big-data/228

[6] Mark Liberman, "Replicability vs. reproducibility — or is it the other way around?" *Language Log*, October 31, 2015. http://languagelog.ldc.upenn.edu/nll/?p=21956

independent study, whereas a study is typically defined as reproducible if reanalysis of data collected during that study, using the same or similar methods, produces the same findings.

The vast disparity in these definitions, and the fact that both terms are mentioned multiple times between the proposed rule and its supporting information, leaves us to guess what the intent of the rule really is, which means commenters simply can't interpret how this rule will be implemented. But, because the rule itself says it must be possible to "replicate" studies' findings, we should assume that the rule may intend the strongest possible meaning: that it must genuinely be possible to conduct all studies used in rulemaking again, from scratch, and obtain the same findings. As we explain below, this then establishes a standard that would preclude an enormous quantity of studies form being used in the rulemaking process.

The rule will undermine the use of scientific evidence in rulemaking

Scientific studies that could inform rulemaking will be thrown out

Essentially, the proposed rule would require that the Agency only use studies for which the underlying data is fully public or whose findings can be replicated in their entirety. So it's reasonable to conclude that, if the rule goes into effect, the EPA will no longer be able to use a large portion of the studies that it currently relies on, including important longitudinal human health studies, to craft public safeguards. Major health studies often collect large amounts of information about the people who agree to participate and there are laws, like the Health Insurance Portability and Accountability Act of 1996,[7] that strictly prohibit sharing a person's medical information.

In the letter from the six major scientific journals,[8] after the editors raise concerns about limiting scientific evidence, they also conclude that "excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes."

The Agency also uses many studies, such as those that link living in proximity to an airport to toxic blood lead levels in children[9] or studies that found a link between fine particulate air pollution and premature deaths,[10] that cannot be repeated, because they were based on environmental disasters or major exposures to toxic substances. Just because they can't—or shouldn't—be repeated, however, doesn't mean we should ignore the vital insights they provide. The knowledge we have gained from these tragedies can and should be used to help safeguard the public in the future.

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[7] https://www.gpo.gov/fdsys/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf

[8] Jeremy Berg, *et al.*, "Joint statement on EPA proposed rule and public availability of data," *Science*, April 30, 2018. http://science.sciencemag.org/content/early/2018/04/30/science.aau0116

[9] Marie Lynn Miranda, *et al.*, "A Geospatial Analysis of the Effects of Aviation Gasoline on Childhood Blood Lead Levels," *Environ Health Perspect*, Vol. 119, Issue 10, October 2011, p. 1513–1516. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3230438/

[10] Douglas W. Dockery, *et al.*, "An Association between Air Pollution and Mortality in Six U.S. Cities," *N Engl J Med*, Vol. 329, December 9, 1993, p. 1753-1759. Results were then confirmed by an independent reanalysis: Health Effects Institute, "Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality" July 2000. https://www.healtheffects.org/system/files/HEI-Reanalysis-2000.pdf

Instead, banned from being allowed to make use of the vast wealth of scientific evidence based on human subjects, Agency officials will be left with studies that don't have any personal privacy concerns, such as industry studies that often rely on animal test subjects.[11]

The rule will put the EPA in the position of setting standards for studies, significantly reducing the number of studies the EPA can rely on

The rule's constraints on the use of scientific studies mean that even the use of studies that don't end up being haphazardly tossed out by this rule will be hindered substantially.

The rule also puts the Agency in a position in which it's forced to serve as an independent reviewer of all scientific data underlying studies it uses, effectively having to peer-review these studies, which will severely hamstring Agency scientists, who already have limited resources. When the EPA was sued over air quality standards for particulate matter and ozone during the George W. Bush administration, the U.S. Court of Appeals for the District of Columbia Circuit said a requirement to make public the underlying data for the key studies used in the rulemaking process would be "impractical and unnecessary."[12]

The three judge panel concluded that, "if EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment ..."

The Congressional Budget Office (CBO), in response to the HONEST Act of 2017,[13] a piece of legislation with very similar provisions to the proposed rule, has said that this type of policy, without a major funding commitment, would significantly reduce the number of studies that the EPA is able to rely on when proposing rules.[14]

If the EPA wants to address the accessibility of scientific studies and data, an important issue to scientists as well as members of the public, it should acknowledge that those efforts, which might include building a new public-facing platform or carefully considering certain types of standards, will amount to a years-long process and will require an enormous investment of Agency time and funding. That type of proposal shouldn't be made in a brief proposed rule, however, and should only be made, as described above, if extensive studies demonstrate that there is a real need for an update to how scientific studies are used in Agency rulemaking.

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[11] Warren Cornwall, "New rule could force EPA to ignore major human health studies," *Science*, April 25, 2018. http://www.sciencemag.org/news/2018/04/new-rule-could-force-epa-ignore-major-human-health-studies

[12] *American Trucking Associations, Inc., et al., Petitioners, v. Environmental Protection Agency*, 283 F.3d 355 (D.C. Cir. 2002). https://law.justia.com/cases/federal/appellate-courts/F3/283/355/484491/

[13] *https://www.congress.gov/bill/115th-congress/house-bill/1430

[14] EPA analysis of Honest Act to CBO, 2017. https://www.scribd.com/document/344731162/EPA-analysis-of-Honest-Act-to-CBO

The process for creating this rule was severely flawed and will result in procedural issues for future rules

There is no statutory authority for this rule

The EPA is proposing this rule without any clear statutory authority from Congress. Agencies are not permitted to create new laws or requirements unless duly authorized by Congress. While an agency has authority in its given issue area, which, in the case of the EPA, is protecting the environment, that authority is not absolute.

The EPA claims that its authority for this rule stems from "provisions providing general authority to promulgate regulations necessary to carry out the Agency's functions" under a number of environmental laws. This is a grave misinterpretation of the Agency's authority under these laws, as none of these laws require or mention transparency requirements for scientific studies. Agencies do offer new regulations or update existing ones under the authority of long-standing statutes, but these are done because of changes in technology, science, or law that then require new rules to properly enforce the original intent of the statute. But this proposal to regulate what counts as usable science during rulemaking is far removed from the intent Congress had in passing laws about keeping our air and water clean and protecting the public from hazardous chemicals.

In fact, this proposal would directly contradict requirements in several of the laws cited by the Agency that instruct the EPA to consider available science in rulemakings. For instance, the Safe Drinking Water Act directs the EPA to base its determination about whether to regulate any particular contaminant "on the best available public health information."[15] Additionally, the Toxic Substances Control Act requires the EPA to take regulatory action "consistent with the best available science."[16]

The rule violates the Administrative Procedure Act[17]

The Agency also seems to claim it derives some authority from "requirements in the Administrative Procedure Act (APA) to ensure public participation in the rulemaking process." However, that is again an overly broad interpretation. Federal agencies have overseen public participation in rulemakings for years. The proposed rule would not improve the key public participation components such as rulemaking disclosures or the notice and comment process.

If anything, the rule is in violation of the APA, which makes it clear that an agency can not engage in arbitrary and capricious actions or decisions in rulemakings. The Agency must have clear and strong justification for actions taken in a rulemaking. Given the lack of supporting evidence or statutory requirement for this policy, the EPA will be hard pressed to prove that this untested standard for scientific transparency is not arbitrary.

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[15] *42 U.S.C. § 300g-1(b)(1)(B)(ii)(II)
[16] *15 U.S.C. § 2625(h)
[17] *5 U.S.C. §§ 553, 706.

In fact, if the rule were put into effect, it could undermine future rulemakings by the EPA. Many of the proposed rules using these standards could be challenged in court and deemed "arbitrary and capricious" because they exclude relevant data and studies for failing to meet poorly established data transparency requirements. Separately, if a commenter referred substantively to a study that the EPA was barred from using, the Agency's failure to respond to the comment could also cause the rule to be deemed "arbitrary and capricious."

The proposed rule gives the Administrator alone discretion to exempt future rulemakings from this rule "on a case-by-case basis if he or she determines that compliance is impracticable," either because scientific data underlying the rule cannot be made appropriately publicly available or because a review of the science cannot be conducted in accordance with cited guidance from the Office of Management and Budget. Because the rule does not provide any mechanism for evaluating if studies should be exempted from the rule's requirements, however, there is no reason to conclude that the Administrator will make case-by-case exemptions appropriately and there is no way to prevent exemptions from be granted arbitrarily.

The rule should be withdrawn

In conclusion, POGO finds the EPA to be without sufficient authority to propose this rule and the proposed rule itself to be incomplete, ill-considered, and contrary to the Agency's mission to protect the public and environment. Therefore, we again urge the EPA to withdraw this rule.

We appreciate your consideration and attention to this matter. If you have questions or need additional information, please contact us at 202-347-1122 or smoulton@pogo.org.

Sincerely,

Sean Moulton
Senior Policy Analyst

Andrew Bergman
Special Environmental Advisor

August 16, 2018

VIA ELECTRONIC SUBMISSION

The Honorable Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Attn: EPA–HQ–OA–2018–0259

Re: Comment of the Environmental Defense Fund on the Environmental Protection Agency's *Proposed Rule: Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18768 (Apr. 30, 2018) ("Proposal")

Environmental Defense Fund ("EDF") submits the following comments on EPA's April 30, 2018 proposed rule, "Strengthening Transparency in Regulatory Science" (the "Proposal").[1] Representing over two million members and supporters, EDF applies science, economics, and the law to solve our most urgent public health and environmental problems. EDF regularly engages in policy advocacy, regulatory proceedings, and litigation to secure and defend protections for human health and the environment under the Clean Air Act ("CAA"), Toxic Substances Control Act ("TSCA"), and other statutes administered by EPA—protections that save lives, improve well-being, and provide a more vibrant economy for all Americans, including our members. EDF and our members therefore have a profound stake in ensuring that EPA actions are anchored in the best available science, and are not distorted by policies and practices that seek to unjustifiably limit EPA's use of science for the purpose of weakening health and environmental protections.

For the reasons explained below, the Proposal would violate EPA's substantive and procedural obligations, is arbitrary and capricious, and must be withdrawn. Indeed, the Proposal is the classic wolf in sheep's clothing. Cloaked in vague platitudes about scientific quality and promoting "transparency," the Proposal would establish a sweeping new regulatory requirement prohibiting EPA from considering public health studies for which underlying data cannot be made "publicly available in a manner sufficient for independent validation."[2] This requirement would bar EPA from considering many vital public health studies that are based on confidential patient information that cannot be legally or ethically disclosed, and have been rigorously vetted using time-tested approaches that are widely accepted in the scientific community. Nowhere does the Proposal document what deficiencies in existing EPA regulatory science it is trying to solve, much less why such draconian restrictions on the use of science would improve the quality of EPA decision-making.

This wolf's true nature, however, cannot be covered up: the Proposal is in fact directed at excluding the best available science demonstrating significant health and welfare effects from

[1] *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18,768 (Apr. 30, 2018).
[2] *Id.* at 18,773 (proposed 40 C.F.R. § 30.5).

agency decision-making in order to thwart the agency's ability to protect the public health and welfare. As our comments document, the Administration hastily concocted this Proposal as a way of unilaterally implementing failed legislative proposals backed by prominent opponents of accepted climate change science and patterned on proposals put forward by the tobacco industry in the 1990s. According to records obtained from EPA through the Freedom of Information Act when this Administration's own political staff discovered that earlier versions of the Proposal might also restrict industry-funded science supporting the registration of pesticides and other chemicals, it decided to "thread this one real tight!" to ensure that *only* those studies supporting public health regulations would be subject to this new "transparency" rule.[3]

Ultimately, this Proposal does not "strengthen science." EPA's Science Advisory Board ("SAB") and the scientific community were not even consulted in its development, and a host of scientific authorities—including members of the SAB, editors of the nation's leading scientific journals, the National Academies, and numerous scientific and medical organizations—have raised fundamental concerns about the Proposal. Rather than strengthen science, the Proposal grants the Administrator vague and manipulable authority to *censor* science that by any scientific definition is the best simply because it conflicts with this Administration's political goals. We urge EPA to abandon this deeply destructive and misguided Proposal.

Respectfully submitted,

Tomás Carbonell
Ben Levitan
Jennifer McPartland
Ryan O'Connell
Martha Roberts
Ananya Roy
Surbhi Sarang
Robert Stockman
Environmental Defense Fund

Keri Powell
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Susannah Weaver
Consultants for Environmental Defense Fund

[3] *See* discussion *infra* Section VII.

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OVERVIEW

The Proposal acknowledges that "[t]he best available science must serve as the foundation of EPA's regulatory actions."[4] But it then requires EPA to systematically ignore the best available science when it regulates to protect human health and welfare. This is counter to EPA's statutory mandates to use "best available science," and the proposal is a transparent attempt not to *strengthen* science, but rather to *censor* science that is inconvenient to the current Administration's political goals.

Since EPA was established nearly half a century ago, the Agency and its leadership—under Administrations of both parties—have recognized the central role that rigorous science plays in fulfilling the Agency's mission of protecting human health and the environment.[5] EPA's obligation to consider the best available science is not only a policy commitment that flows from the Agency's mission; it is a legal obligation enshrined in many of the fundamental public health and environmental statutes that EPA is charged with administering. The agency has established an array of mechanisms over the last five decades—including "rigorous review" by its scientific advisory boards "that goes beyond the typical journal peer review procedures"[6]—to ensure that the Agency's decisions are grounded in the best available science.

The Administrator's proposal does not build on this strong foundation; to the contrary, it crumbles it. The purpose and effect of the proposal would be to *degrade* the quality of science in EPA's decision making. While the proposal suggests that its aim is to improve transparency by increasing public availability of data, in actuality it proposes none of the steps that a proposal seriously aimed at that goal would propose, such as increasing funding for EPA grantees to undertake this effort, or proposing solutions to real concerns about patient confidentiality. Instead, the heart of the proposal is a bar on considering science simply because the underlying data is not publicly available, regardless of whether the science has been peer reviewed, reproduced, or contains other hallmarks of scientific quality. Indeed, the agency's recent communication to the Congressional Budget Office that a similar Congressional proposal could be implemented at "no cost" proves the point: EPA's aim here is not to make more data available (which costs money), but to rely on less science in decisionmaking.

The agency's arbitrary, single-minded focus on considering studies for which certain data and models are publicly available (but only the dose-response studies relevant to health

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[4] 83 Fed. Reg. at 18,769.

[5] Brady Dennis, *Outgoing EPA chief: Science is 'fundamental to absolutely everything we do'*, Washington Post (Dec. 21, 2016) (quoting former EPA Administrator Gina McCarthy as saying, "Science is everything. Almost every action we take is bounded by what the science tells us. It's based on a factual record of where the world is today and what is our obligation under our mission. Science needs to be protected. Any effort to undermine that science in a way that would give undue influence to folks that aren't scientists is a really big problem."), https://www.washingtonpost.com/news/energy-environment/wp/2016/12/21/outgoing-epa-chief-science-is-everything-it-is-fundamental-to-absolutely-everything-we-do/?utm_term=.6f1e45472169; Christine Todd Whitman, *No room for science in Trump Administration*, CNN (May 15, 2017), https://www.cnn.com/2017/05/15/opinions/no-science-in-trump-administration-whitman/index.html (describing Administrator Pruitt's actions as a "trend away from science as the backbone of the EPA and other key federal agencies").

[6] Memorandum by Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science 4 (May 12, 2018) (observing that the Proposal "fails to mention that EPA has mechanisms for vetting science through several expert panels," including the SAB and others).

protective regulation, not the ones supporting registration of chemicals) stands in stark contrast to the way the scientific community validates research findings. The scientific community, and scientific journals look to a range of attributes when assessing the quality of a scientific study, including whether the study has been peer reviewed, whether the scientists used rigorous scientific methods, and whether the study's results have been reproduced or replicated. While scientific journals and other institutions have encouraged making data and models publicly available, there is widespread recognition in the scientific community that doing so is often legitimately constrained due to legal and ethical protections on the confidentiality and privacy of data, or because the data is unavailable. Moreover, no scientist or scientific organization supports the Proposal's approach of *excluding* research for which the underlying data cannot be disclosed. Indeed, *none* of the materials EPA cites support such an extreme approach. To the contrary, the scientific community recognizes that the quality of a study is not determined by whether the underlying data is publicly available and has long utilized a variety of tools for ensuring the integrity and rigor of research findings.[7]

For all these reasons, numerous representatives of the scientific community—including editors of the very scientific journals whose policies EPA cites to in the Proposal, the American Association for the Advancement of Science, members of the SAB, and other scientists cited to by EPA—have already voiced serious concerns about the Proposal.[8] As these experts have recognized, it is not consistent with good scientific practice, and certainly not consistent with the Agency's responsibility to utilize "best available science," to deem certain scientific studies unworthy of consideration simply because these studies cannot meet an arbitrary public availability requirement.[9] Far from promoting the integrity of Agency decisions, the Proposal's simplistic approach would impoverish the Agency's decision-making by excluding the consideration of scientific studies that, standing alone or in combination with other studies, have significant bearing on vital public health and environmental protections. This, in turn, would result in regulations that are *not* based on "best available science" and that will provide inadequate protection for the very public health and welfare that EPA has been charged by Congress to safeguard.

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[7] *See id.* at 4 ("The proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods.").

[8] *E.g.*, Anne Q. Hoy, *Scientific Leaders Speak Out on EPA's Proposed "Transparency Rule,"* https://www.aaas.org/news/scientific-leaders-speak-out-epa-s-proposed-transparency-rule; Jeremy Berg et al., *Joint Statement on EPA Proposed Rule and Public Availability of Data,* Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116; Letter to Acting Administrator Wheeler from Marcia McNutt, President of the National Academy of Sciences, C.D. Mote, Jr., President of the National Academy of Engineering, and Victor J. Dzau, President of the National Academy of Medicine (July 16, 2018) (Warning that "overly stringent requirements for transparency may cause valid evidence to be discarded and thereby pose a threat to the credibility of regulatory science," and stating that "The National Academies have developed a long-standing body of work that demonstrates scientific literature can be evaluated in a transparent and objective manner without complete disclosure of the underlying data.").

[9] *See* John Ioannidis, *All science should inform policy and regulation,* 15 PLOS 5 (May 3, 2018) ("Past collected and analyzed information can and should still be used for decision-making, taking into account any relevant imperfections. While fully transparent and reproducible information should certainly be valued more highly, studies with weaknesses can still offer insights.").

That, of course, appears to be the current Administration's goal. A close examination of the history of this Proposal confirms that its purpose is not to strengthen science at EPA, but to undermine public health and environmental protections by arbitrarily blinding the agency to vital research. Indeed, the Proposal resembles proposals advanced by the tobacco industry for the specific purpose of suppressing public health science warning about the dangers of tobacco smoke.[10] The Proposal also resembles failed legislation in Congress that was similarly advanced by industry interests seeking to undermine public health and environmental protections, and criticized by scientific experts.[11] EPA documents released in response to Freedom of Information Act (FOIA) requests relating to the Proposal show that Trump Administration appointees deliberately tailored the scope of the Proposal in order to promote industry interests.

EPA's purpose and mission is to protect human health and welfare, *not* to promote the agendas of the worst polluters and their allies in order to weaken health and welfare protections. EPA should withdraw this misguided and harmful proposal.

Terminology

At the outset, it is useful to review relevant terminology, which the Proposal appears to confuse and conflate. A recent National Academy of Sciences workshop produced the following definitions of "reanalysis," "replication," and "reproduction," each of which has a different scientific meaning and different applications and implications.[12] Let's consider each of these definitions separately.

> *A **reanalysis** is when you conduct a further analysis of data. A person doing a reanalysis of data may use the same programs and statistical methodologies that were originally used to analyze the data or may use alternative methodologies, but the point is to analyze exactly the same data to see if the same result emerges from the analysis.*

A reanalysis does validate or invalidate a study findings. If all credible methods of reanalysis yield effectively the same results as the original analysis, this does strengthen the original findings. The use of differing statistical models should be assessed with care and demonstrate that the assumptions supporting a new method of analysis is significantly more credible than the original analysis. It is easy to develop methods of analysis that can demonstrate

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[10] Emily Atkin, *The EPA is Acting Like Big Tobacco*, The New Republic (Apr. 26, 2018), https://newrepublic.com/article/148126/epa-acting-like-big-tobacco (describing the role of Steve Milloy, a leading public proponent of the Proposal who has taken credit for its existence, in crafting similar policy proposals on behalf of the tobacco industry-funded Advancement of Sound Science Coalition).

[11] Letter by U.S. Science, Engineering, and Academic Institutions to Kevin McCarthy, House Majority Whip (Mar. 16, 2015) (opposing "Secret Science Reform Act, H.R. 1030"), https://sciencepolicy.agu.org/files/2013/07/AAAS-Secret-Science-letter-McCarthy-2015.pdf; Letter by Barry Nussbaum, American Statistical Association to Sen. Mike Rounds and Sen. Kamala Harris (May 25, 2017) (opposing HONEST Act, H.R. 1430), https://www.amstat.org/asa/files/pdfs/POL-HONEST_ActLetter.pdf.

[12] National Academies of Sciences, Engineering, and Medicine, *Principles and obstacles for sharing data from environmental health research: Workshop summary*, The National Academies Press (2016), https://www.nap.edu/catalog/21703/principles-and-obstacles-for-sharing-data-from-environmental-health-research.

a different finding, but are created solely for that purpose and these should not be given greater weight in evaluating a particular study.

> ***Replication*** *means that you actually repeat a scientific experiment or a trial to obtain a consistent result. The second experiment uses exactly the same protocols and statistical programs but with different data from a different population*[13]*. The goal is to see if the same results hold with data from a different population.*

Replication predominantly applies to laboratory studies and randomized control trials since you are able to control almost all of the experimental details making replication possible. Replication does not enhance transparency. In environmental epidemiology, randomized control trials are not feasible or ethical, and replication of observational studies is virtually impossible since it is not possible to create the same conditions as seen in the original study. Even in laboratory experiments, replication can be difficult due to uncontrolled factors like genetic drift in cell lines and animal strains. Finally, if you do have replicate studies and one has a positive finding and another has a negative finding, there would have to be additional criteria used to determine which study was correct; thus a failure to replicate should not immediately lead to the conclusion that there is no effect. Rather than replicating a study, it is far better to develop a better study that replicates the results while providing greater insight into the basis underlying any toxicity.

> *And then, finally, when you* ***reproduce*** *a scientific experiment, you are producing something that is very similar to that research, but it is in a different medium or context. For example, a researcher who is reproducing an experiment addresses the same research question but from a different angle than the original researcher did.*

Here, reproduction refers to a body of evidence addressing the same hypothesis, but using different populations, methods, etc. Reproduction does not enhance transparency. The majority of research on the health effects of environmental hazards fall into this category. Here, a series of studies that address the same hypothesis and give the same basic result does indeed strengthen findings of toxicity.

None of these concepts discusses the scientific quality of the study; this is critical. The ability to replicate a study with very poor scientific quality does not strengthen the scientific belief that any toxicity is present. Similarly, studies that attempt to reproduce the same findings must have their quality clearly established before comparisons can be made across the multiple studies.

An example of how some of these different techniques work in practice is the scientific evidence on air pollution and premature death which include the Harvard Six Cities Study and the American Cancer Society Cancer Prevention Study II (ACS CPSII). The extent to which these studies have been reanalyzed and reproduced is extraordinary and by no means necessary. But they provide a good case study of how these techniques work in practice.

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[13] "Different population" in this context means a different set of the same test subjects (e.g., same animal species and strain, same cell lines).

The original Harvard Six Cities and ACS CPSII studies on mortality were published in 1993 and 1995 respectively.

- The Harvard Six Cities study assessed the long-term effects of fine particle pollution (PM2.5) over 12 to 14 years (1974–1989) on premature mortality among 8,111 adult participants who lived in 6 different cities: Watertown, MA; Harriman, TN; St. Louis, MO; Steubenville, OH; Portage, WI; and Topeka, KS. After accounting for cigarette smoking, level of education, body mass index, and occupational exposure to dusts, gases, and fumes, the authors of this study found that for members of the same age and sex group there was a 26% higher risk of premature mortality between the study participants living in the city with the highest levels of particles (Steubenville) and the city with the lowest levels (Portage).[14]

- The investigators of the Harvard Six Cities study, along with others, **reproduced** their finding in a separate assessment of the association between fine particle levels and mortality among 295,223 adults who lived in 50 metropolitan areas across the United States, over a period of 7 years (1979-1983) in the ACS CPSII study. After accounting for smoking, education, body mass index, alcohol consumption, and self-reported occupational exposure to a number of substances, the scientists found that for participants of the same age, race and sex there was a 17% increased risk of mortality with every 25.4 microgram per meter cube change in PM2.5.[15]

The Harvard Six Cities Study and the ACSCPSII were **reanalyzed** by the Health Effects Institute, a nonprofit independent research corporation funded by EPA and the motor vehicle industry, under a data sharing agreement. A research team evaluated the consistency and accuracy of the data and then undertook a series of comprehensive analyses to test the validity of the findings first using the same statistical analyses and then testing the robustness of the original findings and interpretations to alternative analytic approaches. The results of the reanalysis were resoundingly similar to the original studies. For the Harvard Six cities study the reanalysis found a 28% increased risk of mortality per 18.6 microgram per meter cube of PM2.5 in comparison to 26% found in the original study. For the ACS CPSII study the showed that for every 25.4 microgram per meter cube change in PM2.5 there was an associated 18% increased risk of mortality (results of the independent reanalysis) vs 17% reported by the original study.[16]

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[14] Dockery, D.W., Pope, C.A., Xu, X., Spengler, J.D., Ware, J.H., Fay, M.E., Ferris Jr, B.G. and Speizer, F.E., *An Association Between Air Pollution and Mortality in Six US Cities*, 329(24) New England Journal of Medicine 1753-1759 (1993).

[15] Pope, C.A., Thun, M.J., Namboodiri, M.M., Dockery, D.W., Evans, J.S., Speizer, F.E. and Heath, C.W., *Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of US Adults*, 151(3) American Journal of Respiratory and Critical Care Medicine 669-674 (1995).

[16] Krewski, Daniel, et al., *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of particulate air pollution and mortality*, footnote on 249 Health Effects Institute (2000). See also Letter to Andrew Wheeler from Harvard University (Docket ID No. EPA-HQ-OA-2018-0259) (reanalysis and "releasing raw data will not improve the quality of the resulting report/study/analysis, and therefore will do nothing to render any individual study 'better.'").

A large body of literature also shows that this association of fine particle pollution and mortality has been **reproduced** in different populations across the globe,[17] over different periods of time, contexts and using different methods. Most recently, a study of 61 million elderly people enrolled in Medicare across the entire United States followed over 13 years found a strong association between particle pollution and increased risk of mortality, at even the current levels of air pollution and below the current air quality standards for PM2.5.[18] It is this accumulation of evidence of reproducible effects in multiple studies that is critical in determination of causality and validation of an effect and is already an integral part of the EPA process of supporting causality.[19]

Through these different methods, the original findings of the Harvard Six Cities Study have been validated many times over, and they have been used to inform countless EPA rule makings that address particulate matter pollution. Notably, however, the Proposal would appear to preclude EPA from using them because—while the Study has been reanalyzed and reproduced—the underlying data is not publicly available because of patient confidentiality protections bound by individual contractual agreements between the scientists and the research participants and by the Health Insurance Portability and Accountability Act. These reasons are unrelated to the validity, integrity or quality of the Harvard Six Cities Study. Indeed, the Office of Management and Budget's data quality guidelines specifically point to the Harvard Six Cities Study as an example of how data may be validated or corroborated without public release of the underlying raw data.[20] It is critically important to note that reanalysis projects are not simple or inexpensive.[21] The reanalysis of just the Harvard Six Cities Study and the ACS CPSII took three years to complete and cost $899,046 in direct expenditures,[22] without accounting for costs incurred by Health Effects Institute for oversight and review as well as staff compensation.

In summary, reanalysis is a tool to demonstrate the robustness of an effect to changes in the statistical model underlying an analysis of a single data set. However, it is easy to develop methods of reanalysis that can demonstrate a different finding. Therefore, care must be taken to understand the assumptions underlying models applied in reanalysis in order to judge their relevance. Replication in the environmental health context is primarily limited to laboratory studies and, without additional information to guide a decision, provides little information that can be used to decide between replicate studies with differing results. Reproducing effects in multiple studies that are not identical is the basis for almost all scientific decisions on environmental issues and should be the focus of the EPA's approach to regulatory science. Finally, none of these issues address other key aspects of scientific quality such as

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[17] EPA, NCEA, *Integrated Science Assessment for Particulate Matter*, EPA/600/R-08/139F (2009); Beelen, Rob, et al., *Effects of long-term exposure to air pollution on natural-cause mortality: an analysis of 22 European cohorts within the multicentre ESCAPE project*, 383.9919 The Lancet 785-795 (2014).

[18] Di, Qian, et al., *Air pollution and mortality in the Medicare population*, 376.26 New England Journal of Medicine 2513-2522 (2017).

[19] EPA, *Preamble to the Integrated Science Assessments (ISA)* (EPA/600/R-15/067) (2015).

[20] *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information*, 67 Fed. Reg. 8,452, 8,456 (Feb. 22, 2002).

[21] Comments of Daniel Greenbaum, President, Health Effects Institute (HEI), on Proposed Rule EPA–HQ–OA–2018–0259 (July 17, 2018).

[22] Krewski, Daniel, et al., *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of particulate air pollution and mortality*, footnote on 249 Health Effects Institute (2000).

generalizability and bias; how these characteristics of any scientific study are assessed by the EPA directly relate to the transparency of any decisions they might make.

I. EPA's Proposed Rule Violates Numerous Substantive Statutory Requirements.

A. EPA Does Not Have Authority to Issue the Proposed Rule.

Agencies are creatures of Congress; "an agency literally has no power to act . . . unless and until Congress confers power upon it." *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986); *see Am. Library Ass'n v. FCC*, 406 F.3d 689, 691 (D.C. Cir. 2005) ("It is axiomatic that administrative agencies may issue regulations only pursuant to authority delegated to them by Congress."). EPA points to a smattering of statutes as allegedly authorizing the Proposal.[23] None of these authorities, however, authorize EPA to promulgate a one-size-fits-all regulation governing how the agency will consider science under its various statutory authorities, which is perhaps why EPA solicits comment on whether additional authorities might exist to authorize its Proposal. The varied statutes that the Proposal cites have different requirements as to the agency's obligations when considering science. *Compare* CAA § 108(a) (standards must "reflect the latest scientific knowledge useful in indicating" health and welfare effects)[24] *with* TSCA § 4(f) (Administrator must consider "*any other information available*")[25] *with* Safe Drinking Water Act ("SDWA") § 1412(b)(1)(B)(ii)(II) (Administrator must consider "the best available public health information").[26] The Proposal gives no explanation of how *any* of the provisions it cites provide authority for the Proposal, much less how all of them authorize identical requirements.

For example, EPA cites the Clean Air Act, § 301, 42 U.S.C. § 7601, as purportedly granting authority for the Proposal.[27] The authority granted by section 301(a), however, applies only to the Clean Air Act and, in any event, is not broad enough to encompass this Proposal. Section 301 provides that "[t]he Administrator is authorized to prescribe such regulations subject to section 307(d) as are *necessary* to carry out his [or her] functions under this Act."[28] The courts have consistently "decline[d] to read ... open-ended power into section 301,"[29] and instead have required that regulations promulgated under section 301 be both necessary and appropriate.[30] As

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[23] 83 Fed. Reg. at 18769.
[24] 42 U.S.C. § 7408(a).
[25] 15 U.S.C. § 2603(f).
[26] 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II), (b)(1)(A)(i); *see also*, 42 U.S.C. § 300g-1(b)(3)(A)(i) ("the Administrator shall use. . . the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices").
[27] 83 Fed. Reg. at 18769.
[28] 42 U.S.C. § 7601(a)(1) (emphasis added).
[29] *Nat. Res. Def. Council v. Reilly*, 976 F.2d 36, 41 (D.C. Cir. 1992).
[30] *E.g.*, *Alabama Power Co. v. Costle*, 636 F.2d 323, 403 (D.C. Cir. 1979) (finding an EPA rule unauthorized under section 301, and concluding that "[a]n extension of PSD permit requirements beyond the wording of the Act is therefore neither necessary nor appropriate to carry out EPA's functions under the Act."); *Nat. Res. Def. Council v. EPA*, 22 F.3d 1125, 1148 (D.C. Cir. 1994) ("[S]ection 301 does not provide the Administrator '*carte blanche* authority to promulgate any rules, on any matter relating to the Clean Air Act, in any manner that the Administrator wishes,'" and instead "allow[s] the promulgation of rules that are necessary and reasonable to effect the purposes of

discussed in more detail below, EPA's Proposal here is not necessary, and instead directly conflicts with several other provisions of the Clean Air Act. It is axiomatic that a "general grant of authority cannot trump specific statutory provisions."[31]

Nor does Congressional authorization to *conduct* or *fund* research authorize EPA to *ignore* research in regulatory decision-making. Accordingly, provisions like TSCA § 10, which directs that the "Administrator shall ... conduct such research, development, and monitoring as is necessary to carry out the purposes of this [Act],"[32] and CAA § 103, which authorizes the agency to conduct and support research,[33] plainly do not authorize the Proposal.

B. The Proposed Rule Violates EPA's Statutory Authorities.

Not only is there no authority for EPA's pan-statutory Proposal, the Proposal would violate explicit statutory commands. Though EPA admits that "[t]he best available science must serve as the foundation of EPA's regulatory actions,"[34] proposed section 30.5 would ***prohibit*** EPA from considering high quality and critically important scientific studies—precisely that "best available science"—when undertaking regulatory actions. Specifically, section 30.5 would prevent EPA from considering any scientific study for which the underlying "dose response data and models" are not "publicly available in a manner sufficient for independent validation."[35] This would be true even if that scientific study constituted "information available to the Administrator" in a TSCA § 4(f) rulemaking, 15 U.S.C. § 2603(f)(2); "reflect[ed] the latest scientific knowledge useful in indicating" health and welfare effects in a CAA § 108 rulemaking, 42 U.S.C. § 7408(a)(2); or reflected "the best available public health information" in a SDWA rulemaking, 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II). Accordingly, this proposed prohibition would contravene an array of statutes governing EPA's consideration of science when promulgating rules, such as requirements to consider the "best available science" when setting environmental protection standards. *See, e.g.*, SDWA, 42 U.S.C. § 300g-1(b)(3)(A) (EPA must use "[t]he best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" and "[d]ata collected by accepted methods or best available methods"); TSCA, 15 U.S.C. § 2625(h) ("[T]he Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science."); CAA, 42 U.S.C. § 7408(a) (EPA shall establish air quality criteria that "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be

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the Act.") (quoting *Citizens to Save Spencer County v. EPA*, 600 F.2d 844, 873 (D.C. Cir. 1979)); *Nat. Res. Def. Council v. EPA*, 749 F.3d 1055, 1063 (D.C. Cir. 2014) ("[W]e have consistently held that EPA's authority to issue ancillary regulations is not open-ended, particularly when there is statutory language on point."); *North Carolina v. EPA*, 531 F.3d 896, 922 (D.C. Cir. 2008), *on reh'g in part*, 550 F.3d 1176 (D.C. Cir. 2008) (striking down a regulation promulgated under Section 301 because EPA could not demonstrate that it was "necessary" to fulfill the purposes of the Act).

[31] *Nat. Res. Def. Council v. EPA*, 749 F.3d 1055, 1063-64 (D.C. Cir. 2014); *API v. EPA*, 52 F.3d 1113, 1119 (D.C. Cir. 1995) (same).

[32] 15 U.S.C. § 2609(a), cited at 83 Fed. Reg. at 18769.

[33] 42 U.S.C. § 7403, cited at 83 Fed. Reg. at 18769.

[34] 83 Fed. Reg. at 18769.

[35] 83 Fed. Reg. at 18773-74.

expected from the presence of such pollutant in the ambient air, in varying quantities."). And, by excluding science that meets these statutory criteria from supporting regulations to protect public health and welfare, the Proposal would frustrate Congress's policy in these statutes and frustrate EPA from achieving its fundamental mission.[36]

1. EPA's statutory authorities generally require the agency to consider *all* available data when undertaking significant rulemakings.

As just noted, EPA's statutory authorities mandate a variety of requirements for what scientific information EPA must consider in rulemaking. These statutes are discussed in detail, *infra* at Section I.B.3. To take one example that appears in numerous statutes, including TSCA, CAA, SDWA, and the Endangered Species Act, Congress has often required agencies to act on the "best available science." For an agency to comply with this obligation, the agency must at least consider all available scientific information. "Best" means "of the most excellent, effective, or desirable type or quality."[37] "Available" means "able to be used or obtained."[38] And "science" means "the intellectual and practical activity encompassing the systematic study of the structure and behavior of the physical and natural world through observation and experiment."[39] Assessing which science is "best" requires consideration of the overall quality of the science, and the public availability of underlying data is, at best, one of many aspects that should inform that assessment of overall quality.

An agency "cannot ignore available. . . information."[40] Numerous courts have indicated that a plaintiff or petitioner can establish a violation of the "best available science" requirement by "point[ing] to any scientific evidence that the agency failed to consider."[41] "The best available data requirement. . . prohibits [an agency] from disregarding available scientific evidence that is in some way better than the evidence [it] relies on.'"[42] "An agency does. . . have an obligation to deal with newly acquired evidence in some reasonable fashion."[43] EPA's proposal will result in EPA precluding itself from considering certain studies that are "available," thus violating the requirement that EPA rely on the best available science.

In addition, the requirement that agencies use "best available" science or information often means that the agency must act *even if* the available science or information is imperfect.

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[36] *See, e.g., Shays v. FEC*, 528 F.3d 914, 919 (D.C. Cir. 2008) ("[W]e 'must reject administrative constructions of [a] statute that frustrate the policy that Congress sought to implement.'") (*quoting Cont'l Air Lines, Inc. v. Dep't of Transp*, 843 F.2d 1444, 1453 (D.C. Cir. 1988)).
[37] *Oxford American Dictionary* 159 (3d ed. 2010).
[38] *Id.* at 111.
[39] *Id.* at 1564.
[40] *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988); *San Luis & Delta-Mendota Water Auth. v. Jewell*, 747 F.3d 581, 602 (9th Cir. 2014) (quoting *Kern Cnty.*, 450 F.3d at 1080-81 (quoting *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988)).
[41] *Safari Club Int'l v. Salazar (In re Polar Bear Endangered Species Act Listing & Section 4(d) Rule Litig. - MDL No. 1993)*, 709 F.3d 1, 9 (D.C. Cir. 2013).
[42] *Kern Cty. Farm Bureau v. Allen*, 450 F.3d 1072, 1080 (9th Cir. 2006) (quoting *Sw. Ctr. for Biological Diversity v. Babbitt*, 215 F.3d 58, 60 (D.C. Cir. 2000)).
[43] *Catawba County v. EPA*, 571 F.3d 20, 45 (D.C. Cir. 2009) (quoting *American Iron & Steel Institute v. EPA*, 115 F.3d 979, 1007 (D.C. Cir. 1991)).

"Even if the available scientific and commercial data were quite inconclusive, [the agency] may—indeed must—still rely on it" when the agency has a duty to act.[44] "[W]here the information is not readily available, we cannot insist on perfection."[45] Just as the Courts have recognized that they cannot expect perfection, agencies cannot choose to ignore certain studies or sources of information based solely on whether the data is publicly available—especially where the validity of those studies has been established using techniques that do not rely on public availability of underlying data.

EPA cannot reasonably elevate the interest in public availability of all underlying information above all other factors in assessing the "best available science." Textually, EPA's approach is unlawful.

2. The proposal violates these statutory commands by requiring EPA to ignore science when undertaking significant rulemakings.

In direct violation of statutory requirements to consider, for example, "any other information available" or "the latest scientific knowledge [that is] useful" or "best available science," the Proposal would *prohibit* EPA from considering relevant and high quality science whenever the underlying data for a study is not publicly available. Through the Proposal, EPA unlawfully tries to engraft an additional statutory requirement onto each of these statutes, requiring that to be considered a study's underlying data must be publicly available.[46] For EPA's Proposal to succeed, EPA must demonstrate that a study *cannot* be "other information available to the Administrator" or the "latest scientific knowledge useful in indicating" health or welfare effects or the "best available science," or any of a number of other statutory formulations if the underlying data is not publicly available. EPA's Proposal fails to do so, and it could not do so.

As explained *infra* at Section II.A.1, there are many reasons that underlying study data may not be available that have no bearing on the quality or validity of the study. These include legal restrictions or concerns about privacy (especially with respect to studies involving human subjects), confidentiality, confidential business information, or national security. Further, if this requirement were applied retroactively to existing studies, it may no longer be possible to make underlying data and models publicly available. EPA acknowledges these impediments in proposed section 30.9, which provides the Administrator with discretion—but not an obligation—to allow the agency to consider a study for which underlying data or models are not publicly available if he determines that public disclosure is infeasible. But where the Administrator fails to exercise his discretion to grant an exemption pursuant to proposed section 30.9, or where data or models are unavailable for reasons that do not satisfy the infeasibility standard, proposed section 30.5 would prohibit EPA from considering such studies, regardless of whether they meet the statutory criteria for consideration.

The only way that this prohibition could comport with EPA's statutory obligations is if a study for which underlying data is not available *cannot* be, for example, "other information

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[44] *Southwest Ctr. for Biological Diversity v. Babbitt*, 215 F.3d 58, 60 (D.C. Cir. 2000) (quoting *City of Las Vegas v. Lujan*, 891 F.2d 927, 933 (D.C. Cir. 1989)).
[45] *San Luis*, 747 F.3d at 602.
[46] *See Nat'l Ass'n of Homebuilders v. Defenders of Wildlife*, 551 U.S. 644, 663-64 (2007).

available" or "the latest scientific knowledge [that is] useful" or "best available science"—i.e., if the public unavailability of a study's underlying dose response data and models makes the study ineligible to meet these criteria, regardless of whether the study has been peer reviewed, is based on rigorous methodologies, or has been published in a leading journal, and regardless of the reason for the public unavailability. EPA makes no such demonstration—nor could it. There is simply no support for such a proposition; to the contrary, all of the evidence shows that studies may be "best available science," and certainly "other information available" regardless of whether the data underlying them is publicly available.

What the Proposal fails to recognize is that disclosure of data addresses only *one* method of validating scientific research—and a relatively less important aspect at that. Disclosure of data for a given study—the focus of the Proposal—permits independent researchers to determine whether the data and methodology *used in that study* can be applied to generate the *same* results. This may help protect against sources of error or misrepresentation in a particular study. However, both EPA and independent researchers have recognized that such reanalysis does not by itself *validate* a particular study.[47] Rather, a study's evidentiary weight rests both on the strength of its methodology, as well as whether similar results can be obtained by applying the study's methodology to a relevant, but *different* dataset or population, or by using a distinct methodology to interrogate the same hypothesis.[48]

a) The scientific community

Publication in a peer-reviewed scientific journal is the way that scientists communicate their findings to other scientists and is considered the hallmark of scientific quality. Notably, the editors in chief of the world's top scientific journals have notified EPA that "[i]t does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making."[49] In response to EPA's Proposal, the editors-in-chief of *Science* and *Nature*, and other leading scientists explained that though "[d]ata sharing is a feature that contributes to the robustness of published scientific results. . . in not every case can all data be fully shared."[50] For example, full

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[47] *See* EPA, *Preamble to the Integrated Science Assessment* at 20 (2015) ("An inference of causality is strengthened when a pattern of elevated risks is observed across several independent studies. *The reproducibility of findings constitutes one of the strongest arguments for causality*. . . ") (emphasis added); National Academies, *Principles and Obstacles for Sharing Data From Environmental Health Research* 6 (2016) (quoting researcher Lynn Goldman's observation that reproducibility and replicability across independent studies – as distinct from reanalysis of a single set of data using the same methodology – are the most convincing ways of validating a research finding); Lynn R. Goldman & Ellen Silbergeld, *Correspondence on Access to Chemical Data Used in Regulatory Decision Making*, 121 Environmental Health Perspectives A111 (Apr. 2013), https://ehp.niehs.nih.gov/wp-content/uploads/121/4/ehp.1206438.pdf ("Replication in science is quite different; it involves performance of an independent study with the same hypothesis and then testing the extent to which this independent study reaches the same conclusions. . . Designing and conducting a replication study does not require access to raw data from the original study; this would abrogate the concept of independence.")

[48] *See* National Academies, *Principles and Obstacles* at 6.

[49] Jeremy Berg et al., *Joint Statement on EPA Proposed Rule and Public Availability of Data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

[50] *Id.*

sharing is not possible when data sets include "personal identifiers."[51] The scientists confirm that even under circumstances where underlying data cannot be made generally available, it is possible to evaluate the merits of a study, explaining:

> Importantly, the merits of studies relying on data that cannot be made publicly available can still be judged. Reviewers can have confidential access to key data and as a core skill, scientists are trained in assessing research publications by judging the articulation and logic of the research design, the clarity of the description of the methods used for data collection and analysis, and appropriate citation of previous results.[52]

They conclude that EPA's proposal to exclude relevant studies from EPA's consideration based solely on the fact that underlying data or methods cannot be made available to the public "will adversely affect decision-making processes."[53]

In a letter filed in this docket, the Presidents of the National Academies of Science, Engineering, and Medicine similarly observe that the public availability of data is not necessary to ensure the integrity of regulatory science and is not a sufficient criterion for excluding a particular study from consideration. The Presidents' letter notes: "The National Aeademies have developed a long-standing body of work that demonstrates scientific literature can be evaluated in a transparent and objective manner without complete disclosure of the underlying data."[54] The letter goes on to explain: "If the study data are not available, their absence may affect how the study is rated and used in the [agency's] analysis, but the study should not necessarily be eliminated from the assessment."[55]

b) EPA policy and practice

EPA has previously stated in several different forums that a scientific study can be valid even if the underlying dose response data and models are not publicly available. For example, EPA recently explained in its own *Plan to Increase Access to Results of EPA-Funded Scientific Research* that even though "some research data cannot be made fully available to the public but instead may need to be made available in more limited ways," the lack of full public availability "does not affect the validity of the scientific conclusions from peer-reviewed research publications."[56] Under the plan, EPA must make publications resulting from EPA-funded research publicly accessible on National Institute of Health's PubMed Central (PMC).[57] The plan

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[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] Letter to Acting Administrator Wheeler from Marcia McNutt, President of the National Academy of Sciences, C.D. Mote, Jr., President of the National Academy of Engineering, and Victor J. Dzau, President of the National Academy of Medicine 2 (July 16, 2018), http://www.nationalacademies.org/includes/EPA%20Proposed%20Rule%20Docket%20EPA-HQ-OA-2018-0259%20NASEM%20Comment.pdf.
[55] *Id.* at 2-3.
[56] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* 4-5 (Nov. 29, 2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.
[57] *Id.* at 8.

aims to "maximize access, by the general public and without charge, to digitally formatted data resulting from EPA funded research, *while protecting confidentiality and personal privacy, recognizing proprietary interests, business confidential information and intellectual property rights, and preserving the balance between the relative benefits and costs of long-term preservation and access.*"[58] The plan recognizes important exceptions for when "the research data cannot be released due to one or more constraints, such as requirements to protect confidentiality, personal privacy, proprietary interest, or property rights."[59] It specifically declares: "The validity of scientific conclusions drawn from research publications or their associated research data, or EPA's ability to consider those conclusions and data in its actions, does not depend on compliance with this Plan."[60]

Likewise, EPA's Science Policy Council explains in *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* that EPA's determination as to the quality and reliability of a particular scientific study does not depend on one single factor (e.g., the public availability of underlying data), but instead turns on the agency's consideration of five general factors.[61] Congress implicitly endorsed this approach by including a directive for EPA to use these same five factors in evaluating science under the Toxic Substances Control Act Amendments passed in 2016,[62] and just last year this Administration included these same factors in a recent regulation implementing TSCA.[63] The factors comprise: (1) soundness; (2) applicability and utility; (3) clarity and completeness; (4) uncertainty and variability; and (5) evaluation and review.[64] Of these, the only ones with any possible direct relevance to EPA's proposed approach are the third and fifth factors, but neither supports the elevation of public availability of data above all other considerations or the exclusion of studies with non-public data. The third factor, "clarity and completeness" requires EPA to consider "[t]he degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations and analyses employed to generate the information are documented." The fifth factor, "evaluation and review," requires EPA to consider "[t]he extent of independent verification, validation and peer review of the information or of the procedures, measures, methods or models." Even clear and complete "documentation" of the data used does not require that the data be made publicly available. Nor does factor five require either that a study's findings must have been replicated using the same data, or that the data must be available

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[58] *Id.* at 11 (emphasis added).
[59] *Id.*
[60] *Id.* at 6.
[61] EPA Science Policy Council, *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*, EPA 100/B-03/001 (June 2003) https://www.epa.gov/risk/summary-general-assessment-factors-evaluating-quality-scientific-and-technical-information.
[62] *Id.* at 7.
[63] EPA Science Policy Council, *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*; 15 U.S.C. § 2625(h)(1)-(5); 82 Fed. Reg. 33,726, 33,731 (July 20, 2017), 42 U.S.C. § 300g-1(b)(3)(A).
[64] Note that TSCA and the regulations do not include the headers for the five factors ("soundness," "applicability and utility," etc.) included in the Science Policy Council guidance, but the description of each factor to be considered is largely identical.

to allow for such replication. Moreover, these are only portions of two of five key factors to consider.[65]

Similarly, EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of the Information Disseminated by the Environmental Protection Agency*,[66] ("EPA Information Quality Guidelines") issued pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658) (the "Data Quality Act") make it clear that the public unavailability of underlying data or models does not render a study inappropriate for EPA's consideration. Specifically, the EPA Information Quality Guidelines acknowledge that even with respect to science that will have "a clear and substantial impact on important public policies or private sector decisions," there will be circumstances where "access to data and methods cannot occur due to compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections."[67] Significantly, the Guidelines do not instruct EPA to ignore such science. Rather, the Guidelines instruct that if underlying data or methods are unavailable, "EPA should, to the extent practicable, apply especially rigorous robustness checks to analytic results and carefully document all checks that were undertaken."[68] The Guidelines further explain: "Original and supporting data may not be subject to the high and specific degree of transparency provided for analytic results; however, EPA should apply, to the extent practicable, relevant Agency policies and procedures to achieve reproducibility, given ethical, feasibility, and confidentiality constraints."[69]

Far from instructing EPA not to consider scientific studies for which underlying data or models are unavailable, the EPA Information Quality Guidelines expressly acknowledge that EPA must balance a variety of important aims to fulfill its statutory obligations to protect public health and the environment. EPA explains in the guidelines that "most environmental statutes obligate EPA to act to prevent adverse environmental and human health impacts" and that "[f]or many of the risks that we must address, data are sparse and consensus about assumptions is rare."[70] Thus, rather than set rigid rules regarding what science and information EPA can rely upon in its rulemakings, EPA "seek[s] to strike a balance among fairness, accuracy, and efficient implementation."[71] EPA states: "Refusing to act until data quality improves can result in substantial harm to human health, safety, and the environment."[72]

As discussed *infra* at Section I.B.3.b)ii, even this Administration, in the context of promulgating regulations under TSCA, has adopted a regulatory definition of "best available

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[65] *See* EPA Science Policy Council, *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information.*

[66] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the EPA* (2002). https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information.

[67] *Id.* at 21.

[68] *Id.*

[69] *Id.*

[70] *Id.* at 52.

[71] *Id.*

[72] *Id.*

science" expressly incorporating a multi-factor analysis, and that definition recognizes that public unavailability of data does not render a study incapable of being "best available science."

c) The courts

As EPA acknowledges in footnote 3 of the Proposal, in at least two instances the D.C. Circuit Court of Appeals has recognized that studies for which underlying data is not publicly available may constitute "best available science."[73] The D.C. Circuit's decisions in these cases further demonstrate that the public unavailability of a study's underlying data does not render a study incapable of constituting "best available science" otherwise unworthy of EPA's consideration.

In *American Trucking Associations* v. *EPA,* the petitioner challenged EPA's reliance on scientific studies for which underlying data was not publicly available in deciding to strengthen the national ambient air quality standards for particulate matter.[74] The Court held that the Clean Air Act did not require EPA to make public underlying data where EPA relied on the study itself and not the raw data underlying the study. The Court agreed with EPA's position that requiring agencies to obtain and publicize the data underlying all studies on which they rely "would be impractical and unnecessary."[75] Importantly, the Court concluded that:

> If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, *then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment.* . . . Such data are often the property of scientific investigators and are often not readily available because of. . .proprietary interests. . . or because of [confidentiality] arrangements [with study participants].[76]

The court accordingly recognized that ignoring relevant scientific information simply because the underlying data is not available would violate EPA's obligations to consider "best available science." *Coalition of Battery Recyclers Association v. EPA* involved another challenge to EPA's reliance on a scientific study for which the underlying data was not publicly available.[77] In that case, EPA had relied upon the study in question to determine the "concentration-response relationship between blood lead levels and IQ changes."[78] The D.C. Circuit again upheld EPA's reliance on studies without making the underlying data publicly available and explained, "raw data often is unavailable due to proprietary interests of a study's scientific investigators or confidentiality agreements with study participants."[79] Likewise, in *City of Waukesha v. EPA* the

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[73] 83 Fed. Reg. at 18769.
[74] 283 F.3d 355, 372 (D.C. Cir. 2002).
[75] *Id.* at 372 (quoting National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,689 (July 18, 1997).
[76] *Id.* (emphasis added).
[77] 604 F.3d 613, 622-23 (D.C. Cir. 2010).
[78] *Id.* at 622.
[79] *Id.* at 623.

D.C. Circuit concluded that agency peer review satisfies the requirement to use best, peer-reviewed science and supporting studies.[80]

d) The Proposal

Finally, even the Proposal appears to concede that studies for which data is not publicly available could constitute the "best available science" that EPA is statutorily required to consider. The proposed exemption provision in section 30.9 makes it clear that EPA does not consider a study to be invalid or unsuitable for EPA's consideration based only on the public unavailability of underlying data or models. Specifically section 30.9 would give the Administrator discretion to authorize consideration of a scientific study where "[i]t is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available." Of course, EPA could not have intended for proposed section 30.9 to provide the Administrator with discretion to take a study that is not "best available science" into consideration when promulgating a rulemaking. If the Administrator has discretion to allow consideration of a study for which it is infeasible to make the study's underlying data and models publicly available, then it obviously is not necessary for such underlying data and models to be publicly available for a scientific study to constitute "best available science." Yet, unless the Administrator elects to exercise his discretion under proposed section 30.9 and find that it is "infeasible" to make a study's underlying data and models publicly available, proposed section 30.5 broadly prohibits EPA from relying on the study in support of "significant regulatory actions."

Moreover, while proposed section 30.5's prohibition would apply to "pivotal regulatory science" used for "significant regulatory actions," the proposed rule says nothing to prohibit EPA's reliance on these studies for other agency purposes, such as in permitting, enforcement, or regulatory actions that do not qualify as "significant." Thus, EPA clearly does not believe that a study cannot be "best available science" based solely on the fact that underlying data and models are not publicly available.

In sum, if finalized, EPA's proposed rule would restrict EPA's ability to consider "best available science" when undertaking significant rulemakings, contrary to the numerous statutory directives discussed in detail below.

3. By prohibiting EPA from considering all valid and relevant studies when undertaking significant rulemakings, the proposed rule would prevent EPA from complying with an array of statutory provisions governing EPA's consideration of available science.

a) The Proposal Contravenes the Clean Air Act

[80] 320 F.3d 228, 247 (D.C. Cir. 2003).

Under Clean Air Act section 108(a),[81] EPA must establish air quality criteria for each air pollutant that serves as the basis for setting the national ambient air quality standards. Such criteria "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities."[82] As explained above, the scientific community, EPA, and the courts have all concluded that lack of public availability of underlying data does not render the study invalid. And, consideration of such studies can be essential for EPA to fulfill Clean Air Act section 108(a)'s directive that it consider "the latest scientific knowledge" in establishing air quality criteria, that it consider studies "useful" in indicating effects of pollutants on ambient air, and in providing an adequate margin of safety in the standard itself.[83] Thus, EPA's proposal to bar EPA from considering such studies would prevent EPA from complying with its statutory obligation under Clean Air Act section 108(a).

Section 108(a)(2) says nothing about excluding information—its evident purpose is to be inclusive as to information to be considered. EPA's historic practice reflects this broad directive: each NAAQS review evaluates virtually all studies in the area, excluding none, but assigning appropriate weight based on study-by-study evaluation. Since the NAAQS provisions were enacted in 1970, EPA has conducted many NAAQS rulemakings. The agency does not establish *per se, a priori* rules regarding study inclusion or exclusion, but rather evaluates each of the individual studies—and there are thousands typically evaluated for each NAAQS review—on their merits based on reasoned criteria. While details of the development and review of the criteria and standards have evolved over time, in practice, EPA has endeavored to include all relevant scientific studies in the process, even providing provisional assessments of relevant literature that appears after the formal scientific review has been completed. Over the years, tens of thousands of peer-reviewed studies of health effects, exposure, and atmospheric interactions, and monitoring have been included in reviews of criteria and standards. A requirement that they must be excluded from consideration unless the raw data and full methodologies are made available for all of them is inconsistent with the legislative mandate and EPA's practice over the last 40 years.

Thus, a science regulation that applies to the NAAQS is unlawful unless EPA can show that the new standard can be established and implemented consistent with the applicable statutory requirements. To do so, EPA must prove that public unavailability of data means that a study does not constitute "latest scientific knowledge useful" in indicating effects on human health or welfare.[84] EPA's Proposal neither acknowledges this requirement nor explains how the Proposal would not violate this statutory command.

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[81] 42 U.S.C. § 7408(a).
[82] 42 U.S.C. § 7408(a)(2).
[83] *Id.*
[84] 42 U.S.C. § 7408(a)(2).

For example, in past NAAQS reviews, EPA has considered the Harvard Six Cities study[85] and American Cancer Society studies[86], despite the fact that the data underlying these studies is not publicly available. These studies, however, are plainly "useful in indicating the kind and extent of all identifiable effects on public health or welfare."[87] These seminal studies have been part of the air quality criteria since the mid-1990s—they have thus been accepted as "useful" by separate panels of CASAC, and by EPA, in three separate NAAQS reviews. Their use has been upheld by the D.C. Circuit.[88] Both studies have been reanalyzed and validated by highly competent third-party reviewers (the Health Effects Institute) with access to the underlying data.[89] The study results have been reproduced many times over. [90] Extended follow-up analyses of the ACS and Harvard Six Cities studies provide consistent and stronger evidence of an association with PM 2.5 and mortality at even lower air quality distributions than had previously been observed.[91] This type of cumulative weight of evidence is highly probative in assessing both causality and in establishing the level of the NAAQS.[92] The proposal says almost nothing about any of these other attributes that not only make these studies "useful," but indeed make them particularly high quality and reliable.

The primary ozone NAAQS provides further examples of the pernicious effects the proposal would have. Among the key controlled human exposure studies demonstrating that exposure to ozone causes adverse health effects in even healthy subjects at levels below the level of the then-current NAAQS are Adams (2006) and Schelegle (2009).[93] These studies were sponsored by the American Petroleum Institute, which controls access to the underlying data. The American Petroleum Institute refused an EPA researcher access to the data of a related

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[85] Dockery, D.W., Pope, C.A., Xu, X., Spengler, J.D., Ware, J.H., Fay, M.E., Ferris Jr, B.G. and Speizer, F.E., *An association between air pollution and mortality in six US cities*. 329(24) New England Journal of Medicine 1753-1759 (1993).

[86] Pope, C.A., Thun, M.J., Namboodiri, M.M., Dockery, D.W., Evans, J.S., Speizer, F.E. and Heath, C.W., *Particulate air pollution as a predictor of mortality in a prospective study of US adults*. 151(3) American Journal of Respiratory and Critical Care Medicine 669-674 (1995); Krewski, D., Jerrett, M., Burnett, R.T., Ma, R., Hughes, E., Shi, Y., Turner, M.C., Pope, C.A. III, Thurston, G., Calle, E.E., Thun, M.J., *Extended Follow-up and Spatial Analysis of the American Cancer Society Study Linking Particulate Air Pollution and Mortality*. 140 Health Effects Institute, Boston, MA (2009).

[87] CAA section 108 (a)(2), 42 U.S.C. §7408(a)(2).

[88] *Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d at 623.

[89] Krewski, Daniel, et al., *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality*. Health Effects Institute, Cambridge, MA (2000).

[90] *See* EPA, NCEA. *Integrated Science Assessment for Particulate Matter* (EPA/600/R-08/139F), 7-86 (2009).

[91] *See* EPA, *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standard* (EPA 452/R-11-003), 2-31 to 33 (Apr. 2011). *See also* Memorandum by Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science at 4 (May 12, 2018) (noting that "additional studies have confirmed the basic findings" of the Six Cities and American Cancer Society studies and that "the rigorous form of peer review and independent reanalysis" applied "has accomplished a measure of confidence in findings without public access to data and analytic methods.").

[92] *State of Mississippi v. EPA*, 744 F.3d 1334, 1344 (D.C. Cir. 2013) (endorsing EPA's weight of evidence approach, and stating that "incremental (and arguably duplicative) studies are valuable precisely because they confirm or quality previous findings or otherwise decrease uncertainty").

[93] *See* EPA, *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards* (EPA -452/R-14-006, 3-27, 4-10 (Aug. 2014).

Adams study it sponsored (Adams (1998)).[94] So not only would these evidently "useful" (under CAA section 108(a)(1)) studies be barred from consideration under the Proposal, but the Proposal creates a perverse incentive for industry to refuse access to study data. The published studies— peer reviewed—would obviously be providing information "useful" in indicating effects of air pollution, but the Proposal would not only bar their consideration but create an incentive for industry never to provide underlying data for any industry-sponsored study with a result not to industry's liking.

The most recent premiere long-term cohort study for PM is Domenici (2017) which found even greater effects of fine particles at levels below EPA's current standards.[95] This study used a Medicare database available to any research group that can guarantee confidentiality of personal data.[96] Yet the proposal could evidently bar consideration of this powerful study.[97]

NAAQS must be requisite to protect the public health, and to provide an "adequate margin of safety" in doing so.[98] The proposal violates this central statutory requirement. NAAQS are required to provide this margin of safety "to build a buffer to protect against uncertain and unknown dangers to human health."[99] EPA's Proposal would build a buffer against using the very studies necessary to guard against these dangers.[100]

b) EPA's Proposal contravenes the Toxic Substances Control Act (TSCA).

i. TSCA expressly requires that EPA consider reasonably available information and EPA's proposal would preclude EPA from considering some reasonably available information.

When Congress amended TSCA through passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), Congress provided a number of detailed instructions on how EPA should consider scientific information with respect to chemical substances; EPA's proposal contradicts Congress's carefully crafted scheme. In particular, Congress included a provision specifically requiring that EPA consider all "reasonably available

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[94] *See* EPA, *First External Review Draft Integrated Science Assessment for Ozone and Related Photochemical Oxidants* (EPA/600/R-10/076A), 6-7 n. 1 (Feb. 2011).

[95] Qian Di et. al., *Air Pollution and Mortality in the Medicare Population*, 376 New England Journal of Medicine 2513 (2017), https://www.nejm.org/doi/pdf/10.1056/NEJMoa1702747.

[96] *See* CMS, *Limited Data Set (LDS) Files*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.html (last accessed Aug. 9, 2018) (noting data requires a signed data use agreement and data cannot be disclosed).

[97] *See* 83 Fed. Reg. 18768, 18773, Proposed section 30.5 final sentence ("where data is controlled by third parties, EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section"). There appears to be some interaction required before third party studies are considered to be publicly available.

[98] CAA section 109(b); 42 U.S.C. § 7409(b).

[99] *State of Mississippi*, 744 F.3d at 1353.

[100] *See American Farm Bureau v. EPA*, 559 F.3d 512, 525-26 (D.C. Cir. 2009) (remanding primary Particulate Matter NAAQS because inadequate consideration of certain epidemiologic studies resulted in a standard lacking an adequate margin of safety).

information."[101] When making decisions about testing or the risk evaluation or regulation of new or existing chemicals, "the Administrator shall take into consideration *information* relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, *that is reasonably available to the Administrator*." 15 U.S.C. § 2625(k) (emphases added). But under EPA's proposed rule, EPA would often be precluded from considering such reasonably available information if all the underlying data and models were not publicly available. *See* 83 Fed. Reg. at 18,769 n.3 (stating that proposal "would preclude [EPA] from using [non-public] data in future regulatory actions"). EPA's proposal violates the plain language of TSCA § 26(k), as well as Congress's clear purpose of ensuring that EPA consider all reasonably available information relating to a chemical when making a decision about the chemical.

Under its plain language, "available" means "able to be used or obtained; at someone's disposal."[102] Congress chose this standard to ensure that EPA would make decisions based on all reasonably available information. S. Rep. No. 114-67 at 9 (June 18, 2015) ("The section ... requires EPA to consider reasonably available information about potential hazards and exposures of a chemical substance under the conditions of use when making decisions under TSCA.... The Committee intends that EPA systematically search for and identify relevant information that is available to inform safety assessments and determinations."); Oversight of the Environmental Protection Agency's Progress in Implementing Inspector General and Government Accountability Office Recommendations: Hearing before the Subcomm. on Superfund, Waste Management, and Regulatory Oversight of the S. Comm. on Environment and Public Works, 114th Cong. at 63 (June 14, 2016) ("[F]or the EPA to properly evaluate and regulate toxic substances, it is essential that they have the most up-to-date chemical and toxicity data available."). Congress also selected this standard to avoid paralysis by analysis—Congress wanted EPA to act on available information and not to postpone action waiting for new or perfect information to become available. *See, e.g.*, 162 Cong. Rec. S3511, S3517 (daily ed. June 7, 2016) (referring to "information reasonably available to EPA" as "ensur[ing] that such considerations do not require additional information to be collected or developed"). "Congress recognized the need to use available studies, reports and recommendations for purposes of chemical assessments rather than creating them from whole cloth." *Id.* at S3522. And Congress intended for EPA to consider studies even when they had not undergone all possible forms of vetting. "[I]n instances where there were other studies and reports unavailable at the time of the [National Academy of Sciences] recommendations, EPA should take advantage of those studies and reports in order to ensure that the science used for chemical assessments is the best available and most current science." *Id.* at S3522. Congress intended for EPA to consider all reasonably available information, and EPA's proposal would thwart that clear purpose.

Notably, this Administration has adopted two regulations under the amended TSCA defining reasonably available information. These regulations generally provide that:

> Reasonably available information means information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA [for action]. Information that meets the terms of the

[101] Pub. L. No. 114-182, § 17(k), 130 Stat. 448, 502 (June 22, 2016) (codified at 15 U.S.C. § 2625(k)).
[102] *Oxford American Dictionary* 111 (3d ed. 2010).

> preceding sentence is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14.

40 C.F.R. § 702.33; *see also* 40 C.F.R. § 702.3 (similar definition for prioritization decisions). This bears no resemblance to the limitations put forward in the Proposal. Indeed, EPA has defined "reasonably available information" to include information EPA withholds as Confidential Business Information (CBI) under TSCA § 14. 15 U.S.C. § 2613. If the proposed rule forecloses EPA from considering information that cannot be fully disclosed, as it appears to do, then EPA cannot comply with both these regulations and the proposed rule.

EPA's proposal also violates other provisions of TSCA that expressly require EPA to act on "available information." For example, in preparing risk evaluations for existing chemicals, EPA "shall integrate and assess *available information* on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator."[103] Under the proposed rule, EPA would not be able to integrate and assess available information where all underlying data has not been disclosed. Similarly, when developing regulations for existing chemicals, EPA "shall consider and publish a statement based on *reasonably available information* with respect to" a number of factors, including the effects of the chemical on health and the environment.[104] But under the proposed rule, EPA cannot consider all reasonably available information when assessing those health and environmental effects.

Indeed, TSCA § 4(f) imposes a duty upon EPA to initiate regulation in response to any available information that meets certain substantive standards. However, if all the underlying information were not available, EPA's proposed rule would then foreclose EPA from considering that information during the resulting rulemaking. Congress would not have created a scheme where EPA *must* act in response to certain information but then cannot consider that information in taking action. Specifically, under TSCA § 4(f):

> Upon the receipt of—(1) *any information* required to be submitted under this Act, or (2) *any other information available* to the Administrator—which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents a significant risk of serious or widespread harm to human beings, the Administrator shall, ... initiate applicable action under section 5, 6, or 7 to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding, made without consideration of costs or other nonrisk factors, that such risk is not unreasonable.[105]

Thus if "any ... information available" to EPA provides a reasonable basis to conclude that a chemical "presents a significant risk of serious or widespread harm to human beings," then EPA must initiate action to regulate the chemical. But under EPA's proposed rule, EPA would then be

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[103] 15 U.S.C. § 2605(b)(4)(F)(i) (emphasis added).
[104] *Id.* § 2605(c)(2)(A) (emphasis added).
[105] 15 U.S.C. § 2603(f) (emphases added).

required to ignore the information triggering this duty when crafting the final regulation unless the source of the information fully disclosed all underlying data. That result clearly contradicts Congress's intent, which was to create a duty for EPA to react to any available information meeting the substantive standard of TSCA § 4(f).

In sum, Congress repeatedly directed EPA to consider all reasonably available information when making decisions under TSCA. The proposed rule would illegally preclude EPA from considering available information. The two cannot be reconciled, and the rule is unlawful.

ii. TSCA requires an agency to act on the "best available science," meaning that EPA must consider all available science and assess the quality of the science based on a variety of factors.

EPA's proposed blanket prohibition against basing a rulemaking on science for which underlying data or models are not publicly available would be particularly hard to reconcile with the "best available science" standard as articulated in TSCA, which clearly contemplates a case-by-case analysis in which EPA weighs a variety of factors when identifying the best available science. The relevant provision of TSCA requires that:

> (h) Scientific standards. In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the *best available science*, and shall consider *as applicable*—
> (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
> (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
> (3) *the degree of clarity and completeness* with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information *are documented*;
> (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
> (5) *the extent of independent verification or peer review* of the information or of the procedures, measures, methods, protocols, methodologies, or models.[106]

Thus, Congress provided EPA with factors to guide its consideration of the "best available science," and Congress did not make the public disclosure of all underlying data a requirement for material to be the "best available science." Quite the opposite; Congress included aspects of disclosure and independent review as parts of factors to be considered when weighing scientific information. But these are just aspects of five different factors to be weighed "as applicable," and

[106] 15 U.S.C. § 2625(h) (emphases added).

Congress clearly contemplated that EPA would sometimes rely on science that does not meet the proposed rule's requirement of full disclosure of all underlying data.

First, Congress directed EPA to consider these factors when weighing particular information; Congress specifically did not develop (or direct EPA to develop) bright-line criteria for eliminating information from consideration entirely. Thus, each factor includes the phrase "degree of" or "extent to which," without identifying any threshold that would be disqualifying.[107] This shows that Congress intended these factors to help EPA assess the weight information should be given based on its relative scientific reliability, not to create minimum thresholds of reliability below which information must be ignored by EPA altogether. For EPA to insert a screen on top of these factors—excluding information where the underlying data and models are not publicly available as required by the proposed rule—contradicts Congress's unambiguous intent about how EPA should approach its assessment of the best available science.

Second, Congress made the "degree of clarity and completeness" with which the underlying data is documented to be part of one factor for EPA to consider in evaluating whether a particular study is the "best available science."[108] But EPA must also consider "the degree of clarity and completeness" with which "assumptions, methods, quality assurance, and analyses" are documented as well.[109] Thus, Congress contemplated that EPA would still rely on some studies that did *not* document completely all the underlying data, much less disclose all of that information.

Third, Congress made "the extent of independent verification *or* peer review of the information *or* of the procedures, measures, methods, protocols, methodologies, or models" another factor to be weighed when considering whether information is the "best available."[110] Notably, Congress's choice of the disjunctive "or" reflects that "peer review" can be an adequate alternative to "independent verification," and Congress did not require that either "independent verification *or* peer review" be accomplished through public availability of data as required in the proposed rule. Moreover, Congress contemplated scenarios where EPA would give more weight to evidence even if the "information" had not undergone "independent verification or peer review" based on the extent to which the "procedures, measures, methods, protocols, methodologies, or models" had done so.

Fourth and most importantly, EPA cannot rationally elevate the interest in public disclosure of all underlying data above all the other factors that Congress expressly required EPA to consider in evaluating science. Congress required EPA to consider these five factors "as applicable" when weighing information, and Congress did not make full public availability of underlying data one of the factors, much less a decisive or absolute one.

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[107] *See, e.g.* 15 U.S.C. § 2625(h)(1) ("*the extent to which* the scientific information…[are] consistent with the intended use of the information") (emphasis added).
[108] 15 U.S.C. § 2625(h)(3).
[109] *Id.*
[110] 15 U.S.C. § 2625(h)(5).

This administration recently adopted a regulatory definition of "best available science" for purposes of TSCA which expressly incorporated consideration of these five factors and was otherwise inspired by use of the term in the Safe Drinking Water Act (SDWA).[111] EPA defined the phrase:

> Best available science means science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). Additionally, EPA will consider as applicable:
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> [TSCA § 26(h)(1)(5) factors][112]

According to EPA in selecting this definition, "the Agency is remaining consistent with the current approach already used Agency-wide, while also acknowledging the specific standards under TSCA."[113] Notably, this definition does not require public disclosure of all underlying data for science to be the "best available science," yet many studies that meet this definition of "best available science" would be excluded under EPA's proposed rule.

EPA's Proposal cannot be reconciled with EPA's existing definition of best available science, with decades of court and agency precedent, or with text of the statute. When a statute requires the agency to make a decision based on the "best available science," it would be unlawful to follow EPA's proposed rule.

iii. EPA's proposed rule also contradicts TSCA's requirement that decisions be made based on the weight of the scientific evidence.

TSCA § 26(*i*) requires EPA to make decisions regarding testing and regulating new and existing chemicals "based on the weight of the scientific evidence."[114] If EPA excludes certain information, as proposed, then EPA will not be able to weigh the evidence as a whole.

Indeed, this administration recently adopted a regulation defining "weight of scientific evidence" to mean "a systematic review method … that uses a pre-established protocol to *comprehensively*, objectively, transparently, and consistently, identify and evaluate *each stream of evidence*, including strengths, limitations, and relevance of *each* study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."[115] Systematic reviews consider the entire body of scientific evidence, but EPA's proposed rule would prevent EPA from conducting true systematic review because it would prohibit the Agency from considering studies where the data were not publicly available and it would

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[111] *See* 82 Fed. Reg. 33,726, 33,731 (July 20, 2017), 42 U.S.C. § 300g-1(b)(3)(A).
[112] 40 C.F.R. § 702.33.
[113] 82 Fed. Reg. at 33,731.
[114] 15 U.S.C. § 2625(*i*).
[115] 40 C.F.R. § 702.33 (emphases added).

eliminate studies based on criteria other than their "strengths, limitations, and relevance."[116] If the proposed rule forecloses EPA from considering information that cannot be fully disclosed, as it appears to do, then EPA cannot comply with this regulation and the proposed rule.

In sum, EPA's proposed rule is inconsistent with TSCA's plain text. EPA should not adopt the proposed rule because it cannot be reconciled with the agency's duties under TSCA.

iv. Section 10 of TSCA does not authorize this proposal.

Nothing in Toxic Substances Control Act (TSCA) § 10 authorizes EPA to exclude scientific information during rulemakings on any basis. Section 10 authorizes EPA to research and develop information for purposes of carrying out TSCA.[117] Section 10 also authorizes EPA to develop systems to collect and disseminate information about chemical substances.[118] But TSCA § 10 is silent regarding rulemaking or EPA's use of scientific information in rulemaking. It does not authorize EPA to exclude scientific information on *any* basis; if anything, TSCA § 10 reflects a congressional judgment that EPA should be prepared to use any and all "toxicological and other scientific information which could be useful to the Administrator in carrying out the purposes of this [Act]."[119]

c) EPA's Proposal contravenes the Safe Drinking Water Act.

The Safe Drinking Water Act requires EPA to issue national drinking water regulations setting required purity levels for water from public water supply systems.[120] Before regulating, the Administrator must conclude that the contaminant at issue "may have" an adverse effect on the health of persons.[121] In regulating, the Administrator must consider "the best available public health information"[122] The section adds that in setting regulations, the Administrator "shall use ...the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" and in addition "data collected by accepted methods or best available methods."[123] When Congress promulgated these statutory requirements in 1996, the Senate Committee on Environment and Public Works[124] explained that the "Administrator has a *duty* to seek and rely upon the best available science and information to support.... [m]any

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[116] *Id.*

[117] *See* 15 U.S.C. § 2609(a) ("The Administrator shall ... conduct such research, development, and monitoring as is necessary to carry out the purposes of this [Act]."); *see also* 15 U.S.C. § 2609(c), (d), (e).

[118] *See* 15 U.S.C. § 2609(b), (c), (g).

[119] 15 U.S.C. § 2609(b)(2)(A).

[120] 42 U.S.C. § 300g-1.

[121] *Id.* at (b)(1)(A)(i).

[122] *Id.* at (b)(1)(B)(ii)(II).

[123] 42 U.S.C. § 300g-1(b)(3)(A). *See City of Waukesha v. EPA*, 320 F.3d at 247-48 (D.C. Cir. 2003) (holding that agency peer review satisfies requirement to use best, peer-reviewed science and supporting studies); *City of Portland v. EPA*, 507 F 3d 706, 716 (D.C. Cir. 2002) (same).

[124] The Report of the Senate Committee on Environment and Public Works is authoritative on these provisions, as the language adopted in the Committee bill (S.1316) on the use of science was adopted verbatim in Pub. L. 104-182. *See* S. Rep. 104-169 at p. 121 and Pub. L. 104-182 at §103.

of the most important activities including selecting contaminants for regulation, setting standards, designing analytical methods and structuring waivers, variances and exemptions."[125]

By restricting EPA to considering only those scientific studies for which underlying data, models, and other information is publicly available, EPA's proposal prevents EPA from complying with the SDWA directive that it consider the "best available" public health information and science when setting SDWA standards. Specifically, as explained above, the public will not necessarily have access to the underlying information used to produce the "best available, peer-reviewed science and supporting studies."[126] Nowhere does the SDWA authorize EPA to ignore such studies based on the public unavailability of underlying information. Thus, regardless of the merits of the core objective of EPA's proposal—"to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation" (proposed § 30.1 "What is the purpose of this subpart?"), EPA's attempt to elevate this objective above the agency's statutory obligation to consider the "best available" science when promulgating SDWA standards is unlawful.[127]

4. EPA's proposed exemption provision does not remedy the unlawfulness of prohibiting EPA from considering valid and relevant studies due to the public unavailability of underlying data and methods.

Though the proposed exemption provision in section 30.9 would grant the EPA Administrator discretion to authorize the agency to consider studies for which underlying data or models are not publicly available, this provision is insufficient to remedy the proposed rule's unlawfulness and detrimental impacts. It is well established that existence of a waiver or exemption mechanism cannot be used to justify a provision otherwise beyond an agency's legal authority. *Dimension Financial Corp. v. Board of Governors of Federal Reserve System*, 744 F.2d 1402, 1410 (10th Cir. 1984) ("The possible exception to the initial impact of Regulation Y (Part 225.21(B)(4)) contains requirements with no objective standard and thus unbounded agency discretion. This as a device to meet objections to the new regulation cannot cure the exercise of powers denied by Congress or not provided for by Congress. *Public Utilities Comm. of Calif. v. United States,* 355 U.S. 534 (1958); *In re Surface Mining Regulation Litigation,* 627 F.2d 1346 (D.C. Cir. 1980); *ALLTEL Corp. v. FCC*, 838 F.2d 551, 561 (D.C. Cir. 1988) ("The FCC cannot save an irrational rule by tacking on a waiver procedure. 'The very essence of waiver is the assumed validity of the general rule . . . .')(citing *WAIT Radio v. FCC*, 418 F.2d 1153, 1158 (D.C. Cir. 1969)); *United States Telecom Ass'n v. FCC*, 359 F.3d 554, 571 (D.C. Cir. 2004) ("Moreover, even if the FCC had adopted some lawful mechanism for making exemptions from its general national rule, it could not necessarily rely on the existence of that mechanism as the sole justification for not adopting a more narrowly tailored rule. . . . [T]he mere existence of a safety valve does not cure an irrational rule.")

[125] S. Rep. 104-169 at 28 (emphasis added).
[126] 42 U.S.C. § 300g-1(b)(3)(A).
[127] 83 Fed. Reg. at 18773.

First, while the statutory provisions described above *require* EPA to consider best available science and other relevant information when making regulatory decisions, *see, e.g.*, Safe Drinking Water Act, 42 U.S.C Section 300g-1(b)(3)(A)(i) ("The Administrator *shall* use the best available, peer reviewed science."), the Administrator has discretion over whether to grant an exception. *See* Proposed § 30.9 ("The Administrator *may* grant an exemption to this subpart on a case-by-case basis...")(emphasis added).[128] Where a statute requires that the agency consider certain information in reaching a decision, EPA cannot promulgate a rule that gives the Administrator discretion over whether to allow such consideration.

Second, the only basis on which the Administrator may grant an exemption under Proposed § 30.9 is that it "is not feasible" to "ensure that all dose response data and models underlying pivotal regulatory science is publicly available" as the rule requires.[129] However, the Proposal does not explain how "feasibility" is to be determined in this context—or even whether the term encompasses practical feasibility, cost-effectiveness, or other considerations. Moreover, there can easily be situations where it is theoretically "feasible" to make underlying data publicly available, but this information is nonetheless not publicly available. For example, a scientist who intends to rely on the same data to publish multiple papers may be disinclined to make that data available to competitors.[130] Yet, because it is technically "feasible" to make the underlying data publicly available, the proposed rule would not even provide the Administrator with authority to grant an exemption authorizing such consideration, thus forcing the Administrator to violate the law.

Third, even if it were lawful for EPA to ignore relevant science, the exemption provision is arbitrary, as it does not define sufficient criteria or process steps by which the Administrator may decide to exempt a study. The provision instructs the Administrator to rely on a handful of broad (and highly manipulable) policy considerations in determining whether it would be infeasible to make data and methods publicly available.[131] These factors could be applied broadly to give the Administrator nearly absolute discretion. From the face of the Proposal, it is not even clear that the Administrator would be required to provide a public, written explanation of his decision to grant (or deny) a waiver. This lack of accountability could lead to the arbitrary exclusion of studies the Administrator unilaterally chooses to not exempt.

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[128] 83 Fed. Reg. at 18774.

[129] 83 Fed. Reg. at 18774.

[130] Or in cases where companies jointly funded research it may be unclear who owns the data and has the right to share it, and companies may be reluctant to share it with competitors. *See, e.g.*, National Academies of Sciences, Engineering, and Medicine, *Principles and obstacles for sharing data from environmental health research: Workshop summary*, 45 The National Academies Press (2016), https://www.nap.edu/catalog/21703/principles-and-obstacles-for-sharing-data-from-environmental-health-research. ("As you can imagine. . . not all competitors play nicely together. Some even resort to gamesmanship to try to exclude competitors from the market. Things can get nasty and messy in a hurry in these discussions.").

[131] *See* 83 Fed. Reg. at 18774. Under §30.9(a), the Administrator should consider whether it is infeasible "in a fasbion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security." §30.9(b) references 70 Fed. Reg. 2664, which exempts peer review in situations of "disseminations of sensitive information related to certain national security, foreign affairs, or negotiations involving international treaties and trade where compliance with this Bulletin would interfere with the need for secrecy or promptness."

Finally, the exemption provision is impractical and likely could not be implemented effectively. According to the Congressional Budget Office, EPA "relies on about 50,000 scientific studies annually to perform its mission," and at times, relies on thousands of studies for one action.[132] Many of the studies that would be affected by this rule are complex and include large datasets that would lead to an extensive decision-making process under the exemption provision. EPA does not include any rationale in the proposal justifying how the Administrator could reasonably decide to exempt studies on a case-by-case basis given the tens of thousands of studies EPA considers each year. This provision could create a large backlog, which would result in important studies being effectively removed from EPA consideration because of the need to finalize a regulation before an exemption for every relevant study is granted. Accordingly, the exemption provision fails to safeguard against the unlawful exclusion of valid science from EPA's regulatory process.

C. EPA's Proposed Rule Would Violate the Information Quality Act.

EPA's proposed rule is also unlawful because it exceeds EPA's authority under Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 16-554; H.R. 5658), commonly referred to as the Information Quality Act.[133] Specifically, the Information Quality Act requires EPA promulgate data quality guidelines that are consistent with those promulgated by the Office of Management and Budget. Contrary to EPA's assertion in the preamble to the proposal, the Proposed Rule is not consistent with OMB's data quality regulations.

The OMB Guidelines recognize that data availability is not necessary to high quality science, but is one among many factors. While imposing high standards of quality, objectivity, utility, and integrity of information disseminated by Federal Agencies, the Guidelines recognize the need to implement controls "flexibly, and in a manner appropriate to the nature . . . of the information to be disseminated."[134] As part of ensuring "objectivity" these guidelines encourage agencies that disseminate influential scientific, financial, or statistical information, "to include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties."[135] However, they emphasize the need to treat certain data differently, due to privacy and confidentiality concerns.[136] In fact, the OMB Regulations specifically declare that "[w]ith regard to original and supporting data related thereto, *agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement.*"[137] Rather, the OMB Guidelines instruct that agencies "identify, in consultation with the relevant scientific and technical communities, those particular types of data that can

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[132] Congressional Budget Office, *Cost Estimate: H.R. 1430* 2-3 (March 29, 2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf.
[133] Codified at 44 U.S.C. 3504(d)(1) and 3516.
[134] OMB's *Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information*, 67 Fed. Reg. 8,452, 8,453 (Feb. 22, 2002).
[135] 67 Fed. Reg. at 8460.
[136] *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information*, 67 Fed. Reg. 8, 452, 8,460 (Feb. 22, 2002) (interest in making data publicly available "does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections").
[137] 67 Fed. Reg. at 8460 (emphasis added).

practicable [sic] be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints."[138] The OMB Regulations further explain that while "[m]aking the data and methods publicly available will assist in determining whether analytic results are reproducible...*the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections*.[139] OMB explains that "where public access to data and methods will not occur due to other compelling interests, agencies shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken."[140]

By outright prohibiting EPA from relying on a study to support a significant rulemaking if that study's underlying data and models are not publicly available, EPA's proposed rule departs from OMB's unambiguous language instructing agencies that they "shall not" require that all data and models be subject to the reproducibility requirement, and that "the objectivity standard does not override other compelling interests."[141] The fact that EPA's proposed rule includes a discretionary "exemption" provision does not correct this problem, as that provision would not require the Administrator even to consider whether an exemption is warranted, let alone grant such an exemption under appropriate circumstances.

Because Congress expressly granted OMB the authority to set guidelines for data quality and instructed agencies like EPA to follow OMB's lead, EPA lacks statutory authority to adopt a regulation that is contrary to OMB's guidelines. Accordingly, EPA's proposed regulation violates the Information Quality Act and must be withdrawn.[142]

II. EPA's Proposed Rule is Unreasonable and Arbitrary and Capricious.

In addition to violating the requirements of the various statutes that EPA administers or is subject to, the Proposal suffers from a total failure to consider important dimensions of the profound shift in policy that it implements. In the Proposal, EPA neglects to consider the many legitimate reasons why a study's underlying data may not be publicly available—reasons that have nothing to do with the quality of the study—and fails to offer solutions consistent with these legitimate limitations. EPA makes vague gestures to various guidelines and practices issued by other agencies and scientific organizations, none of which actually support the Proposal's radical position that EPA should exclude consideration of studies that rely upon confidential data. EPA does not even establish that there is a real problem that the Proposal would actually address: nowhere in the Proposal does EPA identify any prior agency action that has been called into serious question due to a failure to release study data. EPA's utter failure "to consider an important aspect of the problem" and to provide an explanation for the Proposal

[138] 67 Fed. Reg. at 8460. There is no indication that EPA consulted with the scientific and technical community—or even its own Science Advisory Board—before proposing to require that the underlying data and models be made publicly available for all pivotal regulatory science regardless of ethical, feasibility, or confidentiality constraints.
[139] 67 Fed. Reg. at 8460 (emphasis added).
[140] 67 Fed. Reg. at 8460.
[141] *See* 67 Fed. Reg. at 8460.
[142] *Prime Time Int'l Co. v. Vilsack*, 599 F.3d 678, 685 (D.C. Cir. 2010) ("[B]ecause Congress delegated to OMB authority to develop binding guidelines implementing the IQA, we defer to OMB's reasonable construction of the statute.")

that is consistent with the evidence before the agency renders the Proposal wholly arbitrary and capricious. *See Motor Vehicle Mfrs. Ass'n. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Likewise, EPA's failure to explain its 180-degree change in position from its former belief that the lack of publicly-available data does not render a study inappropriate for consideration in regulating is a hallmark of arbitrary and capricious decision-making. *FCC v. Fox Telev. Stations, Inc.*, 556 U.S. 502, 515-16 (2009).

A. EPA Failed to Consider the Legitimate Reasons That Underlying Data May Not be Made Publicly Available, or to Propose Solutions to Remedy These Actual Limitations.

1. There are multiple reasons why underlying data are not publicly available for all studies.

There are legal and ethical requirements that restrict making public the data underlying studies, including rules to shield private personal information, requirements to maintain confidential business information, situations where obtaining the necessary permissions to release data are logistically difficult or impossible, and situations in which researchers have made significant investments in developing datasets that they intend to continue to work with for future studies. Not all of these barriers can be overcome, nor can they be overcome in every case. While there are ways potentially to address some of them, they can be extremely costly and burdensome, and/or may harm the prospects for further research. Accordingly, while the scientific community has made efforts to make more data publicly available, to the best of our knowledge all of the policies adopted by government and academic journals recognize that data is not, and need not be, publicly available to evaluate their quality.

a) Strong legal and ethical requirements limit the release of data in human subjects studies.

Particularly with respect to human subjects, there are strong legal and ethical privacy and confidentiality protections, which researchers are bound to respect.[143] In some cases, researchers would be subject to civil or criminal penalties for violations.[144]

The environmental health dose response studies targeted by EPA's proposal are likely to include human population studies (or epidemiological studies). Often the best available epidemiological studies contain extensive and sensitive data on individuals, such as environmental exposures, medical history (such as infant reproductive developmental abnormalities, children's behavioral and development problems, heart attacks or dementia among the elderly), dates of birth, residential address, drug use, race, socio-economic status (income,

[143] *See, e.g.*, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report* (Apr. 18, 1979), https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf; *Federal Policy for the Protection of Human Subjects; Final Rule*, 82 Fed. Reg. 7,149 (Jan. 19, 2017); HIPAA Privacy Rule, 45 C.F.R. §§ 160, 164.102-06, 164.500-534.

[144] *See*, The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191 (enacted Aug. 21, 1996) (providing for criminal and civil penalties for violations).

education), status of subjects' marriages, employment history, etc. For example, air pollution studies commonly use residential address information to assign air pollution exposures and link them to health effects.[145] Other studies focused on genetically susceptible populations may also be linked to genetic databases or contain information on key genetic mutations that are strongly predictive of serious health risks, such as risk of Alzheimer's disease, and are thus very sensitive.[146]

To conduct these studies, investigators must obtain informed consent from the study participants to collect protected health information, and investigators must sign documents promising to protect the privacy of this individually identifiable health information. Absent complex, difficult and costly de-identification and redaction techniques, these data simply cannot be released publicly. As discussed below in section II.A.2.b), in some cases such techniques are simply not applicable or still leave significant risk of breach of privacy.

Additional protections apply to specific types of human subject information. For example, medical records are subject to strict requirements governing the use and disclosure of such information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[147] HIPAA requires researchers to protect identifiable information, and it provides that such information may only be disclosed for research purposes with the written consent of the person providing the information.[148]

Another limitation on public availability of data is the requirement under the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) that for all federally funded studies involving human research subjects, researchers must first obtain Institutional Review Board (IRB) approval and informed consent from study participants.[149]

An IRB reviews each human subjects research project to ensure that the specific research protocol protects individual rights. Participants must be notified about the degree to which the confidentiality of their records will be maintained, and must receive appropriate notification and

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[145] *See, e.g.*, Kaufman, Joel D., et al., *Association between air pollution and coronary artery calcification within six metropolitan areas in the USA (the Multi-Ethnic Study of Atherosclerosis and Air Pollution): a longitudinal cohort study*, 388.10045 The Lancet 696-704 (2016).

[146] *See, e.g.*, Richardson JR, Roy A, Shalat SL, von Stein RT, Hossain MM, Buckley B, Gearing M, Levey AI, German DC, *Elevated serum pesticide levels and risk for Alzheimer disease*, 71(3) JAMA Neurology 284-90 (Mar. 1, 2014).

[147] Public Law 104 – 191.

[148] National Research Council, *Expanding Access to Research Data: Reconciling Risks and Opportunities*. The National Academies Press (2005).

[149] 45 C.F.R. §§ 46.101-124 is the U.S. Department of Health and Human Services ("HHS") citation for the Common Rule. A total of 18 federal agencies have adopted it; each agency has its own separate entry in the Code of Federal Regulations. This federal rule governs ethical constraints that federally funded studies must follow, including academic research, responding to earlier concerns of ethical lapses in medical research. *See, e.g.*, Jerry Menikoff, *Could Tuskegee happen Today?*, 1 St. Louis U. J. Health L. & Pol'y 311, 312-16 (2008) (describing the Congressional response to public outcry when the details of the Tuskegee experiment were brought to light). The thrust of the Common Rule is to address such matters of research ethics as informed consent, informational risk, and institutional oversight when research involves human subjects.

give consent if study data is to be shared outside the research team.[150] The IRB also considers risks to the participants and how use of the information obtained may adversely impact the rights and welfare of the subjects.[151] Most institutions have committed to comply with the Common Rule for all of their research, even when it is not federally-funded.[152]

For studies that had received IRB approval prior to finalization of this proposed rule, there may be no practical opportunity to make the data publicly available. Even for new studies going forward, it may be extremely difficult, require additional (often unavailable) funding for elaborate protective measures, or simply impossible to obtain IRB approval for protocols that would allow the data to be made publicly available.

EPA's own Science Advisory Board voiced these concerns that EPA was discounting the challenges to making even limited releases of data, saying:

> The proposed rule oversimplifies the argument that "concerns about access to confidential or private information can, in many case, be addressed through the application of solutions commonly in use across some parts of the Federal government." For studies already completed or underway, the participation of human subjects is undertaken according to terms approved by the cognizant IRB. These terms can vary from study to study. In some cases, the data cannot be released simply by redacting portions of it. For example, data may have been collected with an assurance to the participating individuals that their data would be kept confidential.[153]

Some researchers might respond by choosing to work only on public administrative datasets, but this would harm rather than strengthen science quality by curtailing scientific inquiry. Thus, the effects of EPA's proposed approach would cause some researchers to choose not to pursue research with human subjects, stifling scientific discovery, while others would forgo compliance with EPA's regulatory requirements and have their research ignored by EPA. As a result, EPA's proposal would both discourage the development of best available science as well as EPA's use of it.

> b) There are especially significant barriers to public release of underlying data and models from studies that have already been completed.

With respect to studies that have already been completed, there are additional formidable barriers to public release of underlying data and models. Particularly, with older studies, simply finding the data sets and determining ownership may be expensive or impossible. For older studies with human subjects, obtaining consent to release of data may be practically impossible,

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[150] *See*, 82 Fed. Reg. 7,149-7,274.
[151] *Id.*
[152] HHS, *Federalwide Assurance (FWA) for the Protection of Human Subjects*, https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjects/index.html (last accessed Aug. 13, 2018).
[153] Memorandum by Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science (May 12, 2018).

and the data may have been collected in ways that would make protecting privacy with release difficult or impossible.[154]

For some studies, administrative issues related to the data could be the most difficult barrier to overcome in providing for public release. Larger and more costly studies are often performed by groups of researchers within a university, across multiple institutions, or across multiple individual companies. Over time, the data itself may become lost or misplaced, or it may become unclear who actually owns and controls access to the data. Academics move among institutions, companies merge and spin off, and the initial agreements were not always clear in the first instance. Obtaining consent from multiple institutional players takes extensive time and resources, at minimum, and simply may no longer be possible in some instances.[155]

These problems are exacerbated with respect to human subject studies. Researchers are legally and ethically obliged either to protect the privacy of the individual study subjects or attain each subject's consent to share data.[156] This can be impractical for older studies and virtually impossible for larger studies, and extremely burdensome. For example, the Harvard Six cities study was started in 1975 and had 8,111 participants.[157] The ACS CPSII extended analysis by Krewski in 2009, which is central to $PM_{2.5}$ NAAQS standards, was initiated in 1979 and encompassed data from 500,000 study participants who lived in 116 metropolitan areas.[158] For these types of situations, tracking down participants (or where the participants have passed away, their family members) to get consent is simply not realistically possible.

Even in situations where investigators might theoretically be able to attain consent, it would require extensive financial and human resources, which are usually simply not available, especially to academic researchers or to EPA. EPA ignores this prohibitive constraint and makes no attempt to address it.

c) There are additional significant barriers to public release of data in some situations, even for prospective studies.

Even with respect to prospective application of EPA's proposal, providing for public release of underlying data and models is costly and resource intensive, creating a serious disincentive for researchers to meet EPA's proposed requirements. Investigators willing to make their study underlying data publicly available would still face the logistical hurdle of making the data and models available in a manner sufficient for independent validation by the public. In

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[154] *See, e.g.*, National Academies of Sciences, Engineering, and Medicine, *Principles and obstacles for sharing data from environmental health research: Workshop summary*, 61-63 The National Academies Press (2016), https://www.nap.edu/catalog/21703/principles-and-obstacles-for-sharing-data-from-environmental-health-research.

[155] *Id.* at 45.

[156] *Federal Policy for the Protection of Human Subjects; Final Rule*, 82 Fed. Reg. 7,149 (Jan. 19, 2017); HIPAA Privacy Rule, 45 C.F.R. §§ 160, 164.102-106, 164.500-534.

[157] Dockery, D.W., Pope, C.A., Xu, X., Spengler, J.D., Ware, J.H., Fay, M.E., Ferris Jr, B.G. and Speizer, F.E., *An association between air pollution and mortality in six US cities,* 329(24) New England Journal of Medicine, 1753-1759 (1993).

[158] Krewski D, Jerrett M, Burnett RT, et al., *Extended Follow-Up and Spatial Analysis of the American Cancer Society Study Linking Particulate Air Pollution and Mortality*, 140 Health Effects Institute, Boston MA (2009).

addition to the cost of thoughtful and effective deidentification or redaction of sensitive information, the proposed text would likely require researchers to prepare annotated manuals including precise detail as to what variables were collected, how information was collected, and the rationale for each step taken. Some manuals alone run into hundreds of pages. One press account noted the example of publicly available datasets from the National Center for Health Statistics, which can come with 100-page manuals; researchers would need to hire additional staff to meet such requirements.[159] Yet EPA fails even to recognize (much less propose any means to address) the cost to researchers in time and money, on top of the constraints on academic research already imposed by the very limited funding available for this type of work.

In addition, there are other barriers to public release of underlying data. Studies conducted on behalf of industry or with industry cooperation may contain confidential business information, the release of which could jeopardize a company's competitiveness.

Also, in some instances, researchers cannot make their data sets public without losing much of the value to the researcher of these laboriously and meticulously collected sets of information. Research, especially those studies that include large numbers of human subjects, are incredibly human and capital intensive endeavors. Moreover researchers may base years of work and multiple papers on unique datasets they developed and hold, and many scientists build their careers on carefully harvesting information from single large studies for years to come. It is not only unreasonable, but also unfair, to expect academic scientists to turn over their intellectual property and research investments, forgoing potential earnings and career advancements. Moreover, EPA's myopic and inflexible approach to data access gives no consideration to data sharing arrangements between researchers and the agency that could be developed to support EPA's consideration and integration of research.

If scientists are forced to choose between giving away their hard-earned data or forgoing any regulatory impact, it will discourage scientists from engaging in critical science that is targeted to help prevent disease and disability in our population. It appears that in many cases, scientists will choose to retain their datasets, with a worst-of-both-worlds result—EPA will be deprived of valid scientific information and the scientific community will be discouraged from contributing their critical expertise to policy-making. EPA's Proposal does not consider the real-world implications of forcing such choices on researchers.

The agency's failure to consider or examine any of these legitimate reasons for not making data publicly available is arbitrary and capricious.

2. The Proposal fails to propose any actual solutions to remedy the legitimate reasons for why data may not be made publicly available.

In the proposal EPA blithely and irrationally ignores or assumes away the real and significant issues raised above, suggesting that existing mechanisms and techniques can be used

[159] Alessandra Potenza and Rachel Becker, *Scott Pruitt's new 'secret science' proposal is the wrong way to increase transparency. Here's what scientists think a science transparency rule should include*, The Verge (May 1, 2018, 8:30am EDT), https://www.theverge.com/2018/5/1/17304298/epa-science-transparency-rule-scott-pruitt-data-sharing.

to protect privacy and confidentiality while making underlying research data publicly available. In fact, the evidence (including several of the sources that EPA cites) indicates that the potential mechanisms alluded to by EPA would only have the potential to address some of the barriers cited above, have serious limitations even for those, and are actually becoming less effective as it becomes easier to combine and manipulate public data sets.

a) EPA vaguely references a range of possible approaches to protecting privacy and confidentiality, but provides no evidence that any of these are sufficient to address the legitimate concerns raised above.

EPA vaguely claims "concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government."[160] EPA claims that there are examples from the Department of Health and Human Services, the National Institute of Standards and Technology, the Department of Education, and the Census Bureau. Unfortunately, apart from a reference to HHS guidance on data de-identification (discussed below), EPA does not actually identify or cite to any specific examples from these agencies in the proposed rule itself, making it impossible to discern what examples EPA believes exist or to meaningfully comment upon the degree to which such examples, if they exist, might suggest that these issues are manageable. The additional hyperlinks added to the docket on May 25, 2018, weeks into the comment period, also link to examples that provide no further assurance that this proposal can be implemented without implicating privacy concerns, and as discussed in detail below, the vaguely referenced other agencies' "solutions" are unlikely to be of much help.

The "solutions" EPA might have in mind do not address the issues raised by the Proposal because no other agency has tried to implement a requirement such as the one EPA proposes. Other agencies provide guidance and techniques to protect privacy during data collection and disclosure to allow more use of data collected by the *government*, not to mandate that data collected by academic or industry researchers be publicly available for purposes of replicating analyses. The Department of Education, for example, has shared techniques for institutions to provide data on students and schools to meet reporting requirements without compromising privacy.[161] They recognize that each technique "requires some loss of information."[162] While de-identified information may still be useful, e.g., to show overall school progress, in the context of the Education Department, it is not clear these techniques are transferable to other contexts.

EPA links to a document of the Privacy Technical Assistance Center, *Data De-identification: An Overview of Basic Terms*, which provides a high-level overview of key terms and practices to help educational agencies and institutions comply with the Family Educational Rights and Privacy Act (FERPA).[163] This document is concerned with data disclosure that occurs

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[160] 83 Fed. Reg. 18,770.
[161] National Center for Education Statistics, *SLDS Technical Brief: Statistical Methods for Protecting Personally Identifiable Information in Aggregate Reporting* (Dec. 2010), https://nces.ed.gov/pubs2011/2011603.pdf.
[162] *Id.* at 27.
[163] Privacy Technical Assistance Center, *Data De-identification: An Overview of Basic Terms* (2001), https://studentprivacy.ed.gov/sites/default/files/resourcedocument/file/datadeidentificationterms.pdf.

"when schools, districts, or states publish reports on student achievement or share students' data with external researchers" not to make underlying data publicly available for independent validation.[164] Thus, it is unclear that methods used to de-identify but preserve data for those purposes would be adequate in this context. For example, one of the methods that the U.S. Department of Education uses for disclosure avoidance for tabular data is to not release information for any cell that has a size below some minimum, which essentially means not disclosing information where there are small numbers in a certain cell.[165] Thus, it is quite possible that techniques that result in a loss of information would prevent researchers from repeating the experiment. Yet EPA fails to acknowledge the nuances and limitations of these policies.

EPA links to a NIST document entitled *De-Identification of Personal Information* by Simson L. Garfinkel (NISTIR 8053), which discusses de-identification, but not in the context of making research data publicly available for independently validating scientific studies. The document instead notes that "that there is a trade-off between the amount of de-identification and the utility of the resulting data" and that "[i]t is thus the role of the data controller, standards bodies, regulators, lawmakers and courts to determine the appropriate level of security, and thereby the acceptable trade-off between de-identification and utility."[166] It further notes that "de-identification approaches based on suppressing or generalizing specific fields in a database cannot provide absolute privacy guarantees, because there is always a chance that the remaining data can be re-identified using an auxiliary dataset."[167]

EPA's reference to the U.S. Census Bureau is similarly unhelpful. Here EPA provides a link to a website titled *Data Ingest and Linkage* that details the U.S. Census Bureau's approach to linking data across many records they hold.[168] The Website links to a working paper that describes the method by which the Census assigns a unique person identifier to records it holds that enables it to link records together to create the final file.[169] It is totally unclear how this process on linking together records is a solution that EPA could implement to protect privacy of individuals when disclosing data as it concerns how to identify data with specific people—not protecting privacy.

While other agencies are clearly grappling with the issue of how to make government-collected data available, they have also highlighted the many challenges in protecting privacy and confidentiality while doing so—such as the ability for de-identified data to be re-identified—and these agencies accept that there is more work to be done before these concerns are fully

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[164] *Id.* at 1.
[165] *Id.* at 4.
[166] Simson L. Garfinkel, *De-Identification of Personal Information* (NISTIR 8053), 11-12 NIST (Oct. 2015), https://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf.
[167] *Id.* at 5.
[168] U.S. Census Bureau, *Data Ingest and Linkage*, https://www.census.gov/about/adrm/linkage/technical-documentation/processing-de-identification.html (last accessed Aug. 13, 2015).
[169] Deborah Wagner & Mary Layne, *The Person Identification Validation System (PVS): Applying the Center for Administrative Records Research and Applications' (CARRA) Record Linkage Software*, CARRA Working Paper Series, Working Paper # 2014-01, U.S. Census Bureau (July 1, 2014).

addressed.[170] The letter filed in this docket by the Presidents of the National Academies of Science, Engineering and Medicine underscores these difficulties, specifically noting the National Academies' previous work finding that "statistical analyses of data sets that generate highly precise results—such as geographic specificity or other characteristics that identify respondents—may result in privacy breaches . . . This presents a new challenge that federal statistical agencies are just beginning to address."[171] EPA does not even acknowledge, much less try to address, these gaps in agencies' abilities to protect sensitive data.

EPA cursorily mentions a range of options for facilitating secure access to confidential data, including: "[r]equiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements."[172] EPA does not indicate whether it would deem providing access with these types of controls in place sufficient to meet EPA's proposed requirement "publicly available in a manner sufficient for independent validation." EPA also fails to recognize the significant costs associated with implementing most of these options or the risks to privacy that remain even if these methods are employed.

b) EPA cites to one example—the technique of deidentification—but fails to acknowledge, let alone address, the significant costs and limitations of this approach.

As already discussed, it is legally and ethically necessary to ensure the privacy of the individuals whose data have been collected, as some of these data, such as medical history or employment data, can be quite sensitive. EPA suggests deidentification and redaction of sensitive information can be used to protect privacy when study data is made public. EPA fails to recognize that these techniques are generally burdensome and costly, and may lose too much information for replication purposes. EPA also ignores the real concerns, based in empirical evidence, about reidentification of individuals through cross linking with existing public datasets and the ensuing breach of privacy.[173]

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[170] *See, e.g.*, Simson L. Garfinkel, *De-Identification of Personal Information* (NISTIR 8053), NIST (Oct. 2015) (detailing methods of re-identification and challenges to de-identifying information, concluding "there is comparatively little known about the underlying science of de-identification" and "there is a clear need for standards and assessment techniques that can measurably address the breadth of data and risks described in this paper.").

[171] Letter to Acting Administrator Wheeler from Marcia McNutt, President of the National Academy of Sciences, C.D. Mote, Jr., President of the National Academy of Engineering, and Victor J. Dzau, President of the National Academy of Medicine at 4 (July 16, 2018) (citations removed).

[172] 83 Fed. Reg. 18,771.

[173] "Recently, a peer reviewed study examined the identifiability of records from an environmental health study in Northern California. Using data considered by HIPAA to be sufficiently de-identified to be made public, which involved far fewer variables than would be required to make public in the cohort studies, they were able to correctly identify over 25% of the participants. Another study searched the Lexis-Nexis database for stories that mentioned hospitalization, and by matching that with age, race, sex and Zip code from a supposedly anonymized hospital admissions data base was able to match 43% of the people named in the news stories to their medical records." Comments of the International Society for Environmental Epidemiology on EPA's proposed rule on Strengthening Transparency in Regulatory Science (EPA-HQ-OA2018-0259-0001), https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1973 (citing Sweeney L, Yoo JS, Perovich L, Boronow KE, Brown P and JG B., *Re-identification Risks in HIPAA Safe Harbor Data: A study of data from one*

Indeed, experts have observed that even the disclosure of redacted or "de-identified" data sets has become more fraught as public health studies have become more rigorous, because these studies are relying upon greater quantities of ever more granular personal information.[174]

i. Deidentification is complicated and costly.

EPA states that "[o]ther federal agencies have developed tools and methods to deidentify private information," but then cites to only one source, which does not address the concerns raised here.[175] EPA cites to the U.S. Department of Health and Human Services' *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*.[176] This guidance provides two methods for de-identifying data: (1) expert determination method, where an expert determines that, after application of statistical and scientific principals and methods, the risk is very small that the information alone or with other available information could be used to identify the subject; and (2) the safe harbor method, requiring that a number of identifiers are removed.[177] The first method requires case-by-case work, and EPA has provided no information regarding how EPA or others could potentially implement it or how much it might cost. In addition, there is no indication of how broadly this technique might be applicable to adequately de-identify data. *I.e.*, EPA must provide its views on whether this technique is likely to be applicable to the majority of studies relevant to EPA with non-public data, some studies, or only a handful. The second method requires removal of much information that may be necessary to be able to reanalyze or reproduce the research results, so it is unclear whether it would satisfy EPA's requirements in the Proposal. The second method is also costly, which EPA also completely disregards. Furthermore, even the safe harbor method has been shown to provide potentially insufficient privacy protections due to the mosaic effect, discussed more below.

EPA further states: "The National Academies have noted that simple data masking, coding, and de-identification techniques have been developed over the last half century. . . ," seemingly suggesting that data can easily be modified to address privacy concerns.[178] This is incorrect. The National Academies in fact recognizes that complex, evolving, and yet undeveloped techniques are needed to resolve these concerns: "Initially, relatively simple data masking techniques, such as top coding income amounts. . .were used to generate restricted data

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environmental health study, Technology Science (2017) and Sweeney L., *Only You, Your Doctor, and Many Others May Know*, Technology Science (2015)).

[174] *See* Letter from Daniel S. Greenbaum, Health Effects Institute, to Lek Kadeli, Environmental Protection Agency 3 (Aug. 27, 2013) (describing the use of increasingly fine-grained community-level and zip code-level data in public health studies, and noting that "these characteristics – which have in general enhanced the quality and the sensitivity of the studies – increase the difficulty of providing a fully "de-identified" data set while also enabling a different investigator to conduct a full replication and sensitivity analysis of the original study results.").

[175] 83 Fed. Reg. at 18,771.

[176] 83 Fed. Reg. at 18,771 n. 17.

[177] HHS, *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*, https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html

[178] 83 Fed. Reg. at 18,771.

products [,] [d]uring the last decade the increasing risks of confidentiality breaches have led researchers to develop increasingly sophisticated methodologies for restricted data products."[179] They state, "more research is clearly needed to assess the relative ability of different masking methods, and of synthetic data, to reduce the risk of disclosure while preserving data utility."[180] They recognize the current limitations of producing restricted data that sufficiently limits identifiability to allow it to be made publicly available in a useful form. They note that "well-informed policy making" requires "[r]esearch using detailed confidential data" that cannot be made public—which the Proposal fails to acknowledge to the detriment of the quality of EPA's policy decisions.[181] In the meantime, the National Academies state that more work is needed to allow "[h]igh-quality public-use files" that still assure "the inferential validity of the data while safeguarding their confidentiality."[182]

ii. Ongoing developments in data analytics make data deidentification more difficult to conduct and less likely to adequately protect privacy and confidentiality.

In pointing to the option of deidentification and redaction techniques, EPA also fails even to mention, let alone address, the increasing risk of re-identification through data analysis using multiple data sets. The so-called "mosaic effect" makes even very limited, redacted releases of data to the public a threat to the privacy of study subjects. OMB has recognized the threat to privacy from the mosaic effect, which it describes as "when the information in an individual dataset, in isolation, may not pose a risk of identifying an individual (or threatening some other important interest such as security), but when combined with other available information, could pose such risk."[183] OMB specifically highlighted the complicated nature of this threat and the need for agencies to address it carefully, particularly as they may not possess the needed expertise.[184]

Studies show the reality and scope of the re-identification threat. For example, Dr. Latanya Sweeney, professor of government and technology in residence at Harvard University, has examined deidentified datasets and combined them with other public data sets to test this concern. She was able to use information in medical information and a voter list, such as birth date, gender, and zip code, to identify individuals in the deidentified Massachusetts Group Health Insurance Commission dataset in 1997, including the then Massachusetts Governor,

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[179] National Research Council, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, 27 The National Academies Press (2005).
[180] *Id.* at 28.
[181] *Id.* at 2.
[182] *Id.*
[183] OMB Memorandum M-13-13, Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset 4-5 (May 9, 2013).
[184] *Id.* at 9-10 ("Agencies should note that the mosaic effect demands a risk-based analysis, often utilizing statistical methods whose parameters can change over time, depending on the nature of the information, the availability of other information, and the technology in place that could facilitate the process of identification. Because of the complexity of this analysis and the scope of data involved, agencies may choose to take advantage of entities in the Executive Branch that may have relevant expertise, including the staff of Data.gov.")

William Weld.[185] Studies have indicated that between 63% and 87% of the population of the United States could be uniquely identified by using only gender, ZIP code, and date of birth.[186] Dr. Sweeney was also able to link data in the Personal Genome Project to names and contact information, identifying between 84 to 97% of profiles.[187] In 2011 she was able to identify 43% of individuals in a department of health in Washington state hospital discharge database using newspaper stories.[188] Another study[189] showed how "data on air and dust samples from 50 homes in two communities in California could be combined with data released under the Safe Harbor provisions of the Health Insurance Portability and Accountability Act (HIPAA) to 'uniquely and correctly identify [in one community] 8 of 32 (25 percent) by name and 9 of 32 (28 percent) by address.'"[190]

The Commission on Evidence-Based Policymaking, which EPA also cites in the Proposal[191], also stresses the dangers of re-identification of data that has been stripped of direct identifiers. They note: "No existing statistical disclosure limitation method. . . is able to completely eliminate the risk of re-identification," despite increasingly complex techniques that have been developed since the 1970s.[192] They also note the threat posed by the "cumulative amount of information available about individuals and businesses that could be used for re-identification,"[193] with the threat increasing as available information grows and technology to allow re-identification improves.[194]

Further, the National Academies note, "data that are most useful to legitimate researchers typically have characteristics that pose substantial risk of disclosure."[195] This includes information such as:

- detailed geographic information;
- repeated data collection from the same subjects;
- outliers, such as people with very high incomes;
- many attribute variables; and

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[185] Rothstein, Mark A., *Is deidentification sufficient to protect health privacy in research?*, 10.9 The American Journal of Bioethics 3-11, 6 (2010).
[186] *Id.* at 5.
[187] Sweeney, Latanya and Abu, Akua and Winn, Julia, *Identifying Participants in the Personal Genome Project by Name* (April 29, 2013), https://ssrn.com/abstract=2257732 or http://dx.doi.org/10.2139/ssrn.2257732.
[188] Sweeney L., *Matching known patients to health records in Washington State data*, Harvard University, Data Privacy Lab (2013), https://dataprivacylab.org/projects/wa/1089-1.pdf.
[189] Latanya Sweeney, Ji Su Yon, Laura Perovich, Katherine E Boronow, Phil Brown, and Julia Green Brody, *Re-identification Risks in HIPAA Safe Harbor Data: A Study of Data From One Environmental Health Study*, Technology Science (Aug. 28, 2017), https://techscience.org/a/2017082801/.
[190] Commission on Evidence-Based Policymaking, *The Promise of Evidence-Based Policymaking*, 54 (2017), https://www.cep.gov/content/dam/cep/report/cep-final-report.pdf.
[191] 83 Fed. Reg. at 18771, n. 19.
[192] Commission on Evidence-Based Policymaking, *The Promise of Evidence-Based Policymaking* 53 (2017).
[193] *Id.* at 54.
[194] *Id.* at 55.
[195] National Research Council, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, 21 The National Academies Press (2005).

- complete census data rather than a survey of a small sample of the population.[196]

There is increased vulnerability in "[d]ata with geographic detail, such as census block data" and longitudinal data obtained in panel surveys, which is often salient in environmental research.[197]

iii. Deidentification may make data sets unusable for reanalysis purposes.

Work by other experts in this area suggests that deidentification can be carried out and help protect privacy, but it may produce datasets that have lost vital information needed for specific analyses.[198] Even the HIPPAA guidelines document states: "Of course, de-identification leads to information loss which may limit the usefulness of the resulting health information."[199] Such results limit the utility of deidentified data sets and would not meet the requirements of the proposed rule which state that "*EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis*."

Further, even if it may be technically possible to release some amount of data while preserving privacy in some cases, doing so imposes substantial additional costs.[200] The preamble of the proposed rule suggests that privacy concerns can be addressed through mechanisms such as data masking, coding, and de-identification techniques—all of which would impose additional costs on researchers. The preamble also indicates that requirements for dose response data and availability may differ and involve a range of mechanisms such as deposition in public data repositories, and controlled access in federal research data centers—which would require EPA funding to maintain the facilities.[201] As discussed further in Section V of these comments, the proposed rule fails to acknowledge these costs, let alone provide any information about them or suggest ways to provide for them. Nevertheless, the costs can be significant, and even smaller costs could be prohibitive for many researchers.

At a time when federal funding for research in environmental and public health-related fields has largely flat-lined, academic researchers, in particular, are likely to have few additional

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[196] *Id.* at 21-22.
[197] *Id.* at 22.
[198] Simson L. Garfinkel, *De-Identification of Personal Information* (NISTIR 8053), NIST (Oct. 2015) (saying the goals of allowing data to be used while providing privacy protections "are antagonistic, in that there is a trade-off between the amount of de-identification and the utility of the resulting data.").
[199] HHS, *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*, https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.
[200] National Academies of Sciences, Engineering, and Medicine, *Principles and obstacles for sharing data from environmental health research: Workshop summary*, 46-47 The National Academies Press (2016), https://www.nap.edu/catalog/21703/principles-and-obstacles-for-sharing-data-from-environmental-health-research.
[201] *See*, The National Academies, *Improving Access to and Confidentiality of Research Data: Report of a Workshop*, National Academies Press 48 (2000) (At present, [costs for federal research data centers] are being covered partly by federal agency budgets and partly by user fees. The Census Bureau's research data centers have been supported in part by grants from the National Science Foundation and NIA, but may eventually have to recover more of their costs from users.").

funds available to undertake these activities.[202] This raises additional concerns—if researchers funded by industry are generally able to support the additional costs of making data publicly available, while academic researchers are far less likely to be able to do so, EPA's proposed approach could institutionalize a dangerous bias in the source of studies that EPA is allowed to use for regulatory activity.

With respect to the potentially very large costs that would accrue to EPA, EPA's proposal provides no indication that any funding to support such activities would be available. EPA funding is at its lowest level since the 1980s.[203] Absent a significant change in Congressional priorities, any EPA expenditures for the purposes of supporting making data publicly available would necessarily require cutbacks in other critical areas of environmental protection, which might include supporting additional research, conducting inspections, issuing permits, setting standards, or many other activities. EPA's Proposal includes no discussion of whether funds would be made available, nor whether other activities would be sacrificed, whether these trade-offs would make any sense, and what the overall impacts might be on public health and the environment.

B. The Proposal Will Not Advance the Supposed Cause of "Transparency" Upon Which it is Based.

The Proposal does not present or support the case that public accessibility to underlying data is necessary to vet scientific research—which, as discussed above, it is not—but even if it was, as discussed above, the scientific community is already taking steps to make underlying data publicly available where feasible, with the widespread understanding that this is neither necessary nor appropriate in all cases.[204] The Proposal does not examine the policies and practices that are already working to make data publicly available where feasible, the extent to which existing policies may already be sufficient to meet EPA's alleged transparency goals, or the reasons why some data is still not released publicly. Still less does EPA question whether this proposal would add anything to the current efforts, or whether it would have any effect whatsoever in increasing public accessibility of data.

1. Where there are lower hurdles to making data publicly available, this is already commonly occurring, with support from various initiatives.

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[202] *See*, American Association for the Advancement of Science, *Trends in Federal Research by Discipline FY 1970-2017*, chart, (last updated July 2018), http://mcmprodaaas.s3.amazonaws.com/s3fs-public/Disc-1_0.jpg?RrBDGaSpG5edeDsiBRyoQyApdamjOs4Q.

[203] *Compare* FY 2018 budget of $5.655 billion (EPA, *FY 2018 Budget in Brief* (May 2017)) and projected FY 2019 EPA budget of $6.146 billion (EPA News Release, *EPA FY 2019 Budget Proposal Released* (Feb. 12, 2018), https://www.epa.gov/newsreleases/epa-fy-2019-budget-proposal-released) with fiscal year 2017's budget of $8.058 billion and historical budgets (*EPA's Budget and Spending*, https://www.epa.gov/planandbudget/budget (last accessed July 26, 2018)).

[204] *See* National Academies of Sciences, Engineering, and Medicine, *Principles and obstacles for sharing data from environmental health research: Workshop summary*, The National Academies Press (2016), https://www.nap.edu/catalog/21703/principles-and-obstacles-for-sharing-data-from-environmental-health-research.

There are already various ongoing initiatives to make scientific data and models more commonly publicly available, where appropriate, as discussed more below. For example, EPA cites the ongoing implementation of the 2016 *Plan to Increase Access to Results of EPA-Funded Scientific Research*.[205] This Plan aims to maximize access to "research data underlying a publication" resulting from EPA-funded research.[206] It is worth emphasizing the Plan also exempts "research data [that] cannot be released due to one or more of constraints, such as requirements to protect confidentiality, personal privacy, proprietary interest, or property rights."[207] There is also a 12-month embargo period before publications are made publicly available.[208] The Plan also explicitly indicates that

> [i]t is important to recognize that some research data cannot be made fully available to the public but instead may need to be made available in more limited ways, e.g., establishing data use agreements with researchers that respect necessary protections. *Whether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications.*[209]

EPA also mentions the data availability policies or requirements of many scientific journals (although EPA does not specifically discuss any of these policies or indicate how or why they are not sufficient to address EPA's concerns).[210] Thus, where there are not significant barriers due to costs, or confidentiality or other concerns, there are increasing mechanisms to encourage scientists to make their data meaningfully and responsibly publicly available, and in response to these mechanisms, scientists frequently do so already.[211]

2. EPA's proposed approach does not require researchers to make underlying data publicly available.

There are multiple real and significant barriers to the public release of underlying data from some studies, and the Proposal cites no reason to believe that, in the majority of cases where data is not already released, one or more of those barriers are not present. Because those barriers are significant, this is not a situation where creating an incentive to private action is likely to be sufficient to drive such action where it is not already occurring.

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[205] 83 Fed. Reg. at 18770.

[206] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* 11 (Nov. 29, 2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.

[207] *Id.* at 11.

[208] *Id.*

[209] *Id.* at 4-5 (emphasis added).

[210] 83 Fed. Reg. at 18,770 (stating that the policies and recommendations EPA considered were "informed by the policies recently adopted by some major scientific journals and cites to "related policies from the Proceedings of the National Academy of Sciences, PLOS ONE, Science, and Nature."); 83 Fed. Reg. at 18,771 n. 20 (claiming the "policies or recommendations of publishers Taylor & Francis, Elsevier, PLOS, and Springer Nature" support the Proposal because they require authors to deposit the data underlying their studies in public data repositories).

[211] Jeremy Berg, *Obfuscating with transparency*, 360 Science 133 (Apr. 13, 2018), http://science.sciencemag.org/content/360/6385/133/tab-pdf ("Increasingly, many publications, including those from the Science family of journals, are linked to underlying data in accessible forms in repositories where they are readily available to interested parties, particularly those who seek to reproduce results or extend the analysis.").

Yet, with respect to release of data, the Proposal would only create an incentive for private action, not an actual requirement that data be released. First, this Proposal addresses data produced and held by external scientists, not data held by EPA itself or that EPA has authority to gain access to. Where EPA holds data, it is already governed by the Information Quality Act, OMB Circular A-110, and the Freedom of Information Act.[212] The Shelby Amendment required OMB to amend Circular A-110 to require that federal agencies provide "research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law" to the public through the Freedom of Information Act.[213] Importantly, the term "research data" excludes "[t]rade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law" as well as "[p]ersonnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study."[214] Many voiced concerns that even this provision could compromise scientific research and personal privacy.[215] This Proposal presumably is also not directed at studies funded by EPA, where the researchers must generally make data publicly available as a condition of receiving funding.[216] There are already mechanisms by which EPA is making research data publicly available where it has the authority and access to do so, and only after carefully ensuring that doing so will not compromise privacy interests.

Second, EPA has no authority to regulate the authors of studies or the scientific journals in which the studies are published, and EPA makes no attempt to regulate them directly. The preamble to the proposed rule states: "EPA should ensure that the data and models underlying scientific studies that are pivotal to the regulatory action are available to the public."[217] It further states that the proposed regulation is "designed to provide a mechanism to increase access to dose response data and models underlying pivotal regulatory science...."[218] The proposed regulations then state that for significant regulatory actions EPA "shall ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner

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[212] OMB Circular A-110 Revised 11/19/93 As Further Amended 9/30/99 36(d)(1) ("In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA."); *See also*, Lynn R. Goldman & Ellen K Silbergeld, *Assuring Access to Data for Chemical Evaluation*, 121 Environmental Health Perspectives 149 (Feb. 2013), https://ehp.niehs.nih.gov/wp-content/uploads/121/2/ehp.1206101.pdf (noting the numerous feasibility concerns that would arise were EPA to be required to make raw underlying data available for studies not governed by these mechanisms , given the large number of studies it usually relies on and that fact that EPA is usually not in possession of the raw data, in addition to funding and ethical limitations).

[213] OMB Circular A-110 (36)(d)(1).

[214] OMB Circular A-110 (36)(d)(2)(i).

[215] *See* Eric A. Fischer, *Public Access to Data from Federally Funded Research: Provisions in OMB Circular A-110*, Congressional Research Service. 13 (Mar. 1, 2013), https://fas.org/sgp/crs/secrecy/R42983.pdf.

[216] U.S. EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* (Nov. 29, 2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.

[217] 83 Fed. Reg. at 18769.

[218] 83 Fed. Reg. at 18770.

sufficient for independent validation."[219] But (apart from studies that EPA funds) EPA has no authority to require those data and models to be made public.

Hence, this proposal would regulate not the scientists, but EPA itself. EPA would "ensure" that data and models underlying scientific studies "pivotal" to regulatory action are publicly available *simply by barring EPA's own use in regulatory actions of any studies for which the authors do not make the data and models publicly available.* The "mechanism" mentioned in the preamble is not technical assistance or funding to encourage greater availability of data; it is simply the pressure generated by EPA's refusal to consider the results of a study if the authors do not release publicly the underlying data and models. The obvious question that EPA has neither asked nor attempted to answer in the Proposal is whether such a ban would be sufficient to incentivize study authors to make their data and models publicly available, where they have not already done so, or whether the ban will largely result in just limiting the studies available to EPA. Most of the significant barriers to release detailed above are not a matter of the researcher's preference, but rather take the form of legal and ethical constraints, significant costs, large time investments, or the loss of proprietary data critical to a researcher's future career prospects. While it seems plausible that having their research applied in a regulatory context would be viewed as an incentive by some, or perhaps many, researchers, there is no reason to believe that such an incentive would be sufficient to overcome the significant barriers to public release of data where those barriers exist. Indeed, the party most likely to be incentivized by EPA's proposed requirements is the regulated community which has vested financial interests in regulatory actions the agency may take—a situation that almost certainly will lead to significant bias and conflicts of interests in the scientific evidence that the agency considers.

Yet EPA barely acknowledges the nature of the "mechanism" it is proposing, and EPA certainly does not explore in any way how the mechanism would operate or whether it would be effective in driving release of data. Still less does EPA admit that the primary effect of this approach is very likely to be the exclusion of critical valid scientific studies from EPA's consideration. Finally, EPA utterly fails to contemplate what the effect of such exclusion would be on EPA's ability to adopt regulatory standards that protect public health and the environment.

C. The Proposal does not Acknowledge, Much Less Examine, its Likely Actual Effect—Reducing the Quality and Quantity of Studies upon which Regulatory Decisions are Based.

1. EPA fails to recognize that forcing the disclosure of all data and models would have harmful effects on the quality and quantity of scientific research used by EPA.

Although it appears highly unlikely that this proposal would drive additional data to be released, EPA presumes otherwise, and fails to recognize the harms that would likely result if EPA actually were successful in finalizing the rule. One reason researchers are particularly cautious about releasing human subjects data is that they understand that public willingness to

[219] 83 Fed. Reg. 18773.

participate in research studies depends upon protecting the privacy of the participants. Risks of privacy breaches and researchers' inability to control use of subject data will undermine potential participants' confidence in scientists' ability to protect their information.[220] This will likely reduce participation in studies or even lead to biases in responses from participants.[221] It could also result in attrition of participation by select subpopulations, particularly those who may be most vulnerable, such as children or people with disabilities or disease, or those with the most to protect, such as high socioeconomic populations. Reduced participation and particularly reduced participation among select subpopulations will reduce scientists' ability to draw meaningful inferences from their results to broader populations, the whole of which EPA is charged with protecting.

In addition, the prospect that their research would not be used if researchers were unable to make their data public is likely to deter researchers from even engaging in environmental health research, particularly research involving human subjects.[222] Lynn Goldman and Ellen Silbergeld conclude that a requirement by EPA that researchers release raw data underlying studies reviewed for rulemakings on pesticides and chemicals "would not be tenable" and would in fact "have a chilling effect on the engagement of the global scientific community in research relevant to the protection of human health and the environment."[223] Overall, the result will be to diminish and undermine the strength of the scientific information available to EPA.

2. Because EPA will be barred from using many valid scientific studies with nonpublic data, the net effect of this proposal will be to harm, not strengthen, EPA's use of science in the regulatory process.

The most damaging aspect of EPA's proposal is that it will bar EPA from using many valid scientific studies that provide critically important information supporting regulatory standards and requirements. This will significantly harm, not strengthen, EPA's use of science in the regulatory process—especially since the public availability of data is neither necessary nor sufficient to ensure the validity of the studies EPA relies upon. It is clearly arbitrary and

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[220] *See* Eugenia Economos, Farmworker Association of Florida, Testimony at EPA Public Hearing on Proposed Rule "Strengthening Transparency in Regulatory Science" (July 17, 2018); Leila Jamal et. al, *Research Participants' Attitudes Towards the Confidentiality of Genomic Sequence Information*, 22 Eur. J. Hum. Genetics 964 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4350593/.

[221] Christine Lothen-Kline et al., *Truth and Consequences: Ethics, Confidentiality, and Disclosure in Adolescent Longitudinal Prevention Research*, 33 Journal of Adolescent Health 385-394 (2003).

[222] *See* Augusta Wilson, Climate Sci. Legal Def. Fund, Testimony at EPA Public Hearing on Proposed Rule "Strengthening Transparency in Regulatory Science" (July 17, 2018), https://www.csldf.org/2018/07/16/why-we-oppose-to-the-epas-proposed-transparency-rule/ ("This could have a deeply concerning chilling effect on the conduct of important human health studies. Privacy concerns could influence what science gets done and what does not. Lines of scientific inquiry that would have been pursued may not be. The quality of data may be poorer than it otherwise would have been."); Augusta Wilson, *Big Tobacco's Smoke and Mirrors Revived by Pruitt's Science Transparency Policy*, The Hill (June 4, 2018, 5:00 PM), http://thehill.com/opinion/energy-environment/390638-big-tobaccos-smoke-and-mirrors-revived-by-pruitts-science ("Good scientists may understandably hesitate to pursue important lines of scientific inquiry if doing so will make them targets for regulators, interest groups and legislators who seek to impugn their credibility and troll through their emails looking for ways to publicly embarrass them.").

[223] Lynn R. Goldman & Ellen K Silbergeld, *Assuring Access to Data for Chemical Evaluation*, 121 Environmental Health Perspectives 149, 150 (Feb. 2013), https://ehp.niehs.nih.gov/wp-content/uploads/121/2/ehp.1206101.pdf.

capricious for EPA to sacrifice the agency's use of the best available science under these circumstances.

a) The prohibition on using studies with underlying nonpublic data will operate to exclude quality research results from EPA's regulatory process.

The next subsection provides an extensive discussion of some of the types of studies and specific studies that EPA would be unable to use under the Proposal.[224] Prior analyses by the Congressional Budget Office of related legislative proposals have also concluded that public availability requirements would significantly reduce the number of studies EPA relies upon—perhaps by as much as one-half.[225] Bizarrely, however, EPA does not even mention this probable effect of the Proposal, let alone provide information on which particular studies or types of studies would be excluded (absent a case-by-case exemption). Further, EPA utterly fails to consider what the effects of such exclusions could be on EPA's ability to develop and support standards to protect public health and the environment. There are many areas where these effects might be extremely damaging, as the examples below detail.

Not only would this proposal exclude valid studies, but it may well disproportionately exclude high quality studies. Some of the most robust and informative environmental health studies are human subjects studies with a large number of geographically distributed participants who are tracked over very long periods of time. These attributes make the results of these studies especially useful in regulatory decision making, since they are more representative of the population being addressed and provide information on exposure and health effects over a period of time. But these are also the attributes that make public release of the underlying data most difficult, and frequently impossible, as discussed above in Section II.A.1. Excluding these studies is highly likely to distort and undermine regulatory decision making by removing support for standards that are actually health protective. EPA has not identified any harms it is aiming to address through this Proposal, but whatever they are perceived to be, it is hard to see how they could outweigh the harm from barring EPA from considering the best available scientific information.

This Proposal also could be particularly harmful to EPA's ability to act in areas where the science is less developed, such as emerging threats. If there are a relatively small number of studies, the inability to consider some or all of them could cripple EPA's ability to act. This is

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[224] Note that EPA has proposed to allow the Administrator to grant exemptions to the prohibition on a case-by-case basis, but the hurdle of requiring case-by-case determinations is so high (EPA relies on roughly 50,000 studies per year according to the CBO) and the criteria are sufficiently stringent (public availability must be "not feasible," which may well exclude, e.g., cost concerns) that it appears most plausible to assume that many studies will not be granted an exemption. *See* Section I.B.4 for further discussion.

[225] *See* Susanne S. Mehlman, Jon Sperl & Amy Petz, Cong. Budget Office, H.R. 1030: Secret Science Reform Act of 2015 at 2-3 (2015) ("CBO expects that EPA . . . would base its future work on fewer scientific studies . . . . CBO expects that the agency would probably cut the number of studies it relies on by about one-half . . . ."); Jon Sperl & Amy Petz, Cong. Budget Office, H.R. 1430: Honest and Open New EPA Science Treatment (HONEST) Act of 2017 at 1-2 (2017) ("EPA officials have explained to CBO that the agency would implement H.R. 1430 with minimal funding . . . . That approach to implementing the legislation would significantly reduce the number of studies that the agency relies on . . . .").

precisely the type of situation where a proactive early response could avoid extensive contamination (which is expensive to address) and multiple exposures (which are impossible to reverse), and the resulting adverse outcomes. Yet, apart from a question about how to apply the proposed rule to existing administrative records such as for the NAAQS, the closest EPA comes to hinting at the possibility of the regulatory and public health effects of excluding valid studies is when EPA asks the public to comment "on the effects of this proposed rule on individual EPA programs." None of these extremely consequential impacts of the Proposal are acknowledged or explored in any depth in the Proposal.

b) Examples of scientific studies that would be excluded

The proposed rule seeks to "ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation."[226] The proposal indicates that "[i]nformation is considered 'publicly available in a manner sufficient for independent validation' when it includes the information necessary for the public to understand, assess, and replicate findings."[227] Further, footnote three of the proposal states:

> Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use [sic] non-public data in support of its regulatory actions. *See Coalition of Battery Recyclers Ass'n v. EPA, 604 F.3d 613, 623 (D.C. Cir. 2010); American Trucking Ass'ns v. EPA, 283 F.3d 355, 372 (D.C. Cir. 2002).* EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.[228]

Taken together, EPA is proposing to prohibit the use of studies involving dose response data and models in significant regulatory decisions where the underlying data are not publicly available. Such a prohibition would affect virtually all pending and future regulatory actions and, if applied retrospectively, past regulatory actions. Regulatory actions would not reflect the best available science, leading to inadequate or absent critical public health and environmental protections.

Eight examples of pending, past, and future regulatory actions that are themselves put at risk from the proposed regulation, or cite to studies that under the Proposal may not be able to be utilized in future actions, explained in more detail below, include:

- **proposed bans of trichloroethylene (TCE) for use in vapor degreasing, aerosol degreasing, and spot cleaning in dry cleaning facilities under TSCA section 6(a);[229]**

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[226] 83 Fed. Reg. at 18773 (emphasis omitted).
[227] *Id.* at 18773–74.
[228] *Id.* at 18769 n.3.
[229] Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 6(a), 82 Fed. Reg. 7432 (Jan. 19, 2017); Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a), 81 Fed. Reg. 91,592 (Dec. 16, 2016).

- **proposed ban of methylene chloride for use in paint and coating removal under TSCA section 6(a);**[230]
- **final rule setting formaldehyde emission standards for composite wood products under TSCA Title VI;**[231]
- **National Primary Drinking Water Regulation for arsenic under the SDWA;**[232]
- **NAAQS for oxides of nitrogen under the CAA;**[233]
- **NAAQS for ozone under the CAA;**[234]
- **forthcoming proposed National Primary Drinking Water Regulation for perchlorate in development under the SDWA;**[235] **and**
- **future regulatory action on the perfluoroalkyl substances (PFASs) perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) under SDWA and Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).**[236]

Explanations of the likely effect of EPA's Proposal on these regulatory activities are described below.

Proposed bans of TCE for use in vapor degreasing, aerosol degreasing, and spot cleaning in dry cleaning facilities under TSCA section 6(a)

EPA has proposed two regulations under TSCA section 6(a) to ban the use of TCE in vapor degreasing, aerosol degreasing and spot cleaning in dry cleaning facilities.[237] Exposure to TCE is linked to several adverse health outcomes, including liver and kidney issues, developmental effects, and several forms of cancer.[238] The scientific basis for these proposed regulations is provided in the agency's 2014 risk assessment: *TSCA Work Plan Chemical Risk Assessment, Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses*[239] which

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[230] Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(e), 82 Fed. Reg. 7464 (Jan. 19, 2017).
[231] Formaldehyde Emission Standards for Composite Wood Products, 81 Fed. Reg. 89,674 (Dec. 12, 2016).
[232] National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. 6976 (Jan. 22, 2001).
[233] Review of the Primary National Ambient Air Quality Standards for Oxides of Nitrogen, 83 Fed. Reg. 17,226 (Apr. 18, 2018).
[234] National Ambient Air Quality Standards for Ozone, 80 Fed. Reg. 65,292 (Oct. 26, 2015).
[235] Drinking Water: Regulatory Determination on Perchlorate, 76 Fed. Reg. 7762 (Feb. 11, 2011).
[236] Press Release, EPA, In Case You Missed It: "EPA Chief Vows that Clean Drinking Water is National Priority" (May 22, 2018), https://www.epa.gov/newsreleases/case-you-missed-it-epa-chief-vows-clean-drinking-water-national-priority.
[237] 82 Fed. Reg. at 7432; 81 Fed. Reg. at 91,592
[238] 82 Fed. Reg. at 7435–36.
[239] EPA, Office of Chem. Safety & Pollution Prevention, EPA Doc. No. 740-R1-4002, "TSCA Work Plan Chemical Risk Assessment: Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses" (2014) [hereinafter TCE Work Plan Risk Assessment], https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

drew heavily from the 2011 EPA Integrated Risk Information System (IRIS) Toxicological Review of TCE.[240] As noted in the 2014 work plan risk assessment,

> EPA/OPPT's work plan risk assessment for TCE is based on the hazard and dose-response information published in the toxicological review that the U.S. EPA's [IRIS] published in 2011. EPA/OPPT used the TCE IRIS assessment as the preferred data source for toxicity information. . . . The TCE IRIS assessment used a weight-of-evidence approach, the latest scientific information and physiologically-based pharmacokinetic (PBPK) modeling to develop hazard and dose-response assessments for TCE's carcinogenic and non-carcinogenic health effects. . .. Development of TCE's hazard and dose-response assessments considered the principles set forth by the various risk assessment guidelines issued by the National Research Council and the U.S. EPA.[241]

EPA clearly found the TCE IRIS assessment to be scientifically rigorous. EPA made this determination without the data underlying the key, peer-reviewed studies[242] used in the assessment being publicly available. EPA's proposed science rule would preclude the use of these studies, severely jeopardizing the fate of the proposed TCE bans and allowing high-risk uses of TCE to continue.

Proposed ban of methylene chloride for use in paint and coating removal under TSCA section 6(a)

EPA has proposed a ban on the use of methylene chloride in paint and coating removers.[243] Methylene chloride is associated with a number of hazardous health effects, including impaired visual and motor functions, respiratory irritation, headaches, nausea, and death.[244] The scientific basis for this proposed regulation is provided in the agency's 2014 risk assessment, *TSCA Work Plan Chemical Risk Assessment: Methylene Chloride: Paint Stripping Use*.[245] The work plan risk assessment for methylene chloride identified both cancer and non-cancer risks resulting from exposure to the use of methylene chloride in paint and coating

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[240] EPA, EPA/635/R-09/011F,"Toxicological Review of Trichloroethylene" (2011), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0199tr/0199tr.pdf.

[241] TCE Work Plan Risk Assessment at 65.

[242] The key studies used by EPA to derive the noncancer toxicity values for TCE are Deborah E. Keil et al., *Assessment of Trichloroethylene (TCE) Exposure in Murine Strains Genetically-Prone and Non-Prone to Develop Autoimmune Disease*, 44 J. Envtl. Sci. & Health, Part A 443 (2009); Margie M., Peden-Adams et al., *Developmental Immunotoxicity of Trichloroethylene (TCE): Studies in B6C3F1 Mice*, 41 J. Envtl. Sci. & Health, Part A 249 (2006), and Paula D. Johnson et al., *Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat*, 111 Envtl. Health Persp. 289 (2003). The key studies used by EPA to derive the cancer toxicity values for TCE are B. Charbotel et al., *Case-control Study on Renal Cell Cancer and Occupational Trichloroethylene Exposure in the Arve Valley (France)* (2006); and Ole Raaschou-Nielsen et al., *Cancer Risk Among Workers at Danish Companies Using Trichloroethylene: A Cohort Study*, 158 Am. J. Epidemiology 1182 (2003).

[243] 82 Fed. Reg. at 7464.

[244] *Id.* at 7468.

[245] EPA, Office of Chem. Safety & Pollution Prevention, EPA Doc. No. 740-R1-4003, TSCA Work Plan Chemical Risk Assessment: Methylene Chloride: Paint Stripping Use (2014) [hereinafter Methylene Chloride Work Plan Risk Assessment], https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf.

removers. As detailed in the work plan assessment, the proposed ban notes that liver toxicity and central nervous system effects are the most sensitive non-cancer endpoints for chronic and acute exposure, respectively.[246] Accordingly, these endpoints were used to evaluate the extent of risk resulting from exposure to methylene chloride using a margin of exposure (MOE) approach. The raw data underlying key studies used to derive the benchmark MOE for chronic exposure[247] and acute[248] exposures to methylene chloride are not publicly available. As with TCE, EPA's proposed regulation would preclude the agency from using these key studies to support the proposed rule to ban methylene chloride in paint and coating removers. The effect would be to severely jeopardize the finalization of this life-saving ban.

Final rule setting formaldehyde emission standards for composite wood products under TSCA title VI

In 2016, EPA issued a final rule establishing federal formaldehyde emission standards for composite wood products.[249] Formaldehyde exposure is associated with several adverse health impacts, including respiratory issues, eye and nose irritation, and lung and nasopharyngeal cancers.[250] As part of the rulemaking process, EPA conducted an economic analysis to determine which of several prospective regulatory actions would result in the largest net benefit after weighing the compliance costs that firms would incur and the public health benefits that would result from reduced formaldehyde exposure.[251] The monetary benefit that would result from the alleviation of adverse health outcomes associated with formaldehyde exposure was a core component of the economic analysis. Specifically, EPA calculated the annual estimated monetary benefits of avoided cases of eye irritation and nasopharyngeal cancer.

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[246] *Id.* at 115.

[247] K.D. Nitschke et al., *Methylene Chloride: A 2-Year Inhalation Toxicity and Oncogenicity Study in Rats* 11 Fundamental & Applied Toxicology 48 (1988).

[248] As discussed in the work plan chemical assessment for methylene chloride, EPA considered two different benchmark MOEs in its assessment of acute exposure risks—one derived from a 1-hour Spacecraft Maximum Allowable Concentration (SMAC) and the other from a California acute reference exposure level (REL). Methylene Chloride Work Plan Risk Assessment at 23. EPA preferred the SMAC-derived approach for reasons articulated in the work plan assessment. Raw data underlying many of the key studies used to derive the SMAC are not publicly available (Melvin E. Andersen et al., *Physiologically Based Pharmacokinetic Modeling with Dichloromethane, its Metabolite, Carbon Monoxide, and Blood Carboxyhemoglobin in Rats and Humans*, 108 Toxicology & Applied Pharmacology 14 (1991); Irma, Åstrand et al., *Exposure to Methylene Chloride: I. Its Concentration in Alveolar Air and Blood During Rest and Exercise and Its Metabolism*, 1 Scandinavian J. of Work, Env't & Health 78 (1975); G.D. DiVincenzo and & C.J. Kaplan, *Uptake, Metabolism, and Elimination of Methylene Chloride Vapor by Humans*, 59 Toxicology & Applied Pharmacology 130 (1981); Jack E. Peterson, *Modeling the Uptake, Metabolism and Excretion of Dichloromethane by Man*, 39 Am. Indus. Hygiene Ass'n J. 41 (1978); V.R. Putz et al., *A Comparative Study of the Effects of Carbon Monoxide and Methylene Chloride on Human Performance*, 2 J. Envtl. Pathology & Toxicology 97 (1979); Ronald S. Ratney et al., *In Vivo Conversion of Methylene Chloride to Carbon Monoxide*, 28 Archives of Envtl. Health: An Int'l J. 223 (1974); Richard D. Stewart et al., *Experimental Human Exposure to Methylene Chloride*, 25 Archives of Envtl. Health: An Int'l J. 342 (1972).

[249] 81 Fed. Reg. at 89,674.

[250] *Id.* at 89,677–78.

[251] EPA, Economic Analysis of the Formaldehyde Standards for Composite Wood Products Act Final Rule (2016) [hereinafter Formaldehyde Standards Econ. Analysis], Docket ID: EPA-HQ-OPPT-2016-0461-0037.

EPA relied on several robust, peer-reviewed studies to demonstrate the relationship between exposure to formaldehyde and these endpoints. For nasopharyngeal cancer, EPA referenced the highly regarded U.S. National Toxicology Program (NTP) Report on Carcinogens (RoC).[252] The U.S. NTP concluded that chronic exposure to formaldehyde increases risk of nasopharyngeal cancer as evidenced by several key human epidemiological studies.[253] For eye irritation, EPA relied on two epidemiological studies that examined residential exposure to formaldehyde.[254] Both these studies showed that the prevalence of eye irritation increases with heightened exposure to formaldehyde. The data underlying key, peer-reviewed studies that identify nasopharyngeal cancer and eye irritation resulting from formaldehyde exposure are not publicly available. EPA would have been forced ignore these studies were the proposed rule in place at the time the formaldehyde rule was developed. If the proposed rule is applied retrospectively, the formaldehyde rule will be at significant risk.

National Primary Drinking Water Regulation (NPDWR) for arsenic under the Safe Drinking Water Act (SDWA)

In 2001, EPA published a final rule, pursuant to its obligations under the Safe Drinking Water Act, establishing a new maximum contaminant level (MCL) for arsenic.[255] Ingestion of high levels of arsenic can result in death, and even low-level ingestion can lead to severe health impacts, including skin diseases.[256] As part of the rulemaking process, EPA requested that the National Research Council (NRC) review the agency's prior standards and risk assessments for arsenic as well as the available scientific data regarding the risks of arsenic exposure and ingestion.[257] Among the critical studies that the NRC analyzed were two epidemiological studies performed in the 1960s and 1970s that documented the relationship between arsenic in well water and skin diseases of an affected community in Taiwan.[258] The studies found that ingestion of high levels of arsenic through well water correlated to a higher likelihood of developing skin

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[252] Nat'l Toxicology Program, Formaldehyde, in Report on Carcinogens (RoC), 14th ed. 2016), https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf; Nat'l Toxicology Program, *Final Report on Carcinogens Background Document for Formaldehyde* (Jan. 22, 2010) (used to develop the 2011 RoC review for formaldehyde).

[253] *Id.* at 1–2 (citing M. Hauptmann et al., *Mortality from Solid Cancers Among Workers in Formaldehyde Industries*, 159 Am. J. Epidemiology 1117 (2004); Allan Hildesheim et al., *Occupational Exposure to Wood, Formaldehyde, and Solvents and Risk of Nasopharyngeal Carcinoma*, 10 Cancer Epidemiology, Biomarkers & Prevention 1145 (2001); Thomas L. Vaughan et al., *Occupational Exposure to Formaldehyde and Wood Dust and Nasopharyngeal Carcinoma*, 57 Occupational & Envtl. Med. 376 (2000); Sheila West et al., *Non-viral Risk Factors for Nasopharyngeal Carcinoma in the Philippines: Results from a Case-Control Study*, 55 Int'l J. Cancer 722 (1993)).

[254] Formaldehyde Standards Econ. Analysis at 4-24 to -25 (citing Lawrence P. Hanrahan et al., *Formaldehyde Vapor in Mobile Homes: A Cross-Sectional Survey of Concentrations and Irritant Effects*, 74 Am. J. Pub. Health 1026 (1984); Kai-Shen Liu et al., *Irritant Effects of Formaldehyde Exposure in Mobile Homes*, 94 Envtl. Health Persp. 91 (1991)).

[255] 66 Fed. Reg. at 6976.

[256] CDC Fact Sheet, Arsenic – ToxFAQs (2007), https://www.atsdr.cdc.gov/toxfaqs/tfacts2.pdf.

[257] *See* Nat'l Research Council, *Arsenic in Drinking Water* (1999).

[258] *See generally id.* (citing Wen-Ping Tseng, *Effects and Dose-response Relationships of Skin Cancer and Blackfoot Disease with Arsenic*, 19 Envt'l Health Persp. 109 (1977); Wen-Ping Tseng et al., *Prevalence of Skin Cancer in an Endemic Area of Chronic Arsenicism in Taiwan*, 40 J. Nat'l Cancer Inst. 453 (1968)).

cancer and other skin diseases. NRC's report concluded that based on the available evidence, EPA's previous standard for arsenic was inadequate for protecting the public health.[259]

Following the NRC report, EPA finalized a MCL of 10 ppb for arsenic, which was based on the two epidemiological studies from Taiwan.[260] Both studies were peer reviewed, published in prestigious health and environmental journals, and have been cited numerous times by other researchers. Yet it is unlikely the data from these studies could be made publicly available, as the data are four to five decades old and include confidential individual health information. If applied retroactively, or if EPA re-evaluates the MCL for arsenic, the proposed rule would likely mean that EPA could not rely on these studies.

National Ambient Air Quality Standards (NAAQS) for oxides of nitrogen under the Clean Air Act (CAA)

In 2004, EPA awarded a grant to the University of Washington to study the effects of long-term air pollution on the development of cardiovascular disease. More than 6,000 patients across the nation participated in the 10-year study, called the Multi-Ethnic Study of Atherosclerosis Air Pollution Study ("MESA Air").[261] Results from the initial study showed that long-term exposure to oxides of nitrogen (NO_x) and fine particulate matter contributes to cardiovascular disease.[262] MESA Air was the first study to show the negative health effects of long-term exposure to air pollution. Through funding from EPA, the National Institutes of Health, and the Health Effects Institute, MESA Air research is ongoing.[263]

On April 18, 2018, EPA published a final rule maintaining the current NAAQS for NO_x.[264] As part of the rulemaking process, EPA published the *Integrated Science Assessment for Oxides of Nitrogen – Health Criteria*.[265] This assessment incorporated research from MESA Air, including research related to modeling and statistical techniques, and was relied on by EPA in maintaining the NAAQS for NO_x in 2018. Yet because confidential health data comprises most of the research's data, as well as other identifying data such as ages and addresses, it is extremely unlikely the underlying data can be made publicly available. Researchers seeking to use the study's data must formally request and be granted access to de-identified datasets and are prohibited from further distributing data received.[266] Despite initially funding the research, under the proposed rule, EPA would be restricted from relying on this research in future rulemakings.

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[259] *See* Nat'l Research Council, *Arsenic in Drinking Water* 8-9 (1999).
[260] EPA, Six-Year Review 2 Health Effects Assessment: Summary Report 34 (2009) (citing Tseng (1977); Tseng et al. (1968)), https://www.epa.gov/sites/production/files/2014-12/documents/822r09006.pdf.
[261] *Multi-Ethnic Study of Atherosclerosis (MESA) Air Study*, EPA (last visited Aug. 13, 2018), https://www.epa.gov/air-research/multi-ethnic-study-atherosclerosis-mesa-air-study.
[262] Dr. Wayne Cascio, *EPA's MESA Air Study Confirms that Air Pollution Contributes to the #1 Cause of Death in the U.S.*, The EPA Blog (May 25, 2016), https://blog.epa.gov/blog/2016/05/epa-mesa-air-study/.
[263] MESA AIR HOME, Univ. of Wash. Sch. of Pub. Health, Dep't of Envtl. & Occupational Health Servs. (last visited Aug. 13, 2018), http://deohs.washington.edu/mesaair/home.
[264] 83 Fed. Reg. at 17226.
[265] EPA, EPA/600/R-15/-68, Integrated Science Assessment for Oxides of Nitrogen—Health Criteria (2016).
[266] Memorandum from W. Craig Johnson, MESA Coordinating Ctr., on MESA Deidentified Dataset Distribution Policy Statement (Apr. 12, 2016), https://www.mesa-nhlbi.org/PublicDocs/MESA_DeidentifiedDataDistribution_PolicyStatement_04122016.pdf.

NAAQS for ozone under the CAA

In October of 2015, EPA strengthened the NAAQS for ozone,[267] which is the main component of smog. Ozone pollution is linked to asthma and other respiratory health problems, and it is particularly dangerous for children and the elderly. As part of the rulemaking process, EPA published the *Integrated Science Assessment for Ozone and Related Photochemical Oxidants* in 2013, which reviewed the available science to build the scientific basis for the NAAQS.[268] In the Integrated Science Assessment, EPA relied on recent epidemiological studies demonstrating the causal relationship between ozone and childhood asthma as well as other developmental effects.[269] These studies were peer-reviewed and are invaluable to ensuring that all people, and especially children and older adults, are protected from the dangerous impacts of smog. However, the studies include individual demographic and genetic data. It is unlikely the data could be made publicly available. Under the proposed rule, when EPA reviews the ozone NAAQS, the agency would likely be unable to rely on these studies.

Forthcoming proposed NPDWR for perchlorate in development under the SDWA

In 2011, EPA made a regulatory determination to develop a national primary drinking water regulation for perchlorate under the SDWA, based on the conclusion that "there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern."[270] Underlying this conclusion is a body of literature detailing the health risks associated with perchlorate, namely the chemical's interference with normal thyroid function by inhibiting uptake of iodide into the thyroid gland. Iodide is essential to making thyroid hormones that regulate the body's metabolism and orchestrate fetal and infant brain development. In its determination, EPA cited a study by Michael Zimmermann, which reviews the adverse effects that iodine deficiency has on children's health.[271]

Currently EPA is using peer-reviewed studies[272] to develop the dose-response model central to deriving the maximum contaminant level goal (MCLG) for perchlorate in drinking water. These studies demonstrate that perchlorate exposure during pregnancy results in low

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[267] 80 Fed. Reg. at 65292.
[268] EPA, EPA/600/R-10/076F, Integrated Science Assessment for Ozone and Related Photochemical Oxidants (2013), https://www.momscleanairforce.org/wp-content/uploads/2015/05/Ozone-2013-ISA-Executive-Summary.pdf.
[269] *See, e.g.*, Muhammad T. Salam et al., *Roles of Arginase Variants, Atopy, and Ozone in Childhood Asthma*, 123 J. of Allergy & Clinical Immunology 596 (2009); Talat Islam et al., Glutathione-S-transferase (GST) P1, GSTM1, *Exercise, Ozone, and Asthma Incidence in School Children*, 64 Thorax 197 (2009).
[270] 77 Fed. Reg. at 7762.
[271] *Id.* at 7763 (citing Michael Zimmerman, *Iodine Deficiency*, 30 Endocrine Reviews 376 (2009)).
[272] EPA, Post-Meeting Peer Review Summary Report: External Peer Review for EPA's *Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water* (Mar. 2018), https://www.regulations.gov/document?D=EPA-HQ-OW-2016-0439-0012, Docket ID: EPA-HQ-OW-2016-0439-0012.

maternal level of the thyroid hormone T4 leading to neurodevelopmental problems in children.[273] As with the Zimmermann study, the data underlying these studies are not publicly available. Under EPA's Proposal, the agency would be unlikely to rely on these studies putting at risk both the 2011 regulatory determination itself and EPA's ongoing work to develop the perchlorate NPDWR.

Future regulatory action on PFOA and PFOS under the SDWA and CERCLA

In May 2018, EPA announced that the agency will begin the process of developing, under the SDWA, maximum contaminant levels (MCLs) for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), in addition to designating these chemicals as "hazardous substances," possibly under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).[274]

EPA developed health advisories for PFOA and PFOS in 2016. The supplementary documents[275] provided with these advisories detail the various sources of evidence that EPA considered in its characterization of the health impacts of PFOA and PFOS. Among the sources of health effect information was the C8 Health Project,[276] a community-wide assessment of approximately 69,000 individuals living in or near Parkersburg, West Virginia, that was mandated as part of a lawsuit following a major release of PFOA from the DuPont Washington Works production plant into the area's drinking water. Based on this data set and other relevant studies, the researchers leading the C8 Health Project concluded that there was a probable link between PFOA exposure and several harmful health effects, including thyroid disease, ulcerative colitis, kidney cancer, and testicular cancer.[277]

The presiding judge sealed the data from the C8 Health Project to protect participant privacy.[278] Under EPA's proposed rule, when the Agency is developing regulations for PFOA—as it intends to do in the near future—it would not consider publications from the C8 Health

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[273] Martjin Finken, et al., *Maternal Hypothyroxinemia in Early Pregnancy Predicts Reduced Performance in Reaction Time Tests in 5- to 6-Year-Old Offspring*, 98 J Clin Endocinol Metab, 1417 (2013). ; Korevaar et al., *Association of Maternal Thyroid Function During Early Pregnancy with Offspring IQ and Brain Morphology in Childhood: A Population-Based Prospective Cohort Study* 4 Lancet Diabetes & Endocrinology 35 (2016); Victor J. Pop et al., *Low maternal free thyroxine concentrations during early pregnancy are associated with impaired psychomotor development in infancy*, 50 Clinical Endocrinology 149 (1999); Victor J. Pop et al., *Maternal hypothyroxinaemia during early pregnancy and subsequent child development: a 3-year follow-up study* 59 Clinical Endocrinology 282 (2003); F. Vermiglio et al., *Attention deficit and hyperactivity disorders in the offspring of mothers exposed to mild-moderate iodine deficiency: a possible novel iodine deficiency disorder in developed countries*, 89 J. Clinical Endocrinology & Metabolism 6054 (2004).

[274] Press Release, EPA, In Case You Missed It: "EPA Chief Vows that Clean Drinking Water is National Priority" (May 22, 2018), https://www.epa.gov/newsreleases/case-you-missed-it-epa-chief-vows-clean-drinking-water-national-priority.

[275] EPA, EPA-822-R16-003, Health Effects Support Document for Perfluorooctanoic Acid (PFOA) (2016); EPA, EPA-822-R16-002, Health Effects Support Document for Perfluorooctane Sulfonate (PFOS) (2016).

[276] Frisbee, et al., *The C8 Health Project: Design, Methods, and Participants*, 117 Envtl. Health Persp. 1873 (2009), https://ehp.niehs.nih.gov/wp-content/uploads/117/12/ehp.0800379.pdf.

[277] C8 Science Panel, *The Science Panel Website*, http://www.c8sciencepanel.org/index.html (last updated Jan. 4, 2017).

[278] Frisbee et al., at 1876.

Project because the raw underlying data are not publicly available. In failing to consider such crucial case studies, EPA would be ignoring best available science, thereby undermining its own attempt to protect Americans from emerging health threats such as PFOA and PFOS.

c) Prominent scientists and leaders in public health agree that this Proposal would harm science-based public health protections.

Leading experts in public health, science, and environmental policy agree that the proposed rule would have far-reaching, detrimental impacts on public health and would constrain EPA's decision-making capabilities. By limiting the scientific studies that EPA may consider, the proposed rule would lead to less effective environmental policies and weaker public health protections. Experts have said the following:

- "[The proposed rule] will threaten the lives of real people." – Commissioners of the Minnesota Pollution Control Agency and Department of Health[279]
- "If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim." – John P. A. Ioannidis, C.F. Rehnborg Chair in Disease Prevention at Stanford University[280]
- "It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them. . . . Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes." – Editors of *Science* family of journals, *Nature, Public Library of Science* journals, *Proceedings of the National Academic of Sciences*, and *Cell*.[281]
- "Without access to the restricted data, regulatory programs could become more or less stringent than they otherwise would be, with consequences for both regulatory costs and benefits. . . . [the proposed rule] could have the effect of removing legal, ethical, and peer-reviewed studies of health effects as sources to support the agency's regulatory efforts." – Members of the Science Advisory Board[282]
- "[The proposed rule] would prevent the best science from informing policy decisions and result in weaker health safeguards." – Harold P. Wimmer, National President and CEO of the American Lung Association[283]

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[279] Letter from John Linc Stine, Comm'r, Minn. Pollution Control Agency, & Jan Malcolm, Comm'r, Minn. Dep't of Health, to E. Scott Pruitt, Adm'r, EPA (May 15, 2018), http://www.documentcloud.org/documents/4465265-MPCA-MDH-Joint-Letter-to-EPA-Science.html#document/p1.

[280] John P.A. Ioannidis, *All Science Should Inform Policy and Regulation*, 15 PLoS Med. 5 (2018), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002576.

[281] Jeremy Berg et al., *Joint Statement on EPA Proposed Rule and Public Availability of Data*, 360 Science (2018), http://science.sciencemag.org/content/360/6388/eaau0116?utm_campaign=toc_sci-mag_2018-05-03&et_rid=296581013&et_cid=2008556.

[282] Memorandum from Alison Cullen, Chair of SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science to the Members of the Chartered SAB and SAB Liaisons (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.

[283] Press Release, Am. Lung Ass'n, American Lung Association Strongly Opposes EPA's Proposed Rule to Limit Critical Health Science (Apr. 24, 2018), http://www.lung.org/about-us/media/press-releases/epa-propose-limit-health-science.html.

- "If [the proposed rule] had been in effect 20 years ago, the nation might have forgone programs that are preventing over 50,000 premature deaths each year." – Environmental Protection Network[284]
- "[The proposed rule] would greatly weaken EPA's ability to comprehensively consider the scientific evidence across the full array of health effects studies. This would negatively impact EPA public protections that reduce levels of lead, harmful chemicals, and fine particle pollution, among others." – 985 scientists in a joint letter to Administrator Pruitt[285]
- "[The proposed rule] would severely hamstring the agency when it comes to developing and enforcing public health rules by limiting the kinds of research the EPA can use in crafting rules." – Union of Concerned Scientists[286]
- "[Administrator] Pruitt is moving to rid the EPA of the science needed for effective regulation. . . . Its potential impact goes well beyond the EPA's regulatory effectiveness to the underlying role of science in American society." – Dr. Bernard Goldstein, Professor Emeritus of Environmental and Occupational Health at the University of Pittsburgh and former EPA Assistant Administrator for Research and Development.[287]

Additionally, when the U.S. House of Representatives passed similar legislation in 2017, H.R. 1430, numerous professional organizations raised concerns about the implications of the proposed legislation.[288] The Environmental Data & Governance Institute (EDGI) found that:

> A bill that provided genuine provisions for public data access and usability, and did not focus on mandating the reproducibility of studies and on prohibiting the use of any data that could not be divulged to the general public in its entirety, would not be expected to hamper the EPA in a significant way. EDGI's analysis of H.R. 1430 shows that it does not achieve its stated goals. Instead, our research shows that H.R. 1430 would not promote transparency and that its passage would instead block the EPA from using the data it needs to fulfill its mission of protecting public health and the environment.[289]

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[284] Memorandum from Envtl. Prot. Network on Preliminary Assessment of Pruitt's Proposed Regulation to Restrict EPA's Use of Sound Science 2 (Apr. 26, 2018), https://docs.wixstatic.com/ugd/4868e0_8bbc47f8b66848e4a60503d4dd3a9e72.pdf.

[285] Letter from 985 Scientists to E. Scott Pruitt, Adm'r, EPA (Apr. 23, 2018), https://s3.amazonaws.com/ucs-documents/science-and-democracy/secret-science-letter-4-23-2018.pdf.

[285] Press Release, Union of Concerned Scientists, Scientists Oppose Pruitt's Research Restrictions (Apr. 23, 2018), https://www.ucsusa.org/news/press-release/scientists-oppose-new-pruitt-restrictions#.WwM1Mu4vyUl.

[286] Press Release, Union of Concerned Scientists, Scientists Oppose Pruitt's Research Restrictions (Apr. 23, 2018), https://www.ucsusa.org/news/press-release/scientists-oppose-new-pruitt-restrictions#.WwM1Mu4vyUl.

[287] Bernard Goldstein, *Why the EPA's 'Secret Science' Proposal Alarms Public Health Experts*, The Conversation (May 18, 2018, 6:40 AM), https://theconversation.com/why-the-epas-secret-science-proposal-alarms-public-health-experts-96000.

[288] *See* Vivian Underhill et al., Envtl. Data & Governance Initiative, Public Protections Under Threat at the EPA: Examining Safeguards and Programs that Would Have Been Blocked by H.R. 1430 (2017), https://envirodatagov.org/wp-content/uploads/2017/03/Public-Protections-under-Threat-at-the-EPA.pdf; Jon Sperl & Amy Petz, Cong. Budget Office, H.R. 1430: Honest and Open New EPA Science Treatment (HONEST) Act of 2017 (2017).

[289] *See* Vivian Underhill et al., Envtl. Data & Governance Initiative, Public Protections Under Threat at the EPA: Examining Safeguards and Programs that Would Have Been Blocked by H.R. 1430 18 (2017), https://envirodatagov.org/wp-content/uploads/2017/03/Public-Protections-under-Threat-at-the-EPA.pdf.

D. EPA's Policy Rationales for its Proposal are Arbitrary and Capricious

1. EPA arbitrarily fails to provide a reasoned explanation for why the proposed rule is needed.

In essence, EPA's proposed regulation is a solution in search of a problem—a problem that does not exist. The administrative record for the Proposal fails to show that the Agency's past regulatory decisions inappropriately relied on scientific information of questionable value. In fact, EPA fails to point to a single example of a case in which, in developing regulations, EPA relied upon a study or studies later found to be questionable or invalid. Having failed to address this foundational question, EPA also misses the questions that would build on that—even if EPA actually had used invalid science in some instance, EPA would still have to ask whether the underlying data for that study had been made publicly available, and if not, if the problems with the study could have been avoided through having made the data publicly available.

The Proposal neither acknowledges the mechanisms EPA already uses to ensure the integrity of science in decision-making nor establishes that there is a problem that the Proposal is needed to solve. The reality is that both Congress and EPA have established an array of mechanisms and safeguards over the last five decades to ensure that the Agency's decisions are grounded in best available science. These mechanisms include review of agency science and decisions by EPA's scientific advisory boards, including the Science Advisory Board (SAB), the Clean Air Scientific Advisory Committee, Board of Scientific Counselors, the Science Advisory Committee on Chemicals, and the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel[290]—a process that a work group of the SAB recently described as a "rigorous review process that goes beyond the typical journal peer review procedures,"[291] and that the National Research Council recognized as playing an "important role in helping EPA to ensure the credibility and quality of . . . science-based decisions."[292] The Proposal also ignores EPA's use of independent peer review processes to evaluate certain studies used in regulatory decisions;[293] the use of transparent literature surveys that are themselves subject to peer review

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[290] *See* 42 U.S.C. § 4365 (establishing the Science Advisory Board and requiring that EPA seek its review of, among other things, certain rulemakings under the Clean Air Act, Federal Water Pollution Control Act, Resource Conservation and Recovery Act, Noise Control Act, Toxic Substances Control Act, and Safe Drinking Water Act); 42 U.S.C. § 7409 (requiring the Clean Air Scientific Advisory Committee to advise EPA on matters relating to the National Ambient Air Quality Standards); 7 U.S.C. § 136w (requiring EPA to seek comments from the FIFRA Science Advisory Panel on certain rulemakings under FIFRA, and to seek advice on operating guidelines for scientific analyses by EPA that lead to actions carrying out FIFRA);

[291] Memorandum by Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science 4 (May 12, 2018) (observing that the Proposal "fails to mention that EPA has mechanisms for vetting science through several expert panels," including the SAB and others).

[292] Nat'l Research Council, Science for Environmental Protection: The Road Ahead 181 (2012) ("External advisory groups—including SAB, BOSC, and NACEPT—play an important role in helping EPA to ensure the credibility and quality of its scientific studies and science-based decisions.").

[293] *See, e.g.*, EPA Sci. and Tech. Policy Council, *Peer Review Handbook* xiii, 15 (4th ed. 2015) (noting that EPA has a "long-standing history of peer review" and providing for peer review of internally generated studies designated as "Influential Scientific Information" or "Highly Influential Scientific Assessments"); Nat'l Research Council,

and public comment, such as the Integrated Science Assessments (ISA) that inform the National Ambient Air Quality Standards;[294] and independent review of EPA science programs and risk assessment practices by authorities such as the National Research Council.[295] Major regulatory decisions—and the underlying scientific bases for those decisions—are also subject to public comment and judicial review, which serves as an important check on agency decisions that fail to properly account for the best available science.

Thanks to these multiple and overlapping safeguards, the quality of the science underlying EPA decisions is robust.[296] More to the point, there is no indication that EPA science suffers from the so-called "replication crisis" that the Proposal identifies as the principal reason for requiring the public disclosure of underlying data or models for studies used in EPA decisions.[297] It is telling that the sources EPA cites in support of its claims of a "replication crisis"[298] call into question its existence[299] and in many instances promote solutions that do not involve access to underlying data[300]—such as looking at cumulative evidence using a variety of methods instead of over-emphasizing the results of a single study.[301] It is even more telling that

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Science for Environmental Protection: The Road Ahead 180 (2012) ("In rule-making processes that rely on extensive reviews of scientific information, EPA generally imposes a strong preference for reliance on published, peer-reviewed studies. The agency's peer review policy states that 'peer review of all scientific and technical information that is intended to inform or support Agency decisions is encouraged and expected.'").

[294] *See* EPA, EPA/600/R-15/067, *Preamble to the Integrated Science Assessments* 5-25 (2015) (describing the steps EPA undertakes in preparing an Integrated Science Assessment, including extensive and transparent compilation and screening of relevant literature; public comment and independent review by the CASAC; and EPA's application of recognized frameworks in evaluating public health causation relationships).

[295] *See*, e.g., Nat'l Research Council, *Review of EPA's Integrated Risk Information System (IRIS) Process* 3 (2014) (describing the charge of the authoring committee as encompassing a review of recent changes to EPA's IRIS program as well as to "review current methods for evidence-based reviews and recommend approaches for weighing scientific evidence for chemical hazard and dose-response assessments."); Nat'l Research Council, Science for Environmental Protection: The Road Ahead at x (explaining that EPA asked authoring committee "to assess independently the overall capabilities of the agency to develop, obtain, and use the best available scientific and technologic information and tools to meet persistent, emerging, and future mission challenges and opportunities").

[296] *See* Nat'l Research Council, Science for Environmental Protection: The Road Ahead at 13 ("For over 40 years, EPA has been a national and world leader in addressing the scientific and engineering challenges of protecting the environment and human health."); Wendy Wagner, *Science in Regulation: A Study of Agency Decisionmaking Approaches* 29 (2013) (describing EPA's NAAQS review process as "exemplary" and a "five-star process for incorporating science into regulatory policy").

[297] 83 Fed. Reg. at 18770.

[298] It is additionally unclear what EPA means by "replication crisis," and EPA appears to be misusing the term, as the source it cites to describes a "reproducibility crisis," Marcus R. Munafò et. al, *A Manifesto for Reproducible Science*, 1 Nature Human Behavior 1 (2017), and another source details how "[a]s the movement to examine and enhance the reliability of research expands, it is important to note that some of its basic terms—reproducibility, replicability, reliability, robustness, and generalizability—are not standardized," Steven N. Goodman et al., *What Does Research Reproducibility Mean?*, 8 Sci. Translation Med. 1 (2016).

[299] Munafò et. al, *A Manifesto for Reproducible Science*, 1 Nature Human Behavior 1 (2017) ("Whether 'crisis' is the appropriate term to describe the current state or trajectory of science is debatable. . . . ")

[300] *See, e.g.*, Marcia McNutt, *Reproducibility*, 343 Science 229 (2014) ("[J]ournals can only do so much to assure readers of the validity of the studies they publish. The ultimate responsibility lies with authors to be completely open with their methods, all of their findings, and the possible pitfalls that could invalidate their conclusions.").

[301] John P.A. Ioannidis, *Why Most Published Research Findings Are False*, 2 PLoS Med. 0696, 0700-01 (2005) ("Second, most research questions are addressed by many teams, and it is misleading to emphasize the statistically significant findings of any single team. What matters is the totality of the evidence.").

the Proposal identifies *no* EPA actions that have been called into question because the science underlying those actions cannot be validated or replicated. In any event, the Proposal does not require replication of studies and only limits the cumulative evidence and context in which to interpret any given study—only hampering EPA's reliance on more robust scientific findings even if such a crisis were to exist.[302]

In addition, numerous independent reviews of EPA's science-based aetions by the courts, as well as the consistency with which the Agency has solicited and relied on the advice and approval of its external Science Advisory Board committees have added to the credibility of EPA's decisions. The Proposal provides no information supporting the notion that the overarching processes of EPA assessment of relevant scientific studies and subsequent peer review of such assessments, as well risk and policy assessments that EPA has developed and improved over time, are in any way insufficient to address the concerns that arc allegedly the main focus of the proposal.

EPA's failure to identify a problem or inadequacy that new regulations are needed to address is not only arbitrary—it is also contrary to the directive of E.O. 12866 which states that:

> [f]ederal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. [303]

E.O. 12866 further directs each agency to "identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem." [304] Before proceeding any further with this proposal, EPA should clearly identify the problem it is trying to solve, provide evidence that there is, in fact, a problem, and allow for public comment on whether a problem exists that could be addressed through EPA regulation.

This is not to say that EPA's use of science cannot be improved or strengthened—of course continued improvement is always desirable. But to improve upon current practices it is necessary to identify what is deficient, why, how it can be corrected and the potential effects of such deficiency and any proposed changes to practice. EPA does none of these.

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[302] Marcus R. Munafò & George Davey Smith, *Repeating Experiments Is Not Enough*, 553 Nature 399, 399–400 (2018), https://www.nature.com/articles/d41586-018-01023-3#ref-CR3 (noting that "[i]f a study is skewed and replications recapitulate that approach, findings will be consistently incorrect or biased" and suggesting that instead, "an essential protection against flawed ideas is triangulation," or "the strategic use of multiple approaches to address one question").

[303] Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

[304] *Id.*

2. EPA arbitrarily fails to offer a reasoned explanation for its departure from existing policies that broadly require the agency to consider all available scientific information when undertaking rulemakings.

In addition to the statutes discussed in Section I.B.3 that require EPA to use the best available science when making regulatory decisions, a number of EPA's own policies embed this requirement as well. By arbitrarily limiting the science EPA considers when making regulatory decisions, the Proposal contravenes these policies, injuring the scientific integrity of EPA's actions. As discussed in more detail in Section II.E because EPA is changing course from established policy, EPA must fully acknowledge and justify its decision, which it has failed to do in the Proposal.

EPA's own existing Scientific Integrity Policy states:

> To support a culture of scientific integrity within the Agency, this policy. . . [r]ecognizes . . . policy makers within the Agency weigh the best available science, along with additional factors such as practicality, economics, and societal impact, when making policy decisions.[305]

The Proposal conflicts with this policy by restricting what may be the best available science on a given topic from EPA's consideration solely because the underlying data cannot be made public. As described above, public availability of data is neither necessary nor sufficient to ensure that studies constitute "best available science." The Proposal does not acknowledge this departure from the agency's Scientific Integrity Policy, much less explain why such a departure is reasonable.

Likewise, the Proposal is in tension with EPA's Information Quality Guidelines, developed in response to OMB guidelines issued under Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, which require EPA to ensure the objectivity of influential scientific information it disseminates by using "the best available science and supporting studies conducted in accordance with sound and objective scientific practices."[306] EPA considers information to be disseminated when EPA prepares and distributes information to support an Agency decision or regulation or when EPA distributes information in a way that suggests EPA agrees with it, that it supports EPA's viewpoint, or if in the distribution EPA proposes to use it to support or formulate a regulation or agency decision.[307] Thus, the Proposal conflicts with the Guidelines by restricting scientific studies that EPA may use to support regulations, which may cause it to disseminate other information to support its regulations that is not based on the best available science.

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[305] EPA, Scientific Integrity Policy 3-4.
[306] EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency 21-22 (2002), https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf.
[307] *Id.* at 15-16.

EPA's Peer Review Handbook similarly acknowledges that "EPA strives to ensure that the scientific and technical bases of its decisions meet two important criteria: (1) they are based upon the best current knowledge from science, engineering, and other domains of technical expertise; and (2) they are credible."[308] EPA's Science Policy Council Handbook on Risk Characterization also requires reasonableness in the agency's risk assessments, which is achieved when "the characterization is based on the best available scientific information."[309] These policies clearly impact EPA's regulatory actions, and thus will be impacted by the Proposal. Yet EPA completely fails to analyze the impact the Proposal will have on its ability to comply with these policies and fails to explain why it is changing course or justify its decision to do so. Indeed, the Proposal fails to even acknowledge that the agency *is* changing positions.

3. EPA's Proposal arbitrarily fails to consider and deviates from best practices in scientific review, which support using a broad array of information, informed by a "weight of the evidence" approach, rather than arbitrarily excluding certain studies up front.

There is broad agreement in the scientific literature, reflected in EPA's own guidance, that a "weight of the evidence" approach is an optimal way to analyze and synthesize an array of scientific information in a decision-making context.[310] This approach, which is described in more detail below, calls for scientific assessments to be based on a broad array of studies—reflecting multiple lines of inquiry, where appropriate—each of which is carefully weighted based on various indicia of credibility. This careful and rigorous process is incompatible with the requirements of the Proposal, which would bar EPA from considering even highly credible, persuasive studies based solely on whether the underlying data is available. Yet the Proposal never acknowledges the conflict between its requirements and EPA's proven practices for scientific assessments, and never provides any good reasons for this change of course.

One prominent example of this "weight of the evidence" approach is contained in EPA's *Preamble to the Integrated Science Assessments*.[311] The *Integrated Science Assessments* are pollutant-specific reports that EPA produces as the scientific basis for establishing and updating

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[308] EPA. EPA Peer Review Handbook 4th Edition A-4 (Oct. 2015). https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf.
[309] EPA, Sci. Policy Council. Risk Characterization Handbook 18 (2000), https://www.epa.gov/sites/production/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf.
[310] *See, e.g.*, Matthew E. Bates, Olivia C. Massey, & Matthew D. Wood, *Weight-of-Evidence Concepts: Introduction and Application to Sediment Management* 5-8 (US Army Corps of Engineers ERDC/EL SR-18-1, Mar. 2018), http://www.dtic.mil/dtic/tr/fulltext/u2/1048843.pdf (reviewing literature on development of and best practices in weight-of-evidence assessment, and observing that "Within the US, the USEPA and its partner agencies use and recommend the use of WOE extensively."); *Cf.* John P.A. Ioannidis, *All science should inform policy and regulation*, PLOS Med 15:5 (May 3, 2018) ("Even the strongest science may have imperfections. In using scientific information for decision-making, it is essential to examine evidence in its totality, recognize its relative strengths and weaknesses, and make the best judgment based on what is available."); U.S. EPA. Preamble to the Integrated Science Assessments (ISA). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-15/067, 2015. *See also* EPA Science Policy Council, *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* at 2 (June 2003) (describing EPA's guidance for carcinogen risk assessment and ecological risk assessment as additional examples of the agency's "weight-of-evidence" approach).
[311] EPA. Preamble to the Integrated Science Assessments (ISA) (EPA/600/R-15/067) (2015).

EPA's National Ambient Air Quality Standards (NAAQS), which establish health-based standards for critical air pollutants. The Integrated Science Assessments are intended to implement the Clean Air Act's directive to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health and welfare which may be expected from the presence of [a] pollutant in the ambient air."[312] These are some of the most consequential scientific evaluations that EPA performs, in terms of the health, environmental, and economic impacts of the resulting standards, and they must withstand the highest level of technical and legal scrutiny.[313] Thus, EPA uses the very best and most defensible scientific methods to produce them, which are described in the *Preamble to the Integrated Science Assessments*.

The *Preamble to the Integrated Science Assessments* is an "overview document outlining the basic steps and criteria used in developing the Integrated Science Assessments," which EPA references as a companion document to each Integrated Science Assessment.[314] As EPA explains, the "Preamble describes the process of searching the literature, selecting studies for consideration, evaluating study quality, synthesizing and integrating the evidence, and characterizing the evidence for public health and welfare impacts of criteria air pollutants."[315] It also "describes the five-level causal framework for evaluating weight of evidence and drawing scientific conclusions and causal judgments."[316] Central to this scientific assessment process is the understanding that evidence from all types of studies, such as animal studies, human observational studies (cohort, time series), controlled chamber studies, and exposure assessments, among others, must be evaluated and incorporated into final determinations of effects. No single study alone drives the final determinations of causality; rather, the weight of evidence from several lines of inquiry is critical.[317] This framework to evaluate all available science builds upon decades of accrued knowledge and thinking drawing from expertise across several disciplines, including evidence-based decision making.[318]

The Preamble states: "In its evaluation and integration of the scientific evidence on health or welfare effects of criteria pollutants, the U.S. EPA determines the weight of evidence in support of causation and characterizes the strength of any resulting causal classification."[319] The

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[312] *Learn About the ISAs*, EPA (quoting 42 U.S.C. § 7408(b)) (alteration in original), https://www.epa.gov/isa/learn-about-isas (last visited Aug. 14, 2018).

[313] *See Mississippi v. EPA*, 744 F.3d 1334, 1344-45 (D.C. Cir. 2013) (upholding EPA's use of the "weight of evidence" approach in setting NAAQS, saying EPA "evaluated the evidence as a whole through an 'integrative synthesis,' what it called a 'weight of evidence approach.' And appropriately so: one type of study might be useful for interpreting ambivalent results from another type, and though a new study does little besides confirm or quantify a previous finding, such incremental (and arguably duplicative) studies are valuable precisely because they confirm or quantify previous findings or otherwise decrease uncertainty") (citations omitted).

[314] EPA, Preamble to the Integrated Science Assessments.
https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244 (last visited Aug. 14, 2018).

[315] *Id.*

[316] *Id.*

[317] *See* EPA, Preamble to the Integrated Science Assessments at 22.

[318] *See* Marcus R. Munafò & George Davey Smith, *Robust research needs many lines of evidence*, Nature (Jan. 23, 2018), https://www.nature.com/articles/d41586-018-01023-3#ref-CR3.

[319] EPA, Preamble to the Integrated Science Assessments at 18.

Preamble explains in further detail:

> In the ISA, the U.S. EPA assesses the body of relevant literature, building upon evidence available during previous NAAQS reviews, to draw conclusions on the causal relationships between relevant pollutant exposures and health or environmental effects. ISAs use a five-level hierarchy that classifies the weight of evidence for causation. This weight-of-evidence evaluation is based on the integration of findings from various lines of evidence from across health and environmental effect disciplines that are integrated into a qualitative statement about the overall weight of the evidence and causality.[320]

Similarly, section 26 of the Toxic Substances Control Act (TSCA) requires that decisions made under sections 4, 5, or 6 of the law must adhere to certain scientific standards including use of best available seience and a weight of the scientific evidence approach.[321] In its final regulation, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, EPA defines weight of scientific evidence as:

> Weight of scientific evidence means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance. [322]

Systematic review in turn requires a full review of the body of scientific evidence available, where study quality is evaluated largely according to methodological design and not the degree to which underlying data are publicly available.[323] EPA's Proposal contravenes TSCA's requirements to apply a weight of the scientific evidence approach, as defined by the agency, by instating a process that, among other things, conflicts with applying a systematic review approach in the evaluation of chemicals under TSCA.

The Proposal's approach of preemptively barring studies based on the unavailability of data cannot be reconciled with EPA's detailed policies for scientific assessment.

> 4. EPA irrationally conflates scientific "validity" and "transparency" with data availability, incorrectly assuming that eliminating the use of studies without publicly available data will improve scientific validity and transparency.

In the preamble to the proposed rule, EPA states that the intent of the regulation is "to strengthen the transparency of EPA regulatory science." [324] Later in the preamble, EPA states: "[e]nhancing the transparency and validity of the scientific information relied upon by EPA

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[320] *Id.* at 22 (footnote omitted).
[321] 15 U.S.C. § 2625(h), (*i*).
[322] 40 C.F.R. § 702.33.
[323] Nat'l Research Council, Review of EPA's Integrated Risk Information System (IRIS) Process, https://www.nap.edu/catalog/18764/review-of-epas-integrated-risk-information-system-iris-process.
[324] 83 Fed. Reg. at 18,768.

strengthens the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions."[325] EPA then leaps to the unexplained conclusion that barring the use of studies without publicly available data will enhance transparency and validity. EPA's assumption that data availability (or "transparency" in the form of data availability) ensures the use of valid science or its equivalent to using the best available science is manifestly incorrect, and hence provides an irrational basis for the proposed rule. In fact, neither data availability in particular, nor transparency in general, is equivalent to or a guarantee of "validity" in scientific studies.

a) EPA arbitrarily fails to explain why EPA's existing mechanisms are inadequate to ensure the scientific integrity of its actions.

The Proposal ignores both the available approaches embraced by the scientific community and the record of past EPA assessments, which reveal alternative methods for ensuring the credibility of potentially useful scientific studies. These alternatives include, but are not limited to: confidential sharing of data with independent research teams that are in a position to validate results; comparisons of research findings with the results of other peer-reviewed research efforts, including through meta-analyses and literature reviews that are designed to shed light on consistent findings across studies; and strong peer-review processes led by scientific journals, by EPA, or by advisory bodies such as the SAB.[326] Indeed, the SAB workgroup that examined the Proposal expressly noted its failure to acknowledge any of these mechanisms:

> The proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods. For example, the Health Effects Institute (HEI) conducted a re-analysis of the influential Harvard Six Cities and American Cancer Society (ACS) epidemiologic studies and was able to replicate its findings and to assess the robustness of the findings via sensitivity analysis . . . in this particular case, an unusually rigorous form of peer review and independent reanalysis, coupled with many follow-up studies, has accomplished a measure of confidence in findings without public access to data and analytic methods. . . . The proposed rule fails to mention that EPA has mechanisms for vetting science through several expert panels . . . . For example, the EPA CASAC routinely reviews and evaluates epidemiologic and toxicological studies that are the basis for dose-response relationships used in risk and exposure assessments for air pollutants regulated under the National Ambient Air Quality Standards. Although such mechanisms do not typically engage in reanalysis of original data using the same methods as the original investigators, they do entail a rigorous review process that goes beyond the typical journal peer review procedures.[327]

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[325] *Id.* at 18,769.

[326] *See, e.g.*, Letter to Acting Administrator Wheeler from Marcia McNutt, President of the National Academy of Sciences, C.D. Mote, Jr., President of the National Academy of Engineering, and Victor J. Dzau, President of the National Academy of Medicine 2 (July 16, 2018) ("The National Academies have developed a long-standing body of work that demonstrates scientific literature can be evaluated in a transparent and objective manner without complete disclosure of the underlying data.").

[327] Memorandum from Chair of the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, Alison Cullen, to Members of the Chartered SAB and SAB Liaisons 4 (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf//E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.

EPA scientific assessments typically begin with expert staff identifying and assessing peer reviewed studies and studies published in reputable scientific journals. This includes examining the strengths and weaknesses of individual studies, including factors such as design, the reputation and past work of the researchers, quality assurance, methods and analyses. This is followed by a broader look to examine the consistency and coherence of the study with respect to the findings of similar study types across multiple studies, as well as a more integrated assessment of the weight-of-evidence that considers multiple lines of scientific evidence. The assessments are in turn peer reviewed by EPA scientific advisory committees as well as the public.[328] In certain exceptional cases, reanalysis by EPA or competent third party investigators can provide some additional credibility.

As the SAB workgroup that examined the Proposal noted, the record of EPA's treatment of the evidence in the case of two landmark fine particle epidemiology studies shows how scientific researchers and EPA used all of these approaches in examining the association between long-term exposures to fine particles and mortality. This effort began with Harvard's "Six Cities" study, reported in (Dockery et al., 1993).[329] The researchers initially sought to reproduce their initial findings using a data base with a much larger number of subjects and cities and did indeed reproduce those findings (Pope et al., 1995) (see below).[330] By 2009 enough new evidence had accumulated for EPA's integrated assessment for particulate matter to conclude that the number of large U.S. cohort studies, together with supporting evidence from other epidemiology and toxicological studies were sufficient to infer a causal relationship between long-term PM2.5 exposures and mortality and cardiovascular effects. This conclusion regarding causality (the strongest finding possible under the causality classification methodology[331]) based on these studies was endorsed by the external Clean Air Scientific Advisory Committee (CASAC), which noted: "The five-level classification of strength of evidence for causal inference has been systematically applied; this approach has provided transparency and a clear statement of the level of confidence with regard to causation, and we recommend its continued use in future ISAs."[332] (Samet, 2009). Thus, the link between particulate matter exposure and mortality that was observed in the Six Cities study has been vetted through multiple mechanisms that have confirmed the validity of the findings *without* public access to the underlying data—including extensive reanalysis using larger datasets with longer duration of follow up and different statistical methods; reproduction and corroboration with independent studies using distinct populations and methodologies; and rigorous external review by independent scientists.

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[328] *See, e.g.*, EPA, Preamble to the Integrated Science Assessments 3, Figure II. (2015) https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244.

[329] Douglas W. Dockery et al., *An Association Between Air Pollution and Mortality in Six U.S. Cities*, 329 New Eng. J. Med. 1753 (2003).

[330] C. Arden Pope, III et al., *Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults*, 151 Am. J. Respiratory & Critical Care Med. 669 (1995).

[331] The Preamble to the Integrated Science Assessments Sections describes the five-level hierarchy that classifies the weight of evidence for causation and methodology to make the determination, and "causal relationship" is the strongest finding.

[332] Letter from Dr. Jonathan M. Samet, Professor & Chair, Dep't of Preventive Med, Univ. of S. Cal., to Lisa P. Jackson, Adm'r, EPA (Nov. 2, 2009).

The Proposal says virtually nothing about the use of these existing mechanisms in EPA's current scientific assessment practices, or the level of confidence those mechanisms afford in EPA's regulatory science. Yet despite the proven track record of these mechanisms in assuring the validity of landmark studies such as the ACS and Six Cities studies, the Proposal would effectively reject their use and require EPA instead to exclude consideration of studies based on the sole criterion of public availability of underlying data. The Proposal's failure to explain this choice is arbitrary and capricious.

b) EPA arbitrarily equates data availability with valid science.

As discussed in detail in Section II.C.2, the absence of publicly available underlying data does not make the results of a study invalid or even suggest that the study is likely to be invalid. Nor has EPA presented evidence to suggest that studies with publicly available underlying data are more likely to represent strong science than studies without such data availability. As discussed in Section II.A.1, key reasons why researchers do not make data for some studies publicly available have nothing to do with scientific quality. Further, as discussed below and in the *Terminology* section, while reanalyzing study results using the same data is one way to help validate those results, it is neither the primary nor a sufficient way to do so. Hence, EPA's apparent conflation of data availability and best available science is not based on any evidence cited by EPA, is contrary to the evidence before EPA, and is simply arbitrary.

EPA's Preamble to the Integrated Science Assessments provides another discussion of how EPA evaluates study quality, and similarly, does not call out publicly available data:

> [T]he individual study quality is evaluated by considering the design, methods, conduct, and documentation of each study, but not the study results. This uniform approach aims to consider the strengths, limitations, and possible roles of chance, confounding, and other biases that may affect the interpretation of individual studies and the strength of inference from the results of the study.[333]

A statement by the American Statistical Association on p-Values: Context, Process, and Purpose further emphasizes the multiple considerations related to quality, stating "Researchers should bring many contextual factors into play to derive scientific inferences, including the design of a study, the quality of the measurements, the external evidence for the phenomenon under study, and the validity of assumptions that underlie the data analysis."[334] Similarly, the letter filed by the Presidents of the National Academies of Sciences, Engineering, and Medicine in this docket lists multiple reports conducted since 2007 that have examined EPA's scientific assessment processes and "that advise EPA on the scientific bases of regulatory decisions related to human health and the environment."[335] According to the NASEM Presidents,

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[333] EPA, Preamble to the Integrated Science Assessments at 7, https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244.

[334] Ronald L. Wasserstein & Nicole A. Lazar, *The ASA's Statement on p-Values: Context, Process and Purpose*, 70:2 The American Statistician 129, 131 (2016).

[335] Letter to Acting Administrator Wheeler from Marcia McNutt, President of the National Academy of Sciences, C.D. Mote, Jr., President of the National Academy of Engineering, and Victor J. Dzau, President of the National Academy of Medicine 2 (July 16, 2018).

> These reports encourage EPA to consider *all available science in the rule-making process* and provide guidance about how the agency could be more transparent in describing how evidence is gathered and evaluated. . . . Individual study quality should be evaluated on the basis of information that is available in standard journal articles, such as the study design elements, analytical techniques, and statistical methods. Researchers may be contacted to answer questions about the conduct of the study or be asked to provide additional data. *If the study data are not available, their absence may affect how the study is rated and used in the analysis, but the study should not necessarily be eliminated from the assessment.*[336]

OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies* provide another important example of the distinction between information transparency and quality. Unlike the Proposal, which conflates transparency with quality, OMB's Guidelines encourage transparency as a means to obtain greater objectivity in data, but do not consider it an absolute requirement or the only means by which objectivity can be achieved. The Guidelines specifically provide that it is possible to verify the objectivity of information that cannot be made publicly available through other types of "robustness checks."[337]

As an example, the OMB Guidelines point to the Harvard Six Cities Study, where underlying data could not be made publicly available due to confidentiality concerns. In that case, the raw data was released only to researchers at the Health Effects Institute, who were bound to the same confidentiality requirements as the original researchers, and who were able to reanalyze and reproduce the study's results. [338]

c) Reanalyzing a study using publicly available data is not necessary to ensure valid science nor sufficient to ensure against invalid results.

To ensure the validity of scientific research, the scientific community relies most heavily upon peer review. In peer review, independent scientists with related expertise evaluate a study's quality using the types of factors discussed above. Studies used by EPA are often further evaluated by one of EPA's scientific advisory boards, such as the Clean Air Science Advisory Committee or the Science Advisory Board. These types of reviews do not depend on a study's data being made publicly available.

Making data available does allow independent researchers to try to reanalyze the same data and produce the same results. But reanalyzing a study is just one of many ways the scientific community ensures integrity, and it is not, in fact a widely used mechanism.[339]

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[336] *Id.* (emphasis added).
[337] OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8,452, 8,460 (Feb. 22, 2002).
[338] *Id.* at 8,456.
[339] *See* John P.A. Ioannidis, *All science should inform policy and regulation*, 15 PLOS Med 1, 2 (May 3, 2018), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002576 (However, we should recognize that

Reproducing study results using a different population or method is generally considered a stronger validation than simply reanalyzing the results using the same data, as it shows that the results hold across a different population.[340]

5. EPA arbitrarily attempts to bolster one element of scientific transparency, while ignoring significant other transparency-related concerns.

Another arbitrary aspect of this proposal is that EPA appears to assume that the only way to enhance transparency in regulatory science is to ensure that the underlying data and modeling for individual studies are publicly available. In fact, significant concerns have been raised about other non-public aspects of the modern scientific research and publication process that may undermine the accuracy of scientific results. For example, there are rising concerns about the increasing numbers of predatory pay-to-publish journals, which provide little-to-no guarantee of scientific integrity of their published studies.[341] Other areas of concern include undisclosed financial bias.[342] But rather than evaluating concerns related to transparency across the spectrum of peer-reviewed science, EPA has arbitrarily seized upon one narrow area. This area also happens to be a target of regulated industries, as discussed further in Section VII.

6. EPA's justification of the proposal is incoherent and lacks almost any evidentiary support.

Although as discussed above, EPA has not identified a problem with EPA's use of science, EPA may be assuming (without any basis of support) that it needs to strengthen the validity of the science EPA uses in rulemaking. If so, EPA then appears to leap to the conclusions (again without any supporting evidence) that the only way to strengthen the validity of the science is by enhancing transparency, that no other possible steps to enhancing integrity are worth considering, and that enhancing transparency means making underlying data and models publicly available. This is all before EPA even gets to its obviously illogical conclusion

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most of the raw data from past studies are not publicly available. In a random sample of the biomedical literature (2000–2014), none of 268 papers shared all of their raw data. Only one shared a full research protocol. The proportion of studies that have had all their raw data independently re-analyzed is probably less than one in a thousand. The number of studies that have been exactly replicated in new investigations is quite larger, but still a minority in most fields.") (citing Iqbal S, Wallach J, Khoury MJ, Schully S, Ioannidis JPA., *Reproducible research practices and transparency across the biomedical literature*, 14 PLoS Biol. 1 (2016) ("Replication studies were rare ($n = 4$), and only 16 studies had their data included in a subsequent systematic review or meta-analysis.")).

[340] *See, e.g.*, Comments of the International Society for Environmental Epidemiology on EPA's proposed rule on Strengthening Transparency in Regulatory Science Section 2 (EPA-HQ-OA2018-0259-0001), https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1973 ("However, although data reanalysis has a role to play, ultimately, the key determination of the consistency of scientific evidence comes from replication, not reanalysis.") (note that ISEE uses the term "replicate" to mean what we have defined in these comments as "reproduce").

[341] *See* Gina Kolata, *Many Academics are Eager to Publish in Worthless Journals*, N.Y. Times (Oct. 30, 2017), https://www.nytimes.com/2017/10/30/science/predatory-journals-academics.html; *Publish and Don't Be Damned*, The Economist (June 23, 2018), https://www.economist.com/science-and-technology/2018/06/23/some-science-journals-that-claim-to-peer-review-papers-do-not-do-so.

[342] EPA, *Scientific Integrity Policy*, https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf (seeking to protect agency reliance on science from political interference, personal motivations, conflicts of interest, bias, etc.).

that threatening exclusion of studies without publicly available data will "increase access to dose response data and models underlying pivotal regulatory science,"[343] rather than simply bar EPA from considering a vast universe of useful and rigorously vetted studies. The evidence cited by EPA in support of the need to strengthen science through its proposed approach is so vague and perfunctory that it is largely impossible even to tell which conclusions various sources are supposed to support. EPA's rationale for its data availability requirements consists of a few conclusory statements by EPA itself, a reference to "the replication crisis," and citations to a handful of articles and guidance issued by EPA and OMB. None of these provide a rational basis of support for the Proposal.

EPA begins by stating that the "proposed rule is consistent with the principles underlying the Administrative Procedure Act and programmatic statutes that EPA administers to disclose to the public the bases for agency rules and to rationally execute and adequately explain agency actions."[344] While EPA is correct that it must disclose the basis and provide an adequate explanation for rulemaking (principles EPA manifestly fails to follow in this Proposal), it does not follow that these principles either require or support the quite specific notion that dose response data and models must be publicly available. Nor does EPA attempt to explain how these broadest of rulemaking principles support EPA's specific proposed approach here.

Next, EPA states that the proposal is "consistent with" two recent executive orders and OMB guidelines on information quality and agency information management.[345] One of the executive orders says nothing more than that environmental regulations should be "developed through transparent processes that employ the best available peer-reviewed science . . . ."[346] The other is targeted at eliminating regulations including those that are "unnecessary" and "ineffective," which, as our comments detail, the Proposal clearly would be.[347] While the OMB guidelines on information quality generally support transparency in science, they call for a far more nuanced approach than EPA proposes here and do not call for agencies to exclude studies for which underlying data is not available, as discussed above in section I.C. In fact, as discussed above, EPA's proposal unlawfully contravenes these guidelines.

EPA then states that the Proposal "builds upon" prior EPA actions in response to government-wide data access and sharing policies.[348] In support of this claim, EPA cites generally to five prior EPA policy documents related to science. EPA fails to point to a single statement, provision or requirement in any of these documents, however, as support for the specific approach proposed here. This is not surprising, as EPA's proposal to exclude studies with non-public data is actually a significant change from the prior policies, which supported balancing the interest in access to data with interests in privacy and confidentiality, as discussed in more detail in Section II.E. In fact, one of the documents cited by EPA, the *Plan to Increase Access to Results of EPA-Funded Scientific Research*, directly contradicts an apparent premise of

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[343] 83 Fed. Reg. at 18,770.
[344] 83 Fed. Reg. at 18,769.
[345] *Id.*
[346] Exec. Order No. 13,783, 82 Fed. Reg. 16,093, 16,093 (Mar. 31, 2017); *see also* discussion in Appendix A.
[347] Exec. Order No. 13777, 82 Fed. Reg. 12285, 12286 (Mar. 1, 2017); *see also* discussion in Appendix A.
[348] 83 Fed. Reg. at 18,770.

EPA's Proposal, stating: "Whether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications."[349] EPA ignores this contradiction altogether and provides no explanation whatsoever as to how the Proposal "applies concepts and lessons learned from [EPA's] ongoing implementation" of this plan, as EPA asserts.[350]

EPA also claims that the Proposal builds on the "experience of other federal agencies in this space."[351] In this case, EPA simply lists other federal agencies without referring to any policies, documents or actions by those agencies, except for one particular Census Bureau database that allows federal Census data to be shared securely. Obviously a bald uncited statement that other federal agencies have "experience in this space" is far too vague to allow meaningful comment by the public on EPA's rationale for its action, much less provide any support or rationale for the proposed policy. Further, the Census Bureau database cited is an example of how an agency can provide secure access to its own data, but it does nothing to explain or justify EPA's Proposal to exclude third party studies with nonpublic data from consideration in rulemaking. The U.S. Census Bureau operates the Federal Statistical Research Data Centers, which are secure facilities providing authorized access to restricted-use microdata for statistical purposes only. To gain access, researchers must obtain Census Bureau Special Sworn Status—passing a moderate risk background check and swearing to protect respondent confidentiality for life. This approach meets the U.S. Census Bureau's needs by allowing access to confidential information only to researchers whose proposals meet certain criteria, who go through a vetting process, and who agree to protect the information. Yet again, this is a structure designed to protect data collected by the government, not third parties, and there are substantial costs to this approach, which are borne by the Census Bureau. It is clearly not directly transferable to the context of the Proposal.[352] It is also unclear whether such a structure, even if it were practical (which it is not), would be sufficient to satisfy EPA's requirement to make data and models "publicly available."

Next, EPA vaguely refers to recommendations from third party advocates supporting "open science."[353] EPA does not specify, let alone discuss, those recommendations. EPA certainly does not explain how EPA's current use of science is inconsistent with any such recommendations or inadequate in light of them, or whether any of these third party organizations believe that studies with nonpublic data are insufficiently valid for use in rulemaking. Indeed, one of the organizations cited by EPA—the Bipartisan Policy Center

[349] EPA, Plan to Increase Access to Results of EPA-Funded Scientific Research 4–5 (2016) (emphasis omitted), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.
[350] 83 Fed. Reg. at 18,770.
[351] *Id.*
[352] *See* Letter to Acting Administrator Wheeler from Marcia McNutt, President of the National Academy of Sciences, C.D. Mote, Jr., President of the National Academy of Engineering, and Victor J. Dzau, President of the National Academy of Medicine 3 (July 16, 2018). ("There are several differences in the confidential microdata collected from individuals and businesses by federal statistical agencies through surveys, versus data and results from the kinds of studies that are within the scope of the EPA proposed rule. These differences have important implications about making data publicly accessible. What works well in the federal statistical environment may not translate effectively to EPA, where stakeholders might be strongly motivated to discount study results that run counter to their regulatory preferences.").
[353] 83 Fed. Reg. at 18770.

("BPC")—filed a letter in this docket stating emphatically that "the proposed rule is not consistent with the BPC report in substance or intent. While the Science for Policy Project panel encouraged greater transparency and access to data, the report never suggested excluding studies from consideration in developing regulation if data from those studies were not publicly available."[354] Again, the policy documents cited in the footnote accompanying this statement generally undercut rather than support EPA's Proposal, as discussed in detail in Appendix A.

EPA also suggests that "these policies" (which policies it is unclear) "are informed by the policies recently adopted by some major scientific journals."[355] EPA does not cite any specific policies adopted by the journals named in the footnote, but it does not appear that any of those journals has determined that studies with nonpublic data are invalid and should not be relied upon or used. To the contrary, the editors of these journals issued a strong public statement affirming that "in not every case can all data be fully shared," that "the merits of studies relying on data that cannot be made publicly available can still be judged," and that "[i]t does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them…Excluding relevant studies simply because they do not meet rigorous transparency standards will adversely affect decision-making processes."[356] Again, however, EPA's failure to provide any specific information or citations in support of its conclusory statements make it impossible to meaningfully comment on the support for EPA's Proposal.

Further, EPA mentions "the replication crisis,"[357] but provides no information on the reality, seriousness, scope, implications, or causes of such a crisis. EPA fails to explain what it understands the "replication crisis" to be, much less how EPA's proposal might ameliorate it. It is not even clear whether EPA understands the meaning of the term "replication," as the agency fails to distinguish between "replicability" and "reproducibility," and uses both terms apparently interchangeably.[358] *See* earlier discussion of key terminology at page 9.

The proposed regulatory text provides, "[i]nformation is considered 'publicly available in a manner sufficient for independent validation' when it include the information necessary for the public to understand, assess, and *replicate* findings" and then lists "data" as the first type of information that may be included.[359] Yet "replicating findings" is essentially limited to laboratory animal and randomized controlled trials and does not capture the vast majority of human epidemiological studies. More importantly, replicating studies does not require access to underlying study data, but rather details regarding the methodological design. Further "reproducing" studies is generally viewed as a more informative and resource efficient approach to validation of research.

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[354] Letter from Jason Grumet, President of BPC to Administrator Scott Pruitt (May 22, 2018).
[355] *Id.*
[356] Jeremy Berg et al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018).
[357] *Id.*
[358] *Compare, e.g.*, 83 Fed. Reg. at 18774 (proposed rule requires information to be available "for the public to understand, assess, and replicate findings"), *and* 83 Fed. Reg. at 18770 (alluding to "replication crisis" as a basis for the need for the proposed rule), *with* 83 Fed. Reg. at 18772 (discussing an analysis purporting net benefits from the proposal due to "greater reproducibility"), *and* 83 Fed. Reg. at 18769 ("EPA must. . . ensure that its decision-making is marked by independence, objectivity, transparency, clarity, and reproducibility.").
[359] 83 Fed. Reg. at 18773-74 (emphasis added).

Finally, to the extent that specific circumstances justify actually replicating a study, EPA fails to explain why it is necessary to make a study's underlying data broadly available to the public rather than employing a more secure approach that protects personal privacy. For example, to quell concerns about the validity of the American Cancer Society Cancer Prevention Study II (ACS CPSII) and the Harvard Six Cities Study—both seminal air pollution studies that are described earlier in these comments—an independent panel of Canadian and American scientists independently audited and reanalyzed them. Due to personal privacy concerns, the data was not made publicly available but was instead held in a restricted access data warehouse at the Health Effects Institute, an organization funded by both the automotive industry and EPA. The independent audit and reanalysis took three years and roughly one million dollars. It evaluated the consistency and accuracy of the data and then undertook a series of comprehensive analyses to test the robustness of the original findings and interpretations to alternative analytic approaches. The results of the independent analysis found resoundingly similar results for both studies.[360]

The results of this reanalysis suggest that routine assessment of quality indicators such as methodology, confounding and bias routinely evaluated in the peer review process are generally sufficient to confirm a study's validity. Further, while it plainly would be infeasible to undertake such an expensive and time-consuming reanalysis for the vast majority of studies, this example demonstrates that it is possible to undertake a reanalysis without making underlying data broadly available to the entire public. Yet EPA's proposed rule apparently would bar regulators from relying on these high quality and extensively vetted studies due to the fact that the underlying data was never made publicly available. EPA does not—and cannot—explain how a rule that would prohibit the agency from considering these seminal, high quality scientific studies comports with its goal of strengthening the agency's use of science in regulatory actions.

7. EPA has failed to explain why it has singled out dose response studies to be excluded if their underlying data and models are not publicly available, but has not similarly targeted any other types of studies commonly used by EPA.

EPA also has proposed to target the requirements for public availability specifically to the data and modeling underlying one specific subset of scientific research—dose response studies. EPA has provided no explanation or justification for targeting dose response studies in particular or for not including other types of studies or scientific information. EPA has not suggested that these studies are inherently less reliable than other studies, that they more

[360] For the Harvard Six cities study, the reanalysis results were 1.28 hazard ratio for mortality per 18.6 microgram per meter cube of PM2.5, in comparison to a hazard ratio of 1.26 found in the original study. For the ACS CPSII study, the reanalysis showed that for every 25.4 microgram per meter cube change in PM2.5 there was an associated hazard ratio for mortality of 1.18 (results of the independent reanalysis), as compared to the hazard Ratio of 1.17 reported by the original investigators. Daniel Krewski, et al., *Overview of the reanalysis of the Harvard six cities study and American Cancer Society study of particulate air pollution and mortality*, 66 J. Toxicology & Envtl. Health Part A 1507 (2003); Health Effects Inst., Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality (2000).

commonly fail to publicly disclose data and modeling information, that replication is more necessary for these studies than others, or any other conceivable reason. Absent any explanation from the agency, it is impossible to comment on the factual predicates for EPA's proposed decision, or the reasonableness of EPA's justification, except to state that it appears completely arbitrary in the absence of any rationale. *See, e.g., Transactive Corp., v. United States*, 91 F.3d 232, 237 (D.C. Cir. 1996) ("A long line of precedent has established that an agency action is arbitrary when the agency offered insufficient reasons for treating similar situations differently.").

8. EPA arbitrarily failed to consider the implications of this proposal on interagency coordination.

Additionally, EPA arbitrarily failed to consider the far-reaching implications this Proposal could have on inter-agency coordination and consultation given that other agencies normally rely on research potentially excluded by the Proposal.[361] In the numerous environmental statutes that EPA cites, there are dozens of provisions that require EPA to coordinate or consult with other Federal entities—especially when implementing research programs and issuing information or guidelines.[362] The Proposal would almost certainly frustrate and impair this coordination and consultation, either by forcing EPA to ignore the science provided by other agencies or by severely restricting the science that EPA itself would be able to share with other agencies in these statutorily required processes. The Proposal arbitrarily ignores these potential impacts.

In addition to the many examples of statutorily required consultation that are identified in Appendix B, other federal agencies routinely incorporate and rely upon EPA science assessments in their own efforts to carry out their mandates to protect human health and safety. As with statutorily required consultations, the Proposal utterly fails to acknowledge or consider what impacts restricting EPA's own use of dose-response studies would have on the work of these other agencies. Indeed, there is no evidence that these other agencies were even permitted to comment on the Proposal as part of the usual process of interagency review.

Some selected examples of other federal agency programs that rely on EPA science include:

- The Food and Drug Administration (FDA) enforces tolerances established by EPA for pesticide chemical residues in human and animal foods under the Federal Insecticide,

[361] *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem.").

[362] *See* 42 U.S.C. §§ 7403, 7408(a), 7408(c), 7408(f), 7412 (Clean Air Act §§ 103, 108, 112); 33 U.S.C. §§ 1314, 1317(a)(7), 1345(d)(1) (Clean Water Act §§ 304, 307(a)(7), 404(d)(1)); 42 U.S.C. §§ 6907(a), 6911, 6912(a)(2)-(6), 6942(b), 6981(a) (Resource Conservation and Recovery Act §§ 1008(a), 2001, 2002(a)(2)-(6), 4002(b), 8001(a)); 7 U.S.C. §§ 136w-3, 136w(d), 136a-1(n)(2)-(3), 136(ll)(2), 136t(b), 136i-2(c) (Federal Insecticide, Fungicide, and Rodenticide Act §§ 2, 4, 11, 22, 25, 28); 15 U.S.C. §§ 2608(d), 2604(f)(5), 2604(h)(2)(B)(ii) (Toxic Substances Control Act); 42 U.S.C. § 300g-1 (b)(1)(D), 300g-1(d), 300j-13(a)(5), 300j-3d, 300j-19(b)(2)(A) (Safe Water Drinking Act). *See also* Appendix B: Table of Consultation Requirements.

Fungicide, and Rodenticide Act, including through a comprehensive pesticide residue monitoring program that tests for approximately 700 pesticide residues in both imported and domestic commodities.[363] To the extent the Proposal affects EPA's tolerances, the nature and effectiveness of FDA's own work to monitor for violations of those tolerances would be impacted.

- FDA also regulates contaminants in bottled water under the Federal Food, Drug and Cosmetics Act. Section 410 of the Act requires that FDA regulations for bottled water be issued in coordination with the effective date of National Primary Drinking Water Regulations issued under the Safe Drinking Water Act, and be no less protective of public health than those standards. If the Proposal impedes EPA's work to establish drinking water standards, this may affect FDA's own ability to justify protective bottled water standards.[364]
- In certain circumstances, FDA also coordinates with EPA to provide the public with information and advice on environmental contaminants in foods. For example, in 2017 FDA and EPA released a joint advisory on mercury hazards associated with the consumption of fish and shellfish, which was based in part on EPA's assessment of the "reference dose" or level of exposure that a person can experience over a lifetime without a risk of harm.[365] The Proposal could radically alter the science EPA would be permitted to consider in future such initiatives, and frustrate the ability of FDA and other agencies to coordinate effectively with EPA to develop joint advice and information.
- The Department of Housing and Urban Development is required by statute to assist EPA in assessing the extent of radon contamination in the United States and developing measures to avoid and reduce radon contamination.[366] HUD has also developed policies to require radon testing at properties receiving federal financing, which incorporate EPA radon standards.[367] To the extent the Proposal affects future EPA assessments of radon risks, the scope, cost and effectiveness of HUD radon programs could be affected as well.

9. EPA's proposal irrationally excludes proceedings that tend to benefit industry interests, even though these proceedings are far less transparent than the rulemakings EPA has targeted.

EPA's claims that it values transparency are clearly a pretext for eliminating "inconvenient," life-saving science from rulemakings that increase public health protection. Among other things, by excluding adjudications, permit proceedings, and certain rulemakings, EPA has excluded proceedings where EPA and industry regularly rely on nondisclosed information and where agency action in general, and particularly expeditious action, tends to

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[363] FDA, *Pesticide Residue Monitoring Program Questions and Answers*, *https://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm583711.htm* (last visited Aug. 13, 2018).
[364] FDA, *Guidance for Industry: Bottled Water and Total Coliform and E. Coli: Small Entity Compliance Guide*, *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm206215.htm* (last visited Aug. 14, 2018).
[365] Advice About Eating Fish, From the Environmental Protection Agency and Food and Drug Administration; Revised Fish Advice; Availability, 82 Fed. Reg. 6572 (Jan. 19, 2017).
[366] *See* Pub. L. 100-628, title X, § 1091, Nov. 7, 1988, 102 Stat. 3283.
[367] *See* HUD, HUD Office of Multifamily Development Radon Policy, Notice H 2013-03 (Jan. 31, 2013), *available at https://www.hud.gov/sites/documents/13-03HSGN.PDF*.

favor industry. By limiting the proposal to "significant regulatory actions," the proposed rule would treat exactly the same study differently depending on whether it supports regulation or non-regulation in a particular context. The proposed rule will tend to exclude evidence when it supports a health-protective regulation that is costly to industry, but the proposed rule will then allow the use of the exact same evidence when the ultimate agency decision avoids regulation or deregulates industry activities or otherwise has low compliance costs. Thus, the Proposal is clearly shaped to favor industry interests, not to further transparency.

Specifically, EPA has chosen to limit the application of this Proposal to "significant regulatory actions" under E.O. 12866, and thus EPA does not extend this Proposal to adjudications, permit proceedings, or many less economically significant rulemakings.[368] In particular, EPA has effectively exempted the TSCA new chemicals program where industry seeks expeditious actions allowing market access and EPA regularly fails to disclose its own analyses and the studies and materials supporting those decisions, much less any underlying data. As explained below, in these proceedings industry seeks affirmative authorization from EPA to commercialize chemicals, so industry has a vested interest in expeditious government action.

EPA's decision to exempt these proceedings is particularly egregious because these proceedings are extraordinarily more opaque than the rulemakings EPA has targeted with this Proposal. In the TSCA new chemicals program, EPA often provides no meaningful opportunity for public review or comment before EPA takes action, and EPA regularly violates its existing statutory and regulatory obligations by disclosing almost none of its analyses or the information supporting its decisions to authorize the manufacture of new chemicals. Notably, much of the information at issue has never been peer-reviewed or subjected to nearly the level of public scrutiny as have the studies that EPA is trying to exclude from health-protective rulemakings under the proposed rule. EPA cannot credibly claim to pursue transparency with this Proposal while running certain programs as "black boxes" where little, if any, information is disclosed. To be clear, the problem is that EPA often does not disclose its own analyses or many of the underlying studies at all, much less underlying data; it is outrageous for EPA to then turn around and suggest that, in other contexts, disclosure of its analyses and the supporting peer-reviewed studies provides insufficient transparency.

As drafted, EPA's Proposal will not apply to EPA's New Chemicals Review Program under TSCA. TSCA § 5 governs EPA's review of "new chemical substance[s]," generally chemicals that have not previously been distributed in U.S. commerce.[369] By and large, no person may manufacture (defined to include import) a "new chemical substance" in the United States without providing EPA notice at least 90 days beforehand.[370] When a person submits a pre-manufacture notice (PMN), EPA must review the PMN and make one of three types of determinations under TSCA § 5(a)(3).[371] EPA then must take the actions required by the

[368] 83 Fed. Reg. at 18,771.
[369] *See* 15 U.S.C. §§ 2604, 2602(11).
[370] *Id.* § 2604(a)(1).
[371] *Id.* § 2604(a)(1)(B). Depending on the circumstances, instead of submitting a PMN, a person may seek to obtain one of several exemptions from the PMN process, such as the Test Marketing Exemption. The proceedings governing applications for these exemptions involve even less public disclosure than EPA's processing of PMNs. EPA's proposal will also not apply to the proceedings governing these exemptions.

relevant determination, and the person must comply with any applicable requirement imposed.[372] The person may not begin manufacturing the chemical substance until EPA has completed its review and made a determination. These proceedings do not qualify as significant regulatory actions under E.O. 12866, because EPA does not consider them rulemakings and because the regulation of chemicals that have not yet been introduced to the market generally will not be economically significant within the meaning of the E.O.

Because industry generally cannot manufacture a new chemical substance until EPA has completed its review, industry has a strong interest in expeditious action on PMNs. Nor is this idle speculation; industry commenters have repeatedly called for EPA to move more expeditiously.[373] Providing disclosure in these proceedings would likely, at a minimum, take additional time, and thus it seems likely that EPA has exempted these proceedings to serve industry's interest in hasty resolution.

Moreover, the New Chemicals Program is infinitely more opaque than the rulemakings EPA is currently targeting with its Proposal, often in direct violation of law. EPA does not make the public files for new chemicals electronically available, and when a person does obtain a copy of the public file from EPA,[374] the files generally reveal almost none of EPA's analyses supporting its decisions or the information submitted to support those decisions, with massive amounts of data redacted or concealed as Confidential Business Information (CBI). It's not a question of failing to disclose all the underlying data; EPA often fails to disclose the supporting studies or information at all.

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[372] *Id.*

[373] *See, e.g.*, Am. Coatings Ass'n Comment on New Chemicals Review Program 2 (Jan. 20,2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0068 ("We urge the Agency to expedite the process as much as possible, so that manufacturing is able to commence."), Docket ID: EPA-HQ-OPPT-2017-0585-0068; Am. Chemistry Council Comment on New Chemicals Review Program 7 (Jan. 19,2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0062 ("These delays underscore industry's continuing concerns that the section 5 program remains too slow . . . ."), Docket ID: EPA-HQ-OPPT-2017-0585-0062; U.S. Chamber of Commerce Comment on New Chemicals Review Program 3 (Jan. 19, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0057 ("[T]he Chamber believes that EPA should continue to strive to meet the 90-day goal in a timelier and more effective fashion . . . ."), Docket ID: EPA-HQ-OPPT-2017-0585-0057; Am. Petrol. Inst. Comment on New Chemicals Review Program 2 (Jan. 19, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0053 ("EPA should respond to a request for a Pre-Notice Consultation in a short timeframe—two to four days, rather than two to four weeks."), Docket ID: EPA-HQ-OPPT-2017-0585-0053; Int'l Fragrance Ass'n N. Am. Comment on New Chemicals Review Program 1 (Jan. 20, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0064 (identifying as a problem "review periods far exceeding 90 days – some exceeding a year"), Docket ID: EPA-HQ-OPPT-2017-0585-0064.

[374] As EDF has previously explained, EPA is already committing systematic procedural violations by failing to make the public files for new chemicals electronically available to the general public. Envtl. Def. Fund Comment on New Chemicals Review Program 23–26 (Jan. 20, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0071, Docket ID: EPA-HQ-OPPT-2017-0585-0071. Under TSCA § 5(d), each Pre-manufacture Notice (PMN) "shall be made available, subject to section 14, for examination by interested persons." 15 U.S.C. § 2604(d)(1). EPA's implementing regulations provide that "[a]ll information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the public file for that notice," 40 C.F.R. § 720.95, and those public files are supposed to be "available in the electronic docket at http://www.regulations.gov." *Id.* § 700.17(b)(1). But EPA generally does not make the public files for PMNs electronically available.

As EDF detailed in prior comments and in various blog posts, EPA regularly conceals vast swathes of information in this program, including providing many blank documents identified as consisting of health and safety studies.[375] Notably, in this same context, industry commenters have urged EPA to take steps to accept data and information that will not be publicly disclosed or where EPA will only be provided with or make public industry-prepared summaries of the underlying data. *See, e.g.*, Comment submitted by Raleigh Davis, Assistant Direction, EHS, American Coatings Association (ACA), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0068 ("ACA strongly encourages EPA to develop as many of these [non-disclosure agreements] as possible."); Comment submitted by Jared Rothstein, Senior Manager, Regulatory Affairs, Society of Chemical Manufacturers & Affiliates (SOCMA), p.1 https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0049 ("EPA should accept the submission of robust summaries."). Thus, industry has expressed a desire for EPA to continue to operate the new chemicals program with limited disclosure, and thus far, EPA has acceded to that wish.

If EPA extended the rule articulated in proposed § 30.5 to the new chemicals program, it would seem that EPA would either have to make much of the information in the public files available *or* EPA would be precluded from using this information. 83 Fed. Reg. at 18.769 n.3 (stating that EPA is proposing to preclude itself from using such data in future regulatory actions). Without this information, EPA generally would not be able to find that the new chemical "is not likely to present an unreasonable risk of injury to health or the environment," the finding that allows unregulated manufacture of the chemical. *See* 15 U.S.C. § 2604(a)(3)(C). Notably, TSCA expressly provides a resolution when EPA has insufficient information, requiring that EPA regulate the chemical. *Id.* § 2604(a)(3)(B)(i), (e). When "the information available to [EPA] is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance; … [EPA] shall issue an order" regulating the chemical "to the extent necessary to protect against an unreasonable risk of injury to health or the environment." *Id.* 2604(e).Thus, excluding the information would require EPA to regulate the new chemicals before they could enter the market.

Thus, EPA's exclusion of the new chemicals program clearly favors industry, allowing industry to conceal information and evade regulation. In addition, EPA cannot rationally impose stringent new disclosure requirements that exclude extensive peer-reviewed, high-quality studies in some contexts while simultaneously authorizing the commercial distribution of new chemicals with almost no disclosure and no peer-review.

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[375] Envtl. Def. Fund Comment on New Chemicals Review Program 24-25, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0071. For more detail, see EDF's series of blog posts on its finding in its our review of public files for nearly 70 new chemicals for which EPA made "not likely to present an unreasonable risk" determinations, *E.g.*, Stephanie Schwartz & Richard Dennison, *EPA's Appalling Failure to Provide Public Access to Public Data on TSCA New Chemicals*, EDF Health Blog (Jan. 24.2018), http://blogs.edf.org/health/2018/01/24/epas-appalling-failure-to-provide-public-access-to-public-data-on-tsca-new-chemicals/.

E. EPA's Proposal is Arbitrary Because it is Inconsistent With Long-Standing EPA and Federal Government Policies and Ongoing Efforts to Strengthen Science Quality in a Measured and Balanced Way through EPA's Existing Science Policies.

EPA claims throughout the Proposal that it is consistent with EPA and other federal government policies and approaches to transparency. However, a closer look reveals that the documents that EPA itself cites do not support the over-simplified and drastic approach taken by the Proposal. Federal government policies to promote data transparency have instead advocated a careful approach that balances the benefits of data disclosure with the costs and risks associated with it. Nowhere do they suggest that confidential information that cannot be made public is no longer valid for agency use. Instead, they aim to maximize the integrity and usability of data through data sharing when possible and practical—to enhance rather than hinder the ability of government agencies to achieve their missions. The Proposal is based on unsubstantiated claims that lack evidence, deviates from existing EPA and broader federal government policy without acknowledgement or explanation, and conflicts with leading research and policy proposals in this area— rendering the Proposal arbitrary and capricious.

Agencies are required to justify reversals in policy by addressing the existing record and reasons for why a change in policy is appropriate.[376] They must acknowledge the change and "show that there are good reasons for the new policy."[377] The agency must supply a reasoned analysis beyond which would be required in the absence of the old policy.[378] An agency may not "disregard contrary or inconvenient factual determinations that it made in the past."[379] EPA in the past took the position that:

> [EPA] does not believe that it is appropriate to refuse to consider published studies in the absence of underlying data. The EPA frequently relies on peer reviewed studies in the public literature across agency programs without possessing underlying data and the Federal courts have made clear that the EPA is not required to obtain or analyze the raw data in order to rely on such studies. If the EPA and other governmental agencies could not rely on published studies without conducting independent analyses of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment.[380]

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[376] *FCC v. Fox Television Stations, Inc.* 556 U.S. 502, 515 (2009).

[377] *Id.*

[378] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) ("[A]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance").

[379] *FCC v. Fox Television Stations, Inc.* 556 U.S. 502, 537 (2009) (Kennedy, J. concurring).

[380] House of Representatives, Committee on Agriculture, *Hearing to Consider the Impacts of the Environmental Protection Agency's Actions on the Rural Economy* Serial No. 114-41, 82 (Feb. 11, 2016) (response to questions from Gina McCarthy, Administrator, EPA); *See also* Email from Nancy Beck to Justin Schwab and Richard Yamada (Mar. 5, 2018, 1:42:01 AM) (part of FOIA release to request by Union of Concerned Scientists citing EPA pesticide program documents from December 2016) (email flags language from EPA pesticide program documents: "To be clear, EPA continues to believe that the raw data should be made available for public inspection to ensure that EPA's assessments are as transparent as possible. While the EPA therefore strives to ensure that data underlying research it relies upon are accessible to the extent possible, it does not believe that it is appropriate to refuse to consider published studies in the absence of underlying data. The EPA frequently relies on peer reviewed studies in

Thus, EPA in the past set forth a view diametrically opposed to the one it is taking now—in the past relying heavily on studies it would now be excluded from using. EPA previously recognized that there are other ways to validate scientific studies, such as through peer review, that do not require release of underlying data and its prior view rightly saw the danger in adopting a policy that would require EPA to make public underlying data.

EPA's current policies set forth standards of scientific integrity that involve use of the best scientific information available (see II.D.2), which the Proposal also now re-writes. While previously EPA took the view that all valid science (with proper quality control and assessment measures in place) should be considered as it sets standards, EPA now takes the position that it is more important to use only those studies where the underlying data and models are made available to the public, even if this compromises EPA's ability to use the best available science. EPA's existing open data policies recognize with exceptions and exemptions that as much as the pursuit of making data public is a worthy goal, there are competing interests. EPA has always taken the view that not releasing certain kinds of data to uphold these competing interests does not in fact compromise its scientific integrity or commitment to transparency—and the balance it strikes is the one most suitable to help its achieve its greater mission. The Proposal is arbitrary because EPA does not even acknowledge that it is now changing its view drastically and does not address the valid reasons underlying its prior policies or explain why they now merit changing.

1. Instead of providing a reasoned explanation for its change in policy, EPA wrongfully claims the Proposal is consistent with existing EPA, federal government, and third-party practices and policies.

As discussed further below in Section VIII.D, the footnotes of EPA's Proposal in many cases provide only vague references to policies and reports that purportedly support the Proposal, leaving the public to guess as to what EPA is referring and embark on a treasure hunt for the relevant item. But even where EPA provides specific citations, examination quickly reveals that frequently they do not fully support the propositions they accompany, and, when viewed in full context, provide evidence against the Proposal. Because EPA makes a series of conclusory statements provided with no explanation or reasoning that would help the reader understand why EPA interpreted the cited record to support the Proposal, the Proposal appears to be completely unsupported by evidence and explanation—rendering it arbitrary and capricious. A full documentation of the misrepresentations made in the footnotes of the Proposal is available in Appendix A and demonstrates that EPA is not able to substantiate its claims that the Proposal has been informed by or is consistent with the policies of EPA, other agencies, or other organizations.

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the public literature across agency programs without possessing underlying data and the federal courts (see Coalition of Battery Recyclers Association v. EPA, 604 F.3d 613 (D.C. Cir. 2010); American Trucking Associations v. EPA, 203 F.3d 355 (D.C. Cir. 2002)) have made clear that EPA is not required to obtain or analyze the raw data in order to rely on such studies. If EPA and other governmental agencies could not rely on publisbed studies without conducting an independent analysis of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment.").

EPA claims: "The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science."[381] The sentence is accompanied by a footnote listing a number of organizations, for most of them not providing reference to any specific policies, recommendations, or statements.[382]

One of these vague references points to the Administrative Conference of the United States' Science in the Administrative Process Project, without providing further detail. Assuming that EPA is referring to the Administrative Conference of the United States' *Recommendation 2013-3: Science in the Administrative Process*, Wendy Wagner, sole author of ACUS's final report *Science in Regulation: A Study of Agency Decisionmaking Approaches* and who served on the panel that produced the Bipartisan Policy Center's recommendations also cited by the Proposal has stated: "They don't adopt any of our recommendations, and they go in a direction that's completely opposite, completely different. . . . They don't adopt any of the recommendations of *any* of the sources they cite. I'm not sure why they cited them."[383] While ACUS recommends agencies increase transparency of how they rely on scientific information and strive to make data underlying scientific information publicly available, nowhere does it suggest that agencies should not consider or rely on studies where underlying data and models cannot be made publicly available, or that these circumstances make scientific information less valid. ACUS instead suggests that information be made publicly available "to reproduce or assess the agency's technical or scientific conclusions" "[c]onsistent with the limitations in the Information Quality Act (IQA) guidelines issued by the Office of Management and Budget and its own IQA guidelines"[384] Moreover, ACUS acknowledges valid limitations on public disclosure of data such as legal protections for privacy, trade secrets, and confidential business information.[385] Thus, ACUS recommends data be made public only "[t]o the extent practicable and permitted by law and applicable policies."[386] Unlike the Proposal, the recommendation acknowledges that agencies may still use information where underlying data cannot be publicly disclosed, and suggest agencies "note that fact and explain why they used the results if they chose to do so."[387] It thus provides a much more nuanced policy recommendation than that outlined in the Proposal—which suggests EPA either find a way to make underlying data and models public, despite the numerous potential obstacles and concerns in doing so, or completely disregard the research study.

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[381] 83 Fed. Reg. at 18,770.

[382] 83 Fed. Reg. at 18,770. n. 10 ("These include policies and recommendations from: The Administrative Conference of the United States' Science in the Administrative Process Project; National Academies' reports on *Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data,* and *Access to Research Data in the 21st Century;* the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project").

[383] Robinson Meyer, *Scott Pruitt's New Rule Could Completely Transform the EPA*, The Atlantic (Apr. 25, 2018), https://www.theatlantic.com/science/archive/2018/04/how-the-epas-new-secret-science-rule/558878/.

[384] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process,* 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).

[385] 78 Fed. Reg. 41,352, 41,358 n.12 (July 10, 2013).

[386] 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).

[387] 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).

EPA's claims that its Proposal is consistent with the policies of major science journals is similarly misleading. [388] EPA does not explain why the policies of scientific journals regarding the disclosure of data underlying their published studies *should* inform how an agency with a mission to protect human health and the environment uses research for regulatory actions. Additionally, these journals' policies provide exceptions for when privacy or other concerns do not allow for public sharing of data, and they never represent that this on its own weakens the validity of the research.[389] And, as discussed supra in Section I.B.2.a), the editors of these journals have specifically dismissed the Proposal.[390]

EPA wrongfully claims its policy is consistent with existing OMB and EPA policies, while failing to recognize that these polices—while advocating for more transparency—take a measured, nuanced approach to data disclosure.[391] EPA cannot finalize this policy without acknowledging and providing a reasoned explanation for its divergence from long-standing policy and without providing actual evidence that supports the Proposal, which it has not done. Prior policies recognize that government decision-making requires considering all scientific information, and legitimate limitations to data disclosure should not obstruct sound policy-making. EPA cannot rely on these documents to support the rule, leaving an inadequately thin record of evidence to support the Proposal, and must respond to policy rationales articulated in these documents as it now changes course.

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[388] 83 Fed. Reg. at 18,770 (EPA states that the policies and recommendations it considered were "informed by the policies recently adopted by some major scientific journals and cites to "related policies from the Proceedings of the National Academy of Sciences, PLOS ONE, Science, and Nature."); 83 Fed. Reg. at 18,771 n. 20 (citing "policies or recommendations of publishers Taylor & Francis, Elsevier, PLOS, and Springer Nature" as potential mechanisms for compliance with Proposal).

[389] Taylor & Francis, *Data Sharing FAQs*, https://authorservices.taylorandfrancis.com/data-sharing-faqs/ (All our policies allow exceptions where data sharing violates protection of human subjects or other valid subject privacy concerns.) (last accessed Aug. 15, 2018); Elselvier, *Research Data Policy*, https://www.elsevier.com/about/our-business/policies/research-data (policy merely encourages when possible, rather than requires, data sharing: "Research data should be made available free of charge to all researchers wherever possible and with minimal reuse restrictions.") (last accessed Aug. 15, 2018); PLOS One, *Data Availability*, http://journals.plos.org/plosone/s/data-availability (allows exceptions to making data public "for ethical or legal reasons, e.g., public availability would compromise patient confidentiality or participant privacy" or present other threats) (last accessed Aug. 15, 2018); Springer Nature, *Research data policies FAQs*, https://group.springernature.com/gp/authors/research-data-policy/faqs/12327154 ("reasonable restrictions on data availability are permitted to protect human privacy, biosafety or respect reasonable terms of use for data obtained under license from third parties.") (last accessed Aug. 15, 2018). *See, also,* discussion in Appendix A.

[390] Jeremy Berg et. al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

[391] EPA states: "This proposed rule is also consistent with . . . the focus on transparency in OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies* (the Guidelines) and OMB *Memorandum 13–13: Open Data Policy—Managing Information as an Asset*." 83 Fed. Reg. at 18,769-70. EPA says the Proposal "builds upon prior EPA actions in response to government wide data access and sharing policies," that it applies "concepts and lessons learned" from implementation of to the 2016 *Plan to Increase Access to Results of EPA-Funded Scientific Research*, 83 Fed. Reg. at 18,770, also citing to EPA *Open Government Plan 4.0, Open Data Implementation Plan, EPA's Scientific Integrity Policy*, and *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*, 83 Fed. Reg. at 18,770 n. 8.

The *Plan to Increase Access to Results of EPA-Funded Scientific Research*, discussed supra at I.B.2.b), represents the view EPA has consistently espoused in the past, that when it can make data available without compromising other critical values, it does, but will not exclude information from its consideration when it cannot.[392]

EPA cites to its implementation of OMB's guidelines, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*. These Guidelines note "[t]he mission of the EPA is to protect human health and safeguard the natural environment upon which life depends" and "[t]he collection, use, and dissemination of information of known and appropriate quality are integral to ensuring that EPA achieves its mission."[393] They thus highlight that the controls on data quality exist to allow EPA to meet its mission—unlike the Proposal, which changes EPA's existing view by placing transparency of data, apparently for its own sake even when unrelated to data quality, ahead of EPA's ability to achieve its mission. As explained above in Section I.C, the Proposal violates the Information Quality Act and these Guidelines.[394]

EPA disregards the careful approach to data disclosure outlined in OMB Memorandum M-13-13, *Open Data Policy-Managing Information as an Asset*, which requires agencies to collect or create information in a way that supports downstream information processing and dissemination activities, and does not establish a policy of requiring agency data to be made public in order for the agency to be able to rely on it.[395] It recognizes that sharing agency data with the public can result in numerous benefits, but requires careful thought about privacy and confidentiality concerns. The memorandum establishes "a framework to help institutionalize the principles of effective information management at each stage of the information's life cycle to promote interoperability and openness," noting "[w]hether or not particular information can be made public, agencies can apply this framework to all information resources to promote efficiency and produce value."[396] It places consideration of privacy concerns at the forefront, saying "[a]gencies should exercise judgment before publicly distributing data residing in an existing system by weighing the value of openness against the cost of making those data public."[397] EPA has provided no indication that it has carefully weighed these costs and benefits.

Before agencies make data publicly available, OMB Memorandum M-13-13 requires that agencies "review the information collected or created for valid restrictions" such as legal, "privacy, confidentiality pledge, security, trade secret, contractual, or other valid restrictions to release."[398] OMB recognizes these restrictions "may affect the amount, type, form, and detail of

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[392] *See, also,* discussion in Appendix A.
[393] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (EPA/260R-02-008)* 5 (Oct. 2002), https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information.
[394] *See, also,* discussion in Appendix A.
[395] OMB Memorandum M-13-13, *Open Data Policy-Managing Information as an Asset* 1 (May. 9, 2013).
[396] *Id.*
[397] *Id.* at 6.
[398] *Id.* at 9.

data released by agencies."[399] It also requires agencies to consider the "'mosaic effect' of data aggregation," discussed at Section II.A.2.b)ii, which EPA does not acknowledge at all in the Proposal.[400]

EPA's *Open Government Plan 4.0* acknowledges that not all data is releasable to the public, even as it aims to "increase publicly accessible EPA data to support citizens' participation in government and promote transparency and accountability of Agency operations."[401] EPA states: "By providing *releasable* information in open and machine-readable formats, EPA enables the public and other organizations to better leverage the rich wealth of information available."[402] EPA's own *Open Data Policy* notes that it is important to develop "policies and processes to ensure that only appropriate data are released to the public and made available online."[403] To do so, EPA uses different "access levels" for different data sets, (public, restricted public and non-public) and notes that it may not be able to publicize data due to "law, regulation or policy, which address privacy, confidentiality, security or other valid restrictions."[404] EPA has not made clear that restricted access would satisfy the requirement of making information "publicly available." The Proposal seems to completely do-away with this multi-level, nuanced approach, imposing a blanket "publicly available" requirement for all studies EPA intends to rely on, despite obstacles to their release.

The Proposal turns away from EPA's *Scientific Integrity Policy*, which stresses "a firm commitment to evidence,"[405] endorses use of "the best available science"[406] and "[r]equire[s] reviews. . . regarding the content of a scientific product to be based only on scientific quality considerations."[407] The Proposal, on the other hand, inhibits use of sound scientific information and evidence by arbitrarily excluding science for reasons unrelated to its quality. While the policy "[r]ecognizes the value of independent validation of scientific methods"[408] and facilitating "the free flow of scientific information" by making information available "including access to data and non-proprietary models underlying Agency policy decisions,"[409] this is proposed as a flexible standard and an ideal to aspire to, not an absolute rule that takes priority over other competing interests—such as use of the best scientific information. As discussed more in Section VII.C this Administration has blatantly violated key aspects of the policy by silencing scientists and the dissemination of scientific information, which this Proposal seems aimed at continuing, directly undoing "EPA's longstanding commitment to the timely and unfiltered dissemination of its scientific information – uncompromised by political or other interference" and goal to communicate scientific findings openly and actively to the public.[410] By now placing

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[399] *Id.* at 10.
[400] *Id.* at 9-10.
[401] EPA, *Open Government Plan 4.0* 4 (Sept. 2016).
[402] *Id.* (emphasis added).
[403] EPA, *Open Data Policy Implementation Plan* 4, https://www.epa.gov/sites/production/files/2015-05/documents/opendatapolicyimplementationplan_030415_finalb.pdf.
[404] *Id.*
[405] EPA, *Scientific Integrity Policy* 3.
[406] *Id.* at 3-4.
[407] *Id.* at 4.
[408] *Id.*
[409] *Id.*
[410] *Id.* at 5.

"transparency" ahead of use of the best available science, aside from violating statutory requirements, EPA is changing its own policies and priorities and must justify this new position.

In footnote 2, EPA dubiously claims the Proposal is consistent with the *Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity* (Mar. 9, 2009).[411] Notably, the Memorandum specifies, "Except for information that is *properly restricted from disclosure* under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions."[412] Not only does the Memorandum provide no support for the notion that agencies should be barred from relying on studies where the underlying data is properly restricted from disclosure it additionally discusses disclosure only of findings and conclusions, not underlying data.

Thus, despite EPA's claims to the contrary, the Proposal marks a shift in policy that EPA has up to this point followed EPA arbitrarily fails to acknowledge this shift, to identify good reasons for the change, or to explain why EPA believes the proposed rule would be an improvement over current mechanisms utilized by EPA to ensure the integrity of EPA's actions.

2. EPA's Proposal fails to consider important implementation problems that existing EPA and federal government policies place at the forefront.

An agency rule is arbitrary and capricious if it "entirely failed to consider an important aspect of the problem."[413] EPA's Proposal completely fails to consider the numerous barriers that currently exist to making underlying data public. As highlighted in OMB and EPA policies, there is an understanding that the worthy goal of ensuring greater transparency of scientific information is in tension with other compelling, competing interests such as privacy and confidentiality. When these two are in tension, existing policies have recognized that this will prevent certain data from being publicly released—and that agencies still need to be able to use scientific information in these circumstances. Transparency goals should not override the ability of the agency to rely on otherwise valid scientific information as it goes about achieving its core mission. While the Proposal purports to take into account privacy and confidentiality concerns, it appears to do so by either grossly oversimplifying EPA's ability to address these concerns or by deeming all such information unusable—essentially completely failing to consider the problems of this approach.

OMB Circular A-130 recognizes that the values of openness, transparency, and allowing the free flow of information between the federal government and the public are important values, they must be contextualized. Thus, it cautions: "Promoting openness and interoperability, *subject*

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[411] 83 Fed. Reg. at 18,769 n. 2 ("If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking.")

[412] *Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity* (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009), https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09 (emphasis added).

[413] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

to applicable legal and policy requirements, increases operational efficiencies, reduces costs, improves services, supports mission needs, and increases public access to valuable Federal information."[414] Similarly it states: "The open and efficient exchange of scientific and technical Federal information, *subject to applicable security and privacy controls* and the proprietary rights of others, fosters excellence in scientific research and effective use of Federal research and development resources."[415] Circular A-130 makes clear that "[p]rotecting an individual's privacy is of utmost importance. The Federal Government shall consider and protect an individual's privacy throughout the information life cycle."[416] It requires that agencies recognize that "Federal information is managed by making information accessible, discoverable, and usable by the public to the extent permitted by law and *subject to privacy, security (which includes confidentiality), or other valid restrictions pertaining to access, use, dissemination, and disclosure*. . . ."[417]

Further, Circular A-130 requires agencies to "[l]imit the creation, collection, use, processing, storage, maintenance, dissemination, and disclosure of [personally identifiable information] to that which is legally authorized, relevant, and reasonably deemed necessary for the proper performance of agency functions" and "[t]o the extent reasonably practicable. . .reduce all [personally identifiable information] to the minimum necessary for the proper performance of authorized agency functions."[418]

The appendix to the Circular realizes that privacy protections require ongoing progress and:

> Emerging technologies and services may continue to shift the ways in which agencies acquire, develop, manage, and use information and technology. As technologies and services continue to change, so will the threat environment. Agency programs must have the capability to identify, respond to, and recover from current threats while protecting their information resources and the privacy of the individuals whose information they maintain.[419]

OMB Memorandum M-14-06 specifically lays out policies intended to help agencies make the most of "administrative data that cannot be made publicly available due to statutory, regulatory, or policy protections," for statistical purposes, including "activities typically characterized as research, evaluation, and analysis, as long as the focus of those activities is on reporting aggregate findings about a group."[420] It notes "[s]ome administrative data can be publicly released, whereas other administrative data cannot be released. . . [and] it is the case that both types of administrative data (public and nonpublic) can be useful for Federal statistical

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[414] OMB Circular A-130 at 3 (emphasis added).
[415] *Id.* at 4 (emphasis added).
[416] *Id.*
[417] *Id.* at 14 (emphasis added).
[418] *Id.* at 17.
[419] *Id.* at Appendix 1-1.
[420] OMB Memorandum M-14-06 at 6.

purposes," suggesting agencies should not abandon reliance on data not able to be publicly released.[421]

OMB Memorandum M-11-02 "strongly encourages Federal agencies to engage in coordinated efforts to share high-value data" but notes that in certain cases sharing data will contravene other compelling concerns and that federal agencies need to think about applicable privacy laws, regulations, and policies to "fully protect[] individual privacy" and preserve public trust.[422] Unlike the Proposal, it takes a more nuanced approach recognizing that sharing data is not always appropriate and should only be done "responsibly and appropriately."[423]

OMB recognizes that even when just sharing information among agencies, privacy concerns must be weighed against those benefits that agencies can achieve with sharing data: "Agencies should work together to determine what data sharing opportunities are desirable, feasible, and appropriate. In general, data sharing should only be pursued if the benefits outweigh the costs."[424]

OMB Memorandum M-10-06 also encourages "a plan for timely publication of the underlying data. . . in an open format and as granular as possible, consistent with statutory responsibilities and subject to valid privacy, confidentiality, security, or other restrictions."[425] The memorandum aims to achieve "transparency, participation, and collaboration,"[426] recognizing that not making data available does not deter those goals when there are valid concerns and the legitimacy of the data is not otherwise questioned.

EPA's *Draft Strategic Data Action Plan Version 1.0* similarly aims to work towards a more open government, and to increase the public's access to high quality data. However, the agency recognizes barriers to this goal, not applying the plan to "data resources containing Confidential Business Information (CBI) or sensitive data that are not available for public access."[427] In similarly recognizes that "[i]n order to protect the privacy and security of the public, businesses, and US Government staff and operations, some types of data may be deemed sensitive and will not be made public or published on Data.gov."[428]

These all highlight instances where EPA and OMB have recognized that privacy and confidentiality present ongoing concerns that are not easily addressed and that conflict with other aims of federal government. Yet, they recognize that protecting information in these cases is a valid path, and not making data public does not compromise the validity of the findings or

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[421] *Id.* at 2.
[422] OMB Memorandum M-11-02.
[423] *Id.*
[424] Memoranda 01-05 -- Guidance on InterAgency Sharing of Personal Data - Protecting Personal Privacy (Dec. 20, 2000), https://www.whitehouse.gov/wp-content/uploads/2017/11/2001-M-01-05-Guidance-on-Inter-Agency-Sharing-of-Personal-Data-Protecting-Personal-Privacy.pdf.
[425] OMB Memorandum M-10-06 on Open Government Directive at 8.
[426] *Id.* at 1.
[427] EPA, *Draft Strategic Data Action Plan Version 1.0* 3 (Mar. 2011) https://www.epa.gov/sites/production/files/documents/epa_sdap_v1.0.pdf.
[428] *Id.* at 14.

conclusions upon which the data is based and should prevent agencies from using those findings, conclusions, and data to inform their work. The Proposal provides no explanation for why EPA is now changing its view to a conflicting one, making the Proposal arbitrary.

III. The Proposed Rule's Peer Review Provisions Raise Numerous Concerns.

Proposed section 30.7 provides that "EPA shall conduct independent peer review on all *pivotal regulatory science* used to justify *regulatory decisions* consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review (70 Fed. Reg. 2664) and the exemptions described therein." This proposed provision generally appears to be designed to enshrine OMB's existing peer review requirements for "influential scientific information."[429]

Remarkably, the preamble to the proposed rulemaking lacks any explanation whatsoever for why EPA is proposing this new peer review requirement or what its impact might be. EPA has additionally not provided any information to suggest that EPA is not already following OMB's Peer Review Bulletin. EPA's lack of any supporting rationale or analysis frustrates the public's ability to provide meaningful comment on this provision,[430] and is itself a sign that this requirement is fundamentally arbitrary. In addition, the discussion below outlines several specific concerns with this proposed regulatory requirement.

A. EPA Has Failed to Consider the Costs of Making OMB Peer Review Requirements Judicially Enforceable.

The most obvious change wrought by EPA's incorporation of OMB's Peer Review Bulletin into EPA's regulations is that it apparently would make the OMB Peer Review requirements judicially enforceable. At present, OMB Peer Review Bulletin requirements are not judicially enforceable.[431] Rather, the Bulletin "specifically disclaims that its contents create any enforceable rights, thereby preserving the agency's discretion to interpret and apply" the Bulletin.[432] If EPA finalizes its proposed peer review rules, EPA may find itself subject to countless legal challenges to its regulations based on compliance with OMB Peer Review requirements. These additional legal challenges would come at a cost, including the financial cost of increased litigation as well as the cost to public health and the environment when unwarranted legal challenges lead to lengthy delays in implementation of needed regulatory protections. Given that EPA is already subject to OMB Peer Review requirements, it is unclear

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[429] OMB, *Final Information Quality Bulletin for Peer Review*, 70 Fed. Reg. 2664, 2677 (Jan. 14, 2005) [Hereinafter: OMB Peer Review Bulletin].

[430] *See Connecticut Light & Power Co. v. Nuclear Regulatory Com.*, 673 F.2d 525, 530 (D.C. Cir. 1982) ("The purpose of the comment period is to allow interested members of the public to communicate information, concerns, and criticisms to the agency during the rule-making process. If the notice of proposed rule-making fails to provide an accurate picture of the reasoning that has led the agency to the proposed rule, interested parties will not be able to comment meaningfully upon the agency's proposals."); *Honeywell Int'l, Inc. v. EPA*, 372 F.3d 441, 445, (D.C. Cir. 2004) ("Under the Administrative Procedure Act, a notice of proposed rulemaking must "provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully.").

[431] OMB Peer Review Bulletin § XII, 70 Fed. Reg. at 2674 ("This Bulletin is intended to improve the internal management of the executive branch, and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.").

[432] *Family Farm Alliance v. Salazar*, 749 F.Supp. 2d 1083, 1095 (E.D. Ca. 2010).

whether the proposed regulation would provide any new benefits in terms of ensuring that EPA's regulations are based on valid and unbiased science. Yet the administrative record for this proposed rulemaking is devoid of any EPA analysis of the costs and benefits of making the existing peer review requirements judicially enforceable. EPA must carefully evaluate the anticipated costs and benefits from these proposed regulatory requirements and provide a reasoned explanation for why they are needed.

B. EPA Must Clarify that Studies that Have Already Been Adequately Peer-Reviewed by Third Parties Need Not be Re-Reviewed by EPA.

Because proposed section 30.7 expressly incorporates the OMB Peer Review Bulletin "and the exemptions described therein," it appears that EPA intends to incorporate the OMB Peer Review Bulletin provision providing that "agencies need not have further peer review conducted on information that has already been subjected to adequate peer review."[433] However, there is some ambiguity due to language in proposed section 30.7 instructing that EPA must "ask peer reviewers to articulate the strengths and weaknesses of EPA's justifications for the assumptions applied and the implications of those assumption for the results." Obviously, peer review conducted prior to EPA's reliance on a study would not have involved review of the strengths and weaknesses of EPA's justifications. If EPA were required to re-peer review all influential scientific information, this rulemaking would burden EPA with needless and significant costs that likely would bring many EPA rulemakings to a standstill, preventing EPA from fulfilling its statutory mission of protecting public health and the environment. To prevent this from happening, EPA must clarify that the proposed rule will not supplant EPA's existing authority under the OMB Peer Review Bulletin not to conduct further peer review where information has already been subject to adequate peer review—and that such prior peer review is not subject to the requirement in proposed section 30.7 that reviewers consider the strengths and weaknesses of EPA's justifications.

C. EPA Must Clarify the Intent of the Exemption Provision with Respect to Peer Review Requirements and Confirm that the OMB Peer Review Bulletin's Waiver Provision Would Remain in Effect for EPA.

EDF does not support the peer review provisions for the reasons detailed in this section, but if EPA moves ahead with these proposed provisions, EPA must revise the proposed regulatory language to clarify that the waiver authority provided by the OMB Peer Review Bulletin—which OMB itself has emphasized "ensure[s] needed flexibility"—would remain in effect for EPA even if EPA finalizes the proposed peer review regulations.[434]

Proposed section 30.9(b) provides that the Administrator may grant an exemption from the peer review requirements if he or she determines that "[it] is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality for Peer Review (70 FR 2664), Section IX." Oddly, however, only two of the seven enumerated exemptions in Section IX of the OMB Peer

[433] OMB Peer Review Bulletin, 70 Fed. Reg. at 2675.
[434] OMB Peer Review Bulletin, 70 Fed. Reg. at 2673.

Review Bulletin pertain to feasibility—Exemption 1 governing "national security, foreign affairs, or negotiations involving international trade or treaties" and Exemption 3 governing time-sensitive health or safety disseminations.[435] If EPA decides to finalize peer review requirements, EPA must amend its proposed regulation to clarify that all of the exemptions set forth in section IX of the OMB Peer Review Bulletin remain in effect regardless of whether they pertain to feasibility. Furthermore, EPA must clarify what, if any, additional effect is intended by the exemption provision in proposed section 30.9.

Additionally, EPA must amend the proposed rule to confirm that the "Deferral and Waiver" provision set forth in Section VIII of the OMB Peer Review Bulletin remains in effect for EPA. That provision provides: "The agency head may waive or defer some or all of the peer review requirements of Sections II and III of this Bulletin where warranted by a compelling rationale. If the agency head defers the peer review requirements prior to dissemination, peer review shall be conducted as soon as practicable."[436] OMB explained that this provision "ensure[s] needed flexibility in unusual and compelling situations not otherwise covered by the exemptions in the Bulletin before information is disseminated."[437] If EPA were to finalize the "exemption" language in proposed section 30.9(b) without clarification, it is possible that it could be read to encompass the entirety of the Administrator's ability to grant exemptions, supplanting Section VIII of the OMB Peer Review Bulletin.

D. EPA Must Clarify How the Proposed Rule Would Impact EPA's Existing Peer Review Handbook.

EPA's Peer Review Handbook incorporates the provisions of OMB's Peer Review Bulletin.[438] In the Handbook, EPA confirms that it "conducts peer review of its products in accordance with the guidance in the OMB Peer Review Bulletin."[439] However, the EPA Peer Review Handbook adds details and specific procedures that are not present in the OMB Peer Review Bulletin.

Surprisingly, EPA's proposed peer review regulations do not even mention EPA's Peer Review Handbook, let alone explain how the new proposed regulations would impact EPA's compliance with the Handbook. For example, EPA's Handbook specifies "exemption criteria" in Section 3.3.[440] EPA must clarify whether anything in the proposed peer review regulation would supplant instructions in the Peer Review Handbook, and if so, provide a reasoned explanation for the change. Likewise, EPA must explain the role of the Peer Review Handbook going forward in administering peer review requirements.

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[435] OMB Peer Review Bulletin, 70 Fed. Reg. at 2674.
[436] OMB Peer Review Bulletin, 70 Fed. Reg. at 2673.
[437] OMB Peer Review Bulletin, 70 Fed. Reg. at 2673.
[438] U.S. EPA, *Science and Technology Policy Council Peer Review Handbook*, 4th Ed. (2015), https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf. [Hereinafter: EPA Peer Review Handbook].
[439] EPA Peer Review Handbook at 26.
[440] EPA Peer Review Handbook at 44-45.

IV. The Proposal Would Impose Arbitrary and Inappropriate Methods for Assessing Health Risks

A. EPA's Proposal Seeks to Undermine Key Scientific and Public Health Tenets Relating to Dose-Response and the Use of Defaults.

The proposed rule asserts that a broad interest of the current Administration is to "ensure that the data and models underlying scientific studies that are pivotal to. . . regulatory action are available to the public"[441] and to "change agency culture and practices regarding data access so that the scientific justification for regulatory actions is truly available for validation and analysis."[442] However, the Proposal specifies a particular interest and initial focus on "dose response data and models" as evident throughout the preamble and proposed regulatory provisions.

Dose-response studies are a critical element of risk assessments for toxicants including air pollutants. Assessment of a toxicants risks typically proceeds through a four-step process: 1) hazard identification, 2) dose-response assessment, 3) exposure assessment, and 4) risk characterization.[443] Dose-response assessment describes the relationship between exposure to a toxicant and observed effect on human or ecological receptor. EPA provides the following description of dose-response on its website: "Dose-Response Assessment...characterizes the quantitative relationship between chemical exposure and each credible health hazard. These quantitative relationships are then used to derive toxicity values."[444] Dose-response plays a central role in the evaluation of chemical risks as it provides the characterization of the potency or effect size of the toxicant. In other words, dose-response assessment is used to determine the levels of exposure at which adverse effects will occur and thus informs what risk management actions should be taken to protect human and ecological health. Dose-response assessments are commonly used to derive chemial toxicity values. The lower a substance's toxicity value the greater its potency and the less exposure is necessary for an effect to occur.

EPA reveals the underlying motivation behind its interest in transparency of dose-response data and models on page eight of the Proposal, where it states:

> In addition, this proposed regulation is designed to increase transparency of the assumptions underlying dose response models. As a case in point, there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects. The use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions. To be even more transparent about these complex relationships, EPA should give appropriate consideration to high quality studies

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[441] Proposed Rule, 83 Fed. Reg. at 18769-70.
[442] Proposed Rule, 83 Fed. Reg. at 18770.
[443] EPA, *Conducting a Human Health Risk Assessment*, https://www.epa.gov/risk/conducting-human-health-risk-assessment (last accessed Aug. 16, 2018).
[444] EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system (last accessed Aug. 16, 2018).

> that explore: A broad class of parametric concentration-response models with a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the exposure range; and spatial heterogeneity. EPA should also incorporate the concept of model uncertainty when needed as a default to optimize low dose risk estimation based on major competing models, including linear, threshold, and U-shaped, J-shaped, and bell-shaped models.[445]

This excerpt raises several troubling and erroneous concepts that are contrary to core scientific tenets and best practices in chemical hazard and risk assessment as discussed extensively in a seminal 2009 report by the National Academies (Academies): *Science and Decisions: Advancing Risk Assessment (Science and Decisions)*.[446] The report was requested and sponsored by EPA's National Center for Environmental Assessment and was developed over a three-year period by a 15-member committee that included state environmental agencies, non-governmental organizations, industry, and academic institutions. The committee was specifically tasked with "developing scientific and technical recommendations for improving risk analysis approaches used by EPA, including providing practical improvements that EPA could make in the near term (2-5 years) and in the longer term (10-20 years)."[447] The report has been cited over 400 times in the scientific literature.

The Proposal fails to discuss these best practices for risk assessment, much less provide any persuasive reason for departing from them. The Proposal provides no support for its assertion that there is "growing empirical evidence" of nonlinearity in dose-response relationships; fails to acknowledge or contend with the National Academies' finding that non-threshold dose-response relationships are common for toxicants, and should be assumed as a default; fails to discuss the well-known rationales put forward by the National Academies for using default models; and irrationally prioritizes consideration of studies that employ a wide range of dose-response models, without any consideration for whether those alternative dose-response models are appropriate for risk assessment. Alarmingly, the Proposal offers no analysis of how the proposed requirements to consider threshold-response relationships and avoid default models would further the protection of human health and the environment—and gives no indication that the Agency has considered whether its proposed approach affords appropriate protection for the public in evaluating the risks of dangerous pollutants and toxicants. The proposed requirement is irretrievably arbitrary and unjustified, and must be withdrawn.

1. The proposal arbitrarily dismisses linear (i.e., non-threshold) dose-response relationships.

EPA makes a blanket assertion that "there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects" without any evidentiary basis.[448] In contrast, in *Science and Decisions*, the Academies discussed at length the

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[445] Proposed Rule, 83 Fed. Reg. at 18770.
[446] National Academies, *Science and Decisions: Advancing Risk Assessment* (2009), https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment.
[447] *Id.*
[448] Proposed Rule, 83 Fed. Reg. at 18770.

evidence for the opposite. Namely, non-linear dose-response relationships—that is the existence of thresholds of chemical exposure below which effects are not expected to be observed—is the exception rather than the rule when considering background exposures, co-exposures, variability across the diverse population and other considerations. The *Science and Decisions* report notes:

> . . . [A]n individual's risk from exposure to an environmental chemical is determined by the chemical itself, by concurrent background exposures to other environmental and endogenous chemicals that affect toxicity pathways and disease processes, and by the individual's biologic susceptibility due to genetic, lifestyle, health, and other factors. How the population responds to chemical insults depends on individual responses, which vary among individuals.[449]

In this regard, it is important to note that risk assessments are typically designed to estimate incremental risk in the population due to exposure to a single hazard. As discussed by the Academies, individual risk is determined by both the chemical exposure and an individual's unique circumstance of factors (e.g., co-exposures and susceptibilities). Cancer incidence in the population illustrates the significance of these additional factors in considering actual individual risk to a particular chemical exposure. Individual lifetime risk of developing cancer is 1 in 3, and 1 in 5 for dying from cancer,[450] indicating a substantial population baseline risk resulting from a large number of exposures and other risk factors. Assuming that there is somehow a threshold for everyone cannot be supported by the evidence. Therefore, given that the mission of EPA is to protect public health, the linear approach is most appropriate unless there is strong evidence in favor of an alternative as recommended in *Science and Decisions*.

EPA currently approaches risk assessment of 1) carcinogens and 2) noncarcinogens and carcinogens "acting through an MOA [mode of action] considered nonlinear at low doses"[451] separately—applying a linear dose-response framework for the former and a non-linear dose-response framework for the latter. The Academies strongly argued against this arbitrary distinction and recommended a uniform *linear* approach to the assessment of all chemicals. Indeed, for carcinogens purported to have a non-linear MOA, the Academies indicated:

> . . . omissions in this overall approach for low-dose nonlinear carcinogens could yield inaccurate and misleading assessments. . . . [T]he current EPA practice of determining "nonlinear" MOAs does not account for mechanistic factors that create linearity at low dose. The dose-response relationship can be linear at a low dose when an exposure contributes to an existing disease process. Effects of exposures that add to background processes and background endogenous and exogenous exposures can lack a threshold if a baseline level of dysfunction occurs without the toxicant and the toxicant adds to or augments the background process. Thus, even small doses may have a relevant biologic effect. That may be difficult

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[449] National Academies, *Science and Decisions: Advancing Risk Assessment* 135 (2009).
[450] American Cancer Society, Lifetime Risk of Developing or Dying From Cancer, https://www.cancer.org/cancer/cancer-basics/lifetime-probability-of-developing-or-dying-from-cancer.html (last revised Jan. 4, 2018).
[451] National Academies, *Science and Decisions: Advancing Risk Assessment* 129 (2009).

> to measure because of background noise in the system but may be addressed through dose-response modeling procedures. Human variability with respect to individual thresholds for a nongenotoxic cancer mechanism can result in linear dose-response in the population.[452]

Similarly, for noncarcinogens, the Academies indicated that "noncarcinogens can exhibit low-dose linearity, for example, when there is considerable interindividual variability in susceptibility and each individual has his or her own threshold, especially when an underlying disease (such as cardiopulmonary disease) can interact with the toxicant (such as particulate matter [PM] or ozone)."[453]

The Academies ultimately and definitively recommended that "cancer and noncancer responses be assumed to be linear as a default. . . [and that] [a]n alternative analytic option. . . is available for cases in which it can be shown that background is unlikely to be an important contributor to risk, according to the recommended evaluation of MOAs and background."[454]

2. The proposal improperly dismisses defaults.

EPA's Proposal also indicates an interest and intent to move away from "default models, without consideration of alternatives or model uncertainty" which purportedly "can obscure the scientific justification for EPA actions."[455] Here, EPA demotes and ignores the purpose of science-based defaults, in suggesting that they "obscure the scientific justification for EPA actions" while simultaneously encouraging routine application of model alternatives without meaningful justification or substantiation.

Again, EPA's Proposal deviates significantly from the recommendations in *Science and Decisions* where the Academies wrote,

> [D]efaults need to be maintained for the steps in risk assessment that require inferences or to fill common data gaps. Criteria are needed for judging whether, in specific cases, data are adequate to support a different inference from the default (or whether data are sufficient to justify departure from a default).[456]

The Academies further recommended that 1) "EPA should continue and expand use of the best, most current science to support or revise its default assumptions," 2) "work toward the development of explicitly stated defaults to take place of implicit or missing defaults," and 3) that "departure [from defaults] should occur only when the evidence of the plausibility of alternatives is clearly superior to the evidence of the value of the default."[457] These recommendations underscore and reaffirm the role of defaults, and make clear that deviations

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[452] National Academies, *Science and Decisions: Advancing Risk Assessment* 129-30 (2009).
[453] National Academies, *Science and Decisions: Advancing Risk Assessment* 131 (2009).
[454] National Academies, *Science and Decisions: Advancing Risk Assessment* 180 (2009).
[455] Proposed Rule, 83 Fed. Reg. at 18770.
[456] National Academies, *Science and Decisions: Advancing Risk Assessment* 207 (2009).
[457] *Id.*

from defaults are to be considered carefully, on a case-by-case basis, and only when adequately justified.

3. The Proposal arbitrarily promotes studies that include a variety of dose-response models.

EPA's Proposal promotes the use of studies that explore a variety of dose-response models. Use of dose-response models to estimate pollutant or chemical risk should generally address issues such as goodness-of-fit, confidence bounds around predicted risks, biological plausibility, and sensitivity of the prediction to untested assumptions.[458]

However, giving higher weight to studies that use a wide range of models just because they use a wide range models is wholly inappropriate, arbitrary, and without scientific or public health justification. In fact, it creates a perverse incentive to apply multiple models to data without regard to appropriateness of fit and underlying assumptions (among other key considerations), and importantly, without regard to public health and ecological protection. It is worth noting that nowhere in the Proposal has the agency articulated how this requirement would further its primary mission and purpose of protecting human health and the environment.

There are numerous dose-response analyses that could be applied to any data set. Any analysis of the data assumes an underlying statistical distribution of the data, models for mean response, variance structures, shapes, and other data fit considerations that are subject to choice in the formal analysis. Scientists have historically used a reduced set of science-based, empirically supported models for specific types of data that have obtained widespread acceptance. EPA's specification of various types of modeling approaches the agency should consider ignores this reality.

4. The proposed rule provides no justification for codifying scientific approaches into regulation.

The proposed rule's provisions addressing dose-response models are inappropriate for the numerous reasons discussed in this section. They also unnecessarily and inappropriately memorialize highly complex and technical scientific issues into regulation—a generally frowned approach given the inherently evolving nature of science. These issues are more appropriately dealt with in guidance, a more flexible vehicle better equipped for adapting to new scientific understanding and in this way supporting use of best available science.

V. EPA Fails to Adequately Consider Costs and Benefits of the Proposal.

It is arbitrary and capricious to "'entirely fai[l] to consider an important aspect of the problem' when deciding whether regulation is appropriate." *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (quoting *State Farm*, 463 U.S. at 43). As in *Michigan*, failure to consider the costs and benefits of a regulation where there is no statutory bar to doing so is arbitrary and capricious.

[458] Nat'l Research Council, Health Risks from Dioxin and Related Compounds: Evaluation of the EPA Reassessment (2006), https://www.nap.edu/catalog/11688/health-risks-from-dioxin-and-related-compounds-evaluation-of-the.

The proposed rule entirely fails to comply with the requirements of non-arbitrary-and-capricious rulemaking because it fails to disclose, much less analyze or consider, any of the costs of the rule; barely discusses and does not analyze or quantify the benefits; does not provide any *reasoned* explanation of why the benefits of the rule justify its costs; and does not consider potential alternatives. The Proposal's discussion of costs and benefits is a scant two paragraphs[459] (and was apparently not included at all in the version sent to the Office of Management and Budget).[460] The proposed rule begins by conclusorily asserting that "EPA believes the benefits of this proposed rule justify the costs."[461] It then briefly discusses the perceived benefits, incorrectly suggesting that the National Academy of Sciences shares EPA's view by citing to a publication that discusses both *risks* and opportunities of expanding access to research data, and does not discuss *at all* the costs and benefits of *ignoring* relevant science in regulatory decisionmaking.[462] It then merely states that the "action should be implemented in a cost-effective manner," citing vaguely to "recent activities of the scientific community and other federal agencies" without any concrete examples or analysis.[463] The preamble's discussion emphasizes that the Proposal does not compel EPA to make information available where it concludes that doing so is not possible, but omits that if compliance is not possible, EPA will not consider the study, which has its own costs. It then concludes by citing the working paper of the Mercatus Center[464] that baldly asserts that improvements in reproducibility "can be thought of as increasing the net benefits of regulation because they would avoid situations in which costs or benefits are wrongly estimated to occur or in which regulatory costs are imposed without corresponding benefits."[465] Setting aside the lack of substantiation for this assertion, it entirely omits situations in which costs and benefits are wrongly estimated because the relevant science is not used—and the costs that would be imposed on society if EPA inadequately protects communities from harmful pollution or toxic exposures.

Indeed, the Proposal *nowhere* discusses its significant costs in either quantitative or qualitative terms, costs that have actually been examined by independent organizations, and that are susceptible to analysis. If the Proposal is truly "designed to provide a mechanism to increase access to" data "in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants," 83 Fed. Reg. at 18,770, then it will have significant costs. And if, as it appears, the Proposal's true "mechanism" is excluding science from regulatory decisionmaking, its costs will be even greater in the form of insufficiently protective regulations.

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[459] Proposed Rule, 83 Fed. Reg. at 18,772.

[460] *Compare*, EO 12866 Proposal 2080-AA14 OIRA Conclusion Document (Docket ID. No. EPA-HQ-OA-2018-0259-0006) *with* EO 12866 Proposal 2080-AA14 OIRA Review Start Document (Docket ID. No. EPA-HQ-OA-2018-0259-0007).

[461] Proposed Rule, 83 Fed. Reg. at 18,772.

[462] *Id.*

[463] *Id.*

[464] For a proposal allegedly aimed at increasing transparency, it is notable that EPA does not disclose that Charles Koch—an outspoken opponent of public health protections who stands to gain financially from deregulation—is a board member of the Mercatus Center. Mercatus Center, *Charles Koch*, https://www.mercatus.org/charles-koch (last accessed: Aug. 1, 2018).

[465] Proposed Rule, 83 Fed. Reg. at 18,772.

If it were not possible to quantify and monetize any of the costs, which is not the case here as discussed below, EPA would still be required under E.O. 12866 and the requirements of rational rulemaking to identify and discuss the qualitative costs of this Proposal. It is inherently irrational for an agency to take an action without any consideration of any costs, disadvantages or negative effects of that action. The qualitative costs of this Proposal include the costs to researchers of actions they must undertake to protect the confidentiality of patient and subject data, as well as to compile and make public their raw data, and the potential loss of subjects (and attendant damage to research efforts and results) due to confidentiality concerns. There are also various costs to the agency of administering the regulation, which include contacting researchers, gathering data, ensuring that patient confidentiality and confidential business information are not disclosed. Additional costs could also be incurred through conducting any additional peer reviews required by proposed section 30.7 and any additional analyses imposed by proposed section 30.6's requirement that "EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions." Most importantly, there are potentially huge costs of regulating without using the relevant science merely because the underlying raw data is not publicly available. If studies supporting a stronger standard are excluded and EPA can therefore only justify a weaker requirement that leaves large numbers of people at risk of health effects from a pollutant, pesticide, or chemical, then this Proposal could impose enormous costs for each insufficiently protective regulation.[466] Yet the Proposal fails even to mention these costs, let alone discuss their scope and significance.

In addition, many of these costs can be quantified and monetized, but EPA has neither attempted to do so nor explained why it could not. For example, EPA has extensive information available to it on what the agency would need to do to implement this Proposal and how much those activities would cost. In fact, EPA already gathered much of this data and provided it to the Congressional Budget Office for use in estimating the costs of a similar (though not identical) proposal from Congress, the HONEST Act. With respect to the Congressional proposal, CBO concluded, just with respect to the costs to EPA, that "based on information from the EPA and other federal agencies, as well as organizations and researchers in the scientific community that publish in peer-reviewed journals," EPA "could spend between a few million dollars per year to more than one hundred million dollars per year ... to ensure that data and other information underlying studies are publicly available in a format sufficient to allow others to substantially reproduce the results of studies."[467] In the 2017 estimate, CBO concluded that "[i]f the EPA continued to rely on as many scientific studies as it has used in recent years ... then CBO

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[466] In footnote 3 of the Proposal, Proposed Rule, 83 Fed. Reg. at 18,769, EPA suggests that the studies underlying the NAAQS for particulate matter, at issue in the case cited—*Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 358 (D.C. Cir. 2002)—are an example of data the agency would be "preclude[d]" from using in the future. The benefits of these NAAQS included up to $75,100 million in annual benefits from avoided cases of mortality in 2010 alone for a partial attainment scenario. National Research Council (US) Committee, *Estimating the Health-Risk-Reduction Benefits of Proposed Air Pollution Regulations*, 43
National Academies Press (2002), https://www.ncbi.nlm.nih.gov/books/NBK221028/.

[467] Congressional Budget Cost Estimate for H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 (Mar. 29, 2017) ("2017 CBO Estimate"); *see also* Congressional Budget Office Cost Estimate, S. 544, Secret Science Reform Act of 2015 (June 5, 2015) (estimating that another similar congressional proposal would cost up to $250 million per year).

estimates that the agency would need to spend at least $100 million dollars per year to upgrade the format and availability of those studies' data," "on average, $10,000 per scientific study."[468] Such costs would cover the costs of "obtaining all the underlying data used in a study, reviewing the data to address any confidentiality concerns, formatting the data for public access, providing access to the computer codes and models used in the study's analysis, and providing descriptions and documentation on how to access the data."[469] Notably, this does not include the cost to researchers to engage in this effort. As Deputy Assistant Administrator Nancy Beck noted, during the development of the Proposal, requiring "a huge amount of data to be submitted to the agency" would "be incredibly burdensome" and "not practical."[470]

Even the Mercatus working paper—apparently the only thing EPA relied upon in discussing the costs and benefits of the Proposal, 83 Fed. Reg. 18,772 n. 24, notes, with respect to the HONEST Act, that "[t]he cost of providing access to data has been one of the primary concerns about requiring access to data used by the federal government."[471] Far from concluding, as the Proposal suggests, an increase in net benefits from greater reproducibility, the Mercatus working paper simply explained a figure the authors were suggesting could be calculated (the point where net benefits would be positive); the authors do not themselves calculate the benefits, and admit that their "estimates of the benefits of public access to data supporting federal regulatory decisions fall short of proving that the benefits outweigh the associated costs."[472] And while the Mercatus working paper disagrees with CBO's cost estimates, it does not argue that that requiring access to data is cost-less; indeed, it discusses the "costly activities and services that need to be performed," including activities related to "data collection and data accessibility."[473] According to that working paper, data collection requires "correspond[ing] with researchers and publishers to obtain the data, review[ing] the data for confidentiality concerns, format[ting] the data for public access, publicly post[ing] the computer code and models used in each study's analysis, and provid[ing] descriptions and documentation on how to obtain the date."[474] Data accessibility requires "computer processing services to construct and maintain data bases to store study-related information."[475] While the actual calculations put forward by the Mercatus working paper appear faulty (for example, it entirely omits the cost to researchers to compile and make their data public, does not include the costs of ensuring patient privacy is protected,[476] and makes assumptions about the similarity of a chemical manufacturer collecting its own studies and EPA collecting and disseminating information of other researchers), the working paper at least acknowledges that there are costs, something EPA's Proposal completely ignores.

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[468] 2017 CBO Estimate at 3.
[469] *Id.*
[470] Email from Nancy Beck to Richard Yamada (Jan. 31, 2018 2:51 PM).
[471] Mercatus Working Paper 19.
[472] *Id.* at 27-29.
[473] *Id.* at 20.
[474] *Id.*
[475] *Id.* at 20-21 (quoting CBO, "Cost Estimate, S. 544, Secret Science Reform Act of 2015," June 5, 2015).
[476] For example, this may require special archiving and access arrangements to limit data sharing, such as those in NIH data sharing plans, which NIH requires only for studies that receive more than $500,000 in federal funding in a year. NIH, NIH Data Sharing Policy and Implementation Guidance, https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm (last accessed Aug. 16, 2018).

Nor does the proposed rule disclose the cost—highlighted on the very first page of a National Academy of Sciences (NAS) report on data access—that "perceived risks to privacy and confidentiality reduce survey participation," a cost that the NAS explains is "borne out by research."[477] NAS explains that this "threatens the research enterprise itself, because concerns about privacy and confidentiality are among the reasons often given by potential respondents for refusing to participate in surveys, and those concerns have been shown to affect behavior as well.[478] The NAS panel emphasized: "Any confidentiality breach that became known would be likely to heighten such concerns and, correspondingly, reduce survey response rates. Efforts to increase researchers' access to data must, therefore, take into account the need to avoid increasing the actual and perceived risks of confidentiality breaches."[479] The Proposal does not so much as discuss this potential cost.

This confidentiality risk has a further cost: it affects the quality of the data collected. As the NAS explained:

> The reason for confidentiality pledges and for stringent procedures to prevent disclosure is that they improve the quality of data collected from individuals, households, and firms. It is essential that respondents believe they can provide accurate, complete information without any fear that the information will be disclosed inappropriately. Indeed, if the information was disclosed, harm might come to an individual respondent.[480]

The Proposal's only acknowledgment of this complex problem and cost is its statement that "EPA believes that concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government."[481] Remarkably, EPA does not cite a single example of these common solutions, citing only vaguely to "examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau" and some hyperlinks not in the Proposal added to the docket almost a month into the comment period.[482] Accordingly, not only does the Proposal include no analysis of these alleged solutions and their costs and benefits, it does not even explain what the solutions are that EPA believes address this concern.

And if EPA complies with the regulation *not* by spending the money to make data publicly available, and if the research community does not bear those costs itself, *see* 83 Fed. Reg. at 18,770-71 ("Nothing in the proposed rule compels the disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections."), then it appears that EPA would simply ignore studies that do not comply with the regulation. *See* 83 Fed. Reg. at 18,769 n. 3 ("EPA is proposing to exercise its discretionary authority to establish a

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[477] National Research Council, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, vii National Academies Press (2005).
[478] *Id.* at 51; *see also id.* at 52-54 (describing the research supporting this risk).
[479] *Id.* at 51.
[480] *Id.*
[481] 83 Fed. Reg. at 18,770.
[482] *Id.*

policy that would preclude it from using such data in future regulatory actions."). That course of action has its own significant costs, and EPA provides no analysis in the Proposal of the magnitude of studies that it has previously relied upon that it could no longer rely upon in regulating. *See* 2017 CBO Estimate ("EPA officials have explained to CBO that the agency would implement H.R. 1430 with minimal funding and generally would not disseminate information for the scientific studies that it uses to support covered actions. That approach to implementing the legislation would significantly reduce the number of studies that the agency relies on when issuing or proposing covered actions…."). As the SAB noted in its May 12, 2018 letter, "[t]he proposed rule does not include any assessment of the impact of data restrictions on existing or future regulatory programs. Without access to the restricted data, regulatory programs could become more or less stringent than they otherwise would be, with consequences for both regulatory costs and benefits."[483]

Likewise, EPA has included only a cursory mention of the expected qualitative benefits of the Proposal, with no discussion of the anticipated likelihood, scope, or impact of the suggested benefits, let alone any effort to quantify them, much less monetize them. EPA simply assumes that the Proposal will "improve the data and scientific quality of the Agency's actions and facilitate expanded data sharing an exploration of key data sets" without any analysis or evidence. In fact, as we have explained, the likely outcome of the Proposal is that it will degrade the data and scientific quality of the Agency's actions by ignoring relevant science simply because the underlying data is not publicly available. Moreover, EPA's finding is not consistent with the conclusions of the National Academies, as the Proposal suggests. As also explained above, the NAS report highlighted both the risks and benefits of making data publicly available and nowhere concluded that there were benefits to excluding data from the agency's regulatory decisions simply because the underlying data was not publicly available. Nor does the agency analyze how likely its Proposal is to actually facilitate expanded data sharing, and its main aim appears to be excluding science as it does not actually provide any funding, mechanisms, or best practices for sharing data.

It is more than ironic that EPA claims—without any data or analysis—that its Proposal will increase the net benefits of other regulations while it does nothing to actually consider the costs and benefits of the Proposal itself. Moreover, there is no reason to think that excluding relevant science merely because the underlying data is not publicly available would increase the net benefits of a regulation. For example, it appears that under the proposed rule EPA would exclude a peer-reviewed, published study whose conclusion had been reproduced based upon numerous different datasets (and whose underlying data, though not publicly available, had been reevaluated by outside experts), while including a study that had had no peer review, was not published, had no corroborating studies, and had not actually been replicated or reproduced, merely because the underlying data was made publicly available. That is simply not a recipe for more accurate decisionmaking.

The proposed rule also violates the APA and other statutes' requirements for reasoned decisionmaking by failing to consider any alternative approaches, much less their costs, here. This is particularly irrational in this context where it appears that many of the benefits sought by

[483] Memorandum from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science to Members of the Chartered SAB and SAB Liaisons 3 (May 18, 2018).

EPA could be largely achieved with much less burdensome and costly approaches. A critical element of reasoned decision making is consideration of alternatives which are congruent with agencies' statutory responsibilities and objectives. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48, 50 (1983) (safety agency acted arbitrarily in failing to consider alternative safety measures after rejecting passive restraints). EPA failed to consider other methods to ensure scientific robustness at the agency. For example, the SAB letter notes that "[t]he proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods."[484] The Proposal does not consider any alternatives to ensuring that studies are reliable even where the underlying data cannot be made public because of privacy or other concerns.

Furthermore, by failing to consider costs and benefits, the Proposal contravenes Executive Order 12866. Executive Order 12866 requires agencies to assess the costs and benefits of proposed regulations and propose or adopt a regulation only upon a reasoned determination that the benefits justify the costs.[485] For "significant regulatory actions," like the proposed rule, 83 Fed. Reg. at 18,772, the agency must provide:

> (i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;
> (ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and
> (iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.[486]

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[484] *Id.* at 4 (pointing to the Health Effects Institute re-analysis of the Harvard Six Cities and American Cancer Society epidemiological studies).
[485] Exec. Order 12866 § 1(b)(6)-(7) (Oct. 4, 1993).
[486] Exec. Order 12866 § 6(a)(3)(C).

The agency must also make these assessments and analyses "available to the public."[487] Executive Order 13563 reaffirms these principles and requirements, explaining that agencies "must take into account benefits and costs, both quantitative and qualitative."[488]

Agencies are further encouraged to weigh the costs and benefits of developing higher information quality in OMB's Information Quality Guidelines.[489] Costs that the Guidelines encourage agencies to consider include "costs attributable to agency processing effort, respondent burden, maintenance of needed privacy, and assurances of suitable confidentiality."[490] EPA's existing information quality guidelines track the OMB Guidelines closely. EPA's disregard of the Guidelines' recommended weighing costs and benefits further contributes to the arbitrariness of EPA's failure to consider the costs of the Proposal.

The Proposal's failure to analyze and disclose costs and benefits cannot be cured in a final regulation. Should EPA not abandon this misguided Proposal, it must re-propose it after first analyzing its costs (both to public health, to researchers, and to the agency itself) and benefits, and providing the requisite opportunity for public comment on its analysis. As discussed further below in Section VIII.D, the public cannot meaningfully comment on the proposed rule without understanding the actual costs and benefits of the Proposal, the alternatives EPA considered, and the analyses underlying EPA's assessments.

VI. EPA Fails to Comply with the Paperwork Reduction Act.

EPA and the White House Office of Management and Budget (OMB) must scrutinize the Proposal for its information collection burden, as that concept is defined under the Paperwork Reduction Act (PRA).[491] The only reference to the PRA in the Proposal is EPA's denial that this action "contain[s] any information collection activities" or "impose[s] an information collection burden."[492] But if finalized, the Proposal would significantly increase that burden in the rulemakings to which it applies. EPA and OMB cannot rationally ignore such an entirely foreseeable impact when considering this Proposal.

The PRA institutes procedural safeguards to "minimize the paperwork burden for individuals, small business, educational and nonprofit institutions," and others.[493] It requires that, prior to initiating a "collection of information," agencies must "provide 60-day notice in the Federal Register . . . to solicit comment to," inter alia, "evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency," "evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,"

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[487] Exec. Order 12,866 § 6(a)(3)(E)(i).
[488] Exec. Order 13563 § 1(a) (Jan. 18, 2011).
[489] OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication.* 67 Fed. Reg. 8452, 8453 (Feb. 22, 2002).
[490] OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication.* 67 Fed. Reg. 8452, 8453 (Feb. 22, 2002).
[491] *See* 44 U.S.C. § 3502(2), (3) (defining "burden" and "collection of information").
[492] *See* 83 Fed. Reg. at 18,772.
[493] 44 U.S.C. § 3501(1).

and "minimize the burden of the collection of the information on those who are to respond."[494] After evaluating public comments, agencies must submit the proposed collection of information to OMB for additional review and publish a notice in the Federal Register setting forth "an estimate of the burden that shall result from the collection of information" and "notice that comments may be submitted to the agency and [OMB]."[495] Any such collection of information is subject to OMB approval.[496] OMB is required to determine "whether the collection of information . . . is necessary for the proper performance of the functions of the agency."[497] A negative determination precludes the agency from initiating the collection of information.[498]

The requirements that EPA would impose through this Proposal qualify as collections of information under the PRA. The statute defines "collection of information" to include "the obtaining [or] causing to be obtained . . . of facts or opinions by or for an agency, regardless of form or format, calling for . . . answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons . . . ."[499] OMB regulations emphasize the breadth of this definition, specifying that "[a] Collection of information may be in any form or format, including . . . reporting or recordkeeping requirements; . . . policy statements; . . . rules or regulations; . . . oral communications;" and others.[500] "Any recordkeeping, reporting, or disclosure requirement contained in a rule of general applicability is deemed to involve ten or more persons."[501] The definition of "collection of information" is agnostic as to whether disclosure is "mandatory, voluntary, or required to obtain or retain a benefit," and to whether disclosure is to an agency or "members of the public or the public at large."[502]

The Proposal would impose a burden that falls squarely within the definition of "collection of information." In order to use scientific research, the agency would "obtain[] or caus[e] to be obtained . . . facts." Assuming the requirements are applied consistently, the "questions posed," or "reporting or recordkeeping requirements imposed," would be "identical." As the requirements are "contained in a rule of general applicability"—i.e., the instant Proposal—they are "deemed to involve ten or more persons." It makes no difference whether the agency seeks the information through a questionnaire, telephone call, or some other format. Nor does it matter whether the agency directly mandates that entities provide the information, or provides that entities must "voluntary[ily]" provide the information in order for research to be eligible for consideration in important rulemakings.

While EPA has refrained from detailing the mechanics by which entities would provide the information, the agency expressly contemplates that the burden of providing such information would fall at least partly to members of the public whom the PRA exists to

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[494] 44 U.S.C. § 3506(c)(2)(i), (ii), (iv).
[495] *Id.* § 3507(a)(1)(D)(ii)(V), (VI).
[496] *See id.* § 3507(a)(2).
[497] *Id.* § 3508.
[498] *Id.*
[499] 44 U.S.C. § 3502(3)(A)(i).
[500] 5 C.F.R. § 1320.3(c)(1).
[501] *Id.* § 1320.3(c)(4)(i).
[502] *Id.* § 1320.3(c), (c)(2).

protect.[503] For example, proposed regulation 40 C.F.R. § 30.5 provides that, "[w]here data is controlled by third parties, EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section." Moreover, the agency specifically "solicits comment on how to incorporate stronger data and model access requirements in the terms and conditions of cooperative agreements and grants."[504] As noted above, the PRA is implicated when collection of information is "required to obtain or retain a benefit,"[505] and OMB guidance has identified grants as a "Federal benefit" for purposes of the PRA.[506]

EPA cannot evade the PRA requirements by narrowly asserting that "this action" imposes no information collection burden and ignoring the action's entirely foreseeable future impacts. The proposal expressly "is intended to apply prospectively," suggesting that it "prospectively" requires burdensome collections of information in future rulemakings. EPA must not ignore the PRA in this rulemaking, only to claim in future rulemakings that this rule moots or constrains the PRA's application by compelling certain collections of information.

In the alternative, if EPA genuinely believes that this Proposal would not burden the public with new collections of information, then EPA's stated basis for this rulemaking is exposed as a farce. EPA claims that the Proposal would "ensure" that certain data "are publicly available" and expresses specific concern for science "developed outside the agency."[507] Collection of information, including from researchers employed outside of the federal government, is central to the purpose—and essential to the implementation—of the Proposal. Providing this information would inevitably impose a burden on researchers. If the agency does not actually intend to collect information under this Proposal, it underscores that EPA's true purpose is not to increase transparency, but rather to thwart the development and maintenance of vital public health protections on the grounds that the agency lacks the information it would need to support them.

At a minimum, EPA must acknowledge and describe the information collection burden that this Proposal would impose so that OMB and the public can conduct a proper evaluation and provide responsive comments.

VII. The Circumstances Surrounding the Proposed Rule Indicate that it Was Based on a Desire to Suppress Vital Public Health Science for the Benefit of Certain Regulated Industries.

The circumstances surrounding the development of this proposed rule underscore that it is not intended to "strengthen the transparency of EPA regulatory science."[508] Far from furthering EPA's mission of protecting human health and the environment based on the best available science, the Proposal is EPA's effort to implement failed congressional legislation that

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[503] *Cf. id.* § 1320.3(k) (defining "person" for purposes of the PRA).
[504] 83 Fed. Reg. at 18,771.
[505] 5 C.F.R. § 1320.3(c).
[506] *See* Memorandum from Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs, re: Information Collection Under the Paperwork Reduction Act 3 (Apr. 7, 2010), *available at* www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/inforeg/PRAPrimer_04072010.pdf.
[507] 83 Fed. Reg. at 18,768, 18770.
[508] 83 Fed. Reg. 18,768.

was intended to suppress rigorous science for the benefit of private industry and at the expense of public health.

EPA's Proposal is largely based upon the HONEST Act of 2017, an unenacted House bill that aimed at undermining climate and regulatory science. Available information about the Proposal's evolution indicates that regulated industries had a disproportionate role in its development. In addition, the Proposal mirrors advocacy tactics employed by the tobacco industry in the 1990's in order to suppress scientific research demonstrating the adverse health effects of cigarettes and second-hand smoke. Finally, the Proposal follows a host of instances in which the Agency, under former EPA Administrator Scott Pruitt, suppressed science and transparency—underscoring the bad faith nature of the purported justifications for this rule.

A. The Proposed Rule is an Attempt by EPA to Implement an Unenacted Congressional Bill, The HONEST Act.

EPA's Proposal is an outgrowth of a failed congressional bill, the HONEST Act. The bill was vigorously supported by Congress members with strong ties to the precise industries that would have benefited from its enactment. Internal and external EPA communications illustrate that the HONEST Act served as a precursor to EPA's Proposal. The intertwined history of the HONEST Act and EPA's Proposal cast doubt on the Agency's proffered rationale.

The HONEST Act

The HONEST Act[509] is a House bill introduced in 2017 by sponsor Representative Lamar Smith (R-TX), and is the latest manifestation of various bills aimed at undermining EPA regulation through limitations on the types of scientific research the Agency may use.[510] The HONEST Act and these related bills were introduced and passed in the House three times, but each time, failed to progress in the Senate.[511]

Like the current Proposal, the HONEST Act was touted by its proponents as an effort to enhance the transparency and credibility of regulatory science at EPA. But the HONEST Act—like the Proposal—would in fact have had the effect of limiting the scope and quality of science underlying EPA actions. Indeed the HONEST Act was widely criticized and opposed by scientists, scientific organizations, medical organizations and other scientific authorities for precisely this reason. For example, eight public health and medical associations including the American Lung Association, American Public Health Association, National Medical Association, and Physicians for Social Responsibility issued an open letter to Congress in spring 2017 opposing the HONEST Act because it "would limit the kinds of scientific data EPA can use

[509] HONEST Act, H.R. 1430, 115th Cong. (2017).

[510] *See* Secret Science Reform Act of 2014, H.R. 4012, 113th Cong. (2014); Secret Science Reform Act of 2015, H.R. 1030, 114th Cong. (2015); H.R. 1430; HONEST Act, S. 1794, 115th Cong. (2017).

[511] On March 2017, Representative Smith introduced the HONEST Act in the 115th Congress. On March 29, 2017, the bill passed the House without amendment. Most recently, Senator Mike Rounds (R-SD) introduced a Senate version of the HONEST Act on September 12, 2017. As with past versions of the bill, the Senate referred the Bill to the Committee on Environment and Public Works, but took no further action.

as it develops policy to protect the American public from environmental exposures and permit violation of patient confidentiality."[512] The American Association for the Advancement of Science and twenty-two other leading scientific organizations and research universities likewise sent a letter to House Majority Whip Kevin McCarthy in March 2017 opposing the bill and warning that it could lead to a "situation where the EPA would be prevented from using the best available science and disseminating public information in a timely fashion."[513] As we have noted elsewhere in these comments, the Congressional Budget Office – after consulting with EPA staff – likewise concluded that the HONEST Act would "significantly reduce the number of studies that the agency relies on when issuing or proposing covered actions."[514]

That the HONEST Act would suppress rather than promote good science at EPA is not surprising, given that the sponsors of the HONEST Act have a history of rejecting established climate science and strong ties to industries that would benefit from limiting the role of science in EPA rulemakings. Representative Lamar Smith is widely known as an opponent of mainstream climate science and public health and environmental safeguards.[515] In a July 24, 2017 opinion piece, Representative Smith lauded the benefits of increased atmospheric carbon dioxide: "A higher concentration of carbon dioxide in our atmosphere would aid photosynthesis, which in turn contributes to increased plant growth."[516] Smith and the sponsor of the Senate version, Mike Rounds, also receive substantial contributions from the same industries that will benefit from the proposal.[517]

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[512] Letter from Alliance of Nurses for Health Environments, American Lung Association, American Public Health Association, American Thoracic Society, Asthma and Allergy Foundation of America, Health Care Without Harm, National Medical Association, and Physicians for Social Responsibility to U.S. House (Mar. 27, 2017), http://www.lung.org/assets/documents/advocacy-archive/letter-to-us-house-opposing-2.pdf.

[513] Letter from American Association for the Advancement of Science et al. to Rep. Kevin McCarthy (Mar. 28, 2017), https://memprodaaas.s3.amazonaws.com/s3fs-public/HR%201430%20HONEST%20Act%20Multisociety%20Letter%20of%20Concern.pdf.

[514] CBO, H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 at 2 (Mar. 29, 2017), *https://www.cbo.gov/system/files?file=115th-congress-2017-2018/costestimate/hr1430.pdf*.

[515] *See, e.g.*, Rep. Lamar Smith, *Climate Change: Seven Indisputable Facts*, The Hill (Sept. 8, 2017, 5:46 PM), http://thehill.com/opinion/op-ed/252989-climate-change-seven-indisputable-facts ("Like all climate alarmists, the president wants Americans to believe there is no uncertainty about climate change....But the truth is there are more questions about climate change than there are answers. For instance, even the most advanced climate models all failed to predict the lack of warming the Earth has experienced over the last 18 years."); Lamar Smith, *The Climate Change Religion*, The Wall Street Journal: Opinion | Commentary (Apr. 23, 2015, 7:35 PM), https://www.wsj.com/articles/the-climate-change-religion-1429832149, ("When assessing climate change, we should focus on good science, not politically correct science."); Lamar Smith, *Smith: EPA Hides Truth about Climate Regulations*, Media Center: Press Releases (Aug. 13, 2014), https://lamarsmith.house.gov/media-center/press-releases/smith-epa-hides-truth-about-climate-regulations.

[516] Lamar Smith, *Don't Believe the Hysteria over Carbon*, The Daily Signal Energy: Commentary (July 24, 2017), https://www.dailysignal.com/2017/07/24/dont-believe-hysteria-carbon-dioxide/

[517] Throughout his congressional career, Representative Smith received over $787,047 in contributions from the oil and gas sector. Center for Responsive Politics, *Rep. Lamar Smith – Texas District 21: Summary*, Open Secrets: Congress, https://www.opensecrets.org/members-of-congress/summary?cid=N00001811&cycle=CAREER&type=I (last visited June 6, 2018). From 2011 to 2018, Senator Rounds received over $215,000 from oil and gas companies alone. Center for Responsive Politics, *Sen. Mike Rounds – South Dakota: Summary*, Open Secrets: Congress, https://www.opensecrets.org/members-of-congress/summary?cid=N00035187&cycle=CAREER&type=I (last visited June 14, 2018).

Representative Smith also has ties to EPA staff who drafted the proposal, underscoring the close connection between his failed legislation and this proposed rule. Dr. Richard Yamada, former professional staff member on Smith's House Committee on Science, Space & Technology now serves as the Deputy Assistant Administrator for EPA's Office of Research and Development.[518] At EPA, Dr. Yamada has participated in the drafting and development of the Agency's version of the proposal.[519]

The HONEST Act as Predecessor for the Proposal

As this section details, it is clear that the HONEST Act is a direct predecessor of this proposed rule and that both initiatives share the same purpose: to undermine EPA's use of rigorous science in crafting health and environmental protections. The language used in the proposal shares strong similarities with the HONEST Act. Furthermore, internal and external communications from EPA leadership demonstrate the proposal's origins in the HONEST Act.

While lengthier than the congressional HONEST Act, EPA's proposal contains parallel language to the bill. One can compare examples from the text of the 2017 HONEST Act as passed in the House, to the text of the proposal from the Final Federal Register Notice:

> *The HONEST Act of 2017*
> An Act: To prohibit the [EPA] from proposing, finalizing, or disseminating regulations or assessments based upon science that is not transparent or reproducible…..
>
> The Administrator shall not proposed, finalize, or disseminate a covered action unless all scientific and technical information relied on to support such covered action is—(A) the best available science; (B) specifically identified; and (C) publicly available online in a manner that is sufficient for independent analysis and substantial reproduction of search results….[520]
>
> *Strengthening Transparency in Regulatory Science Proposal*
> EPA shall clearly identify all studies (or other regulatory science) relied upon when it takes any final action. EPA should make all studies available to the public to the extent practicable . . . When promulgating significant regulatory actions, the Agency shall ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation.[521]

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[518] EPA, *Dr. Richard Yamada*, EPA Research, https://www.epa.gov/research/dr-richard-yamada. (last updated Jan. 12, 2018).

[519] Email from Richard Yamada, Deptuy Assistant Adm'r, Office of Researh and Dev., to Drew Feeley, Policy Counsel, Office of Policy; Brittany Bolen, Acting Assoc. Adm'r, Office of Policy; Clint Woods, Deputy Assistant Adm'r, Office of Air and Radiation; Justin Schwab, Deputy Gen. Counsel, Office of Gen. Counsel; Erik Baptist, Senior Deputy Gen. Counsel, Office of Gen. Counsel; and Nancy Beck, Deputy Assistant Adm'r, Office of Chem. Safety and Pollution Prevention (Jan. 29, 2019, 10:58 PM), https://drive.google.com/file/d/1peMXjBhq6lUYGGNBWbSjpOu1Zh-qLl4p/.

[520] H.R.1430 § 2(b)(1).

[521] Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768, 18,773 (Apr. 30, 2018) (proposed 40 C.F.R. §§ 30.4, 30.5).

The best available science must serve as the foundation of EPA's regulatory actions.[522]

Responsive records released to the Union of Concerned Scientists ("UCS") make evident that the HONEST Act served a predecessor to the proposal. Administrator Pruitt's schedule reveals that he met with Representative Smith on January 9, 2018, less than four months before the Federal Register announcement of the proposal.[523] Emails from Pruitt and his staff, dated just over a week after that meeting, indicate that Smith was working on a "pitch that EPA internally implement the HONEST Act."[524] Subsequent emails sent between Pruitt's EPA staff in February 2018 demonstrate that EPA officials promptly began drafting the proposal.[525]

Before Smith's internal EPA 'pitch,' Agency leadership commented favorably on the HONEST Act of 2017. Although EPA initially estimated that implementation of the act would cost over $250 million per year,[526] that estimate was never reported to the Congressional Budget Office ("CBO"). As CBO's cost estimate determination indicates, EPA political leadership diverged from the earlier estimate and instead assured CBO that the bill could be implemented "with minimal funding."[527] Several news sources have reported that the Administrator's Office of the EPA became involved in communications with CBO, and decided to respond to CBO directly with the assurance the bill could be implemented at 'no cost.'[528]

Finally, in an exclusive interview with the Daily Caller shortly before the proposal's publication, former Administrator Pruitt promised:

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[522] *Id.* at 18,769.

[523] EPA, *Calendar for Scott Pruitt, Administrator*, Senior Leaders Calendars, https://archive.epa.gov/epa/senior-leaders-calendars/calendar-scott-pruitt-former-administrator.html (last visited Aug. 3, 2018) (search starting point field for "Smith," then see entry for Jan. 9, 2018).

[524] Email from Aaron Ringel, Deputy Assoc. Adm'r, Office of Intergovernmental Affairs, to Troy Lyons, Assoc. Adm'r, Office of Congressional and Intergovernmental Relations; David Fotouhi, Deputy Gen. Counsel, Office of Gen. Counsel; Mandy Gunasekara, Principal Deputy Assistant Adm'r, Office of Air and Radiation; and Richard Yamada, Deputy Assistant Adm'r, Office of Research and Dev. (Jan. 16, 2018, 2:28 PM)(on file with Union of Concerned Scientists), https://drive.google.com/file/d/15Z6RKok51uqwkgAmhK3rseTOEJhFo8Sj/.

[525] *See, e.g.*, Email from Richard Yamada, Deputy Assistant Adm'r, Office of Research and Dev., to Nancy Beck, Deputy Assistant Adm'r, Office of Chem. Safety and Pollution Prevention (Jan. 29, 2018, 6:07 PM)(on file with Union of Concerned Scientists), https://drive.google.com/file/d/1DvwXyjzZlPstQx3tVL-jW_Yjv-S7VD2H/; Email from Richard Yamada, Deputy Assistant Adm'r, Office of Research and Dev., to Drew Feeley, Policy Counsel, Office of Policy; Brittany Bolen, Acting Assoc. Adm'r, Office of Policy; Clint Woods, Deputy Assistant Adm'r, Office of Air and Radiation; Justin Schwab, Deputy Gen. Counsel, Office of Gen. Counsel; Erik Baptist, Senior Deputy Gen. Counsel, Office of Gen. Counsel; and Nancy Beck, Deputy Assistant Adm'r, Office of Chem. Safety and Pollution Prevention (Jan. 29, 2019, 10:58 PM), https://drive.google.com/file/d/1peMXjBhq6lUYGGNBWbSjpOu1Zh-qLl4p/.

[526] EPA, Comments on CBO Questions for EPA regarding H.R. xxxx, the HONEST Act of 2017 (n.d.) (on file with Bloomberg Bureau of National Affairs), http://src.bna.com/nAj.

[527] CBO, Cost Estimate: H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 1 (2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf.

[528] *E.g.*, Scott Tong, *Critics Say HONEST Act undercuts EPA's use of science*, Marketplace: Sustainability (Apr. 10, 2017, 1:08 PM), https://www.marketplace.org/2017/04/10/sustainability/honest-act-seen-critics-undercutting-epa-s-use-science.

> If we use a third party to engage in scientific review or inquiry, and that's the basis of rulemaking, you and every American citizen across the country deserve to know what's the data, what's the methodology that was used to reach that conclusion that was the underpinning of what — rules that were adopted by this agency.[529]

The Daily Caller directly linked the proposal to the HONEST Act, "Pruitt's pending science transparency policy mirrors Smith's HONEST Act, which passed the House in March 2017."[530]

Spokeswoman for Chairman Smith's House Committee on Science, Space, and Technology, Thea McDonald, also told the Daily Caller: "[t]he chairman has long worked toward a more open and transparent rule-making process at EPA, and he looks forward to any announcement from Administrator Pruitt that would achieve that goal."[531]

1. Available information on the development of the proposal illustrate its industry origins.

The history of the proposal's internal development indicates that certain representatives of regulated industries had a nearly exclusive role in its promulgation, and that industry concerns were given special solicitude by EPA's senior political leadership. Meanwhile, the scientific community and the EPA's own Science Advisory Board were neither involved in the evolution of the proposal nor notified of its initiation until after its official publication in the Federal Register, further suggesting that this proposal is not grounded in a genuine concern for advancing science at EPA and is, in fact, at odds with EPA's mission of protecting human health and the environment.

Nancy Beck, key decision maker and EPA's current Deputy Assistant Administrator of the Office of Chemical Safety and Pollution Prevention, previously served as the Senior Director, Regulatory & Technical Affairs for the American Chemistry Council.[532] While employed by the ACC, Beck submitted a written statement in general support of the HONEST Act.[533]

In internal EPA emails released pursuant to Union of Concerned Scientists' Freedom of Information Act ("FOIA") request, Beck expressed concerns that repeated those of industry. Her concerns that certain language in the proposal might compromise industry confidential business information ("CBI") or alter individual party adjudications were met with assurances by Deputy Assistant Administrator for the Office of Research and Development, Richard Yamada, that the

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[529] Michael Bastach, *Exclusive: Scott Pruitt Will End EPA's Use of 'Secret Science' to Justify Regulations*, The Daily Caller (Mar. 20, 2018, 1:06 AM), http://dailycaller.com/2018/03/19/epa-scott-pruitt-secret-science/.
[530] *Id.*
[531] *Id.*
[532] Nancy Beck, LinkedIn, https://www.linkedin.com/in/nancybbeck/ (last visited June 6, 2018).
[533] *Written Statement of Nancy B. Beck Before the U.S. Senate Committee on Homeland Security and Governmental Affairs, Subcommittee on Regulatory Affairs and Federal Management Regarding a Hearing on the Agency Use of Science in the Rulemaking Process: Proposals for Improving Transparency and Accountability*, American Chemistry Council 1 (Mar. 9, 2017), https://www.hsgac.senate.gov/imo/media/doc/BECK%20TESTIMONY.pdf.

agency would "thread" the proposal "real tight."[534] Concerns about protecting CBI, expressed in Beck's emails, echo her statement in support of the HONEST Act to the House Subcommittee on Regulatory Affairs and Federal Management while she was employed by the ACC.[535]

The proposal's justifications regarding the private-sector burden of regulatory costs reiterates concerns and suggestions about EPA's policy for evaluating science that the Agency received from industry itself. In emails to EPA leadership from May 2014, the National Association of Manufacturers ("NAM") specifically identified dozens of EPA regulations that were "affecting its members," many of which were chemical, air, and water regulations which were based upon the types of research and studies that would be excluded under EPA's proposed rule.[536]

In response to EPA's 2017 proposed rule, Procedures for Prioritization of Chemicals for Risk Evaluations, NAM made recommendations that EPA ensure that TSCA prioritization relied upon "the best available science" in a process that requires "a heightened level of transparency."[537] NAM also provided the EPA with materials that called for reform of EPA's "process for evaluating science to improve transparency and better involve the public."[538] This parallels NAM's 2014 letter to the House in support of that year's version of Rep. Smith's HONEST Act.[539]

The American Petroleum Institute's ("API") Senior Director of Regulatory and Scientific Affairs wrote to the EPA: "[t]he science and data used to support a regulation should be reviewed to determine if they are still valid based on scientific integrity, consistent with EPA's Principles of Scientific Integrity and Policy (2012), with meaningful disclosure of all potential areas of bias, guarding against manipulation or misinterpretation."[540]

API also issued a press release on that same day, May 15, 2017, in which the organization summarized its conversations with EPA: "API today urged the EPA to adopt a

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[534] Email from Richard Yamada, Deputy Assistant Adm'r, Office of Research and Dev., to Nancy Beck, Deputy Assistant Adm'r, Office of Chem. Safety and Pollution Prevention; Erik Baptist, Senior Deputy Gen. Counsel, Office of Gen. Counsel; and Justin Schwab, Deputy Gen. Counsel, Office of Gen. Counsel (Jan. 31, 2018, 7:54 PM)(on file with Union of Concerned Scientists), https://drive.google.com/file/d/1VlUUz2wDTT7c7oxBAU3gSP8lMfipieO5/.

[535] American Chemistry Council, *supra* note 34, at 7.

[536] Letter from the Nat'l Ass'n of Mfs. to Regulatory Reform Officer and Associate Administrator, Samantha K. Dravis (May 15, 2017) *in* Maxine Joselow, *Emails: EPA all ears as industry pitched 'secret science'*, E&E News: Regulations (May 18, 2018), https://www.eenews.net/greenwire/2018/05/17/stories/1060081997, at 169-88.

[537] *Id.* at 184.

[538] *EPA Meeting Briefing Paper*, Nat'l Ass'n of Mfs. (n.d.), *in* Joselow, at 772-6.

[539] Letter from the Nat'l Ass'n of Mfs. to U.S. House of Representatives (Nov. 19, 2014) *in* Nat'l Ass'n of Mfs., *Key Manufacturing Votes: 113th Congress*, Advocacy: Congressional Voting Record, http://www.nam.org/Advocacy/Key-Manufacturing-Votes/113th-Congress/House/HR-4012--the-Secret-Science-Reform-Act-of-2014-sponsored-by-Representative-Dave-Schweikert-(R-AZ)/?__taxonomyid=211. (last visited June 6, 2018).

[540] Letter from the Am. Petroleum Inst. to Regulatory Reform Officer and Associate Administrator, Samantha K. Dravis (May 15, 2017) *in* Joselow, at 1140.

regulatory system that enhances safety and protects the environment while prioritizing the production and refining of American natural gas and oil."[541]

In contrast, EPA's Science Advisory Board ("SAB") leadership was not notified of the rulemaking activity until it was published in the Federal Register, in contravention of Agency practices for communicating major actions such as the proposed rule.[542] EPA also failed to provide the SAB with a description of the proposal.[543]

Despite the SAB's Congressionally-mandated role to formally review and comment on EPA actions of this nature,[544] the SAB and scientific community were not consulted in the development of the rule.[545] Indeed, SAB leadership questioned the scientific support behind the proposal: "[a]lthough the proposed rule cites several valuable publications that support enhanced transparency, the precise design of the rule appears to have been developed without a public process for soliciting input from the scientific community."[546]

SAB leadership took note of the HONEST Act's connection to the proposal, stating the rule was "highly controversial" as indicated by the fact that "a similar legislative effort in the House has been stalled in Congress for several years."[547]

B. EPA's Proposed Rule Mirrors Policies That the Tobacco Industry Advocated for in the 1990's to Suppress Unfavorable Science.

Both this proposed rule and the HONEST Act bear close similarities to policies promoted by the tobacco industry in the 1990's to suppress unfavorable science—further confirming that the proposed rule would degrade the quality of science at EPA and undermine public health. Before EPA's proposed rule and the HONEST Act, Philip Morris (today, Altria) and public-relations firm APCO partnered to establish The Advancement of Sound Science Coalition ("TASSC") in order to "inform the market of the problem with unsound science" that demonstrated adverse health effects of tobacco and second-hand smoke.[548] TASSC led a worldwide publicity campaign in the 1990s to promote "Good Epidemiological Practices" that

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[541] Reid Porter, *API: Regulatory System Should Promote Technological Innovations and Industry Best Practices*, Am. Petroleum Inst.: News (May 15, 2017), http://www.api.org/news-policy-and-issues/news/2017/05/15/regulatory-system-should-promote-technol. (last visited June 6, 2018).

[542] Memorandum from Chair of the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, Alison Cullen, to Members of the Chartered SAB and SAB Liaisons (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.

[543] *Id.*

[544] Environmental Research, Development, and Demonstration Authorization Act of 1978, 42 U.S.C. § 4365 (1978).

[545] Memorandum from Chair of the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, Alison Cullen, to Members of the Chartered SAB and SAB Liaisons (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.

[546] *Id.*

[547] *Id.*

[548] *See* APCO Assocs., Revised Plan for the Public Launching of TASSC (Through 1993) (Oct. 15, 1993) (internal document) (on file with UCSF, available online through Truth Tobacco Industry Documents portal).

aimed at undermining U.S. and international regulatory efforts based on epidemiologic studies of passive smoking and lung cancer.[549]

During the same period, Philip Morris made it a strategic priority to pursue legislation and policies to require public disclosure of epidemiological data. A May 1997 planning document advocated for using "existing political and business coalitions" that opposed clean air regulations to promote "legislative solutions to ensure that public policy is based on sound science" and "require epidemiological studies to meet a minimum set of criteria and/or require researchers to make public the underlying data before these studies can be used as a basis for regulations at the state or federal level."[550] In 1998, Powell Tate – a lobbying firm that represented R.J. Reynolds – organized a "secret science" working group focused on "requiring the disclosure of taxpayer-funded analytical data upon which federal and state rules and regulations are based, as well as the analytic data underlying health and safety studies funded by the government . . . ."[551]

Although TASSC no longer exists, its executive director, Steve Milloy, continues the organization's "sound science" rhetoric against other types of regulation through his website, JunkScience.com.[552] In fact, Milloy has personally taken credit for EPA's proposal and was one of a select few invited to Pruitt's public announcement of the proposal earlier this year.[553] After the proposed rule was announced, Milloy told reporters, "I look at this as one of my proudest achievements. The reason this is anywhere is because of Steve Milloy."[554]

C. EPA, Under the Trump Administration, Has a History Of Suppressing Science and Transparency, Undermining the Purported Justifications for the Proposal.

A FOIA request submitted by E&E News uncovered a document emailed by former EPA official David Schnare laying out a strategy to overturn the 2009 Greenhouse Gas Endangerment Finding.[555] In the document, one of the steps contemplated as part of the reconsideration included EPA only relying "on information, data and studies where the original data upon which assessment is based is available to the public. . . . EPA would not rely on any study whose authors refuse to

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[549] Elisa K. Ong and Stanton A. Glantz, *Constructing "Sound Science" and "Good Epidemiology": Tobacco, Lawyers, and Public Relations Firms*, 91 Am. J. of Public Health 1749, 1753 (2001).
[550] Annamaria Baba et al., *Legislating "Sound Science": the Role of the Tobacco Industry*, 95 Am. J. of Public Health S20, S22 (2005).
[551] Memorandum from Leslie Gianelli, Powell Tate, to "Secret Science" Work Group (Apr. 10, 1998), available at https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=klyc0069.
[552] Emily Atkin, *The EPA is Acting Like Big Tobacco*, The New Republic (Apr. 26, 2018), available at https://newrepublic.com/article/148126/epa-acting-like-big-tobacco.
[553] Robin Bravender, *Pruitt to unveil 'secret science' effort today—sources*, E&E News: EPA (Apr. 24, 2018), https://www.eenews.net/stories/1060079891.
[554] Robin Bravender, *Trump team wanted to kill agency authority on CO2—emails*, E&E News (June 1, 2018), https://www.eenews.net/stories/1060083175.
[555] Document entitled GHG Endangerment Finding Redux, https://www.eenews.net/assets/2018/06/01/document_cw_13.pdf.

provide the underlying data, including computer code used to evaluate and analyze the data."[556] This is just one example among numerous others that this proceeding is not intended to increase transparency, but rather aimed at weakening EPA standards that the current Administration disapproves of, despite their grounding in robust scientific evidence.

EPA's non-transparent approach to this rulemaking, as well as other Agency actions, underscore that the proposal was not offered in good faith. The Agency has removed thousands of webpages from its website, limited public and press access to Agency events, and withheld key data underlying rulemakings and proceedings. These practices cast doubt on EPA's proffered justifications of transparency and accountability.

In EPA's stay of the Oil and Natural Gas Sector: Emissions Standards for New, Reconstructed, and Modified Sources, EPA failed to disclose directly relevant evidence for the basis of revision of the standards consisting of industry compliance reports.[557] Despite the fact that these compliance reports were in the agency's possession and comprised of public documents containing factual data that should have been available for public inspection, EPA has to date still not released all of the compliance reports in its possession.

In August 2017, EDF received information pursuant a FOIA request revealing that more than 1,900 climate-related webpages and files on EPA's website were removed or modified.[558] Many of the removed and modified pages were related to climate change science and impacts, such as "Climate Impact on Health Through Life Stages," "Climate Change Science," and "Methane and Black Carbon Impacts on the Arctic: Communicating the Science."[559]

In January 2018, EDF received additional responsive records to another FOIA request demonstrating that former Administrator Pruitt directed the removal of many climate change science, impacts, and resources pages as well as all material related to the Clean Power Plan on EPA.gov.[560]

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[556] Document entitled GHG Endangerment Finding Redux, https://www.eenews.net/assets/2018/06/01/document_cw_13.pdf.

[557] Comments of Clean Air Council, Clean Air Task Force, Center for Biological Diversity, Earthjustice, Earthworks, Environmental Defense Fund, Environmental Integrity Project, Environmental Law and Policy Center, Natural Resources Defense Council, Sierra Club, and National Parks Conservation Association on Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources: Stay of Certain Requirements and Oil and Natural Gas Sector Emission Standards for New, Reconstructed, and Modified Sources: Three Month Stay of Certain Requirements Docket No. EPA-HQ-OAR-2010-0505 and Docket No. EPA-HQ-OAR-2017-0346 (Dec. 8, 2017).

[558] *Environmental Defense Fund Obtains Information on Over 1,900 Climate-Related Items Removed from or Modified on EPA Website*, EDF: Press release archive (Aug. 11, 2017), https://www.edf.org/media/environmental-defense-fund-obtains-information-over-1900-climate-related-items-removed-or.

[559] *Id.*

[560] E-mail from Lincoln Ferguson, Senior Advisor, Office of Public Affairs, to Amy Graham, Advisor, Office of Public Affairs; John Konkus, Deputy Associate Administrator, Office of Public Affairs; JP Freier, Associate Administrator, Office of Public Affairs; Liz Bowman, Acting Associate Administrator, Office of Public Affairs; and Jahan Wilcox, Strategic Communications Advisor, Office of Public Affairs (Apr. 5, 2017, 4:15 PM) *in* EDF, *Newly Released Records Refer to Pruitt's Personal Involvement in Removal of Climate Information from EPA Website*, EDF: Press release archive (Jan. 29, 2018), https://www.edf.org/sites/default/files/2018.01.05-partial-production.pdf.

At the same time, EPA was soliciting comments on its proposal to repeal the Clean Power Plan. The removal of webpages related to climate and Clean Power Plan topics from the EPA website restricted the public's ability to formulate informed comments throughout the rulemaking process.[561] Thus, the public lacked the same "access to data and influential scientific information used to inform federal regulation"[562] which EPA claims to observe in its proposal.

The Administration has not rigorously pursued its purported goal of transparency in other contexts by limiting public and press access to Agency events and withholding key data underlying several recent rulemaking proceedings.

At the event where former Administrator Pruitt announced the proposal, reporters were not invited to attend.[563] Documents received in response to a Sierra Club FOIA request to the EPA reveal that the Administrator had requested press access and advertisement to the public be limited for other events.

For his speaking engagement at a Federalist Society event in March 2017, Pruitt's scheduling director asked that organizers not advertise to press directly and directed organized to tell media that the event "is not open to press and is off the record."[564] Emails also demonstrate that the Agency worked with a public relations firm to devise a plan to promote positive comments and censor negative comments on media from the Administrator's facility visits.[565]

EPA additionally failed to provide the public with access to data in key rulemakings and proceedings. For example, in EPA's rulemaking to repeal emissions requirements for glider vehicles, engines, and kits, commenced in November 2017, the Agency failed to release the underlying reports and data before the public comment period closed.[566] At this date, EPA still has not released data used in a key study cited in the Agency's proposal.

In the words of the proposal, EPA acted in contravention of its goals of "better informing the public," "enhancing the public's ability to understand and meaningfully participate in the

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[561] Environmental Data & Governance Initiative on EPA's Proposal, *Repeal of Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units*, 82 Fed. Reg. 48,035 (Apr. 26, 2018), *available at* https://envirodatagov.org/edgi_cpp_proposed_rule_comments_042618/.

[562] 83 Fed. Reg. 18,768, 18,768 (Apr. 30, 2018).

[563] Miranda Green, *Pruitt signs proposed rule to erase 'secret science' from EPA*, The Hill (Apr. 24, 2018, 2:40 PM), http://thehill.com/policy/energy-environment/384636-pruitt-signs-proposed-rule-to-erase-secret-science-from-agency.

[564] Email from Juli Nix, Director of Conferences, Federalist Society, to Millan Hupp, Director of Scheduling and Advance, EPA (Mar. 17, 2017, 12:30 PM)(on file with Sierra Club), https://www.documentcloud.org/documents/4453164-Pruitt-Sierra-Club-NYT-Foia.html#document/p29/a422141.

[565] Email from Gus Wagner, Partner and Creative Dir., ARC Media, forwarded to Barry Hart, CEO, Nat'l Rural Electric Coop. Ass'n; Amy Graham, Dir. of Commc'n, EPA; Tate Bennett, Assoc. Adm'r, Office of Public Engagement and Envvtl. Educ.; Joe Wilkinson, Sr. Vice Pres., Assoc. Electric Coop. (Apr. 18, 2017).

[566] EDF Supplemental Comment on EPA's Proposed Rule, *Repeal of Emission Requirements for Glider Vehicles, Glider Engines, and Glider Kits*, 82 Fed. Reg. 53,442 (Mar. 11, 2018), *https://www.edf.org/sites/default/files/content/EDF%20Third%20Supplemental%20Comment%20re%20TTU%20Study%203.11.18.pdf*.

regulatory process," and "ensur[ing] that its decision-making is marked by independence, transparency, clarity, and reproducibility" as it proceeded through rulemakings that "will affect the public" and where "the public is likely to bear the cost of compliance."[567]

VIII. The Proposal Violates Procedural Requirements of the APA, CAA, and Other Statutes and Executive Orders

The proposed rule fails to meet even the most basic procedural and substantive obligations. The Administrative Procedure Act (APA) requires that the "opportunity for comment must be a meaningful opportunity," and "[t]hat means enough time with enough information to comment and for the agency to consider and respond to the comments." *Prometheus Radio Project v. FCC*, 652 F.3d 431, 450 (3d Cir. 2011) (internal citation and quotation marks omitted). *See also Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1044-45 (D.C. Cir. 1987) (noting the "obvious importance of the [APA's] policy goals of maximum participation and full information."). For its part, the Clean Air Act (CAA) "requires a much more detailed notice of proposed rulemaking than does the APA." *Union Oil Co. of Cal. v. EPA*, 821 F.2d 678, 682 (D.C. Cir. 1987); *see Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 550 (D.C. Cir. 1983) ("[T]he additional notice requirements in § 307(d)(3) suggest that Congress intended agency notice under the Clean Air Act to be more, not less, extensive than under the APA."). Executive Order 13563 underscores these obligations requiring that to promote "open exchange of information and perspectives among State, local, and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole," agencies "shall endeavor to provide the public with an opportunity to participate in the regulatory process."[568]

Moreover, notice has to be provided by the agency; it cannot be bootstrapped from the public comments.[569] The reasons are evident: there is no requirement for parties to monitor all of the thousands or tens of thousands of submitted comments in order to guess the issues on which to comment.[570] A contrary rule "would turn notice into an elaborate treasure hunt, in which interested parties, assisted by high-priced guides (called 'lawyers'), must search the record for the buried treasure of a possibly relevant comment."[571]

Drafting these comments has entailed a great deal of guesswork. The comments of EDF or any other commenter on a particular issue thus should not be taken to mean that EPA provided sufficient notice of that issue.

The proposed rule lacks essential elements needed to understand it, rendering the opportunity for comment meaningless. The Proposal contains vague and contradictory statements about its actual substance and effect, fails entirely to analyze and disclose its costs

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[567] 83 Fed. Reg. 18,768, 18,768-9 (Apr. 30, 2018).
[568] Exec. Order 13563 § 2.
[569] *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 547 (D.C. Cir. 1983); *Shell Oil Co. v. EPA*, 950 F.2d 741, 760-61 (D.C. Cir. 1991); *CSX Trans. v. Surface Transp. Bd.* 584 F.3d 1076, 1082 (D.C. Cir. 2009); *City of Waukesha v. EPA*, 320 F.3d 228, 234 (D.C. Cir. 2003).
[570] *Am. Fed'n of Labor v. Donovan*, 757 F.2d 330, 340 (D.C. Cir. 1985); *Fertilizer Inst.v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991).
[571] *Small Refiner Lead Phase Down*, 705 F.2d at 550.

and benefits, and is littered with vague references to entire websites and executive branch departments. The cursory reasoning and wholly inadequate record offered in support of the proposed rule prevents stakeholders from engaging with the agency on its rationale for the proposed action and its costs and benefits, or offering contrary evidence. Finally, EPA has not provided any basis whatsoever to warrant the gross inadequacies of the proposed rule and the process to consider it. With such a deeply deficient basis for action, the only legally viable course is to withdraw the Proposal.

A. The Proposed Rule is a Binding, Legislative Rule and Subject to the Requirements of the APA

The Administrative Procedure Act, the Clean Air Act, and other federal statutes proscribe procedures that must be followed in agency rulemaking, and which EPA has failed to meet in its Proposal. This proposed rule does not fit into any of the exceptions the APA provides for the procedural requirements of rulemaking—it is neither an interpretive rule, general statement of policy, or a rule of agency organization, procedure or practice.[572]

The proposed rule does not purport to clarify or explain an already existing statute or rule, and thus is not an interpretive rule.[573] The proposed rule is not a general statement of policy, because it establishes a standard of conduct, which has the force of law. It uses mandatory language indicating a requirement: "When promulgating significant regulatory actions, the Agency *shall* ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation."[574] Unlike a general statement of policy, which "does not establish a 'binding norm,'. . . [and] is not finally determinative of the issues or rights to which it is addressed," EPA here makes no qualifications that it has any leeway to not follow the Proposal's new requirements in all future regulatory actions.[575] The provision allowing the EPA Administrator to grant exceptions in a limited number of cases does not turn this rule into a general statement of policy because it also binds the Administrator's discretion, allowing deviation from the policy only when they make specific findings.[576] EPA has not indicated that "in subsequent proceedings it will thoroughly consider not only the policy's applicability to the facts of a given case but also the underlying validity of the policy itself," but seems poised to apply the policy in all instances—granting exceptions only in limited circumstances where compliance is deemed impracticable.[577] It nowhere indicates that EPA may reassess in each case whether following this rule is the best means to achieve scientific integrity as it undertakes regulatory action. The Proposal has other indications of a binding rule, including that EPA intends to codify it in the Code of Federal Regulations, and EPA has itself characterized the Proposal as a binding rule.[578]

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[572] 5 U.S.C. § 553.
[573] *Guardian Fed. Sav. & Loan Asso. v. Fed. Sav. & Loan Ins. Corp.*, 589 F.2d 658, 665 (D.C. Cir. 1978).
[574] Proposed Rule, 83 Fed. Reg. at 18,773 (emphasis added); *Pac. Gas & Elec. Co. v. Fed. Power Com.*, 506 F.2d 33, 38-39 (D.C. Cir. 1974).
[575] *Pac. Gas & Elec. Co. v. Fed. Power Com.*, 506 F.2d 33, 38 (D.C. Cir. 1974).
[576] Proposed Rule, 83 Fed. Reg. at 18,774.
[577] *Pac. Gas & Elec. Co. v. Fed. Power Com.*, 506 F.2d 33, 39 (D.C. Cir. 1974).
[578] Robinson Meyer, *Scott Pruitt's New Rule Could Completely Transform the EPA*, The Atlantic (Apr. 24, 2018), https://www.theatlantic.com/science/archive/2018/04/how-the-epas-new-secret-science-rule/558878/ (as

This rule is also not a rule of agency organization, procedure or practice, for purposes of the APA. Agency actions in this category are those "that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency."[579] An agency action that "trenches on substantial private rights and interests" does not fall under this exemption.[580] By restricting the scientific studies on which EPA may base final significant regulatory actions, EPA severely limits parties from relying on excluded studies in advocating for particular safeguards. In the preamble, EPA makes clear that the rule is about "EPA's regulatory actions" and underlying conclusions.[581] Because the rule substantively impacts agency conclusions and regulations, it impacts private rights and interests. The rule does not allow private individuals to submit for consideration (or renders such submittal a nullity) studies that they would have been permitted to prior to the proposed rule, thus impacting the substantive standards that EPA is able to justify setting—which has implications for the regulated community as well as for public health. The Proposal "encodes a substantive value judgment or puts a stamp of approval or disapproval on a given type of behavior" by requiring regulatory actions to be supported only by certain scientific information deemed acceptable by the proposed rule.[582]

In *CropLife Am. v. E.P.A.*, the Court held that a similar rule promulgated by EPA, barring third-party human studies from agency consideration during pesticide registrations was a binding regulation because it used "clear and unequivocal language" reflecting "an obvious change in established agency practice" that created a "binding norm."[583] The Court stated: "EPA's stated rule is binding on petitioners, who are now barred from relying on third-party human studies (even in cases where such studies formerly were approved), and is binding on the agency because EPA has made it clear that it simply 'will not consider' human studies."[584] Similarly, the Proposal appears to bind EPA to not consider scientific information it could consider before, unless it falls under certain narrow, ambiguously defined exceptions, and binds the public and organizations such as EDF who can no longer submit studies to EPA that EPA would previously have been required to consider as part of the rulemaking process.

B. The Proposal is Subject to the Procedural Requirements of the Clean Air Act.

Administrator Pruitt signed the Proposal, he stated: "This is not a policy. This is not a memo. This is a proposed rule.").

[579] *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980).

[580] *Batterton v. Marshall*, 648 F.2d 694, 708 (D.C. Cir. 1980).

[581] 83 Fed. Reg. 18,769.

[582] *Am. Hosp. Asso. v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987). *See also Pharm. Mfrs. Asso. v. Finch*, 307 F. Supp. 858, 865 (D. Del. 1970) (finding that a regulation promulgating new criteria for clinical investigations that will meet the standards of evidence necessary to demonstrate the effectiveness of drug products, and excluding certain kinds of clinical investigations, was not merely a procedural rule, because they "did effect a material narrowing of the range of evidence which previously had been considered relevant in evaluating a drug's efficacy. Because of the important clarification of acceptable testing standards effected by the September regulations and because of the substantial impact of these regulations on the drug industry. . . . ")

[583] 329 F.3d 876, 881 (D.C. Cir. 2003).

[584] *Id.*

Section 307(d) applies to "such. . . actions as the Administrator may determine."[585] EPA claims to take this action under "authority of the statutes it administers. . . including Clean Air Act sections 103, 301(a)."[586] By issuing this Proposal through notice and comment procedures, Administrator Pruitt appears to have determined that 307(d) procedures apply.

Even without that invocation, the proposed rule is subject to these procedural requirements because it materially impacts many of the actions delineated in 307(d)(1) to which the CAA rulemaking procedures explicitly apply. The Proposal applies to "significant regulatory actions," which many of these actions are. The CAA requires science-based decision-making that the Proposal will materially affect. For example, by restricting the science EPA may rely on in regulatory actions, the Proposal materially impacts residual risk determinations for hazardous air pollutants (§ 307(d)(1)(C)), standards for mobile source air toxics (§ 307 (d)(1)(K)), and residual risk standards for municipal solid waste combustors (§ 307(d)(1)(D)).[587]

This proposed rule directly affects EPA's setting and review of National Ambient Air Quality Standards (NAAQS),[588] the promulgation or revision of which is subject to the CAA rulemaking requirements.[589] Section 108(a) of the Clean Air Act requires the Administrator to set air quality criteria for air pollutants that "reflect the latest scientific knowledge." This Proposal amends the science EPA can consider for air quality criteria. Under CAA section 109 EPA must use the air quality criteria to set primary and secondary NAAQS and periodically review them—which EPA is currently doing for Particulate Matter.[590] In the Proposal, EPA cites *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 358 (D.C. Cir. 2002) as an example of an instance where EPA relied on a scientific study where the underlying data was not publicly available. EPA states that under the Proposal use of such science would be "preclude[d]".[591] In *Am. Trucking Ass'ns* the Court upheld EPA's use of key studies underlying the NAAQS for PM. Under the Proposal, EPA would not have been permitted to use those studies, and it is unclear how the Proposal will affect EPA's reliance on these studies as it undertakes its review. This demonstrates how this Proposal would have an immediate impact on EPA NAAQS-setting under the CAA. EPA is thus subject to the CAA 307(d) procedural requirements for this Proposal.

C. EPA Has Failed to Provide a Properly Developed Docket and Record as Required by the APA and CAA and Has Thereby Violated the Notice Requirements of these Statutes

EPA has failed to provide a properly developed record in support of the proposed rule. EPA has not identified sufficient supporting evidence in the Proposal or in its docket and has failed to provide adequate notice of the supporting evidence for the public to respond to

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[585] 42 U.S.C.S. § 7607(d)(1)(V).
[586] 83 Fed. Reg. at 18,769.
[587] 83 Fed. Reg. at 18,773.
[588] CAA Section 108(a).
[589] CAA Section 307(d)(1)(A).
[590] *See Release of the Final Integrated Review Plan for the National Ambient Air Quality*, 81 Fed. Reg. 87,933 (Dec. 6, 2016).
[591] 83 Fed. Reg. at 18,769 n. 3.

meaningfully, as the Administrative Procedure Act, the Clean Air Act, and other substantive statutes require.

Under the APA, agencies must base their actions on examination of the facts, "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'"[592] The factual determination underlying the agency decision must be based on substantial evidence and will be set aside "if the agency 'relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'"[593]

Rulemaking under the Clean Air Act is subject to the same general requirements of statutory conformity and reasoned decision-making derived from the APA and basic principles of administrative law. Clean Air Act rules cannot be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law."

As noted in Appendix A and below in Section VIII.D EPA's citations for support in the Proposal are vague and uninformative, and even where the particular citation can be identified and located, it is often not clear how EPA thinks the citation supports the Proposal. This does not meet the standards of the APA and CAA.

Additionally, EPA has failed to meet the docket requirements of the CAA. CAA section 307(d)(3) requires that publication of the proposed rule in the Federal Register include a summary of the factual data on which the proposed rule is based, the methodology used in obtaining the data and in analyzing the data, and the major legal interpretations and policy consideration underlying the proposed rule. It also requires the agency to place "[a]ll data, information, and documents. . . on which the proposed rule relies" in the rulemaking docket on the date of publication of the proposed rule.[594] The undifferentiated citation of articles and policies, most of which contradict the Proposal or otherwise offer no support for it, fails abjectly to satisfy these requirements.[595] Any document that becomes available after the proposed rule

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[592] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43-44, (1983).

[593] *Cablevision Sys. Corp. v. FCC*, 597 F.3d 1306, 1310 (D.C. Cir. 2010).

[594] CAA Section 307(d)(3).

[595] *See Kennecott v. EPA*, 684 F.2d 1007, 1018 (D.C. Cir. 1982)("Section 307(d)(3) requires that notice of proposed ... regulations be accompanied by a statement of their basis and purpose, including the factual data on which the proposed regulations are based, the methodology used in obtaining and analyzing the data, and the major legal interpretations and policy considerations underlying the proposed regulations. . . . Though EPA states in its preamble to the final regulations that its current eligibility test is based upon a closure policy adopted by EPA before 1977, and that it has used financial tests similar to the present closure test under the agency's existing policy, no documents embodying those tests or demonstrating the methodology used before 1977 were ever placed in the docket. The only document in the docket purporting to explain that a closure test was ever employed by EPA was a memorandum in which EPA economist Hale sets forth his recollection that such a test had been used before 1977 to determine whether smelters would be permitted to rely upon dispersion techniques to meet the ambient standards. That memo, dated August 17, 1979, was placed in the docket on March 12, 1980, approximately eleven months after

has been published and that is of central relevance to the rulemaking must also be placed in the docket as soon as possible after its availability.[596] The agency must allow enough time for participants in the rulemaking to respond to those documents with comments.[597]

As of the date of the publication of the Proposal, the docket at regulations.gov contained only the following 12 documents: (1) OIRA Review Start Document (Apr. 17, 2018); (2) OIRA Review Conclusion Document (Apr. 23, 2018); (3) White House Memorandum on Scientific Integrity (Mar. 9, 2009); (4) *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*; Republication, 67 Fed. Reg. 8,452 (Feb. 22, 2002); (5) Exec. Order 13,777, *Enforcing the Regulatory Reform Agenda*, 82 Fed. Reg. 12,285 (Feb. 24, 2017); (6) EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* (Nov. 29, 2016); (7) OMB Memorandum M-05-03 on Issuance of OMB's "Final Information Quality Bulletin for Peer Review" (Dec. 16, 2018); (8) EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (Oct. 2002); (9) Exec. Order 13,563, *Improving Regulation and Regulatory Review*, 76 Fed. Reg. 3,821 (Jan. 18, 2011); (10) Exec. Order 16, 093, *Promoting Energy Independence and Economic Growth*, 82 Fed. Reg. 16,093 (Mar. 28, 2017); (11) OMB Memorandum M-13-13: Open Data Policy-Managing Information as an Asset (May 9, 2013); (12) Commission on Evidence-Based Policymaking, *The Promise of Evidence-Based Policymaking* (Sep. 2017).

This clearly is not enough to meet the APA's or CAA's requirements. Aside from the drafts of the proposed rule submitted to OIRA, each of these documents was a pre-existing memorandum, policy document, or executive order that contains no specific analysis—factual, legal, policy or otherwise—that pertains to the impacts of or at all justifies *this* proposed rule. While EPA in the proposed rule cites to some of these documents as purportedly being consistent with these prior policies, *see, e.g.*, 83 Fed. Reg. at 18,769-70, as is discussed in Section II and in Appendix A, these policies do not in fact provide any basis for the Proposal. The record that EPA provides clearly fails to support its proposed action. Some of the factual data, legal interpretations, and policy considerations that EPA has not sufficiently provided evidence for include: the number of scientific studies that would be precluded from consideration under the Proposal; whether there are fields of research where the Proposal would result in insufficient scientific information available for EPA to meet its statutory duties; how EPA will address the substantial privacy concerns implicated by the Proposal; how application of this Proposal will impact substantive agency actions; what the costs of implementing this Proposal are if EPA intends to not just exclude studies from consideration where too costly to provide access, etc.

EPA, for instance, includes Executive Order 13,563 in the docket to support its statement that "[t]he best available science must serve as the foundation of EPA's regulatory actions."[598] While Executive Order 13,563 makes that statement, it does not support EPA's Proposal, which

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the close of the public comment period, and reveals neither the actual tests nor the methodology used by EPA. The failure of EPA to observe the procedures mandated by §§ 307(d)(3) and 307(d)(6) was thus arbitrary and capricious.")

[596] CAA Section 307(d)(4).

[597] *Sierra Club v. Costle*, 657 F.2d 298, 352 (D.C. Cir. 1981); *Union Oil Co. v. EPA*, 821 F.2d 678, 683 (D.C. Cir. 1987).

[598] 83 Fed. Reg. at 18,769 n. 1.

as explained above, hinders EPA's use of the best available science. EPA provides no evidence or explanation in the docket or Proposal for why EPA believes this policy would further that goal. The executive order only states that agencies should make available to the public the scientific or technological *findings or conclusions* on which rules rely, as opposed to underlying raw data that EPA has targeted with this Proposal. Meanwhile, EPA blatantly violates the executive order's provisions requiring agencies to weigh costs and benefits; to write regulations that are easy to understand; and to provide the scientific and technical findings underlying the rule for the public to comment on.

Section 307(d)(3) of the CAA requires that "[a]ll data, information, and documents ... on which the proposed rule relies shall be included in the docket on the date of publication of the proposed rule." Many items that EPA cites to in the Proposal as providing a basis for the proposed rule do not appear in the docket. For example, EPA states: "The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science."[599] In a footnote, EPA provides: "These include policies and recommendations from: The Administrative Conference of the United States' Science in the Administrative Process Project; National Academies' reports on *Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data,* and *Access to Research Data in the 21st Century;* the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project."[600] Many of these policies and recommendations did not appear in the docket on the data of publication of the Proposal and still do not appear in the docket—a clear violation of the CAA—nor are the specific documents or reports even identified or properly cited so that they may be tracked down. This is evidently prejudicial to commenters—it undermines commenters ability to submit meaningful feedback when the agency is hiding the ball in this manner.

These policies and recommendations are not easily identifiable on their own either, even after significant internet research. This is also true of footnote 16, where EPA lists a number of agencies to support its claim that the federal government is already implementing solutions to data disclosure.[601] EPA cites, for example, the National Institute of Standards of Technology. NIST has numerous policy documents on protecting privacy concerns and keeping data secure as well as its own internal policies on releasing data. It is hard to see how any are relevant here, but without a particular cite the public is denied even a chance to respond to whatever EPA is trying to use as support—or must respond to *everything* that might be being referenced, creating a burdensome task. Throughout these comments, as we attempt to respond to EPA's Proposal, we have been very practically limited by our inability, even after much research and consideration, to be fully certain we have identified the appropriate policies to respond to. This presents a situation that the CAA's docket requirement was exactly formulated to prevent.

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[599] 83 Fed. Reg. at 18,770.
[600] 83 Fed. Reg. at 18,770 n. 10.
[601] 83 Fed. Reg. at 18,770 n. 16.

On May 25, 2018, EPA added a memorandum to the docket for this rulemaking.[602] This memorandum contains hyperlinks apparently intended to accompany various citations in the footnotes of the Proposal. This document does not cure the former procedural defect, as the CAA requires information the proposed rule relies on to be placed in the docket on the day the proposed rule is published.[603] Further, these hyperlinks still link ambiguously to various documents and agency websites without providing any information about what specifically EPA intends to cite or how the cited information is being used or considered by EPA. Additionally, simply adding such a document to the docket does not provide adequate notice to the public. Someone who had access only to the proposed rule and was not carefully monitoring the docket would have no indication or notice of this new document.

Either EPA is failing to comply with the CAA's requirements by failing to include in the docket factual data, legal interpretations, and policy considerations that support the Proposal, or these supporting items do not exist, deeming this rulemaking completely arbitrary—in either case the Proposal fails to meet the standards of the APA and CAA. Under the CAA the rulemaking docket "must provide the entire basis for the final rule and the exclusive record for judicial review," this docket clearly cannot support a final rule.[604]

D. The Proposal is too Vague for Meaningful Comment.

Section 553 of the APA, 5 U.S.C. § 553(b)(3), requires that an agency proposing a rule "provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully."[605] The Clean Air Act requires even more, that the Federal Register notice be accompanied by a statement of basis and purpose that includes a summary of the factual data on which the proposed rule is based, the methodology used in obtaining the data and in analyzing the data; and the major legal interpretations and policy considerations underlying the proposed rule.[606] As discussed above, all data, information, and documents on which the proposed rule relies must be included in the docket on the date of publication of the proposed rule.[607]

These core requirements are "designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review."[608] In addition, "a chance to comment ... [enables] the agency [to] maintain[] a flexible and open-minded attitude towards its

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[602] EPA Memorandum RE: Omitted Hyperlinks for Footnotes in the Proposed Rule (May 25, 2018), EPA-HQ-OA-2018-0259-0812.
[603] Section 307(d)(3).
[604] *Union Oil Co. of California v. EPA.*, 821 F.2d 678, 681-82 (D.C. Cir. 1987).
[605] *United States Telecom Assn. v. FCC*, 825 F.3d 674, 700 (D.C. Cir. 2016) (quoting *Honeywell Intl., Inc. v. EPA*, 372 F.3d 441, 445 (D.C. Cir. 2004) (internal quotation marks omitted).
[606] 42 U.S.C. § 7607(d)(3).
[607] 42 U.S.C. § 7607(d)(3).
[608] *Int'l Union, United Mine Workers of Am. v. Mine Safety and Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005).

own rules,"[609] and "avoid[s] the inherently arbitrary nature of unpublished ad hoc determinations."[610] The "notice required by the APA ... must disclose in detail the thinking that has animated the form of a proposed rule and the data upon which that rule is based .... [A]n agency proposing informal rulemaking has an obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible." *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35-36 (D.C. Cir. 1977); *see also Horsehead Res. Dev. Co., Inc. v. Browner*, 16 F.3d 1246, 1268 (D.C. Cir. 1994) ("[A]n agency must describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decision-making.") (internal citations and quotation marks omitted).

The failure to include critical documents relevant to the proposed rule in the docket, as required by the Clean Air Act, itself constitutes a notice violation because "absence of those documents, or of comparable materials. . . makes impossible any meaningful comment on the merits of EPA's assertions."[611] By failing to provide a more developed docket, EPA is frustrating the terms and purposes of these statute's notice requirements. These procedures are in place to form a "specific" proposal that can serve as a "focus for comments," *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 548-49 (D.C. Cir. 1983); *see Home Box Office, Inc. v. FCC*, 567 F.2d 9, 36 (D.C. Cir. 1977) (agency must "make its views known . . . in a concrete and focused form so as to make criticism or formulation of alternatives possible"). Because EPA has not provided supporting evidence, has not included key items it points to as major considerations underlying the Proposal, and has generally presented a vague and unspecified proposed rule and docket, EDF and the public are hindered in our ability to provide specific comment focused on the underpinnings of the Proposal, because we do not know and can only guess as to what they are.[612]

Even the text of EPA's proposed rule and the statement of basis and purpose fails to provide the requisite notice to allow meaningful comment. At the most fundamental level, it contains vague and contradictory statements about the actual effect of the Proposal. The Proposal generally appears to make its requirements mandatory—i.e., failure to make information publicly available will preclude the agency from relying on the study at all. *See* 83 Fed. Reg. at 18,769 n. 3 ("EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions."); *id.* at 18,771 ("the regulatory text would impose requirements"); *see also id.* at 18,769 ("EPA *will* ensure that the data and models underlying the science is publicly available...") (emphasis added) and proposed section 30.5 ("When promulgating significant regulatory actions, the Agency shall ensure that does response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation"). In a few places, however, the Proposal makes it sound as if its aims are more aspirational. *See id.* at 18,770 ("Where *available and appropriate*, EPA will use peer-reviewed information, standardized test methods, consistent data evaluation procedures,

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[609] *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1325 (D.C. Cir. 1988) (internal citation and quotation marks omitted).

[610] *United States v. Reynolds*, 710 F.3d 498, 519-20 (3d Cir. 2013).

[611] *Kennecott Corp. v. EPA*, 684 F.2d 1007, 1018 (D.C. Cir. 1982).

[612] "Without a readily accessible statement of the agency's rationale, interested parties [could not] comment meaningfully during the rulemaking process." *Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 949 (D.C. Cir. 2004).

and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments.") (emphasis added); *id.* at 18,772 ("The proposed rule directs EPA to make *all reasonable efforts* to" make data publicly available, but "does not compel the Agency to make that information available where it concludes after all such reasonable efforts that doing so in way [sic] that complies with the law and appropriate protections is not possible.") (emphasis added); *see also id.* at 18,768 ("EPA *should* ensure that the data underlying those are publicly available...") (emphasis added). The difference between a *requirement precluding* use of science and making *all best efforts* to make data publicly available is enormous.

To the extent EPA intends to propose a rule that would *preclude* use of science, as it appears the Proposal would do, the proposed rule is further flawed because it contains no analysis of how that would affect regulations. How many studies does EPA typically rely on in promulgating regulations? What percentage of these would meet EPA's new requirements? For those that do not, how many could not meet these requirements for patient privacy, confidential business information, or other reasons? How would EPA set standards if it must rely on many fewer studies? Would EPA be precautionary in the face of less evidence? Would EPA delay promulgating regulations in order to comply with this new mandate? How does this mandate interact with statutory deadlines or statutory requirements that EPA look at a wide range of science? None of these very basic questions are addressed in the proposed rule and without answering them, it is impossible for the public to assess the import and likely consequences of the Proposal. Even more basically, the agency gives no notice as to the Proposal's impacts, its costs, its benefits, why it applies only to regulatory requirements but not to any regulatory actions (like licensing or permitting) that confer a benefit, substantive and procedural criteria for adjudicating waivers, or even the legal theory under which the Proposal issues—the plaintive solicitation for comment as to "additional or alternative sources" of authority, 83 Fed. Reg. at 18771, does not suffice.

To the extent the Proposal is intended to solicit comment on how EPA may make reasonable efforts to make data publicly available it is also unlawfully vague. The proposed rule includes numerous footnotes referencing entire websites or even Departments of the Executive Branch. For example, the Proposal claims that "EPA believes that concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly used across some parts of the Federal government."[613] To support this proposition, EPA remarkably cites (without any further elaboration or explanation in the proposal itself) to "examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau."[614] *See Small Lead Refiner Phase Down,* 705 F. 2d at 548 (requirement that comments are to raise issues with "reasonable specificity" applies equally to the agency giving notice). For example, it is not possible to identify whether the sources referenced support EPA's claim that there are approaches available to address the serious privacy issues raised by the Proposal—without providing the specific policies and recommendations, a public commenter has no way of knowing whether they are consistent or why EPA believes them to be consistent. It is impossible to respond in a meaningful way without significant guesswork.

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[613] Proposed Rule, 83 Fed. Reg. at 18,770.
[614] *Id.* at 18,770 n. 16.

Similarly, in footnote 10, where EPA lists a number of organizations whose "policies and recommendations" the Proposal allegedly took under consideration—no explanation is provided.[615] In addition, in the proposed rule EPA fails to adequately define key terms like "validation", "independence", "reproducibility," "replication," and "uncertainty," while also citing a "replication crisis" in science. It is important that these terms are defined clearly as these terms are not defined consistently across the scientific community nor governments—which has implications for the scope and purview of the proposed rule.

This amount of information is wholly insufficient to allow a public commenter to provide meaningful comments about these issues.

Courts have been reluctant to find that important information appearing solely in the footnote of a rulemaking document satisfied the notice requirement of the APA, holding that "an agency may not turn the provision of notice into a bureaucratic game of hide and seek."[616] Refereneing a key document without further discussion in the rulemaking document itself, and without incorporating it by reference or publishing it in the Federal Register, also does not satisfy the notice requirements of the APA.[617] Subsequent publication of the document may not be enough to cure a defect of notice where an important issue is "belied by the obscurity of the footnote intended to give notice" and further agency procedure is required to provide the public with "the opportunity to comment on a significant part of the agency's decisionmaking process as required by section 553."[618] Thus, the undifferentiated citations in the footnotes of the Proposal do not give adequate notice for public comment.[619]

E. EPA Must Comply With Other Requirements of the Clean Air Act

As discussed above, the Proposal impacts EPA's process for setting NAAAQs in material ways by amending the scientific information that can be used as air quality criteria. Under the CAA air quality criteria cannot be amended without review by the Clean Air Science Advisory Committee (CASAC).[620] Thus, EPA must submit this proposal to CASAC for review, consider

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[615] 83 Fed. Reg. at 18,770. n. 10 ("These include policies and recommendations from: The Administrative Conference of the United States' Science in the Administrative process Project; National Academies' reports on *Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data,* and *Access to Research Data in the 21st Century;* the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project.)

[616] *MCI Telcommunications Corp. v. FCC*, 57 F.3d 1136, 1142 (D.C. Cir. 1995).

[617] *PPG Indus., Inc. v. Costle*, 659 F.2d 1239, 1249-50 (D.C. Cir. 1981).

[618] *PPG Indus., Inc. v. Costle*, 659 F.2d 1239, 1250 (D.C. Cir. 1981).

[619] *See, e.g., Chamber of Commerce v. SEC*, 443 F. 3d 890, 899 (D.C. Cir. 2006); *Jackson v. Des Moines Mun. Housing Agency*, No. 4:07-cv-00438-HDV, 2008 U.S. Dist. LEXIS 125003, at *8-9 (S.D. Iowa June 4, 2008); *Billington v. Underwood*, 613 F.2d 91, 94 (5th Cir. 1980) ("Such a statement must be sufficiently specific for it to enable an applicant to prepare rebuttal evidence to introduce at his hearing appearance."); *Edgecomb v. Housing Auth.*, 824 F.Supp. at 312, 314-15 (1993); *Driver v. Housing Auth.*, 713 N.W.2d 670,673 (Wis. Ct. App. 2006); *Owner-Operator Independent Drivers Ass'n, Inc. v. Federal Motor Carrier Safety Admin.*, 494 F.3d 188, 209 (D.C. Cir. 2007) ("It is certainly true that a notice can be "too general to be adequate.").

[620] CAA § 109(d)(2)(B).

their recommendations, and provide reasonable explanation for deviation from those recommendations.[621]

F. EPA Failed to Submit the Proposal to the SAB or to Consult with the Scientific and Technical Community

There is no indication that EPA consulted with the scientific and technical community—or even its own Science Advisory Board—before proposing to require that the underlying data and models be made publicly available for all pivotal regulatory science regardless of ethical, feasibility, or confidentiality constraints. As detailed in a June 28, 2018 letter from the chair of the SAB, the SAB learned of the rule only through a press event, federal register notice, and news articles.[622] The letter further explained that the proposed rule "was not identified as a major action in either of the Spring 2017 or Fall 2017 semi-annual Regulatory Agendas," and that SAB members "had no information regarding the timeline for finalizing the rule . . . ."[623] The letter also points out that "the precise design of the proposed rule appears to have been developed without a public process for soliciting input specifically from the scientific community," even though the proposed rule raises important scientific questions.[624]

Not surprisingly, the SAB concluded in its May 31, 2018 meeting that the Proposal merits SAB review because it "deals with issues of scientific practice and proposes constraints to the use of scientific studies in particular contexts."[625] Moreover, the SAB chair's June 28 letter raises a number of questions that echo the concerns we have detailed in our comments, including the feasibility of providing access to data and methods for already-completed studies; "legitimate confidentiality and privacy interests" that would counsel against providing "complete public access"; the costs and effort associated with implementing the Proposal; the relationship between the Proposal and previous EPA efforts to encourage transparency; and the need to consider "the multiple existing methods to assess the validity of prior epidemiologic studies" that "do not provide public access to data and analytic methods."[626]

EPA's failure to consult with the SAB is contrary to statute and to EPA's well-established practice. EPA must submit its Proposal to the SAB pursuant to the requirements of 42 U.S.C. § 4365(c)(1) (the Environmental Research Development Demonstration Authorization Act or "ERDAA"), which requires the Administrator to submit to the SAB any proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the (EPA) on which the proposed action is based at the time it provides that proposal to another agency of the government for formal review. The SAB must

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[621] CAA § 109(d)(2)(B); 307(d)(3).

[622] Letter from Dr. Michael Honeycutt, Chair, Science Advisory Board, to Scott Pruitt, EPA Administrator (June 28, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/4ECB44CA28936083852582BB004ADE54/$File/EPA-SAB-18-003+Unsigned.pdf.

[623] *Id.*

[624] *Id.*

[625] *Id.*

[626] *Id.*

then review and comment on the proposal.[627] While the Administrator need not receive the SAB's final approval, the Administrator must consider the SAB's advice and comments.[628]

As the SAB chair's letter notes, EPA's "usual process" is to inform the SAB about the publication of the agency's semi-annual regulatory agenda and provide descriptions of actions that are contained in the agenda, including "available information regarding the science that is informing these agency actions."[629] That procedure was not followed here. In its evident zeal in the name of purported "transparency," EPA has ignored major statutory and regulatory requirements that provide *actual* transparency to the Clean Air Act's scientific review process.[630] Should EPA decide to move forward with this Proposal, it must first allow the SAB to complete its review and take into account the SAB's recommendations in any final rule.

G. EPA's Proposal Fails to Meet the Procedural Requirements of FIFRA

The Proposal lists FIFRA section 25 as an authority for the rulemaking.[631] The agency, however, has already failed to follow several required procedures for issuing a valid regulation under this section of FIFRA. FIFRA section 25 requires the agency to seek comments from the Secretary of Agriculture on all draft proposed regulations 60 days prior to signing a proposed regulation for publication,[632] and 30 days prior to publication for a final rule. If the Secretary of Agriculture provides comments, the Administrator must also respond in writing as part of the proposed rulemaking package.[633] FIFRA additionally requires EPA to publish a notice in the Federal Register simultaneously with the transmission of the proposed rule to USDA.[634] And the statute requires the agency to submit a copy of the proposed rule for comment to the Scientific Advisory Panel ("SAP"),[635] as well as a copy to the Agriculture Committees in the House and Senate *any time* the agency is required to consult with the Secretary of Agriculture.[636] This means that EPA here should have provided both committees and the SAP with a copy of the proposed regulation at least 60 days prior to publication of the Proposal in the Federal Register.

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[627] 42 U.S.C. §4365(c)(2).
[628] *See* H. Rep. No. 95-722 (95th Cong. 1st Sees. (1977) (Conference Report).
[629] Letter from Dr. Michael Honeycutt, Chair, Science Advisory Board, to Scott Pruitt, EPA Administrator (June 28, 2018).
[630] *See* Memorandum "Identifying EPA Planned Actions for Science Advisory Board Consideration of the Underlying Science" from Michael Goo, Assistant Administrator for Policy, Glenn Paulsen, EPA Science Advisor, and Vanessa Vu, Science Advisory Board Office Director (Dec. 27, 2012;) Memorandum from James Mihelcic, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science to Members of the Chartered SAB and SAB Liaisons (Nov. 12, 2013) (explaining SAB Work Group process, where EPA sent to the SAB "short descriptions of major planned actions that were not yet proposed" and the SAB Work Group determined which of the actions merited their consideration in a public forum).
[631] 83 Fed. Reg. 18769.
[632] 7 U.S.C. 136w(a)(2)(A).
[633] 7 U.S.C. 136w(a)(2)(B).
[634] 7 U.S.C. 136w(a)(2)(D).
[635] 7 U.S.C. 136w(d)(1).
[636] 7 U.S.C. 136w(a)(3).

The agency did not comply with any of these requirements, and does not indicate that it will in any final rule. The Proposal is therefore unlawful.[637]

To be sure, in some instances the Administrator and Secretary may together agree to waive some of the consultation requirements among themselves,[638] but there is no indication that Administrator Pruitt did that with this Proposal. And even if the Administrator and Secretary later agree to waive the consultation requirement section 25(a)(2)(A) and (B), that waiver would not alter EPA's obligation to provide the SAP and the House and Senate Committees with a copy of the regulation. Nor would it change the fact that the Administrator illegally issued the Proposal without consulting the Secretary of Agriculture. A very serious consequence of these procedural mistakes is to deprive the agency of a full understanding of how the proposed rulemaking might affect the regulation of pesticides and thereby affect agriculture, human health, and the environment.[639] Therefore, the only lawful path forward here is for the Agency to withdraw the Proposal, consult with the entities required by FIFRA, and then subsequently re-notice the Proposal.

H. EPA's Proposal Fails to Meet the Procedural Requirements of the Safe Drinking Water Act, 42 U.S.C. § 300f Et Seq.

EPA cites the Safe Drinking Water Act as an authority for the Proposal, but has failed to comply with the procedural requirements of the statute. The SDWA provides authority to promulgate regulations at 42 U.S.C. 300g-1(d). Though EPA does not cite this particular section, it is the only provision of the SDWA that provides EPA with rulemaking authority. The SDWA requires the Administrator to consult with the Secretary of Health and Human Services and the National Drinking Water Advisory Council in proposing and promulgating regulations under this section. EPA has not met these requirements here, and as such cannot claim to be using SDWA authority to promulgate this rule.

I. EPA Unlawfully Failed to Consult with Other Agencies as Required by TSCA.

When promulgating the Proposal, EPA unlawfully failed to consult with other entities as required by TSCA. For example, consider the sole statutory authority EPA cites under TSCA—§ 10.

To the extent EPA acts under TSCA § 10, TSCA § 10 repeatedly directs EPA to consult, cooperate, and/or coordinate with the Secretary of Health and Human Services, and sometimes other agencies as well.[640] EPA has not identified any specific provision of TSCA § 10 that authorizes the proposed rule, and as noted above, no provision does. But if EPA acts under TSCA § 10, then EPA needs to comply with the requirements of whichever provision EPA

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[637] If finalized, the proposal will also have to be transmitted to the Secretary of the Senate and Clerk of the House of Representatives. See 7 U.S.C. 136w(a)(4). The rule does not become effective until 60 days after this rule or regulation is transmitted.
[638] 7 U.S.C. 136w(a)(2)(C).
[639] *See also,* Section II.D.8.
[640] 15 U.S.C. § 2609(a), (b)(2)(A), (b)(2)(B), (c), (d), (e), (g).

considers relevant. Most of the provisions of TSCA § 10 expressly require that EPA consult, coordinate, or cooperate with, at least, the Secretary of Health and Human Services (section 10(a), 10(b)(2)(A), 10(b)(2)(B), 10(c), 10(d), 10(e), 10(g)). For example, the provision that mentions "research and development results" states that EPA shall act "in consultation with the Secretary of Health and Human Services and other heads of appropriate departments and agencies."[641] EPA does not appear to have complied with any of the procedural requirements of TSCA § 10.

J. EPA Has Failed to Consult with the Science Advisory Committee on Chemicals

As discussed above, this proposed rule has severe implications for the implementation of TSCA. The Science Advisory Committee on Chemicals' purpose is "to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this subchapter."[642] This rulemaking specifically involves "the scientific and technical aspects of issues relating to the implementation of [this Act]," yet there is no indication that the Administrator has consulted with the committee.[643] Congress specifically created this Committee to consult on these types of issues, and thus EPA is abusing its discretion to not consult with this Committee about a proposal that will so radically affect the scientific and technical aspects of issues relating to the implementation of TSCA.

K. EPA Has Failed to Provide Documents in Response to EDF's FOIA Requests

EDF currently has two Freedom of Information Act Requests directly related to the substance of this rulemaking pending at EPA, for which we have received *no* responsive documents thus far, despite the passage of the statutory deadlines for a response. The first request (No. EPA-HQ-2018-005636) was submitted on March 20, with a determination from EPA statutorily due by April 19—which has not been provided. EDF submitted a second request (No. EPA-HQ-2018-007397) on May 4. Given the lack of transparency and information around the basis for this rule, its impacts, and its true motivations, EDF and the public cannot provide informed comment on this rule without the public records that have been requested. For EPA to close the public comment period on this Proposal before all relevant records are released to the public is arbitrary and prevents our ability to meaningfully comment.

L. The OIRA Review Process for the Proposal Was Too Rushed to be Meaningful and EPA Has Not Sufficiently Coordinated with Other Federal Agencies

EPA did not provide enough time for the Office of Information and Regulatory Affairs ("OIRA") to meaningfully review the Proposal. Executive Order 12,866 requires agencies to

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[641] 15 U.S.C. § 2609(g).
[642] 15 U.S.C. § 2625(o)(2).
[643] 15 U.S.C. § 2625(o)(2).

submit all significant regulatory actions to OIRA.[644] This submission must contain "an assessment of the potential costs and benefits of the regulatory action" in addition to other analyses.[645] Executive Order 12,866 provides OIRA 90 days to review and return the draft regulatory action to the agency.[646] As indicated above, the Proposal gives scant consideration to the costs of the proposed action. The April 17, 2018 draft sent to OIRA for review contained *no* mention of cost and benefits of the Proposal at all.[647] It appears that OMB drafted the two paragraphs on costs that appear in the Proposal as published in the federal register.[648]

EPA transmitted the Proposal to OIRA on April 19, and OIRA's website indicates that its review concluded on April 23.[649] This is not nearly sufficient time for White House review of this far-reaching Proposal that raises important inter-agency issues. Further, media outlets report that there were discrepancies in the date when OIRA concluded its review of the proposed rule, suggesting that the date was backdated from April 25 to April 23 only after Administrator Pruitt signed the proposed rule on April 24.[650] The public record also shows OIRA convened no Executive Order 12,866 meetings in regards to this rule. EDF requested such a meeting on the morning of April 24; our request was not granted, even though the Proposal was still listed as under OIRA review.

The rushed process is particularly concerning given the proposed rule's complex cross-agency impacts. A letter from a group of Democratic senators to OIRA raising these concerns highlighted that, on average, OIRA review of EPA rules takes 55 days.[651] Given how bare-bones EPA's proposed rule was, lacking many of the elements required by Executive Order 12,866, it seems that OIRA should have required even more time to review the Proposal. Because this rule affects EPA's regulatory actions across program areas and statutes and interacts with the work of other agencies, as discussed more in Section II.D.8, adequate OIRA review was required to ensure consistency across the federal government. Certain other agencies base their standards on standards set by EPA. For example, FDA and EPA work together to promulgate advice on fish consumption, based on the reference dose calculated by EPA. The Proposal could thus have an impact on FDA's ability to promulgate advice on fish consumption sufficient to protect human health.[652] Thus, EPA's disregard of scientific evidence as it sets these standards will directly impact the sufficiency of standards set by these agencies.

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[644] Exec. Order 12,866, *Regulatory Planning and Review*, 58 Fed. Reg. 51,735 (Sept. 30, 1993).
[645] *Id.*
[646] *Id.*
[647] EO 12866 Proposal 2080-AA14 OIRA Review Start Document (Apr. 17, 2018), ID EPA-HQ-OA-2018-0259-0007.
[648] *Compare* EO 12866 Proposal 2080-AA14 OIRA Review Start Document (Apr. 17, 2018), ID EPA-HQ-OA-2018-0259-0007 *with* EO 12866 Proposal 2080-AA14 OIRA Conclusion Document (Apr. 23, 2018), ID EPA-HQ-OA-2018-0259-0006.
[649] OIRA, *OIRA Conclusion of EO 12866 Regulatory Review for Strengthening Transparency and Validity in Regulatory Science*, https://www.reginfo.gov/public/do/eoDetails?rrid=128014 (last accessed Aug. 16, 2018).
[650] *See* Sean Reilly, *OMB backdates completion date for 'secret science' review*, E&E News (Apr. 27, 2018), https://www.eenews.net/greenwire/2018/04/27/stories/1060080331.
[651] Letter from Senators Hassan, Carper, McCaskill, Markey, Harris, and Whitehouse to Neomi Rao, Administrator, OIRA (May 9, 2018), https://www.hassan.senate.gov/imo/media/doc/RaoEPALetterFinal.pdf.
[652] FDA, *Technical Information on Development of Fish Consumption Advice - FDA/EPA Advice on What Pregnant Women and Parents Should Know about Eating Fish*,

As noted above, EPA failed to consult with other federal agencies before proposing this rule. EPA also violated its own data access plan, which says EPA "will consider how, when, and whether to apply the EPA policy to research that is subject to public access policies from other agencies" as it recognizes that "duplicative or conflicting requirements might result when research is subject to public access policies from multiple federal agencies".[653] There is no evidence that EPA considered these issues or that EPA followed its own policy to "coordinate with other agencies and the private sector" as it implements new data access policies.[654]

The usual procedures appear to have been set aside for this proposed rule, and EPA has provided no explanation for why shortened review procedures were necessary. It was initially reported that this Proposal was categorized as a "tier 3" measure, subject to the lowest amount of scrutiny in EPA's own internal review process, and developed largely by political appointees with no input from career staff, despite having characteristics of a "tier 1" measure, subject to the highest level of scrutiny.[655] These characteristics include being precedent-setting; controversial; having cross-Agency, cross-media, and inter-agency impacts and controversies; and raising external interest, all of which are present here. Though the agency appears to have now raised it to "tier 1" status, the Proposal that is now available for public comment was subject only to these initial hasty procedures, calling into question its validity.[656]

EPA must withdraw the Proposal and release it only under the full, proper procedures.

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https://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm531136.htm (last accessed Aug. 1, 2018).
[653] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* at 8 (Nov. 29, 2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.
[654] *Id.* at 15.
[655] Inside EPA, *EPA Science Plan Skirted Usual Process, Raising Finalization, Legal Doubts* (May 14, 2018). https://insideepa.com/daily-news/epa-science-plan-skirted-usual-process-raising-finalization-legal-doubts.
[656] Inside EPA, *EPA Strengthens Internal Review Of Science Rule As SAB Seeks Scrutiny* (June 1, 2018), https://insideepa.com/daily-news/epa-strengthens-internal-review-science-rule-sab-seeks-scrutiny.

Appendix A. Analysis of Sources Cited to in the Proposal

This appendix provides an analysis of the sources EPA cites in the proposed rule, showing ultimately that EPA has provided no sources or authorities that support or provide a reasoned basis for the proposed rule and that many of the sources raise key implementation concerns that EPA fails at all to address—rendering the proposal arbitrary and capricious.

Footnote 1: See Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011). "Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science."

Exec. Order No. 13563 requires agencies to utilize the "best available science" in regulatory actions.[657] This requirement is further encoded in numerous statutes and policies that EPA implements. EPA states in the proposed rule that: "The best available science must serve as the foundation of EPA's regulatory actions."[658] However, as the comments raise more thoroughly, by arbitrarily restricting the scientific studies EPA will consider, this proposed rule will *hinder* EPA's use of the best available science and therefore violates the command of Exec. Order No. 13563 and other versions of these requirements.

Furthermore, this executive order requires agencies to "ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions" consistent with the President's Memorandum for the Heads of Executive Departments and Agencies, "Scientific Integrity" (March 9, 2009). As the comments note, however, the proposed rule along with the provision allowing the Administrator to grant discretionary exemptions will harm the objectivity of scientific and technological information and processes at EPA by paving the way for politics, rather than objective scientific criteria, to dictate which scientific studies are considered.

Footnote 2: See Memorandum for the Heads of Executive Department[sic] and Agencies on Scientific Integrity (Mar. 9, 2009). "If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."

EPA claims about the proposal that "[b]y better informing the public, the Agency in[sic] enhancing the public's ability to understand and meaningfully participate in the regulatory process." EPA then cites to the Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity. [659] Not only does the proposal conflict with this memorandum, but it will make it more difficult for the public to meaningfully participate in the regulatory process.

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[657] Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011).
[658] 83 Fed. Reg. at 18,769.
[659] 83 Fed. Reg. at 18,769 n. 2.

The memorandum sets out a number of actions for agencies to take to ensure scientific integrity.[660] Just *one* of these factors involves making scientific and technological information publicly available, notably specifying, "*Except for information that is properly restricted from disclosure* under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological *findings or conclusions* considered or relied on in policy decisions."[661] The memorandum thus supports only making scientific findings and conclusions publicly available, not the data underlying those findings and conclusions. Further, it correctly notes that some information is properly restricted from disclosure. It does not say that the inability to disclose such information should prevent it from being considered by agencies. The memorandum thus provides *no* support for the notion that agencies should be barred from relying on studies where the underlying data cannot be disclosed. The memorandum's narrow approach to public disclosure should not be taken to support EPA's proposal but rather counsels against the proposal's mandate that all underlying data be made publicly available.

EPA's proposal fundamentally conflicts with the heart of the memorandum—that "[t]he public must be able to trust the science and scientific process informing public policy decisions."[662] To earn this trust, the memorandum declares: "Political officials should not suppress or alter scientific or technological findings and conclusions."[663] By discarding scientific studies where underlying data cannot be made publicly available, this proposal will result in scientific findings being suppressed. By allowing the Administrator to grant exemptions to this policy based on their discretion with no public record or explanation, the proposal allows for the Administrator to pick and choose based on their preference the science informing the agency's actions, eroding the public's trust in the science informing public policy decisions.

The memorandum provides a number of ways in which agencies can ensure scientific integrity which the proposal does not consider including: hiring candidates for science and technology position based on their "knowledge, credentials, experience, and integrity," having in place appropriate rules and procedures to ensure integrity of the scientific process, establishing scientific processes such as peer review and accurately reflecting scientific and technological information, establishing procedures to identify when scientific integrity may be compromised, including establishing whistleblower protections.[664] EPA does not explain why any of these pathways would not serve as a better means of ensuring scientific integrity.

Footnote 3: EPA has the authority to establish policies governing its reliance on science in the administration of its regulatory functions. Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use

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[660] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009).
[661] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009) (emphasis added).
[662] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009).
[663] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009).
[664] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009).

non-public data in support of its regulatory actions. See Coalition of Battery Recyclers Ass'n v. EPA, 604 F.3d 613, 623 (D.C. Cir. 2010); American Trucking Ass'ns v. EPA, 283 F.3d 355, 372 (D.C. Cir. 2002). EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.

In footnote 3 of the proposal, EPA notes that "courts have at times upheld EPA's use [sic] non-public data in support of its regulatory actions" and cites to *Coalition of Battery Recyclers Ass'n* v. *EPA,* 604 F.3d 613, 623 (D.C. Cir. 2010) and *American Trucking Ass'ns* v. *EPA,* 283 F.3d 355, 372 (D.C. Cir. 2002).[665] These cases indeed held that EPA's prior, long-standing position of relying on scientific studies even when the underlying data could not be made publicly available was reasonable. It is well-established that agencies must acknowledge changes in position and "show that there are good reasons for the new policy."[666] This footnote, the only mention of EPA's previous policy, does not sufficiently acknowledge or explain why EPA is now changing its position.

In *American Trucking Ass'ns* v. *EPA* the Court held that the Clean Air Act did not require EPA to make public underlying data where EPA relied on the study itself and not the raw data underlying the study.[667] The Court stated that such a requirement "would be impractical and unnecessary."[668] They agreed with EPA's then statement that:

> If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment.... Such data are often the property of scientific investigators and are often not readily available because of ... proprietary interests ... or because of [confidentiality] arrangements [with study participants].[669]

In *Coalition of Battery Recyclers Ass'n* v. *EPA*, the Court cited *American Trucking Ass'ns* v. *EPA* and held, again, that EPA was permitted to rely on studies without making the underlying data public.[670] They noted, "raw data often is unavailable due to proprietary interests of a study's scientific investigators or confidentiality agreements with study participants."[671] These court cases thus not only upheld EPA's prior practice as permissible, but went on to agree that EPA's prior practice was preferable and necessary in light of these other policy concerns.

EPA provides no response to this history, saying only: "Historically, EPA has not consistently observed the policies underlying this proposal. . . . "[672] EPA fails explicitly to

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[665] 83 Fed. Reg. at 18, 769.
[666] *FCC v. Fox Television Stations, Inc.* 556 U.S. 502, 515 (2009).
[667] 283 F.3d 355, 372 (D.C. Cir. 2002).
[668] *Id. at 372* (quoting Particulate Matter NAAQS, 62 Fed. Reg. at 38,689.)
[669] *Id.*
[670] 604 F.3d 613, 623 (D.C. Cir. 2010).
[671] *Id.* at 315.
[672] 83 Fed. Reg. at 18, 769.

recognize that this proposal changes its past policy and provides no justification in light of the compelling opposing points that both EPA and the Courts previously recognized as deterring this approach.

Footnote 4: Exec. Order No. 13777, 82 Fed. Reg. 12285 (Mar. 1, 2017). Regulatory reform efforts shall attempt to identify "those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility."

EPA claims that the proposal is consistent with Exec. Order No. 13777.[673] This executive order provides no support for the proposal, and in fact is targeted at eliminating regulations including those that are "unnecessary" and "ineffective," which, as our comments detail, the proposal clearly would be.[674]

This executive order creates a Regulatory Reform Task Force and calls for them to identify for repeal, replacement, or modification regulations that among other criteria

> are inconsistent with the requirements of section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note), or the guidance issued pursuant to that provision, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility.[675]

As described in detail in our comments and below, contrary to the inference drawn here in Exec. Order No. 13777, the Data Quality Act and OMB's guidelines issued pursuant to it *do not* require research data and models to be made publicly available for reproducibility purposes in order for agencies to rely on the scientific findings and conclusions produced using that data.

Executive orders cannot override the statutory requirements that EPA use the best available science or the laws governing administrative procedure including the APA. The proposal's "consistency" with this executive order then cannot serve as a legal basis for EPA to adopt an arbitrary and capricious policy that contravenes these best available science requirements reflected in the statutes EPA administers.

Additionally, Exec. Order No. 13777 by its terms requires only the identification of regulations that rely in whole or in part on data not publicly available, it says nothing about precluding agencies from relying on such studies and does not and cannot require agencies to adopt such practices. However, if the proposed rule is to be "consistent" with the executive order then it must also follow section 3(e):

> In performing the evaluation described in subsection (d) of this section, each Regulatory Reform Task Force shall seek input and other assistance, as permitted by law, from entities significantly affected by Federal regulations, including State, local, and tribal

[673] 83 Fed. Reg. at 18, 769.
[674] Exec. Order No. 13777, 82 Fed. Reg. 12285, 12286 (Mar. 1, 2017).
[675] Exec. Order No. 13777, 82 Fed. Reg. 12285, 12286 (Mar. 1, 2017).

governments, small businesses, consumers, non-governmental organizations, and trade associations.[676]

There is no evidence that EPA consulted with the many stakeholders impacted by this policy, including the medical or scientific research communities, which have been largely opposed to this policy.

Footnote 5: Exec. Order No. 13783, 82 Fed. Reg. 16093 (Mar. 31, 2017). "It is also the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics."

EPA claims the proposal is consistent with Exec. Order No. 13783.[677] However, Exec. Order No. 13783 calls for agencies to consider salient information that the proposal has patently ignored. Exec. Order No. 13783 calls for agencies to consider the costs and benefits "that are based on the best available science and economics" to ensure sound regulatory decision-making.[678] The proposal provides no analysis of the costs and benefits of implementing this new policy, despite there likely being high costs to making research data public with little evidence of significant benefits achieved from this policy alone.

Further, by arbitrarily excluding scientific information that EPA may use in its regulatory analyses, the proposal conflicts with the executive order's command to employ the best available science and economics.[679]

Footnote 6: February 22, 2002 (67 F.R 8453) OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information (2002) https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for- ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information.

EPA wrongly claims that the proposal is "consistent with. . . the focus on transparency in OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies*."[680] To say that OMB's Guidelines have a "focus on transparency" that is furthered by EPA's proposal is a gross oversimplification. EPA here appears to suggest that transparency is the highest objective to be achieved, divorced from any consideration of whether transparency hinders or furthers any other goals. The OMB Guidelines, while imposing high standards of quality, objectivity, utility, and integrity of information disseminated by Federal Agencies, recognize the need to implement controls "flexibly, and in a

[676] Exec. Order No. 13777, 82 Fed. Reg. 12285, 12286 (Mar. 1, 2017).
[677] 83 Fed. Reg. at 18,769.
[678] Exec. Order No. 13783, 82 Fed. Reg. 16093, 16095 (Mar. 31, 2017).
[679] Exec. Order No. 13783, 82 Fed. Reg. 16093 (Mar. 31, 2017).
[680] 83 Fed. Reg. at 18,769-70.

manner appropriate to the nature. . . of the information to be disseminated."[681] They suggest thinking about transparency strategically to further the aims of good government, unlike the proposal, which conflates transparency and quality without consideration of other factors.

As part of ensuring "objectivity" of information these guidelines encourage agencies which disseminate influential scientific, financial, or statistical information, "to include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties." [682] However, they emphasize the need to treat certain data differently, due to privacy and confidentiality concerns.[683] While they recommend agencies "identify the sources of the disseminated information" they note that this is "to the extent possible, consistent with confidentiality protections."[684] Importantly, they take great pains to urge agencies *not* to subject all data to a reproducibility requirement where this could hamper agencies.[685] They require agencies, instead, to consult with "the relevant scientific and technical communities" to identify data that "can practicable [sic] be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints."[686] There is no indication that EPA consulted with the scientific and technical community, with EPA's own Science Advisory Board raising concerns about the proposal and finding that "[t]his action merits further review by the SAB."[687] The Guidelines make clear:

> Making the data and methods publicly available will assist in determining whether analytic results are reproducible. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections.[688]

In direct conflict with the reasoning underlying EPA's proposal, the Guidelines specifically provide that it is possible to verify the objectivity of information that cannot be made publicly available through other types of "robustness checks."[689] As an example, they point to the Harvard Six Cities Study, where underlying data could not be made publicly available due to confidentiality concerns, but the raw data was released instead to researchers at the Health Effects Institute, bound to the same confidentiality requirements as the original researchers, who were able to replicate its results.[690] In contrast, EPA's proposal would not allow for the consideration of this study.[691]

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[681] *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information*, 67 Fed. Reg. 8452, 8453 (Feb. 22, 2002).
[682] 67 Fed. Reg. 8452, 8460.
[683] *Id.*
[684] 67 Fed. Reg. 8452, 8459.
[685] 67 Fed. Reg. 8452, 8460 ("With regard to original and supporting data related thereto, agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement.")
[686] *Id.*
[687] Memorandum from SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science (May 12, 2018).
[688] 67 Fed. Reg. 8452, 8460.
[689] *Id.*
[690] 67 Fed. Reg. 8452, 8456.
[691] 83 Fed. Reg. at 18769 n. 3 (citing to a case challenging EPA's reliance on this study and saying the rule "would preclude it from using such data in future regulatory actions.")

The guidelines also recommend agencies recognize that information quality comes at a cost, and that agencies should weigh the costs and benefits, which EPA has not done in the proposal.[692]

Thus, the proposal completely turns away from OMB's guidelines where OMB "urges caution in the treatment of original and supporting data because it may often be impractical or even impermissible or unethical to apply the reproducibility standard to such data." [693] As the comments discuss further, the proposal rule thus unlawfully conflicts with this flexible approach that prioritizes agencies' ability to use science as set out by OMB under the Information Quality Act.

Footnote 7: Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset (https://project-open-data.cio.gov/policy-memo/). "Specifically, this Memorandum requires agencies to collect or create information in a way that supports downstream information processing and dissemination activities. This includes using machine-readable and open formats, data standards, and common core and extensible metadata for all new information creation and collection efforts. It also includes agencies ensuring information stewardship through the use of open licenses and review of information for privacy, confidentiality, security, or other restrictions to release."

EPA claims the proposal is consistent with OMB's memorandum on Open Data Policy.[694] This is incorrect, however, as the memorandum supports downstream information processing and dissemination—not through complete public disclosure without regard to privacy or security—but through instituting a framework of data collection, formatting, and storage that allows for public dissemination, *if possible*.[695] Recognizing that not all data can be publicly disclosed, and that such data is still useful, the memorandum declares: "Whether or not particular information can be made public, agencies can apply this framework to all information resources to promote efficiency and produce value."[696]

The proposal is thus inconsistent with the memorandum, which stresses the importance of information stewardship and "review of information for privacy, confidentiality, security, or other restrictions to release."[697] When information cannot be released, the memorandum does not suggest agencies ignore the information or not rely on it for regulatory purposes. It focuses on prescribing agency practices to maximize the downstream usability of data that *can* be made publicly available, including through "using machine-readable and open formats, data standards, and common core and extensible metadata for all new information creation and collection efforts"[698] as well as "building or modernizing information systems in a way that maximizes interoperability and information accessibility, maintains internal and external data asset

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[692] 67 Fed. Reg. 8452, 8452-53.
[693] 67 Fed. Reg. 8452, 8456.
[694] 83 Fed. Reg. at 18,769-70.
[695] Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 (May 9, 2013).
[696] *Id.* at 1.
[697] *Id.* at 2.
[698] *Id.* at 1-2.

inventories, enhances information safeguards, and clarifies information management responsibilities."[699] Thus, while the memorandum centers on how agencies can marginally increase the utility of information they possess for use by the public, the proposal turns this on its head by advocating for discard of otherwise high quality scientific information if the data underlying such information cannot be made publicly available.

OMB stresses that to achieve "open data," agencies should adopt a presumption in favor of openness that is importantly limited by countervailing privacy, confidentiality, security, or other valid restrictions.[700] Thus, agencies are expected to "exercise judgment before publicly distributing data residing in an existing system by weighing the value of openness against the cost of making those data public."[701] The proposal does not at all weigh the costs, to the agency or to the public, of requiring all underlying data to be made publicly available.

While requiring agencies to adopt measures to strengthen privacy protections and data security, the memorandum recognizes serious limitation to data disclosure that EPA completely fails to consider. For example, the memorandum mandates that agencies take into consideration the "mosaic effect,"[702] which EPA does not at all acknowledge—all while making superficial and unsupported statements about how privacy concerns can be easily addressed.[703] The memorandum recognizes and stresses the challenge of responding to this threat, which requires undertaking a "risk-based analysis, often utilizing statistical methods whose parameters can change over time, depending on the nature of the information, the availability of other information, and the technology in place that could facilitate the process of identification."[704] OMB importantly notes this analysis "may affect the amount, type, form, and detail of data released by agencies."[705] Because it ignores these concerns, EPA's proposal is arbitrary and capricious.

Footnote 8: Plan to Increase Access to Results of EPA-Funded Scientific Research; EPA Open Government Plan 4.0; Open Data Implementation Plan; EPA's Scientific Integrity

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[699] *Id.* at 2.
[700] *Id.* at 5.
[701] *Id.* at 6.
[702] OMB explains: "The mosaic effect occurs when the information in an individual dataset, in isolation, may not pose a risk of identifying an individual (or threatening some other important interest such as security), but when combined with other available information, could pose such risk. Before disclosing potential PIT or other potentially sensitive information, agencies must consider other publicly available data–in any medium and from any source--to determine whether some combination of existing data and the data intended to be' publicly released could allow for the identification of an individual or pose another security concern." Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 at 4-5 (May 9, 2013).
[703] Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 at 9-10 (May 9, 2013). *See, e.g.*, 83 Fed. Reg. at 18,770 ("EPA believes that concerns about access to confidential or private information can, in many cases, be addressed. . . .")
[704] Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 at 9-10 (May 9, 2013).
[705] Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 at 10 (May 9, 2013).

Policy; Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.

Rather than acknowledge the drastic change in EPA policy this proposal would implement, EPA contrarily claims that the proposal simply "builds upon prior EPA actions."[706] None of the sources EPA cites here call into question the validity of scientific research for which underlying data and models cannot be made public. Indeed, they consistently recognize the legitimate limitation on data disclosure while also acknowledging the need for the agency to rely on information for which underlying data may not be released without compromising important privacy and confidentially concerns.

I. Plan to Increase Access to Results of EPA-Funded Scientific Research, https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

Contrary to EPA's claim that the proposal "builds upon" prior EPA policy, it is actually a radical shift away from the view EPA takes in its *Plan to Increase Access to Results of EPA-Funded Scientific Research*, which notes even though "some research data cannot be made fully available to the public but instead may need to be made available in more limited ways," this availability "does not affect the validity of the scientific conclusions from peer-reviewed research publications."[707] The *Plan to Increase Access to Results of EPA-Funded Scientific Research* thus dictates the view EPA has consistently espoused in the past, that it may make data available when it can without compromising other critical values, but that it will not exclude information from its consideration when it cannot. Yet EPA denies, rather than acknowledging and explaining, its new decision to reverse its past stance.

The *Plan* requires EPA to make publications resulting from EPA-funded research publicly accessible on NIH's PubMed Central (PMC).[708] It aims to "maximize access, by the general public and without charge, to digitally formatted data resulting from EPA funded research, *while protecting confidentiality and personal privacy, recognizing proprietary interests, business confidential information and intellectual property rights, and preserving the balance between the relative benefits and costs of long-term preservation and access.*"[709] It recognizes important exceptions for when "the research data cannot be released due to one or more constraints, such as requirements to protect confidentiality, personal privacy, proprietary interest, or property rights."[710] It specifically declares: "The validity of scientific conclusions drawn from research publications or their associated research data, or EPA's ability to consider those conclusions and data in its actions, does not depend on compliance with this Plan."[711]

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[706] 83 Fed. Reg. at 18,770.
[707] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* 4-5 (Nov. 29, 2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf
[708] *Id.* at 8.
[709] *Id.* at 11 (emphasis added).
[710] *Id.*
[711] *Id.* at 6.

The *Plan* acknowledges making more limited releases of data "e.g., establishing data use agreements with researchers that respect necessary protections," that fall short of full public disclosure.[712] Unlike the proposal, which fails to account for the costs of implementation, the plan also acknowledges the need to "balance between the value of providing long-term access and its associated costs."[713]

The *Plan* thus further enshrines the view that this rule is unnecessary—where EPA has access to data and can release it without compromising other interests, it already does so. It further supports the notion that this type of disclosure is not necessary, and will not help, to ensure EPA's reliance on valid scientific conclusion. EPA must fully explain its decision to deviate from this prior-held stance.

II. EPA Open Government Plan 4.0, https://www.epa.gov/sites/production/files/2016-09/documents/2016epaopengovplan4_0draft091516update1.pdf

EPA's *Open Government Plan 4.0* also acknowledges that not all data is releasable to the public, even as it aims to "increase publicly accessible EPA data to support citizens' participation in government and promote transparency and accountability of Agency operations."[714] EPA states in the *Plan*: "By providing *releasable* information in open and machine-readable formats, EPA enables the public and other organizations to better leverage the rich wealth of information available."[715] Further, in the *Plan* EPA notes the stringent requirements it has in place on the "collection, access, use, dissemination, and storage of personally identifiable information (PII) and Privacy Act information to prevent unwarranted invasions of personal privacy."[716]

Rather than suggesting that EPA release underlying data to the public in order to rely on scientific information, the *Plan* only speaks to utilizing a careful approach—with due regard for privacy and limitations to data release—to making EPA data more accessible to the public where possible.

III. Open Data Implementation Plan, https://www.epa.gov/sites/production/files/2015-05/documents/opendatapolicyimplementationplan_030415_finalb.pdf

EPA's own Open Data Policy, which implements the requirements of White House "Open Data Policy – Managing Information as an Asset" Memorandum M-13-13, notes that it is important to develop "policies and processes to ensure that only appropriate data are released to

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[712] *Id.* at 4.
[713] *Id.*
[714] EPA, *Open Government Plan 4.0* 4 (Sep. 2016), https://www.epa.gov/sites/production/files/2016-09/documents/2016epaopengovplan4_0draft091516update1.pdf.
[715] EPA, *Open Government Plan 4.0* 4 (Sep. 2016), https://www.epa.gov/sites/production/files/2016-09/documents/2016epaopengovplan4_0draft091516update1.pdf (emphasis added).
[716] EPA, *Open Government Plan 4.0* 23 (Sep. 2016), https://www.epa.gov/sites/production/files/2016-09/documents/2016epaopengovplan4_0draft091516update1.pdf.

the public and made available online."[717] To do so, EPA uses different "access levels" for different data sets, (public, restricted public, and non-public) and notes that it may not be able to publicize data due to "law, regulation or policy, which address privacy, confidentiality, security or other valid restrictions."[718]

Thus, while the Open Data Policy applies a multi-level, nuanced approach to data disclosure, the Proposal completely does away with this by applying a blanket requirement to make all underlying data and models publicly available. The Open Data Policy this conflicts with, rather than supports, the Proposal.

IV. EPA's Scientific Integrity Policy, https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf

Contrary to EPA's claim, the Proposal turns away from EPA's Scientific Integrity Policy, which stresses "a firm commitment to evidence," endorses use of "the best available science" and "[r]equire[s] reviews. . . regarding the content of a scientific product to be based only on scientific quality considerations."[719] The Proposal, on the other hand, inhibits use of sound scientific information and evidence by arbitrarily excluding science from EPA's consideration for reasons unrelated to its quality.[720]

While the policy "[r]ecognizes the value of independent validation of scientific methods"[721] and facilitating "the free flow of scientific information" by making information available "including access to data and non-proprietary models underlying Agency policy decisions,"[722] this is a flexible standard and an ideal to aspire to, not to take priority over other competing interests—such as use of the best available science. This measure is meant to "facilitate[] the free flow of scientific information" and "expand and promote access to scientific information."[723] The Proposal, however, limits the free flow of scientific information and restricts access to scientific information by restricting EPA's consideration of scientific studies.

As discussed in our comments, this Administration has blatantly violated key aspects of the policy by silencing scientists and the limiting the dissemination of scientific information, directly undoing "EPA's longstanding commitment to the timely and unfiltered dissemination of its scientific information – uncompromised by political or other interference" and goal to communicate scientific findings openly and actively to the public.[724] The Scientific Integrity Policy is meant to uphold scientific ideals—and prevent arbitrary, politicized decisions about which science to utilize—and the Proposal is thus in strong conflict with it.

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[717] EPA, *Open Data Policy Implementation Plan* 4 (Feb. 2015), https://www.epa.gov/sites/production/files/2015-05/documents/opendatapolicyimplementationplan_030415_finalb.pdf.
[718] EPA, *Open Data Policy Implementation Plan* 4 (Feb. 2015), https://www.epa.gov/sites/production/files/2015-05/documents/opendatapolicyimplementationplan_030415_finalb.pdf.
[719] EPA, *Scientific Integrity Policy* 4, https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf.
[720] *Id.* at 3-4.
[721] *Id.* at 4.
[722] *Id.*
[723] *Id.*
[724] *Id.* at 5.

V. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information

EPA's Proposal also does not "build upon" its *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*. The *Guidelines* note that it may not be possible for underlying data and models to be subject to same degree of disclosure as analytic results, and highlight other methods of ensuring the quality of scientific research where disclosure is not possible.

The *Guidelines* start by noting, "[t]he mission of the EPA is to protect human health and safeguard the natural environment upon which life depends" and "[t]he collection, use, and dissemination of information of known and appropriate quality are integral to ensuring that EPA achieves its mission."[725] They thus highlight that the controls on data quality exist to allow EPA to meet its mission—unlike the Proposal, which makes no mention of EPA's mission or how the Proposal would further that mission. Because the Proposal restricts EPA's ability to rely on the best available science, it obscures EPA in achieving its mission to set safeguards that are protective of human health and the environment, and thus such a statement could not truthfully be made.

While the *Guidelines* seek to maximize the quality of influential information by facilitating the reproducibility of the information—they note:

> In addition, if access to data and methods cannot occur due to compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections, EPA should, to the extent practicable, apply especially rigorous robustness checks to analytic results and carefully document all checks that were undertaken. Original and supporting data may not be subject to the high and specific degree of transparency provided for analytic results; however, EPA should apply, to the extent practicable, relevant Agency policies and procedures to achieve reproducibility, given ethical, feasibility, and confidentiality constraints.[726]

EPA's *Guidelines* detail EPA's long-standing position, that it may validate research studies even when data cannot be made publicly available—unlike the Proposal, which apparently assumes disclosure of underlying data and models is necessary to ensure scientific validity. The *Guidelines* discuss existing programs, such as EPA's Quality System and EPA's Peer Review

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[725] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* 5 (Oct. 2002), https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information.

[726] *Id.* at 21.

Policy[727] that are in place to assure the high quality of EPA information disseminates. EPA does not explain in the Proposal why these other checks are now insufficient.

Footnote 9: For example, see related policies from the National Science Foundation, National Institute of Science and Technology, the National Institutes of Health; and the US Census Bureau, which provides secure access to data from several agencies in an environment that protects against unauthorized disclosure (https://www.census.gov/fsrdc).

EPA purports that the Proposal builds upon "the experience of other federal agencies in this space" but the citations reveal that is simply not the case.[728] To support this statement, EPA provides only a hyperlink to a U.S. Census Bureau website along with vague references to entire executive branch agencies, with no explanation or discussion of which of their policies EPA believes the Proposal is building upon. Without a more specific citation, it is impossible to know which policies EPA is referencing or to respond to them meaningfully.

EPA cites to the U.S. Census Bureau's Federal Statistical Research Data Centers as an example of use of secure facilities that allow the Census Bureau to provide controlled access to authorized researchers to use restricted-use microdata for statistical purposes only. In order to gain access, researchers must obtain Census Bureau Special Sworn Status by passing a moderate risk background check and swearing to protect respondent confidentiality for life. While this "solution" meets the U.S. Census Bureau's needs by allowing access to confidential information only to researchers whose proposals meet certain criteria, who go through a vetting process, and who agree to protect the information, this is done at a cost—which EPA has not accounted for—and would not satisfy EPA's requirement to make data and models "publicly available." Thus, this example provides no support for the Proposal.

Footnote 10: These include policies and recommendations from: the Administrative Conference of the United States' Science in the Administrative Process Project; National Academies' reports on Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data, and Access to Research Data in the 21st Century; the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project.

In footnote 10, EPA lists a number of organizations whose recommendations and policies the Proposal allegedly took into consideration. In fact, since the Proposal was published, many of these organizations have issued statements opposing the Proposal and contesting EPA's claim that their policies and recommendations endorse the Proposal. In this footnote, EPA provided no hyperlinks or specific citations for which recommendations and policies it was referencing, making it impossible to understand why EPA believed these organizations supported the Proposal or to respond to them.

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[727] *Id.* at 10-13.
[728] 83 Fed. Reg. at 18,770.

I. The Administrative Conference of the United States' Science in the Administrative Process Project

EPA cites to the Administrative Conference of the United States' Science in the Administrative Process Project—*Recommendation 2013-3: Science in the Administrative Process*. Wendy Wagner, sole author of ACUS's final report *Science in Regulation: A Study of Agency Decisionmaking Approaches* and who served on the panel that produced the recommendations strongly opposed the notion that the Proposal builds upon these recommendations, saying: "They don't adopt any of our recommendations, and they go in a direction that's completely opposite, completely different. . . . They don't adopt any of the recommendations of *any* of the sources they cite. I'm not sure why they cited them."[729]

While ACUS recommends agencies increase transparency of how they rely on scientific information and strive to make data underlying scientific information publicly available, nowhere do they suggest that agencies should not consider or rely on studies where underlying data and models cannot be made publicly available, or that these circumstances make scientific information less valid. They instead suggest that information be made publicly available for assessment and reproducibility purposes "[c]onsistent with the limitations in the Information Quality Act (IQA) guidelines issued by the Office of Management and Budget and its own IQA guidelines."[730] They acknowledge valid limitations such as legal protections for privacy, trade secrets, and confidential business information.[731] Thus, they recommend data be made public only "[t]o the extent practicable and permitted by law and applicable policies."[732] Unlike the Proposal, the recommendation acknowledges that agencies may still use information where underlying data cannot be publicly disclosed, and suggest agencies "note that fact and explain why they used the results if they chose to do so."[733] It thus provides a much more nuanced policy recommendation than that outlined in the Proposal—which suggests EPA either find a way to make underlying data and models public, despite the numerous potential obstacles and concerns in doing so, or completely disregard the research study.

II. National Academies Improving Access to and Confidentiality of Research Data

Rather than containing any particular recommendations or policy proposals, this report discusses a number of issues pertaining to data disclosure and privacy protection, the tradeoffs "between increasing data access on the one hand and improving data security and confidentiality

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[729] Robinson Meyer, *Scott Pruitt's New Rule Could Completely Transform the EPA*, The Atlantic (Apr. 25, 2018), https://www.theatlantic.com/science/archive/2018/04/how-the-epas-new-secret-science-rule/558878/.

[730] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process*, 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).

[731] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process*, 78 Fed. Reg. 41,352, 41,356 (July 10, 2013).

[732] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process*, 78 Fed. Reg. 41,352, 41,357 (July 10, 2013).

[733] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process*, 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).

on the other,"[734] and "alternative approaches to limiting disclosure risk while facilitating data access the benefits and limitation of various approaches to these issues."[735] Thus, rather than calling on agencies to rely only on scientific studies where the underlying data and models are made public, the report in fact discusses challenges and obstacles to achieving greater data disclosure, for which the Proposal provides no substantive or meaningful explanation.

The report discusses why exercising caution with respect to disclosing confidential personal information is so important, because if such information is exposed it could lead to

> being arrested for a crime, being denied eligibility for welfare or Medicaid, being charged with tax evasion, losing a job or an election, failing to qualify for a mortgage, or having trouble getting into college. Disclosure of a history of alcoholism, mental illness, venereal disease, or illegitimacy can result in embarrassment and loss of reputation. Less directly, research results based on personal data can cause harm by affecting perceptions about a group to which a person belongs.[736]

The report reveals very legitimate reasons why researchers and study participants would be reluctant to allow underlying data to be made publicly available—and these reasons in no way compromise the validity of the scientific conclusions based upon this data.

The report also discusses the nuances of selecting methods to protect privacy while making underlying data publicly available. For example, while EPA casually makes claims that controlled access is an example of a solution in place across federal agencies[737]—this report points out the drawbacks of such an approach:

> The use of restricted access arrangements, which has been deemed necessary to provide adequate protection for confidential information about individuals and businesses, results in increased costs to conduct research. Custodians of the data files need additional resources to process applications, operate inspection systems, staff research data centers, and inspect outputs to ensure that disclosure does not occur. Researchers require resources to prepare applications for access, to provide appropriate physical security for the data, or to visit a secure site.[738]

The report also discusses the difficulty of funding such centers—noting that while the costs are currently covered by a combination of federal agency budgets and user fees, including grants from the National Science Foundation and National Institute on Aging, federal funding may no longer be able to support such efforts.[739] EPA's cursory mention to use of restricted access facilities as a potential solution to the concerns implicated by the Proposal fail to mention or address any of these challenges.

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[734] The National Academies, *Improving Access to and Confidentiality of Research Data: Report of a Workshop*, National Academies Press 2-3 (2000).
[735] *Id.* at 3.
[736] *Id.* at 19.
[737] 83 Fed. Reg. at 18,771.
[738] *Id.* at 48.
[739] *Id.*

III. National Academies Expanding Access to Research Data: Reconciling Risks and Opportunities

EPA's Proposal in no way takes into consideration the recommendations of the National Academies report *Expanding Access to Research Data: Reconciling Risks and Opportunities*. This report considers competing approaches to increase use of research data while protecting confidentiality, and concludes that "no one way is optimal for all data users or all purposes" and, importantly, that "the nation's statistical and research agencies must provide both unrestricted access to anonymized public-use files and restricted access to detailed, individually identifiable confidential data for researchers under carefully specified conditions."[740] In other words, the report finds that making data publicly available without restriction while respecting confidentiality concerns is not currently feasible or compatible with the missions of federal agencies.

Furthermore, the report mainly concerns itself with how agencies might increase access to data in their control and possession to allow for more research in social issues and provide a better basis for more informed policy decisions—it does not discuss whether federal agencies should make data publicly available in order to allow for independent validation of scientific research they rely on for regulatory purposes and thus cannot be a basis for the Proposal.[741] While the report discusses that one of the benefits of data sharing is that it allows for "verification, refutation, or refinement of original results," nowhere does the report suggest that agencies should rely only on research studies that make data publicly available or that such verification is necessary to validate a research study.[742] Indeed, it details a discussion on this topic that presents competing views on requirements to make research data available to the public to allow for replication. John Bailar raised concerns that researchers would be deterred from doing certain kinds of work if they feared it would be subject to "hostile scrutiny" and that competitors could seize data for their interests.[743] Others disagreed with this position.[744] However, EPA failed to engage any of these considerations or at all justify its decision to implement a policy that could have severe negative implications. None of the researchers stated agencies should disregard the study if underlying data could not be made public.

The "recommendations" made by the report do not endorse EPA's proposal. The report provides 15 recommendations in Chapter 5.[745] Recommendations 1-4 concern documentation and data access and call on agencies to better document how the data they make available is used; to use a variety of modes to provide access to data they produce or fund using a combination of restricted access to confidential data and unrestricted access to appropriately altered public-use data; to support research to guide more efficient allocation of resources among different data access modes; and to involve users in planning modes of access to their data.[746]

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[740] The National Academies, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, National Academies Press 2 (2005).
[741] *Id.* at 7.
[742] *Id.* at 39.
[743] *Id.* at 105-06.
[744] *See id.* at 107.
[745] *Id.* at 63.
[746] *Id.* at 66-69.

In this Proposal, EPA does nothing to better document use of data that it makes public, has only called for a requirement to make research data and models "publicly available" rather than recognizing that a variety of modes and levels of access may be necessary, and does nothing to support more research into methods of making data more widely available without compromising confidentiality—indeed blithely assuming that such means are already available and sufficient—and also has not indicated that there has been any widespread call for EPA to make such data available or pointed to any comments of users of this data in this process.

Recommendations 5-8 concern public use data and call on agencies to support research on techniques to provide useful innovative public-use data that minimizes the risk of disclosure; streamlined procedures to allow researchers access to public-use microdata through existing and new data archives; a warning on all public-use data that they are provided for statistical purposes only and that any attempt to identify an individual is a violation, and requiring users to attest to having read the warning; and restricting access to public-use data to those who agree to abide by confidentiality protections, subject to meaningful penalties.[747]

EPA's proposal once again ignores these recommendations that call for greater research and a measured approach to making data more widely available. The Proposal provides no ideas or methods or support for research that would help strengthen confidentiality protections while making data more available.

Recommendations 9-13 concern research data centers, remote access, and licensing agreements and call on the Census Bureau to (1) broaden the interpretation of the criteria for assessing the benefits of access to data; (2) maintain the continuous review cycle; and (3) take account of prior scientific review of research proposals by established peer review processes when awarding access to research data centers; for more research on cost effective means of providing secure access to confidential data by remote access; increasing use of licensing agreements for access to confidential data; working with data users to develop flexible, consistent standards for licensing agreements and implementation procedures for access to confidential data; and including auditing procedures and legal penalties in licensing agreements for willful misuse of confidential data.[748]

EPA's proposal does not increase any research into use of remote data centers or licensing agreements, simply making passing references to these modes as potential solutions with no discussion or explanation—and ignoring the recommendations here suggesting that more work is needed to realize their potential.

Recommendations 14-15 concern maintaining the public's trust and call on agencies to give certain basic information about confidentiality and data access to everyone asked to participate in statistical surveys; and to support continuing research on the views of data providers and the public about research benefits and risks.[749]

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[747] *Id.* at 69-74.
[748] *Id.* at 74-80.
[749] *Id.* at 80-81.

EPA's proposal does not involve anything that increases the public knowledge about confidentiality protections or their views on research benefits and risks.

Recommendations 16-19 concern training, monitoring, and education to complement other protections on data. They call on data collection agencies to provide employees with continually updated written guidelines on confidentiality protection and training in confidentiality practices and data management and to institute procedures for monitoring violations of confidentiality protections practices and confidentiality breaches. They also call on educational and professional organizations to provide training in ethical issues for all those involved in the design, collection, distribution, and use of data obtained under pledges of confidentiality and for the development of strong codes of ethical conduct that reflect the need to protection confidentiality.[750]

EPA's proposal also contains no provisions on increasing training, monitoring, or education, within the agency or among researchers to allow for more careful handling of confidential data.

Thus, EPA's Proposal completely ignores the careful research and thinking the National Academies and researchers have done on what is needed from federal agencies in order to make data more publicly available, and how to do so in a responsible manner. It does not implement any of the recommendations in the report, and in no way builds upon this work.

IV. National Academies Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties: Report of Workshop

EPA cites to the National Academies' *Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties: Report of Workshop* as one for which it took into consideration "policies or recommendations," despite the fact that this report comes with the explicit limitation that:

> The goal of the workshop was not to reach conclusions or recommendations; nor could it address other pressing issues beyond the regulatory process, such as protection of intellectual property, the influence of broader access on scientific competition, the potential for increased administrative burdens and changes in the research process, and the challenge of providing data access in an increasingly electronic world.[751]

Thus, this report stresses the many unanswered, challenging policy questions that must be addressed as agencies contemplate how to make data publicly available. These are the questions EPA should have addressed in its Proposal, but did not.

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[750] *Id.* at 81-84.

[751] Science, Technology, and Law Panel; Policy and Global Affairs; National Research Council, *Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties: Report of Workshop*, The National Academies Press ix (2002).

The Report offers a look into the scientific review process that also calls into question the underlying assumption in EPA's proposal—that making data publicly available is necessary to ensure the validity of a scientific finding. The report notes that scientific claims "are not 'binary'" they instead "fall in the category of being uncertain to various degrees."[752] The reliability of a particular scientific finding can be assessed using various mechanisms, starting with an examination of the strength of the design, methods, and statistical results.[753] Then "one asks whether there is consistency within the data (pertaining to mechanisms of effect or related outcomes) and with other studies and scientific theories."[754] Finally, "the robustness of the findings is evaluated through the use of different analytical approaches."[755]

The report describes how studies may be validated through a range of approaches.[756] While it notes that in some cases it is possible to exactly replicate the original study, this is not always the case, especially in large epidemiological studies where "repeating a study is seldom either possible or desirable."[757] Then "replication" can take a variety of forms, not all of which require access to underlying data, including:

- Additional analyses done on the data set by the original or collaborating Investigators;
- New results generated from older data sets;
- New studies addressing the same hypothesis;
- Independent analysis of the same data set by different people;
- Monitoring of the results of actions taken on the basis of the findings.[758]

Another form of replication the report describes is

> meta-analysis, which is a systematic strategy for comprehensively describing and summarizing a body of research evidence from two or more studies. The goal is to produce a quantitative synthesis of the evidence presented in multiple studies that relate to a research question. In a typical meta-analysis, all the data used have been published in the public domain and are easy to inspect and analyze.[759]

The report specifically mentions the Harvard Six Cities Study as an example of a study where data could not be made publicly available, but which was verified to allow the agency to justifiably rely on it to set important air standards.[760] Thus, unlike the Proposal the report acknowledges the many different pathways that exist to for researchers to assess other studies, and does not suggest that allowing the general public access to underlying data and models is necessary.

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[752] *Id.* at 5.
[753] *Id.* at 7.
[754] *Id.*
[755] *Id.*
[756] *Id.*
[757] *Id.*
[758] *Id.* at 7-8.
[759] *Id.* at 8.
[760] *Id.* at 8-12.

One of the panels of the workshop discussed the Shelby Amendment, and public access to data underlying agency regulation. A bench scientist expressed concerns that, though the idea of sharing data was a good idea, because any person could request information for any reason, this mechanism could be used to harass scientists whose work was found objectionable.[761] A representative of NIH similarly stated that while sharing data with other researchers was good scientific practice, allowing for indiscriminate public access to data serves "little purpose for those without the skills to reanalyze it."[762] Additionally, access through FOIA does not allow for limitations to be put on the use of the data, which is typically available in other data-sharing modes.[763] A representative from EPA raised issues including:

> The Shelby Amendment. . .raises several questions for the EPA about rule making as a legal and deliberative process. At what point should the agency disclose what type of regulation is going to be considered or issued? The timing of the release can influence its reception. Should the agency use contracts to support the research needed for regulations? Contracting, as opposed to grants that support more flexible work, might narrow the type of information the agency receives and could possibly limit the scope of the science underlying the regulation.[764]

These questions and concerns are highly relevant to the Proposal as well, yet EPA provides no indication that it has given them any consideration.

Finally, a representative from NRDC pointed to other mechanisms that are already in place to ensure agencies rely on high quality data. For example, under the Administrative Procedure Act, agencies must respond to any comments that raise questions about a scientific studies design, performance, or conclusion.[765] Courts can determine whether an agency was reasonable in its decision to refuse to accept the findings of a study because it could not access underlying data or refuses a request from a study participant.[766] EPA does not explain why these existing mechanisms are not sufficient to ensure the integrity of the science it relies on.

V. The Health Effects Institute

In the original federal register notice, EPA provided no specificity as to which Health Effects policy EPA was referring to or why it supported the Proposal. Such a vague and unspecified reference does not meet the notice requirements of the APA and other statutes, and makes it impossible to respond.

VI. Center for Open Science

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[761] *Id.* at 14.
[762] *Id.* at 15.
[763] *Id.*
[764] *Id.* at 16.
[765] *Id.* at 17.
[766] *Id.*

In the original federal register notice, EPA provided no specificity as to which Center for Open Science policy EPA was referring to or why it supported the Proposal. Such a vague and unspecified reference does not meet the notice requirements of the APA and other statutes, and makes it impossible to respond.

VII. Members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology

In the original federal register notice, EPA provided no specificity as to which policy of the Members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology EPA was referring to or why it supported the Proposal. Such a vague and unspecified reference does not meet the notice requirements of the APA and other statutes, and makes it impossible to respond.

VIII. Bipartisan Policy Center's Science for Policy Project

In the original federal register notice, EPA provided no specificity as to which Bipartisan Policy Center's Science for Policy Project policy EPA was referring to or why it supported the Proposal. Such a vague and unspecified reference does not meet the notice requirements of the APA and other statutes, and makes it impossible to respond.

Footnote 11: For example, see related policies from the Proceedings of the National Academy of Sciences, PLOS ONE, Science, and Nature

EPA claims that the Proposal takes into consideration policies adopted by scientific journals, but does not specify which "related policies" from these journals.[767] While some of these journals have adopted certain policies encouraging or requiring researchers to share underlying data for the studies they publish, they all allow for exceptions when data cannot be released for compelling reasons, such as confidentiality protections.

Furthermore, the editors of these journals have issued a joint statement opposing the Proposal and noting that their policies do not endorse such an approach by EPA. They note that some data sets cannot be shared publicly, and that there are still other methods available to verify scientific findings. The statement also strongly condemns the notion of excluding scientific information from consideration when underlying data cannot be made publicly available:

> It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes.[768]

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[767] 83 Fed. Reg. at 18,770.

[768] Jeremy Berg et. al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

Thus, EPA cannot claim that the Proposal is in any way supported by the data sharing policies of these scientific journals.

> **Footnote 12: See: https://www.nature.com/articles/s41562- 016-0021; http://journals.plos.org/plosmedicine/ article?id=10.1371/journal.pmed.0020124; http://science.sciencemag.org/content/343/6168/229.long; https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong.; http://stm.sciencemag.org/content/8/341/341ps12.full.**

EPA claims that the Proposal is informed by the policies of scientific journals in response to the "replication crisis."[769] EPA provides no explanation or evidence to support the fact that such a "crisis" is occurring or that EPA's Proposal would do anything to address the crisis. The sources EPA cites for this proposition speak to a concern about scientific studies being reproducible or replicable due to a number of different conditions related to poor scientific practices. While some of the artieles speak about making data more available as an ideal to aspire to, none of them support the idea that a research study whose underlying data has not been made publicly available should, for that reason alone, be considered invalid. Further, many of these articles speak to how current scientific norms do not result in underlying data being available, which is a huge barrier to EPA's Proposal that EPA does not at all address.

I. Marcus R. Munafó et. al, *A Manifesto for Reproducible Science*, 1 Nature Human Behavior 1 (2017)

Far from suggesting that agencies rely only on scientific studies if the underlying data is made public, or even that making underlying data public is necessary to ensure validity of scientific conclusions, the article discusses at a high level a number of systemic and cultural challenges to reproducible science. By ignoring the nuances of this article and presenting it without any explanation as support for its Proposal, EPA runs into the problem the article specifically cautions against, warning: "Some solutions may be ineffective or even harmful to the efficiency and reliability of science, even if conceptually they appear sensible."[770]

This article does not endorse the existence of a "replication crisis" and in fact says, "[w]hether 'crisis' is the appropriate term to describe the current state or trajectory of science is debatable."[771] Instead it notes a very different problem than the one EPA appears to target with the Proposal. It points broadly to an issue of there being "substantial room for improvement with regard to research practices to maximize the efficiency of the research community's use of the public's financial investment in research."[772]

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[769] 83 Fed. Reg. at 18,770.
[770] Marcus R. Munafó et. al, *A Manifesto for Reproducible Science*, 1 Nature Human Behavior 1, 7 (2017).
[771] *Id.* at 1.
[772] *Id.* at 1.

This article makes clear that open data requirements are just *one* of many solutions and steps to take towards increasing efficiency of use of resources and robustness of scientific findings—and never suggests that a lack of publicly available underlying data should automatically disqualify a research finding from consideration. It discusses a number of other improvements including protecting against cognitive biases through blinding, improving methodological training, implementing methodological support, encouraging collaboration and team science, promoting study pre-registration, improving quality of reporting, diversifying peer review, and changing incentives to promote efficient and effective research instead of just innovative outcomes.

While the article recognizes transparency as a "scientific ideal"[773] it notes many challenges that currently exist to achieving this ideal, which EPA does not at all address. The article notes, "In reality, science often lacks openness: many published articles are not available to people without a personal or institutional subscription, and most data, materials and code supporting research outcomes are not made accessible, for example, in a public repository."[774] It further finds "substantial barriers to meeting these ideals, including vested financial interests (particularly in scholarly publishing) and few incentives for researchers to pursue open practices." Nowhere does the article suggest that the many scientific studies for which data is not available due to prevailing scientific norms and practices be completely discarded. These challenges suggest that many studies EPA wishes to rely on may not be able to meet the rigid requirements of EPA's proposal severely restricting the science EPA can use, degrading the quality of its decision-making.

Marcus R. Munafò, lead author on this paper, has since published a piece specifically dismissing science policy approaches that overemphasize the importance of replication.[775] It states that the overemphasis on replicability is detrimental to science—that "[i]f a study is skewed and replications recapitulate that approach, findings will be consistently incorrect or biased."[776] Instead, the author suggests that "an essential protection against flawed ideas is triangulation" or "the strategic use of multiple approaches to address one question."[777] This involves looking at a broad base of different scientific studies and does not require underlying data to be made publicly available, not individual studies based on whether or not they can be replicated.[778] By excluding scientific studies from EPA's consideration, the Proposal overemphasizes the value of replication to the detriment of being able to evaluate a study in the context of many other studies examining the same issue through a variety of methods. The Proposal may well lead to reliance on less robust science and is thus arbitrary.

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[773] *Id.* at 5.
[774] *Id.*
[775] Marcus R. Munafò & George Davey Smith, *Robust research needs many lines of evidence*, Nature (Jan. 23. 2018). https://www.nature.com/articles/d41586-018-01023-3#ref-CR3.
[776] *Id.*
[777] *Id.*
[778] *Id.*

II. John P.A. Ioannidis, *Why Most Published Research is False*, 2 PLoS Medicine 0696 (2005)

The article suggests"the high rate of nonreplication (lack of confirmation) of research discoveries is a consequence of the convenient, yet ill-founded strategy of claiming conclusive research findings solely on the basis of a single study assessed by formal statistical significance, typically for a *p*-value less than 0.05."[779] It looks at a number of different contributors to false positive findings and discusses solutions to this problem. Importantly, it stresses the need to focus on large studies, consider the totality of the evidence, and improve understanding of pre-study odds.[780] These solutions each involve considering more evidence and more scientific studies to contextualize any one given study. Nowhere does the article suggests requiring underlying data be made public or fewer studies be considered. EPA's proposal contrarily emphasizes data disclosure above all other practices for ensuring scientific integrity—and will result in fewer studies being considered to shed light on the scientific truth.

The author of this article has specifically criticized EPA's Proposal, saying that, if it is finalized, "science will be practically eliminated from all decision-making processes" and "[r]egulation would then depend uniquely on opinion and whim."[781] The author highlights the inherent problem in EPA's Proposal, that "most of the raw data from past studies are not publicly available" and that indeed "[i]n a random sample of the biomedical literature (2000–2014) none of 268 papers shared all of their raw data. . . [and] [o]nly one shared a full research protocol."[782] EPA has not addressed this major issue that suggests the Proposal would bar EPA from relying on massive amounts of scientific research. The article notes that reproducibility issues vary across the disciplines and that in many areas in which EPA operates, a solid and large foundation of scientific research has produced credible and widely-affirmed findings, including "in fields such as air pollution and climate change."[783] Even in these other fields, however, it firmly states that "simply ignoring science that has not yet attained such standards, is a nightmare."[784]

III. Marcia McNutt, *Reproducibility*, 343 Science 229 (2014), http://science.sciencemag.org/content/343/6168/229.long

EPA cites an announcement by Science that, in response to reports "that a troubling proportion of peer-reviewed preclinical studies are not reproducible,"[785] Science is adopting new policies requiring authors making submissions to the journal to disclose "whether there was a pre-experimental plan for data handling (such as how to deal with outliers), whether they conducted a sample size estimation to ensure a sufficient signal-to-noise ratio, whether samples were treated randomly, and whether the experimenter was blind to the conduct of the

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[779] John P.A. Ioannidis, *Why Most Published Research is False*, 2 PLoS Medicine 0696 (2005).
[780] *Id.* at 0700-0701
[781] John P.A. Ioannidis, *All science should inform policy and regulation*, 15 PLOS Med 1, 2 (May 3, 2018), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002576.
[782] *Id.* at 1.
[783] *Id.* at 2.
[784] *Id.* at 2.
[785] Marcia McNutt, *Reproducibility*, 343 Science 229 (2014), http://science.sciencemag.org/content/343/6168/229.long.

experiment."[786] While the article considers steps to increase reproducibility of science, it notes that data availability is not a necessary or sufficient step to ensure credibility of research findings, and that "ultimate responsibility lies with authors to be completely open with their methods, all of their findings, and the possible pitfalls that could invalidate their conclusions."[787] EPA's Proposal ignores the ability to assess studies through these other important indicators to assure their validity.

VI. *How Science Goes Wrong*, Economist (Oct. 21, 2013), https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong

This article opposes the view that verification of a study depends solely on the underlying data being made publicly available. While it identifies that much scientific research is unable to be replicated, the solution it proposes include tightening standards, particularly in statistics, registering research protocols in advance and monitoring them, and: "[w]here possible, trial data also should be open for other researchers to inspect and test."[788] Thus, even to the extent it discusses data availability, it suggests data should be open for other *researchers*, as opposed to the public, and recognizes this may not always be possible.[789]

VII. Steve N. Goodman, *What does research reproducibility mean?*, 8 Science Translational Medicine 1 (2016), http://stm.sciencemag.org/content/8/341/341ps12.full

Rather than saying anything about agencies relying only on scientific studies where underlying data is made public, this article discusses the importance of clearly defining key terms in the discussion about scientific reproducibility, noting that there is a lack of standardized definitions of terms such as "reproducibility, replicability, reliability, robustness, and generalizability."[790] This raises a key issue of vagueness in EPA's proposal—EPA does not provide definition for key terms such as "independently validate" or "reproducible" and confusing mentions a "replication crisis" while citing to articles that speak to a "reproducibility crisis."

While providing definitions for these various terms, the article notes that there terms all represent various methods of attempting to verify studies to ensure "scientific claims based on scientific results are true" and cautions against "treating reproducibility as an end in itself—rather than as an imperfect surrogate for scientific truth."[791] Instead, it promoted the view of looking across studies to "assess their cumulative evidential weight."[792] EPA Proposal thus directly contradicts the suggestions of this article.

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[786] *Id.*
[787] *Id.*
[788] *How Science Goes Wrong*, Economist (Oct. 21, 2013), https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong.
[789] *Id.*
[790] Steve N. Goodman, *What does research reproducibility mean?*, 8 Science Translational Medicine 1 (2016), http://stm.sciencemag.org/content/8/341/341ps12.full.
[791] *Id.*
[792] *Id.* at 3.

Footnote 13: EPA has not consistently followed previous EPA policy (e.g, EPA's Scientific Integrity Guidance, referenced above) that encouraged the use of non-proprietary data and models.

While EPA in a footnotes suggests that EPA has not consistently followed EPA's EPA's Scientific Integrity Policy encouraging the use of non-proprietary data and models, it misses the fact that EPA's policy was not written as an absolute standard, but was intended to be a flexible one. The policy states only that "the use of non-proprietary data and models are encouraged, when feasible, to increase transparency."[793] EPA must thus explain and justify its deviation from its prior flexible approach that the Proposal now imposes.

Footnote 14: https://www.whitehouse.gov/wp-content/uploads/2017/11/2005-M-05-03-Issuance-of-OMBs-Final-Information-Quality-Bulletin-for-Peer-Review-December-16-2004.pdf

The Proposal appears to issue a requirement for independent peer review of all *pivotal regulatory science* used to justify *regulatory decisions,* consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review. EPA cites to OMB's Final Information Quality Bulletin for Peer Review, explaining existing peer review requirements that nowhere does EPA suggest are not already being complied with.

As discussed in our comments, there is some vagueness as to whether the Proposal maintains, expands, or narrows these already existing requirements. OMB's bulletin underwent a rigorous stakeholder process including response to comments on multiple drafts from stakeholders, a federal agency workshop at NAS, outreach to major scientific organizations and societies, a formal interagency review.[794] EPA's Proposal has not gone through nearly the same level of review, or as our comments detail, even met the minimum legal requirements for consultation and review. OMB's guidance further provides that agencies should consider the "tradeoffs between depth of peer review and timeliness"[795] This includes considering a benefit-cost framework for peer review that takes into account "the direct costs of the peer review activity and those stemming from potential delay in government and private actions that can result from peer review."[796] As our comments detail, EPA has not provided any meaningful benefit-cost analysis of the Proposal. Thus, it would be improper and in conflict with OMB's guidance for EPA to be expanding the peer review requirements through this Proposal.

Footnote 15: February 22, 2002 (67 FR 8453) OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information (2002)

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[793] EPA, *Scientific Integrity Policy* at 4.
[794] *Final Information Quality Bulletin for Peer Review*, 70 Fed. Reg. 2664 (Jan. 14, 2005).
[795] *Id.* at 2,668.
[796] *Id.* at 2,668

https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information.

As discussed above in the Section on footnote 6, EPA's attempt to align its proposal with OMB's guidelines is misguided.

Footnote 16: See examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau.

In the original Proposal EPA provided no specific "examples" and this vague cite provided very little direction about what EPA was referencing here—making it impossible to review these examples or respond to them.

Footnote 17: https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.

EPA states that other agencies have tools to de-identify information private information, but fails to recognize that these methods are not transferable to EPA's context.[797] EPA links to guidance on de-identification requirements under HIPAA. This guidance provides two methods for de-identifying data: (1) expert determination method, where an expert determines that, after application of statistical and scientific principals and methods, the risk is very small that the information alone or with other available information could be used to identify the subject; and (2) the safe harbor method, requiring that a number of identifiers are removed. The first method requires case-by-case work and EPA has provided no information regarding how EPA could implement it or how much it might cost and thus the feasibility of requiring researchers or EPA to de-identify data this way is questionable. The second method requires removal of much information useful for research that may be necessary to be able to independently validate the research, so it is unclear that it would satisfy the Proposal's demands. Furthermore, the safe harbor method has been shown to provide potentially insufficient privacy protections.[798]

Footnote 18: https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities.

In this footnote, EPA cites to a report by the National Academies for the proposition that "The National Academies have noted that simple data masking, coding, and de-identification techniques have been developed over the last half century. . . " [799] This incorrectly makes it seem as though the National Academies have identified simple techniques to de-identify data for public release without compromising personal piracy. A full review of the report reveals the

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[797] 83 Fed. Reg. at 18,771.

[798] Latanya Sweeney, Ji Su Yon, Laura Perovich, Katherine E Boronow, Phil Brown, and Julia Green Brody, *Re-identifcation Risks in HIPAA Safe Harbor Data: A Study of Data From One Environmental Health Study*, Technology Science (August 28, 2017).

[799] 83 Fed. Reg. at 18,771; National Research Council, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, National Academies Press (2005).

opposite is true, that The National Academies in fact recognize that complex, evolving, and yet undeveloped techniques are needed to resolve these concerns. It offers recommendations that are intended to *improve upon* existing techniques, indicating that this area is under constant change and many advances are left to be made.[800] Further, the report notes this improvement requires "strong partnership between the research community and statistical and research agencies in the design of innovative research on disclosure avoidance techniques and data access modalities and in the implementation of the advances that result from such research."[801] The Proposal takes no steps towards advancing design of new techniques or providing resources to undertake all that needs to be done to make the Proposal remotely feasible.

Further, the Report notes that a changing landscape is making it increasingly difficult to apply past techniques to sufficiently protect data from identification, saying: "Initially, relatively simple data masking techniques, such as top coding income amounts. . . were used to generate restricted data products [,] [d]uring the last decade the increasing risks of confidentiality breaches have led researchers to develop increasingly sophisticated methodologies for restricted data products."[802] They state, "more research is clearly needed to assess the relative ability of different masking methods, and of synthetic data, to reduce the risk of disclosure while preserving data utility."[803] EPA does not acknowledge these newly emerging concerns.

The National Academies recognize the current limitations of producing restricted data that sufficiently limits identifiability to allow it to be made publicly available in a useful form. They note that "well-informed policy making" requires "[r]esearch using detailed confidential data" that cannot be made public—which the Proposal fails to acknowledge to the detriment of the quality of EPA's policy decisions.[804] Just because certain information cannot be made public for legitimate reasons does not mean the government should refuse to use it to inform policy. And much of the data useful for environmental and health research is particularly sensitive—the report notes there is increased vulnerability in "[d]ata with geographic detail, such as census block data" and longitudinal data obtained in panel surveys, which is often salient in environmental research.[805] In the meantime, the National Academies state that more work is needed to allow "[h]igh-quality public-use files" that still assure "the inferential validity of the data while safeguarding their confidentiality."[806]

They also point to broader implications of not implementing sufficient privacy protections that EPA does not consider at all may result from the Proposal. The quality of data collected is likely to suffer as "[i]t is essential that respondents believe they can provide accurate, complete information without any fear that the information will be disclosed inappropriately."[807] Essentially, the report leaves as an open question "decisions about how much disclosure risk is acceptable in order to achieve the benefits of greater access to research data involve weighing the

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[800] *Id.* at 35.
[801] *Id.* at 35.
[802] *Id.* at 27
[803] *Id.* at 28.
[804] *Id.* at 2.
[805] *Id.* at 22.
[806] *Id.* at 2.
[807] *Id.* at 51.

potential harm posed by disclosure against the benefits potentially foregone."[808] Thus, EPA wrongfully points to this report as supporting the notion that simple techniques exist to address privacy concerns. The report recommends only more research to reduce risks and increase data utility along with consultation with data users and providers about these issues—which the Proposal does not implement and thus the report does not support the Proposal.[809]

Footnote 19: https://www.cep.gov/content/dam/cep/report/cep-final-report.pdf; https://www.nap.edu/catalog/24652/innovations-in-federal-statistics-combining-data-sources-while-protecting-privacy; https://www.nap.edu/catalog/24893/federal-statistics-multiple-data-sources-and-privacy-protection-next-steps.

EPA claims that "the National Academies and the Bipartisan Commission on Evidence Based Policy have discussed the challenges and opportunities for facilitating to secure access to confidential data for non-government analysts."[810] The proposal does not explain how these examples are relevant, as there is no indication that secure access to underlying data would meet the requirements of making underlying data "publicly available." Further, even if it were relevant, a review of the sources cited reveal that they do discuss many challenges in this space—which the Proposal does not at all address—and provide no support for the Proposal.

I. Commission on Evidence-Based Policymaking, The Promise of Evidence-Based Policymaking (2017)

This report centers on how to enhance infrastructure to increase the access and use of data between federal agencies to support government policy-making, rather than increase public access to data to non-governmental analysts for purposes of independently validating regulatory science.[811] Further, its focus is to help efforts to make *more* data available for government purposes to better inform policies. The Proposal on the other hand seeks to make data available to validate individual studies while ultimately making *less* data available for EPA to consider as it creates policies.

To the extent the report does speak to making more data *publicly* available, it envisions an entirely new framework to provide adequate privacy protections. Chapter Three of the report discusses increasing threats to privacy as "the amount of information about individuals that is publicly available has grown and the technology that can permit unauthorized re-identification has improved."[812] It notes that forming solutions to this problem while preserving the quality of data is difficult, and that a challenge is "ensuring that enhanced statistical disclosure methods do not change the data in ways that increase the difficulty of reproducing research results." It thus specifically notes that protecting confidentiality can be in tension with allowing data to be used for reproducibility purposes.

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[808] *Id.* at 62.
[809] *Id.*
[810] 83 Fed. Reg. at 18,771.
[811] Commission on Evidence-Based Policymaking, *The Promise of Evidence-Based Policymaking* (2017).
[812] *Id.* at 54-55.

The report recommends: (1) amending federal statutes to require Federal departments to conduct a comprehensive risk assessment on de-identified confidential data intended for public release and release de-identified confidential data subject to the Privacy Act and CIPSEA only after a disclosure review board approves the release and publicly provides the risk assessment and a description of steps taken to mitigate risk; (2) federal departments to adopt state-of-the-art database, cryptography, privacy-preserving, and privacy-enhancing technologies for confidential data used for evidence building; (3) federal departments assign a senior official the responsibility for coordinating access to and stewardship of the department's data resources; (4) new legislation ensuring that data acquired under a pledge of confidentiality are kept confidential and used exclusively for statistical purposes.[813] The Proposal does not discuss or contribute to any of these efforts.

Chapter Four recognizes that some data cannot be made publicly available without sacrificing the utility of the evidence and thus sets forth recommendations for creating a new National Secure Database Service to allow researchers to access "detailed data that cannot be made publicly available, and only for exclusively statistical purposes."[814] This report thus implicitly recognizes the value of using confidential data to "securely generate evidence about government policies and programs."[815] While transparency is a crucial goal, using data that cannot be made publicly available can help inform government policies in important ways.

The Report details the many obstacles to making data publicly available, and ultimately concludes that much more work is needed in this area, none of which is being furthered by EPA's Proposal.

II. NAS, Innovations in Federal Statistics: Combining Data Sources While Protecting Privacy (2017)

This report provides recommendations to increase sharing and use of data by the federal government and between agencies.[816] It places maintaining privacy and confidentiality at the forefront. The report provides a discussion of the benefits and challenges to allowing external researchers to access data held by government agencies. This assumes that agency has access to data in the first place—which may not be the case with the studies EPA wishes to rely on that would be barred by its Proposal.

The report notes multiple risks to privacy and confidentiality from data breaches, identity theft, and the threat from the ability to combine multiple data sources to re-identify anonymized data as more and more data is made publicly available.[817] The solutions that the report proposes to minimize these risks include: data minimization, restricted data, restricted access (including licensing agreements, federal statistical research data centers, nongovernment data enclaves).[818]

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[813] *Id.* at 47.
[814] *Id.* at 66.
[815] *Id.* at 68.
[816] NAS, *Innovations in Federal Statistics: Combining Data Sources While Protecting Privacy*, National Academies Press (2017).
[817] *Id.* at 76-79.
[818] *Id.* at 82-88.

The Proposal does not allow for data minimization since it is aimed at making public complete underlying data that is likely to involve salient personally identifiable information for an unlimited amount of time.[819] Data restriction involves "removing explicit identifiers and applying a variety of statistical disclosure limitation methods to the dataset to reduce the risk of disclosure."[820] However, because these techniques "decrease the precision of the variables in the dataset and. . . introduce errors" it is unclear that they would preserve data for independent validation while also sufficiently protecting privacy.[821] Restricted access involves using "administrative procedures and technology to restrict who can access the dataset and what kinds of analyses can be done with the data to reduce the risk of disclosure."[822] This specifically limits access to data from the general public, which seemingly would not meet the requirements of EPA's proposal. Thus, EPA has not addressed how it would meet any of the challenges raised in this document.

III. NAS, Federal Statistics, Multiple Data Sources, and Privacy Protection: Next Steps (2017)

This report is not directly relevant as it discusses ways to combine diverse data sources from government and private sector sources and the privacy issues that arise from combining multiple data sets.[823] The purpose of the report is to help "federal statistical agencies examine and evaluate data from alternative sources and then combine them as appropriate to provide the country with more timely, actionable, and useful information for policy makers, businesses, and individuals."[824] EPA's proposal will in fact restrict the information that EPA can use.

The report notes that the "privacy status of data is dynamic over time, that datasets that are not individually identifiable today may in the future become individually identifiable" with the availability of new techniques and auxiliary data. [825] It notes that as data sets are linked, these privacy threats increase.[826] The Proposal does not discuss or address threats to privacy from data linkages.

The panel highlighted a number of threats to privacy and data security, including from security threats and inferential disclosure, and concluded "there is awareness of weaknesses of current statistical disclosure limitation methods, but the feasibility for federal statistical agencies of implementing new technologies, such as differential privacy, has not been clearly demonstrated."[827] Finally, they state:

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[819] *Id.* at 82-83.
[820] *Id.* at 83.
[821] *Id.*
[822] *Id.* at 85.
[823] NAS, *Federal Statistics, Multiple Data Sources, and Privacy Protection: Next Steps*, National Academies Press (2017).
[824] *Id.* at 2.
[825] *Id.* at 71.
[826] *Id.* at 72.
[827] *Id.* at 105.

> Overall, much work, interaction, and collaboration will be needed across the various disciplines and stakeholders as agencies seek to move forward to provide stronger privacy protection for the data they either collect from respondents or acquire access to from other administrative and private-sector sources for statistical purposes. It will be critical for there to be robust discussions of the implications of this approach for all stakeholders and these discussions will need to be informed by concrete examples to help everyone understand how use of these technologies will affect them.[828]

The report notes that in order to provide greater access to data much more research and resources are needed. The Proposal identifies no such resources or processes needed to develop needed methods and techniques to allow for greater data disclosure.

Footnote 20: For example, see policies or recommendations of publishers Taylor & Francis, Elsevier, PLOS, and Springer Nature

EPA cites to "policies or recommendation" of several journals that require data be deposited in public data repositories as an example of the Proposal's requirement of data availability.[829] EPA provided only a list of journals with no reference to any specific policies making it difficult to respond fully to this statement.

Each of these journals, however, has exceptions to its data availability requirements when there are valid reasons preventing authors from making their data publicly available via a public data repository. Further, the editors of these journals released a joint statement that explains why their policies with regards to data availability should not be used to support a policy by a federal agency that would in fact restrict the scientific studies it could rely on.[830] Given the vastly different contexts and aims of federal agencies and scientific journals when it comes to making data publicly available, journal policies should not inform EPA's direction. None of these journals claims that lack of data availability in itself calls into question the validity of a scientific conclusion based on that data—and thus these policies do not support the Proposal.

Footnote 21: For example: https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/; https://www.census.gov/fsrdc

As examples of controlled access to data in federal research data centers, EPA cites to the National Institutes of Health's policy for requesting access to controlled-access data maintained in NIH-designated data repositories and the U.S. Census Bureau's website on Federal Statistical Research Data Centers, secure facilities providing authorized access to restricted-use microdata for statistical purposes only. NIH requires researches to be a tenure-track professor, senior

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[828] *Id.* at 106.
[829] 83 Fed. Reg. at 18,771.
[830] Jeremy Berg et. al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

scientist, or equivalent and go through required procedures prior to gaining access.[831] The U.S. Census Bureau requires researchers to obtain Census Bureau Special Sworn Status, which requires passing a moderate risk background check and swearing to protect respondent confidentiality for life, with significant financial and legal penalties under Title 13 and Title 26 for failure to do so.[832]

It is unclear how these policies are informing EPA's proposal. EPA's proposal would require data to be made "publicly available," and these forms of restricted access specifically do not make data publicly available. They require significant resources and infrastructure and careful thought about who will be permitted to access such data and under what conditions—none of which EPA has provided any discussion of in the Proposal.

Footnote 22: These recommendations are consistent with those of Lutter and Zorn (2016). https:// www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.we re.

EPA cites to a working paper by Randall Lutter and David Zorn as supporting the proposition that "EPA should collaborate with other federal agencies to identify strategies to protect confidential and private information in any circumstance in which it is making information publicly available. These strategies should be cost-effective and may also include: Requiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements."[833]

Lutter and Zorn reference these strategies as ones agencies could use to minimize the risks to personally identifiable information when agencies make data publicly available.[834] However, EPA's proposed regulations do not discuss or propose implementation of any of these strategies. The Proposal would result in a rule that mandates only that data be made "publicly available" without any possibility for more restricted release. As the comments discuss, EPA has further not consulted with other federal agencies on this Proposal.

Lutter and Zorn additionally do not argue that agencies should immediately disregard studies where data cannot be made publicly available, and provide alternative procedures agencies should utilize in those cases when still relying on studies.[835] In a separate statement on the HONEST Act, which contains similar requirements as the Proposal, Lutter and Zorn stated that the legislation "should also allow agencies to regulate in instances where they do not possess data."[836] While these additional procedures they recommend agencies follow could still be overly

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[831] NIH, *Requesting Access to Controlled-Access Data Maintained in NIH-Designated Data Repositories (e.g., dbGaP)*, https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/ (last accessed Aug. 10, 2018).
[832] U.S. Census Bureau, *Secure Research Environment*, https://www.census.gov/about/adrm/fsrdc/about/secure_rdc.html (last accessed Aug. 10, 2018).
[833] 83 Fed. Reg. at 18,771.
[834] Randall Lutter & David Zorn, *On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making*, Mercatus Working Paper 31 (Sept. 2016).
[835] *Id.* at 32-33.
[836] Randall Lutter and David Zorn, *The Data That Our Government Uses Must be Transparent*, SmartRegs (Mar. 13, 2017), https://smartregs.org/the-data-that-our-government-uses-must-be-transparent-caa16b3dc19d.

burdensome and barriers to EPA promulgating important safeguards, it is important to note that even they see the dangers in a rule that would force the agency to disregard studies when underlying data could not be made public.

Footnote 23: https://www.nap.edu/catalog/11434/ expanding-access-to-research-data-reconciling-risks-and-opportunities.

The Proposal claims "The benefits EPA ensuring that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation are that it will improve the data and scientific quality of the Agency's actions and facilitate expanded data sharing and exploration of key data sets."[837] EPA cites to a National Academies report. This report does speak to many benefits of making data available to researchers, including helping to maintain and improve data quality;[838] promoting new research and exploration of new questions using existing data;[839] and allowing for verification, refutation, or refinement of original results.[840]

However, the report simply considers the benefits of making data publicly available in a broad sense, it does not consider the issue in the Proposal—which is that new data is not necessarily being made publicly available that was not before, and at the same time EPA's consideration of scientific research is being limited. Thus, it does not consider the costs to government policy-making that come from EPA's refusing to consider scientific research where underlying data is not publicly available. Since it is questionable whether the Proposal will result in any new data being made available to the public, and certain that it will result in EPA's ignoring valid scientific findings, it is unlikely that this Proposal will "improve the data and scientific quality of the Agency's actions" as EPA claims.

Footnote 24: https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.

EPA cites to a paper by Randall Lutter and David Zorn for its analysis that "an increase in existing net benefits from greater reproducibility, which, if it occurred, would cover the costs of obtaining the data and making the data available."[841] However, there are important limitation to this analysis that seriously call this conclusion into question.

First, the statement that EPA cites to is taken out of context. The entire sentence is: "More specifically, we can calculate an increase in existing net benefits from greater reproducibility, which, if it occurred, would cover the costs of obtaining the data and making the data available."[842] This statement is *not* a conclusion that the benefits of making publicly

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[837] 83 Fed. Reg. at 18,772.
[838] The National Academies, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, National Academies Press 48 (2005).
[839] *Id.* at 38.
[840] *Id.* at 39.
[841] Randall Lutter & David Zorn, *On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making*, Mercatus Working Paper (Sept. 2016).
[842] *Id.* at 27.

available data underlying research that federal agencies use to promulgate significant public polices would outweigh the costs. It is describing the figure that Lutter and Zorn go on to calculate—the threshold level of increase in net benefits required by this policy to equal the costs of implementation. They find that "an improvement in net benefits of 0.02 to 2.08 percent would imply that the net benefits of requiring data access are positive."[843] They themselves note that this estimate "fall[s] short of proving that the benefits outweigh the associated costs."[844]

Their analysis itself is suspect because it differs greatly from the cost estimate provided by the Congressional Budget Office for H.R. 1430, Honest and Open New EPA Science Treatment Act of 2017. The CBO estimated that, if the agency were to choose to rely only on studies that met the Act's requirements from the outset, implementing this legislation would cost about $5 million from 2018-2022.[845] They assumed it would cost $10,000 per study to make data available to enable use of studies.[846] They estimated costs of at least $100 million per year if EPA were to continue to rely on as many studies to support its actions as it has done in recent years.[847] An older cost estimate from CBO on a prior version of the HONEST Act estimated that it would cost "about $250 million a year for the next few years."[848] This assumed that EPA would spend from $10,000 to $30,000 per study to make the data available and that EPA would reduce the number of studies it relies on by about one-half.[849]

Zutter and Lorn calculated an alternative amount for the costs to EPA of this legislation. They find that "the total cost to the EPA for data collection and public accessibility would be $2,558 per study, or about 26 percent of the $10,000 per study cost estimated by CBO."[850] They used estimates that EPA reported under the Paperwork Reduction Act for time that entities in the chemical industry would need to spend to comply with EPA's Health and Safety Data Reporting Rule (40 C.F.R. 716).[851] While they purport that the requirements of that rule are similar to the activities that EPA would undertake to comply with the HONEST Act and similar legislation, they provide no further basis for this.[852] Given the great discrepancy between their and CBO's estimates, it is unclear that their estimate sufficiently accounts for the numerous costs associated with EPA locating underlying research data not currently in its possession and upgrading it to enable it to be made publicly available.

They also rely on questionable assumptions in their calculation. They assume that "given modern technology, by the time research has been published, almost all relevant underlying data

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[843] *Id.*
[844] *Id.* at 29.
[845] Congressional Budget Office, *Cost Estimate: H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017* (Mar. 29, 2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf.
[846] *Id.* at 3.
[847] *Id.* at 3.
[848] Congressional Budget Office, *Cost Estimate: H.R. 1030 Secret Science Reform Act of 2015* (Mar. 11, 2015), https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf.
[849] *Id.* at 3.
[850] Randall Lutter & David Zorn, *On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making*, Mercatus Working Paper 23 (Sept. 2016).
[851] *Id.* at 21.
[852] *Id.*

and computer code and models will be in electronic format" so time spend photocopying studies will be reduced.[853] This does not consider that EPA may want to rely on older studies where all relevant information is not available in electronic, easily accessible formats. They provide unsupported estimates for activities that EPA would need to undertake to comply with HONEST Act-like legislation that has no corresponding requirement in EPA's Health and Safety Data Reporting Rule—such as estimating 10 hours for EPA to format unformatted data for public access.[854]

They additionally produce their own estimate for the number of studies that EPA relies on each year, looking at materials posted in dockets on regulations.gov and coming to a total of 18,000 pieces of scientific research per year.[855] CBO estimated 50,000 scientific studies per year.[856] Assuming that EPA continued to rely on all 18,000 studies per year, Zutter and Lorn came to total implementation costs of about $46 million per year, far below the estimate by CBO assuming EPA still relied on at least half of the studies it does currently. Thus, one should view this cost estimate with suspicion, and there is no reason it should be relied on over CBO's cost estimates and does not suffice for EPA providing its own cost benefit analysis.

May 25, 2018 Memorandum

On May 25, 2018, EPA provided a memorandum that provided additional hyperlinks for some of the sources cited in the footnotes.[857]

Footnote 9

- **National Science Foundation: https://www.nsf.gov/bfa/dias/policy/dmp.jsp**
- **National Institute of Science and Technology: https://www.nist.gov/open**
- **National Institutes of Health: https://grants.nih.gov/policy/sharing.htm**

The hyperlinks that EPA provides fail to point to any relevant policies that support EPA's Proposal. First, EPA links to the National Science Foundation's policies requiring investigators who receive NSF grants to share research data with other researchers.[858] Importantly, they are only to release privileged or confidential information "in a form that protects the privacy of individuals and subjects involved" and NSF may make adjustments or exceptions when needed

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[853] *Id.* at 22.
[854] *Id.*
[855] *Id.* at 24.
[856] Congressional Budget Office Cost Estimate: H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 (Mar. 29, 2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf. 3
[857] May 25, 2018 Memorandum Re: Omitted Hyperlinks for Footnotes in the Proposed Rule (Docket ID No. EPA–HQ–OA–2018–0259)
[858] NSF, *Disseminating and Sharing of Research Results*, https://www.nsf.gov/bfa/dias/policy/dmp.jsp (last accessed Aug. 10, 2018).

"to safeguard the rights of individuals and subjects, the validity of results, or the integrity of collections or to accommodate the legitimate interest of investigators."[859]

EPA links to the National Institute of Science and Technology policy on sharing data arising from NIST-funded research.[860] The plan clearly exempts "[p]ersonnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy" from being subject to the data sharing policy.[861]

EPA also cites to The National Institutes of Health. The hyperlink links to a webpage consisting of a number of policies dictating sharing of NIH-funded research with no clarification of which policy EPA is referring to or why it is relevant to the Proposal. While NIH policies do in many cases require data from NIG-funded research to be shared publicly—these policies place protection of personal information at the forefront and thus include controls such as controlled access, de-identification of information, data aggregation and allow exceptions when data cannot be made publicly available.

These examples all deal with policies to share data that the agencies have access to and the ability to share—because they deal with federally-funded research. EPA's Proposal, on the other hand, applies to all data whether or not EPA has the data in its possession or is authorized to release it. They all speak to making data available to increase its utility, not to making data available specifically for the purposes of independent validation of research results, which requires data be available on a more granular level that makes privacy protection more difficult. Further, EPA already has policies in place to make publicly available data that is produced by research it funds. Also, none of these policies address regulating how the agencies themselves rely on or use scientific information. Thus the Proposal in no way "builds upon" the efforts they represent.

Footnote 10

- **Administrative Conference of the United States' Science in the Administrative Process Project: https://www.acus.gov/research-projects/science-administrative-process**
- **Improving Access to and Confidentiality of Research Data: https://www.nap.edu/read/9958**
- **Expanding Access to Research Data: https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities**
- **Access to Research Data in the 21st Century: https://www.nap.edu/catalog/10302/access-to-research-data-in-the-21st-century-an-ongoing**
- **Health Effects Institute: https://www.healtheffects.org/system/files/AppendixD-data-access_3.pdf**

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[859] NSF, *Chapter XI - Other Post Award Requirements and Considerations*, https://www.nsf.gov/pubs/policydocs/pappg17_1/pappg_11.jsp#XID4 (Jan. 30, 2017).
[860] NIST, *Public Access to NIST Research*, https://www.nist.gov/open (last accessed Aug. 10, 2018).
[861] NIST, *Managing Public Access to Results of Federally Funded Research Policy* 1-2 (Jun. 26, 2015), https://www.nist.gov/sites/default/files/documents/2018/06/19/final_p_5700.pdf.

- **Center for Open Science: https://osf.io/x2w9h/?_ga=2.15543670.1160736397.1518527893-776332106.1518527893**
- **Members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology: http://www.isrtp.org/GMU%20WEBINAR_DEC_2013/GMU%20Study%20Document4.pdf**
- **Bipartisan Policy Center's Science for Policy Project: http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf**

I. The Health Effects Institute, https://www.healtheffects.org/system/files/AppendixD-data-access_3.pdf

EPA provides a link to the HEI Policy On The Provision Of Access To Data Underlying HEI funded Studies. This policy is "to provide access expeditiously to data for studies that it has funded and to provide that data in a manner that facilitates review and verification of the work but also protects the confidentiality of any volunteers who may have participated in the study and respects the intellectual interests of the original investigator of the work."[862] It is written to be consistent with OMB Circular A-110, which requires agencies to respond to FOIA requests for data underlying federally supported research used to develop federal agency actions with the force and effect of law. EPA already has policies in place to make public the data underlying research that it funds, and already must comply with OMB Circular A-110, thus, it is unclear how this Proposal builds upon this policy.

Furthermore, the policy specifically excludes "personal and medical information and similar information that is personally identifiable, and the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study" and requires the requestor to pay reasonable costs. In this manner, it further deviates from the Proposal.[863]

II. Center for Open Science, https://osf.io/x2w9h/?_ga=2.15543670.1160736397.1518527893-776332106.1518527893

EPA links to the Center for Open Science's 2017-2020 Strategic Plan.[864] While the strategic plan outlines COS's own mission to "increase openness, integrity, and reproducibility of scholarly research" and to meets its goal of creating "a future scholarly community in which the process, content, and outcomes of research are openly accessible by default" nothing in this

[862] HEI, *APPENDIX D: HEI POLICY ON THE PROVISION OF ACCESS TO DATA UNDERLYING HEIFUNDED STUDIES*, https://www.healtheffects.org/system/files/AppendixD-data-access_3.pdf (last accessed Aug. 10, 2018).
[863] *Id.*
[864] Center for Open Science, *Strategic Plan*, https://osf.io/x2w9h/?_ga=2.15543670.1160736397.1518527893-776332106.1518527893.

strategic plan suggests anything like EPA's Proposal.[865] It does not discuss barring use of studies or ensuring access to underlying data—and thus is completely irrelevant to the Proposal.

III. Members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology: http://www.isrtp.org/GMU%20WEBINAR_DEC_2013/GMU%20Study%20Document4.pdf

EPA links to a survey conducted by the Center for Media and Public Affairs and Center for Health and Risk Communication at George Mason University.[866] They surveyed members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology. However, the survey thus does not represent any official recommendation or policy position from these professional organizations, and represent only the views of the members who chose to participate in the survey.

Thus, while the survey found 69 % of those surveyed "regard it as "very important" for assessors to have access to underlying raw data for the most critical studies in order to independently analyze their results," this should be viewed in the rightful context.[867] The survey did not ask whether agencies should continue to rely on scientific studies where the underlying data cannot be made public or independently analyzed. The survey question further appears to have only asked whether researchers assessing studies should have access to underlying data to independently analyze results, not whether underlying data should be made *publicly available*.

Further, the Dose Response Section of the Society for Risk Analysis has since submitted a comment to EPA that states this footnote and the claim that EPA makes that the Proposal took into consideration these recommendations and policies is "inaccurate" and that "the 'Dose-Response Section [sic] of the Society for Risk Analysis' has never adopted any 'policies or recommendations' on this or any other topic."[868] They have asked that EPA remove all references to the organization and make clear in the comment response for this rule that "'third party Organizations' whose policies and recommendations were considered do not include the Society for Risk Analysis or the Dose-Response Specialty Section."

The Society for Toxicology similarly have said this survey does not constitute support from the Specialty Section or the SOT as a whole, and requesting "that any and all references to "members of the Risk Assessment Specialty Section of the Society of Toxicology" be removed

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[865] *Id.* at 6.
[866] George Mason University, *Expert Opinion on Regulatory Risk Assessment* (Dec. 6, 2013), http://www.isrtp.org/GMU%20WEBINAR_DEC_2013/GMU%20Study%20Document4.pdf.
[867] Id. at 2-3.
[868] Comment from Weihsueh A. Chiu, Chair, Dose-Response Specialty Group, Society for Risk Analysis, Docket ID No. EPA–HQ–OA–2018–0259 (May 24, 2018).

from the Final Rule."[869] They also specifically comment that "invalidating data solely on the basis of public availability is inappropriate."[870]

IV. Bipartisan Policy Center's Science for Policy Project, http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf

EPA provides a hyperlink to the Final Report of the Science for Policy Project *Improving the Use of Science in Regulatory Policy*.[871] This report makes a number of recommendations, none of which endorse the Proposal. In relevant part, Recommendation Three suggests "Agencies and their scientific advisory committees should cast a wide net in reviewing studies relevant to regulatory policy, and should make their methods for filtering and evaluating those studies more transparent."[872] They urge agencies to increase availability of data and information on research studies and subject all studies relied on in the formulation of regulation to be subject to the requirements of the Shelby Amendment and OMB Circular A-110 regardless of who funded the study.[873] Importantly, those requirements contain important exception for confidentiality and privacy concerns—and thus do not support the Proposal.

This recommendation is also aimed at *increasing* use of science in regulatory policy, and does not suggest that agencies not rely on studies where those data access requirements cannot be met because of other concerns. It also highlights that the use of CBI to prevent access to data appears to be overused and urges agencies to make procedures more stringent to allow only for legitimate claims of CBI—which EPA does not address in its Proposal.[874]

Recommendation Four states: "The federal government, universities, scientific journals and scientists themselves can help improve the use of science in the regulatory process by strengthening peer review, expanding the information available about scientific studies, and setting and enforcing clear standards governing conflict of interest."[875] As part of this recommendation, the report "Federal agencies, universities and journals should encourage or require on-line publication of the methods and data underlying published scientific studies."[876] However, it once again does not say that agencies should not consider research studies where this is not possible due to privacy or other compelling reasons.

Wendy Wagner, who served on the panel that produced the recommendations has stated: "They don't adopt any of our recommendations, and they go in a direction that's completely

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[869] Comment from Leigh Ann Burns Naas, Society of Toxicology, Docket ID No. EPA–HQ–OA–2018–0259 (May 25, 2018) at 1.
[870] *Id.* at 2
[871] Bipartisan Policy Center, Science for Policy Project, *Improving the Use of Science in Regulatory Policy* (Aug. 5, 2009), http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf.
[872] *Id.* at 41.
[873] *Id.*
[874] *Id.* at 43.
[875] *Id.* at 45.
[876] *Id.* at 46.

opposite, completely different. . . . They don't adopt any of the recommendations of *any* of the sources they cite. I'm not sure why they cited them."[877]

Footnote 11

- **Proceedings of the National Academy of Sciences: http://www.pnas.org/page/authors/journal-policies#xi**
- **PLOS ONE: http://journals.plos.org/plosone/s/data-availability**
- **Science: http://www.sciencemag.org/authors/science-journals-editorial-policies**
- **Nature: http://www.nature.com/authors/policies/data/data-availability-statements-data-citations.pdf**

While EPA links to journal policies that encourage or require, in some instances, sharing data, they contain exceptions when privacy would be compromised.[878] The editors of these journals issued a joint statement opposing the Proposal. They note that some data sets cannot be shared publicly, and that there are still other methods available to verify scientific findings. The statement also strongly condemns the notion of excluding scientific information from consideration when underlying data cannot be made publicly available:

> It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes.[879]

Thus, journal policies encouraging the sharing of underlying data do not support a proposal by a regulatory agency to exclude from consideration studies when the underlying data is not publicly available.

Footnote 16:

- **U.S. Department of Health and Human Services: https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html**
- **National Institute of Standards and Technology: https://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf**
- **U.S. Department of Education: https://studentprivacy.ed.gov/sites/default/files/resource_document/file/data_deidentification_terms.pdf**
- **U.S. Census Bureau: https://www.census.gov/about/adrm/linkage/technical-documentation/processing-de-identification.html**

EPA suggests the examples linked to could address concerns about privacy and confidentiality arising from the Proposal. However, the cited sources provide no assurance that

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[877] Robinson Meyer, *Scott Pruitt's New Rule Could Completely Transform the EPA*, The Atlantic (Apr. 25, 2018), https://www.theatlantic.com/science/archive/2018/04/how-the-epas-new-secret-science-rule/558878/.

[878] *See* discussion below on footnote 20.

[879] Jeremy Berg et. al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

the Proposal could be implemented to expand disclosure of personal data without serious risks to privacy.

I. U.S. Department of Health and Human Services, https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html

EPA first points to guidance on de-identification requirements under HIPAA. This guidance provides two methods for de-identifying data: (1) expert determination method, where an expert determines that, after application of statistical and scientific principals and methods, the risk is very small that the information alone or with other available information could be used to identify the subject; and (2) the safe harbor method, requiring that a number of identifiers are removed. The first method requires case-by-case work and EPA has provided no information regarding how EPA could implement it or how much it might cost and thus the feasibility of requiring researchers or EPA to de-identify data this way is questionable. The second method requires removal of much information useful for research that may be necessary to be able to independently validate the research, so it is unclear that it would satisfy the Proposal's demands. Furthermore, the safe harbor method has been shown to provide potentially insufficient privacy protections.[880]

II. National Institute of Standards and Technology, https://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf

EPA links to a NIST document entitled *De-Identification of Personal Information* as a potential solution to address concerns about confidentiality and privacy.[881] This document discusses different techniques and issues with de-identification of personal information. However, the document does not discuss de-identification of personal information specifically for the purposes of making research data publicly available for independently validating scientific studies. The document instead notes that:

> The purpose of de-identifying data is to allow some uses of the de-identified data while providing for some privacy protection by shielding the identity of the data subjects. These two goals are antagonistic, in that there is a trade-off between the amount of de-identification and the utility of the resulting data. However, de-identification opens up new uses for the data that were previously prohibited due to privacy concerns. It is thus the role of the data controller, standards bodies, regulators, lawmakers and courts to determine the appropriate level of security, and thereby the acceptable trade-off between de-identification and utility.[882]

EPA completely fails to note this obstacle, that as data is stripped of identifiable material it also loses utility to researchers. EPA cites to broad privacy protection techniques without explaining

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[880] Latanya Sweeney, Ji Su Yon, Laura Perovich, Katherine E Boronow, Phil Brown, and Julia Green Brody, *Re-identifcation Risks in HIPAA Safe Harbor Data: A Study of Data From One Environmental Health Study*, Technology Science (August 28, 2017).
[881] Simson L. Garfinkel, *De-Identification of Personal Information* (NISTIR 8053), NIST (Oct. 2015), https://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf.
[882] *Id.* at 11-12.

whether they could be applied to protect privacy while still allowing enough utility in the data set to allow for independent validation as required by the Proposal.

The document notes many of the challenges to protecting privacy including that: "de-identification approaches based on suppressing or generalizing specific fields in a database cannot provide absolute privacy guarantees, because there is always a chance that the remaining data can be re-identified using an auxiliary dataset."[883] The harms of data linkages and increasing difficulty to preserve privacy as more and more information about individuals is made available is another challenge that EPA has not addressed.

III. U.S. Department of Education, https://studentprivacy.ed.gov/sites/default/files/resource_document/file/data_deidentification_terms.pdf

EPA links to a document of the Privacy Technical Assistance Center, *Data De-identification: An Overview of Basic Terms*, which provides a high-level overview of key terms and practices to help educational agencies and institutions comply with the Family Educational Rights and Privacy Act (FERPA).[884] EPA has not explained why the requirements of FERPA are applicable here. This document is concerned with data disclosure that occurs "when schools, districts, or states publish reports on student achievement or share students' data with external researchers" not to make information publicly available for independent validation.[885] Thus its unclear that methods used to de-identify but preserve data for those purposes would be adequate in this context.

For example, one of the methods that the U.S. Department of Education uses for disclosure avoidance for tabular data is to not release information for any cell that has a size below some minimum, which essentially means not disclosing information where there are small numbers in a certain cell.[886] This could obviously lead to a loss of information that would prevent a de-identified data set from being used to independently validate research findings.

IV. U.S. Census Bureau, https://www.census.gov/about/adrm/linkage/technical-documentation/processing-de-identification.html

EPA provides a link to a website titled *Data Ingest and Linkage* that details the U.S. Census Bureau's approach to linking data across many records held by the Bureau, permitting more detailed information to be linked back to one individual to allow for analysis and research. The website links to a working paper that describes the method by which the Bureau assigns a unique person identifier to records it holds that enables it to link records together to create the

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[883] *Id.* at 5.
[884] U.S. Department of Education, Privacy Technical Assistance Center, *Data De-identification: An Overview of Basic Terms* (Oct. 2012), https://studentprivacy.ed.gov/sites/default/files/resource_document/file/data_deidentification_terms.pdf.
[885] *Id.*
[886] *Id.* at 4.

final file.[887] It is totally unclear how this process on linking together records is a solution that EPA could implement to protect privacy of individuals when disclosing data as it concerns how to identify data to specific people—not how to make data available while protecting their privacy.

Footnote 20:

- Taylor & Francis: https://authorservices.taylorandfrancis.com/data-repositories/
- Elsevier: https://www.elsevier.com/authors/author-services/research-data
- PLOS: http://journals.plos.org/plosone/s/data-availability
- Springer Nature: https://www.springernature.com/gp/authors/research-data-policy/repositories

EPA cites to "policies or recommendation" of several journals that require data be deposited in public data repositories as an example of the Proposal's requirement of data availability.[888] While these journals have policies that encourage authors to deposit data in public data repositories, they all have important exceptions in cases where this is not feasible or ethical.

The hyperlink for Taylor & Francis links to a page that provides information about how to find public data repositories to submit date to in order to comply with journal sharing policies. However, Taylor & Francis' basic data sharing policy "which applies across many of [their] journals" does not *require* data be submitted to a public data repository, but "encourages authors to share and make data open where this does not violate protection of human subjects or other valid subject privacy concerns."[889] Thus, this policy is flexible and allows exceptions for when privacy concerns are at stake.

The hyperlink for Elsevier links to a page providing general information about data sharing. While the web page notes that researchers "are increasingly encouraged, or even mandated, to make. . . research data available, accessible, discoverable and usable," it also provides important qualifications.[890] It notes, "there are times when the data is simply not available to post or there are good reasons why it shouldn't be shared."[891] In these cases, authors are encouraged to provide a data statement explaining why the data cannot be shared.

The hyperlink for PLOS links to a page describing PLOS's data availability policies. It explains, "PLOS journals require authors to make all data underlying the findings described in their manuscript fully available without restriction, with rare exception."[892] The policy recommends deposition of the data into a public repository, however, it recognizes that there are

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[887] Deborah Wagner & Mary Layne, *The Person Identification Validation System (PVS): Applying the Center for Administrative Records Research and Applications' (CARRA) Record Linkage Software, CARRA Working Paper Series*, Working Paper # 2014-01, U.S. Census Bureau (July 1, 2014).
[888] 83 Fed. Reg. at 18,771.
[889] Taylor & Francis Author Services, *Understanding our data sharing policies*, https://authorservices.taylorandfrancis.com/understanding-our-data-sharing-policies/ (last accessed Aug. 10, 2018).
[890] Elsevier, *Sharing research data*, https://www.elsevier.com/authors/author-services/research-data (last accessed Aug. 10, 2018).
[891] *Id.*
[892] PLOS One, *Data Availability*, http://journals.plos.org/plosone/s/data-availability (last accessed Aug. 10, 2018).

instances when this may not be ethical or legal, for instance because the "underlying data pose privacy or legal concerns e.g., where data might reveal the identity or location of participants."[893] In these instances, it allows an exception to this policy.

The hyperlink for Springer Nature links to a page listing recommended repositories. While Springer Nature's data policies support data sharing via public data repositories, it notes, "reasonable restrictions on data availability are permitted to protect human privacy, biosafety or respect reasonable terms of use for data obtained under license from third parties."[894]

[893] *Id.*

[894] Springer Nature, *Research Data Policies FAQs*, https://www.springernature.com/gp/authors/research-data-policy/faqs/12327154 (last accessed Aug. 10, 2018).

Appendix B. Provisions of Federal Environmental Statutes Requiring EPA to Consult With Other Federal Agencies in Implementing Key Programs

Consultation Provisions in Clean Air Act

Section	Section Title	Consultation Requirement
§118(c)	President's Air Quality Advisory Board and Advisory Committees	(c) Prior to- (1) issuing criteria for an air pollutant under section 108(a)(2) (2) publishing any list under section 111(b)(1)(A) or 112(b)(1)(A), (3) publishing any standard under section 111 or section 112, or (4) publishing any regulation under section 202(a), The administrator shall, to the maximum extent practicable within the time provided, consult with appropriate advisory committees, independent experts, and Federal departments and agencies.
§103	Research, Investigation, Training, and other Activities	Consult with other Federal agencies to coordinate research and avoid duplication of activities
§108(a)	Air Quality Criteria and Control Techniques	Consult with Federal agencies to issue information on air pollution control techniques
§108(c)	Air Quality Criteria and Control Techniques	"[A]fter consultation with the Secretary of Transportation…update the June 1978 Transportation-Air Quality Planning Guidelines and publish guidance on the development and implementation of transportation and other measures necessary to demonstrate and maintain attainment of national ambient air quality standards."
§108(f)(1)	Air Quality Criteria and Control Techniques	Consult with Secretary of Transportation to provide information "regarding the formulation and emission reduction potential of transportation control measures related to criteria pollutants and their precursors."
§112(d)(9)	Hazardous Air Pollutants	Allows Administrator not to list radionuclide emissions if Administrator determines, after consultation with Nuclear Regulatory Commission (NRC), that NRC regulations already provide an adequate margin of safety.
§122	Listing of Certain Unregulated Pollutants	Consult with NRC before listing any nuclear or nuclear by-product material
§169A	Visibility Protections for Federal Class 1 Areas	Consultation with Department of Interior and Federal Land Managers for regional haze determinations
§231(a)(2)(B)(i)	Aircraft Emission Standards	Consult with Federal Aviation Administration on aircraft engine emission standards
§250 (d)	General Provisions	Consult with Department of Energy (DOE) and Department of Transportation (DOT) in carrying out Administrator's duties under the this part (Clean Fuel Vehicles)
§404(f)(1)(A)	Energy Conservation and Renewable Energy	Consult with Secretary of Energy to determine Qualified Energy Conservation Measure

§507(b)(3)(A)	Small Business Stationary Source Technical and Environmental Compliance Assistance Program	Consult with SBA Administrator to determine which category of small business sources could be exempted

Consultation Provisions in Clean Water Act

Section	Section Title	Text
§304(c)	Information and Guidelines	Consult with appropriate Federal and State agencies to issue information on pollution-reducing procedures and operating methods to implement standards of performance under §306.
§304(d)(1)-(2)	Information and Guidelines	Consult with appropriate Federal and State agencies to publish the amount of reduction attainable through secondary treatment and information on alternative waste treatment management techniques.
§304(e)	Information and Guidelines	Consult with appropriate Federal and State agencies to publish supplemental regulations to control plant site runoff, leaks/spillage, sludge/waste disposal, and drainage
§304(f)	Information and Guidelines	Consult with Federal and State agencies to issue guidelines for evaluating nonpoint sources and methods to control pollution from those sources.
§307(a)(7)	Toxic Pretreatment Effluent Standards	Consult with Federal departments and agencies prior to publishing regulations pursuant to this section
§404(d)(1)	Disposal of Sewage Sludge	Administrator must consult with Federal agencies on regulations providing guidelines for the disposal of sludge and the utilization of sludge for various purposes.
§118(a)	Lake Tahoe Study	Coordinate with Secretary of Agriculture and other Federal agencies regarding adequacy and need for extending Federal oversight of Lake Tahoe
§311(d)(2)(M)	Oil and Hazardous Substance Liability	Consultation with FWS and NOAA for a fish and wildlife response plan
§312(e)	Marine Sanitation Devices	"Before the standards and regulations under this section are promulgated, the Administrator and the Secretary of the department in which the Coast Guard is operating shall consult with the Secretary of State; the Secretary of Health, Education, and Welfare; the Secretary of Defense; the Secretary of the Treasury; the Secretary of Commerce; other interested Federal agencies...."

Consultation Provisions in Federal Insecticide, Fungicide, and Rodenticide Act

Section	Section Title	Text
136w(a)(2)(A)	Authority of the Administrator: Procedure: Proposed regulations	**(A) Proposed Regulations:** **At least 60 days prior to signing any proposed regulation for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation.** If the Secretary comments in writing to

		the Administrator regarding any such regulation within 30 days after receiving it, the Administrator shall publish in the Federal Register (with the proposed regulation) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 30 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register any time after such 30-day period notwithstanding the foregoing 60-day time requirement.
136w(a)(2)(B)	Authority of the Administrator: Final Regulations	**At least 30 days prior to signing any regulation in final form for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture witb a copy of such regulation.** If the Secretary comments in writing to the Administrator regarding any such final regulation within 15 days after receiving it, the Administrator shall publish in the Federal Register (with the final regulation) the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 15 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register at any time after such 15-day period notwithstanding the foregoing 30-day time requirement. In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the effect of the regulation on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such effect
136w(a)(3)	Authority of the Administrator: Procedure: Congressional Committees	At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, the Administrator shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.
136w(a)(4)	Authority of the Administrator	Simultaneously with the promulgation of any rule or regulation under this subchapter, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.

136w-3	Identification of Pests; cooperation with Department of Agriculture	The Administrator, in coordination with the Secretary of Agriculture, shall identify those pests that must be brought under control. The Administrator shall also coordinate and cooperate with the Secretary of Agriculture's research and implementation programs to develop and improve the safe use and effectiveness of chemical, biological, and alternative methods to combat and control pests that reduce the quality and economical production and distribution of agricultural products to domestic and foreign consumers.
136(r)(a)	Research and Monitoring: Research	The Administrator shall undertake research including research by grant or contract with other Federal agencies, universities, or others as may be necessary to carry out the purposes of this subchapter, and **the Administrator shall conduct research into integrated pest management in coordination with the Secretary of Agriculture.** The Administrator shall also take care to ensure that such research does not duplicate research being undertaken by any other Federal agency.
136a-1(n)(2)-(3)	Reregistration of registered pesticides: Authorization of funds to develop public health data	**(2)** Consultation. In the case of a pesticide registered for use in public health programs for vector control or for other uses the Administrator determines to be human health protection uses, the Administrator shall, upon timely request by the registrant or any other interested person, or on the Administrator's own initiative may, consult with the Secretary [of Health and Human Services] prior to taking final action to suspend registration under section 3(c)(2)(B)(iv) or cancel a registration under section 4, 6(e), or 6(f). In consultation with the Secretary, the Administrator shall prescribe the form and content of requests under this section. **(3)** Benefits to support family. The Administrator, after consulting with the Secretary, shall make a determination whether the potential benefits of continued use of the pesticide for public health or health protection purposes are of such significance as to warrant a commitment by the Secretary to conduct or to arrange for the conduct of the studies required by the Administrator to support continued registration under section or reregistration under section 4
7 USCS 136(ll)(2)	Definitions: Minor Use	(2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and--

136i(a)(1)	Use of restricted use pesticides; applicators	Requires the Administrator to consult with Governor of each state to conduct a program for the certification of use of specific pesticides.
136a(c)(1)(F)(ii)	Registration of Pesticides: Procedure for registration	The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after the date of enactment of this clause [enacted Aug. 3, 1996] and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in **consultation** with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that--(I) there are insufficient efficacious alternative registered pesticides available for the use; (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health; (III) the minor use pesticide plays or will play a significant part in managing pest resistance; or (IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.
136t(b)	Delegation and Cooperation	**(b)** Cooperation. The Administrator shall cooperate with the Department of Agriculture, any other Federal agency, and any appropriate agency of any State or any political subdivision thereof, in carrying out the provisions of this Act and in securing uniformity of regulations.
136o(e)	Imports and Exports	Secretary of the Treasury shall prescribe regulations for this section in consultation with the Administrator.
136p	Exemption of Federal and State Agencies	The Administrator may, at the Administrator's discretion, exempt any Federal or State agency from any provision of this Act if the Administrator determines that emergency conditions exist which require such exemption. The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.
136w-7	Department of Agriculture Minor Use Program	**(A)** Grant authority. The Secretary, in consultation with the Administrator, shall establish a program to make grants for the development of data to support minor use pesticide registrations and reregistrations. The amount of any such grant shall not exceed 1/2 of the cost of the project for which the grant is made.
136i-1(a)(1)	Pesticide Recordkeeping	The Secretary of Agriculture, in consultation with the Administrator of the Environmental Protection Agency, shall require certified applicators of restricted use pesticides
136i-2(c)	Collection of Pesticide Use Information	Coordination. The Secretary of Agriculture shall, as appropriate, coordinate with the Administrator of the Environmental Protection Agency in the design of the

		surveys and make available to the Administrator the aggregate results of the surveys to assist the Administrator.

Consultation provisions under the Toxic Substances Control Act

Section	Title	Text
2609(a)	Research, Development, collection, dissemination, and utilization of data	**(a)** Authority. **The Administrator shall, in consultation and cooperation with the Secretary of Health and Human Services and with other heads of appropriate departments and agencies, conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act.** The Administrator may enter into contracts and may make grants for research, development, and monitoring under this subsection. Contracts may be entered into under this subsection without regard to sections 3648 and 3709 of the Revised Statutes
2609(b)(1), (2)	Research, development, collection, dissemination, and utilization of information: Information Systems	Administrator shall Consult and cooperate with Secretary of HHS and other heads of appropriate departments and agencies, to establish an efficient system for retrieval of toxicological and other scientific information which could be useful
2609(c)	Research, development, collection, dissemination, and utilization of information: Screening Techniques	Administrator shall coordinate with Assistant Secretary for HHS to develop screening techniques
2609(d)	Research, development, collection, dissemination, and utilization of information: Monitoring	Administrator shall, in consultation and cooperation with the Secretary of Health and Human Services, establish and be responsible for research aimed at the development, in cooperation with local, State, and Federal agencies, of monitoring techniques and instruments which may be used in the detection of toxic chemical substances and mixtures and which are reliable, economical, and capable of being implemented under a wide variety of conditions
2609(e)	Research, development, collection, dissemination, and utilization of information: Basic Research	The Administrator shall, in consultation and cooperation with the Secretary of Health and Human Services, establish research programs to develop the fundamental scientific basis of the screening and monitoring techniques described in subsections (c) and (d), the bounds of the reliability of such techniques, and the opportunities for their improvement.
2609(g)	Research, development, collection, dissemination, and utilization of information: Exchange of research and development results	The Administrator shall, in consultation with the Secretary of Health and Human Services and other heads of appropriate departments and agencies, establish and coordinate a system for exchange among Federal, State, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard information format and analysis and consistent testing procedures.

2608(d)	Coordination	"Coordination. In administering this Act [15 USCS §§ 2601 et seq.], the Administrator shall consult and coordinate with the Secretary of Health and Human Services and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act . . ."
2608(e)	Exposure Information	If the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.
2604(f)(5)	Manufacturing and Processing Notices: Protection Against Unreasonable Risks	Consult with Assistant Secretary of Labor prior to adopting any restriction of chemical substance for workplace exposures
2604(h)(2)(B)(ii)	Manufacturing and Processing Notices: Exemptions	Consult with AG of the Federal Trade Commission about exempting persons from information requirements.

Consultation Provisions in the Safe Drinking Water Act

Section	Title	Text
300g-1 (b)(1)(D)	Standards: Listing of Contaminants for Consideration, Urgent Threats to Public Health	The Administrator may promulgate an interim national primary drinking water regulation for a contaminant without making a determination for the contaminant under paragraph (4)(C), or completing the analysis under paragraph (3)(C), to address an urgent threat to public health as determined by the Administrator after consultation with and written response to any comments provided by the Secretary of Health and Human Services, acting through the director of the Centers for Disease Control and Prevention or the director of the National Institutes of Health.
300g-1(d)	Regulations:	Regulations; public hearings; administrative consultations. Regulations under this section shall be prescribed in accordance with section 553 of title 5, United States Code (relating to rule-making), except that the Administrator shall provide opportunity for public hearing prior to promulgation of such regulations. In proposing and promulgating regulations under this section, the Administrator shall consult with the Secretary and the National Drinking Water Advisory Council.
300j-12(i)(2)	Funds: Indian Tribes: Use of Funds	(2) Use of funds. Funds reserved pursuant to paragraph (1) shall be used to address the most significant threats to public health associated with public water systems that serve Indian Tribes, as determined by the Administrator in consultation with the Director of the Indian Health Service and Indian Tribes.
300j-13(a)(5)	Source Water Quality Assessment	Demonstration project. The Administrator shall, as soon as practicable, conduct a demonstration project, in consultation with other Federal agencies, to demonstrate the most effective and protective means of

		assessing and protecting source waters serving large metropolitan areas and located on Federal lands.
300j-5(b)	National Drinking Water Advisory Council	**(b)** Functions. The Council shall advise, consult with, and make recommendations to, the Administrator on matters relating to activities, functions, and policies of the Agency under this title [42 USCS §§ 300f et seq.].
300j-3d	Water Supply Cost Savings	**(a)** Drinking water technology clearinghouse. The Administrator, in consultation with the Secretary of Agriculture, shall— **(1)** develop a technology clearinghouse for information on the cost-effectiveness of innovative and alternative drinking water delivery systems, including wells and well systems; and **(2)** disseminate such information to the public and to communities and not-for-profit organizations seeking Federal funding for drinking water delivery systems serving 500 or fewer persons.
300i-3(a)	Contaminant Prevention, Detection and Response	In general. The Administrator, in consultation with the Centers for Disease Control and, after consultation with appropriate departments and agencies of the Federal Government and with State and local governments, shall review (or enter into contracts or cooperative agreements to provide for a review of) current and future methods to prevent, detect and respond to the intentional introduction of chemical, biological or radiological contaminants into community water systems and source water for community water systems, including each of the following:
300j-19(b)(2)(A)	Algal Toxin Risk Assessment and Management	(b) Information coordination. In carrying out this section the Administrator shall-- (2) as appropriate, consult with-- • (A) other Federal agencies that-- ○ (i) examine or analyze cyanobacteria or algal toxins; or ○ (ii) address public health concerns related to harmful algal blooms;

Consultation Provisions in the Comprehensive Environmental Response, Compensation, and Liability Act

Section	Section Title	Consultation Requirement
§311(a)(1)	Research, Development, and Demonstration	The Secretary of Health and Human Services…in consultation with the Administrator, shall establish and support a basic research and training program…consisting of the following (A) Basic research (including epidemiologic and ecologic studies) which may include each of the following: (i) Advanced techniques for the detection, assessment, and evaluation of the effects on human health of hazardous substances. (ii) Methods to assess the risks to human health presented by hazardous substances. (iii) Methods and technologies to detect hazardous substances in the environment and basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances. (B) Training, which may include each of the following:

		(i) Short courses and continuing education for State and local health and environment agency personnel and other personnel engaged in the handling of hazardous substances, in the management of facilities at which hazardous substances are located, and in the evaluation of the hazards to human health presented by such facilities. (ii) Graduate or advanced training in environmental and occupational health and safety and in the public health and engineering aspects of hazardous waste control. (iii) Graduate training in the geosciences, including hydrogeology, geological engineering, geophysics, geochemistry, and related fields necessary to meet professional personnel needs in the public and private (a) sectors and to effectuate the purposes of this Act.
§311(a)(2)	Research, Development, and Demonstration	The Director of the National Institute for Environmental Health Sciences shall cooperate fully with the relevant Federal agencies referred to in subparagraph (A) of paragraph (5) in carrying out the purposes of this section.
§311(a)(5)	Research, Development, and Demonstration	To assist in the implementation of this subsection and to aid in the coordination of research and demonstration and training activities funded from the Fund under this section, the Secretary shall appoint an advisory council (hereinafter in this subsection referred to as the ''Advisory Council'') which shall consist of representatives of the following: (A) The relevant Federal agencies. (B) The chemical industry. (C) The toxic waste management industry. (D) Institutions of higher education. (E) State and local health and environmental agencies. (F) The general public.
§311(a)(6)	Research, Development, and Demonstration	Within nine months after the date of the enactment of this subsection, the Secretary, acting through the Director of the National Institute for Environmental Health Sciences, shall issue a plan for the implementation of paragraph (1). The plan shall include priorities for actions under paragraph (1) and include research and training relevant to scientific and technological issues resulting from site specific hazardous substance response experience. The Secretary shall, to the maximum extent practicable, take appropriate steps to coordinate program activities under this plan with the activities of other Federal agencies in order to avoid duplication of effort. The plan shall be consistent with the need for the development of new technologies for meeting the goals of response actions in accordance with the provisions of this Act. The Advisory Council shall be provided an opportunity to review and comment on the plan and priorities and assist appropriate coordination among the relevant Federal agencies referred to in subparagraph (A) of paragraph (5).
§311(c)	Research, Development, and Demonstration	HAZARDOUS SUBSTANCE RESEARCH.—The Administrator may conduct and support, through grants, cooperative agreements, and contracts, research with respect to the detection, assessment, and evaluation of the effects on and risks to human health of hazardous substances and detection of hazardous substances in the environment. The Administrator shall coordinate such research with the Secretary of Health and Human Services, acting through the advisory council established under this section, in order to avoid duplication of effort.

§104(i)(4)	Response Authorities	The Administrator of the ATSDR shall provide consultations upon request on health issues relating to exposure to hazardous or toxic substances, on the basis of available information, to the Administrator of EPA
§104(i)(5)(A)	Response Authorities	For each hazardous substance listed pursuant to paragraph (2), the Administrator of ATSDR (in consultation with the Administrator of EPA and other agencies and programs of the Public Health Service) shall assess whether adequate information on the health effects of such substance is available. For any such substance for which adequate information is not available (or under development), the Administrator of ATSDR, in cooperation with the Director of the National Toxicology Program, shall assure the initiation of a program of research designed to determine the health effects (and techniques for development of methods to determine such health effects) of such substance.
§104(i)(6)(C)	Response Authorities	In determining the priority in which to conduct health assessments under this subsection, the Administrator of ATSDR, in consultation with the Administrator of EPA, shall give priority to those facilities at which there is documented evidence of the release of hazardous substances, at which the potential risk to human health appears highest, and for which in the judgment of the Administrator of ATSDR existing health assessment data are inadequate to assess the potential risk to human health as provided in subparagraph (F). In determining the priorities for conducting health assessments
§107(c)	Abatement Action	Within one hundred and eighty days after enactment of this Act, the Administrator of the Environmental Protection Agency shall, after consultation with the Attorney General, establish and publish guidelines for using the imminent hazard, enforcement, and emergency response authorities of this section and other existing statutes administered by the Administrator of the Environmental Protection Agency to effectuate the responsibilities and powers created by this Act.
§120(e)(1)	Federal Facilities	Not later than 6 months after the inclusion of any facility on the National Priorities List, the department, agency, or instrumentality which owns or operates such facility shall, in consultation with the Administrator and appropriate State authorities, commence a remedial investigation and feasibility study for such facility.
§120(e)(6)	Federal Facilities	Administrator, after consultation with other departments, may determine that remedial efforts should be done by another potentially responsible party and may enter into a settlement agreement with such party.

Consultation Provisions in the Resource Conservation and Recovery Act

Section	**Section Title**	**Consultation Requirement**
§2002(a)(1)	Authorities of Administrator	In carrying out this Act, the Administrator is authorized to— (1) prescribe, in consultation with Federal, State, and regional authorities, such regulations as are necessary to carry out his functions under this Act;
§1008(a)	Solid Waste Management Information and Guidelines	Administrator shall consult with Federal agencies, among others, to develop and publish guidelines for solid waste management.

§2001	Office of Solid Waste and Interagency Coordinating Committee	Establishing an Interagency Coordinating Committee for RCRA between EPA, Department of Energy, Department of Commerce, and all other Federal agencies. Includes coordinating research and projects.
§2002(a)(2)-(6)	Authorities of Administrator	(2) consult with or exchange information with other Federal agencies undertaking research, development, demonstration projects, studies, or investigations relating to solid waste; ... (5) utilize the information, facilities, personnel and other resources of Federal agencies, including the National Bureau of Standards 1 and the National Bureau of the Census, on a reimbursable basis, to perform research and analyses and conduct studies and investigations related to resource recovery and conservation and to otherwise carry out the Administrator's functions under this Act; and (6) to delegate to the Secretary of Transportation the performance of any inspection or enforcement function under this Act relating to the transportation of hazardous waste where such delegation would avoid unnecessary duplication of activity and would carry out the objectives of this Act and of the Hazardous Materials Transportation Act.
§4002(b)	Federal Guidelines for Plans	Not later than 18 months after enactment, Administrator shall consult with appropriate agencies to promulgate guidelines for the development and implementation of State plans. Such guidelines should be reviewed and revised at least every three years.
§8001(a)	Research, Demonstrations, Training, and Other Activities	The Administrator, alone or after consultation with the [Department of Energy], or [FERC], shall conduct, and encourage, cooperate with, and render financial and other assistance to appropriate public (whether Federal, State, interstate, or local) authorities, agencies, and institutions, private agencies and institutions, and individuals in the conduct of, and promote the coordination of, research, investigations, experiments, training, demonstrations, surveys, public education programs, and studies relating to— (1) any adverse health and welfare effects of the release into the environment of material present in solid waste, and methods to eliminate such effects....
§8001(b)(2)(D)	Research, Demonstrations, Training, and Other Activities	any activities undertaken under provisions of sections 8002 and 8003 as related to energy; as related to energy or synthetic fuels recovery from waste; or as related to energy conservation shall be accomplished through coordination and consultation with the [Department of Energy]

NRDC's statement on EPA's Proposed Rule to Strengthen Science Transparency in EPA Regulations:

Introduction

Thank you for providing the Natural Resources Defense Council, Inc. (NRDC) this opportunity to present our views on "EPA's proposed rule to strengthen science transparency in EPA regulation." NRDC is a national, non-profit organization of scientists, lawyers, and environmental specialists, dedicated to protecting public health and the environment. Founded in 1970, NRDC serves more than two million members, supporters and environmental activists with offices in New York, Washington, DC, Los Angeles, San Francisco, Chicago, Bozeman, Montana, and Beijing. NRDC has been engaged with the environmental issues surrounding nuclear energy and nuclear weapons since our founding, and NRDC maintains a Nuclear Program staffed by a nuclear physicist, a nuclear engineer, a radiation health physicist and an attorney.

EPA's proposed rule

Despite the failure of the proposed rule to precisely name radiation standards or cite the EPA's authority under the Atomic Energy Act, with the agency's focus on reviewing the underlying science for dose-response models, it is NRDC's presumption that EPA intends to revise the underlying science for radiation standards, and the Linear No-threshold dose-response model (LNT) in particular.

Specifically, EPA's proposed rule states that "... this proposed regulation is designed to increase transparency of the assumptions underlying dose-response models. As a case in point, there is growing empirical evidence of non-linearity in the concentration response function for specific pollutants and health effects." The proposed rule fails to provide a citation or empirical evidence to support the statement. By contrast, the science in radiation epidemiological studies has repeatedly demonstrated, over decades, that the LNT dose-response model provides the most reasonable description of the relation between low dose exposure to ionizing radiation and the incidence of solid cancers that are induced by ionizing radiation.

The Linear No-Threshold (LNT) dose-response model

As it does in every other instance and under every other environmental statute, EPA relies on independent, authoritative scientific bodies to provide analyses and evaluations of scientific evidence in support of its radiation standard-setting policies. EPA bases its regulatory limits, and nonregulatory guidelines for population exposures to low-level ionizing radiation on the linear no-threshold (LNT) dose-response model.[1] EPA's radiation protection standards are based on the premise that any radiation dose carries some risk, and that risk increases directly with dose. This method of estimating risk is called the "linear no-threshold dose-response model (LNT).

This longstanding and well-supported assumption assumes that the risk of cancer due to a low dose exposure is proportional to dose, with no threshold. For over 40 years the LNT dose-response model has been commonly utilized when developing practical and prudent guidance on ways to protect workers and members of the public from the potential for harmful effects from radiation in balance with the commercially justified and optimized uses of radiation. EPA derives the LNT model from reports by authoritative scientific bodies including the U.S. National Academy of Sciences (NAS), the National Council on Radiation Protection and Measurements (NCRP), and the International Commission on Radiological Protection(ICRP). There is strong scientific consistency by these authoritative groups that an LNT model is the best at the current time (and has been for the past half century).[2,3] Indeed, EPA noted as recently as late 2015, "[o]ver the last half century, numerous authoritative national and international bodies have convened committees of experts to examine the issue of LNT as a tool for radiation regulation and risk assessment ... Again and again, these bodies have endorsed LNT as a reasonable approach to regulating exposures to low dose radiation." [4]

NAS Biological Effects of Ionizing Radiation (BEIR) VII committee has studied and published its report on risk models for estimating the relationship between

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1 *See*, e.g., https://www.epa.gov/radiation/radiation-health-effects

2 Puskin, Jerome S. "Perspective on the use of LNT for radiation protection and risk assessment by the US Environmental Protection Agency." Dose-Response 7.4 (2009): dose-response.

3 Valentin, Jack. The 2007 recommendations of the international commission on radiological protection. Oxford: Elsevier, 2007.

4 See https://www.nrc.gov/docs/ML1530/ML15301A820.pdf

exposure to low levels of ionizing radiation and harmful health effects.[5] The Committee judged that the LNT model provided the most reasonable description of the relation between low dose exposure to ionizing radiation and the incidence of solid cancers that are induced by ionizing radiation.

The NCRP published its latest commentary on the LNT issue only weeks ago, in April 2018.[6] The specific purpose of its commentary is to provide a review of recent epidemiologic data from studies with low doses or low dose rates and the Life Span Study (LSS) of atomic-bomb survivors to determine whether these epidemiologic studies broadly support the LNT dose-response model as a reasonable basis for radiation protection. Epidemiologic studies of humans provide evidence that is critically important in establishing potentially causal associations of environmental factors with the disease. The studies were selected by a consensus of experts who have a broad purview of the recent radiation epidemiology literature, and they ensured that the largest and most important eligible studies were included.

NCRP commentary in conclusion of its epidemiology studies states that, "... based on current epidemiologic data, the LNT model should continue to be used for radiation protection purposes, and no alternative dose-response relationship appears more pragmatic or prudent for radiation protection purposes than the LNT model."

How the proposed rule jeopardizes health protections

The epidemiologic science and associated studies that are the basis of adherence to the LNT and decades of protective radiation standards are likely to be expressly excluded from consideration by EPA by the terms of this proposed rule.

NAS and other studies that EPA has long relied upon in the radiation standards setting process are epidemiological human cohort studies. EPA's proposed rule, if implemented, would limit EPA staff from basing regulatory actions on precisely these types of studies by requiring that the underlying data of these studies should

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[5] National Research Council. *Health risks from exposure to low levels of ionizing radiation: BEIR VII phase 2*. Vol. 7. National Academies Press, 2006.

[6] NCRP Commentary 27. "Implications of Recent Epidemiologic Studies for the Linear-Nonthreshold Model and Radiation Protection." NCRP, 2018

fully be publicly shared. This would be a nearly impossible task for the agency. Data for some of the radiation epidemiological studies are accessible to users[7,8] with a detailed description of how a user can access the information. However, public sharing of personally identifiable information (PII) is restricted because the studies rely on confidential health data.

These are profoundly important studies that have been peer reviewed for decades and the science that has emerged from them has been validated multiple times. But these are not studies where the entirety of the public data can be shared or independently replicated. There are no other radiation epidemiologic studies of health and longevity on a large size population (example: more than 120,000 individuals in the atomic-bomb survivor studies) that have continued for more than 60 years. Thus, replication of the studies is impossible as this data comes from individuals exposed to significant acute and protracted dose of radiation. Implementation of the rule would effectively block the use of such key scientific studies and allow for radiation standards to be either wholly weakened or made functionally meaningless.

Adverse consequences

The U.S. EPA relied on the LNT dose-response model to develop the following reports and regulations to protect the general public and radiation workers from the potential for harmful effects from radiation:

Federal guidance reports (FGRs) for radiation protection that provide technical information and policy recommendations for radiation dose and risk assessment:

Nuclear fuel cycle standards and regulations addressing environmental issues for all phases of the uranium fuel cycle, including uranium milling; chemical conversion; fuel fabrication and reprocessing; power plant operations; waste management, storage, and disposal; and site cleanup for milling operations.

Examples of areas that might be impacted by this rule include:

1. Maximum allowed concentrations of radionuclides in drinking water

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7 See https://apps.orau.gov/cedr/#.Wv73Y-4vxEY

8 See http://rerf.jp/index_e.html

2. Soil cleanup levels for Superfund sites
3. Monitoring around radiation-producing equipment used for medical purposes
4. Radioactive waste disposal
5. The concept of ALARA (As Low As Reasonably Achievable) in radiation protection

Conclusion

Abandoning the LNT dose-response model and replacing it with either a threshold model or a concept that low doses of radiation are safe will have an adverse effect on radiation workers and the general public by allowing radiation protection regulations to be relaxed, reinterpreted and then weakened. In conclusion, I urge the EPA to abandon the proposed rule. Thank you!

ECOLOGICAL SOCIETY OF AMERICA
esa

Ecological Society of America
1990 M St, NW, Suite 700
Washington, DC 20036

October 1, 2018

The Honorable John Barrasso
Chairman
Committee on Environment and Public Works
410 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Thomas R. Carper
Ranking Member
Committee on Environment and Public Works
456 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Rounds
Chairman
Subcommittee on Waste Management
and Regulatory Oversight
410 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Cory Booker
Ranking Member
Subcommittee on Waste Management
and Regulatory Oversight
456 Dirksen Senate Office Building
Washington, DC 20510

Re: Oversight of the Environmental Protection Agency's Implementation of Sound and Transparent Science in Regulation

Dear Senators Barrasso, Rounds, Carper, and Booker:

The Ecological Society of America (ESA) is a professional scientific society composed of over 9,000 professional ecologists. I write on its behalf to express ESA's strong opposition to the Environmental Protection Agency's Notice of Proposed Rulemaking, "Strengthening Transparency in Regulatory Science."

The proposed rule stipulates that the U.S. Environmental Protection Agency (EPA) will ensure that the data and models underlying the pivotal science that informs significant regulatory actions are made publicly available and that they are available in a format that allows for outside analysis and validation. Within the scientific community, high-quality scientific studies are judged by scientific methodology and the rigor with which they are conducted during the peer review process, and not solely on data transparency. While the ESA generally supports open science and transparency, the ESA is concerned that overly stringent requirements for transparency may cause valid scientific evidence to be discarded and thereby pose a threat to the credibility of regulatory science and the EPA's ability to use the best available science in decision-making. As a result, the proposed rule could have far-reaching consequences for clean air, clean water, public health and the environment. The proposed rule also ignores the inherent risks involved in data disclosure such as the need to protect confidential human subject data used in epidemiologic studies.

The proposed rule will not improve the quality of science used by the EPA or allow the agency to fulfill its mandate of protecting human health and the environment. The ESA strongly opposes the EPA's efforts to restrict the use of the best available science in its policymaking. The Society stands ready to work with Members of Congress, the EPA and other members of the scientific community to evaluate the unintended consequences of this proposed rule. Thank you for providing oversight on this issue and for your consideration of our concerns.

Sincerely,
Laura Huenneke, Ph.D
President

Phone: (202) 833-8773 • Fax: (202) 833-8775 • Email: esahq@esa.org • Web: http://www.esa.org/

Senator ROUNDS. I would ask unanimous consent to include in the record several articles written by Dr. Calabrese and a letter in support of the proposed science transparency rule from the American Chemistry.

Senator BOOKER. He has published 900 articles. Are you putting them all in the record?

Senator ROUNDS. Five hundred.

Senator BOOKER. Just no requirement that I read them, please.

Senator ROUNDS. Not today, anyway.

Senator BOOKER. Not today. OK.

[The referenced information follows:]

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UNSETTLED SCIENCE

Societal Threats from Ideologically Driven Science

Edward J. Calabrese

I remember clearly my first week in graduate school in the entomology department at the University of Massachusetts Amherst in 1971. One of my fellow graduate students had just reported on a potentially important finding relating to a type of circadian rhythm, the twenty-four-hour cycle of biological processes that many organisms exhibit. The key observation occurred between 1:00 a.m. and 4:00 a.m. He was going to confirm his findings the following day. For reasons that were not shared, my advisor had some doubts about this "major" discovery and decided to be present at the lab between 1:00 a.m. and 4:00 a.m., along with the department chair (in retrospect, a bad sign).

When the student arrived at the lab the next day, my advisor asked whether the significant findings had been confirmed. The student acted very excited, claiming to have confirmed the result, and showed the data. The only problem was that during those early morning hours the student had not been in the lab, where my advisor and chair sat waiting and waiting to see him. The novel discovery proved to be a hoax, and in less than an hour the student had cleared out his office and was never to be seen again.

As for me, I got his office and an eye-opening education on honesty in science, life in general, and the consequences of unethical behavior.

I have never been too preoccupied with issues of honesty over the years because everyone I have worked with has seemed to be truthful about their science. Plus, we have tended to work in very close teams with multiple people checking what everyone else was doing. There have been many disagreements on all aspects of studies and data interpretation, but no challenges on the honesty issue. I have read William Broad and Nicholas Wade's 1982 book *Betrayers of the Truth*, all about

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fraud and deceit in science, but its stories and scenes seem to belong to a different world from mine. Most of the individuals caught in fraud appear to be in a mad race for some type of academic glory, whereas my life in science has been far more quiet, sedate, and mostly fun.

Muller and the History of Dose-Response

The issue of honesty and deceit in science would reenter my life exactly forty years after my first week in graduate school. It all started very quietly. I had written a substantial review paper on the history of the linear dose-response, how it came to be accepted and used by regulatory agencies. The dose-response refers to the means by which drugs and other chemicals and physical agents, like radiation, affect biological systems and how this may be influenced by both the total amount and the rate of agent administered. As has long been my custom, I often send a copy of the draft manuscript to a group of knowledgeable friendly critics prior to journal submission. On this occasion one of the friendly critics, a very experienced expert in the area of genotoxicology, wrote that I had not explained the role of the Nobel laureate Hermann J. Muller and his significance in this area as deeply and insightfully as it probably needed to be covered.

He did not claim to be an expert on Muller, who was awarded the 1946 Nobel Prize in Physiology or Medicine for his discovery of the production of mutations by means of X-ray irradiation, but simply had a strong hunch that I was missing an important part of the story. Based on my respect for this person's past insights and help, this was more than enough for me to put the paper on hold to learn all about Muller's life and accomplishments. I obtained numerous articles by Muller, multiple articles about him, a substantial biography, and his December 12, 1946, Nobel Lecture. I even found a 1957 lecture he gave to other Nobel winners posted on the web. It was interesting to hear his voice, see his mannerisms, and follow his train of thought.

I started with Muller's earliest papers and followed his career until the very end. Then I read and studied his biography and Nobel Lecture. This method was expansive, since it also forced me to look at the lives of other leading scientists of his era who worked with him in one way or another in the area of radiation genetics. This study led me to the previously unexplored world of the history of science, especially the history of radiation, mutation, cancer, and public health. From reading multiple dissertations I came to appreciate the incredible depth and insight that such historians of science offer, and I was upset that I had never

really taken the time to learn about and from these efforts. So much had I missed! It was a bit like peeling an onion.

The story of Muller and his era became progressively more interesting and offered much insight into the scientific process. Little did my friendly critic know that his comment had reawakened in me a latent gene for the unrelenting search for historical truth. In fact, in my freshman year of college I had started out as a history major and then got so inspired by my zoology course that I switched to biology. Now it seemed that I was coming full circle.

I became particularly fascinated with parts of Muller's life because he was a professor at Amherst College (1940–1945), located in the town where I live, something I did not know. I tracked down the house he lived in, which was just a short walk to the college and about 1.5 miles from my home. I learned much about his work on the Manhattan Project with the famous geneticists Curt Stern and Ernst Caspari, and its impact on dose-response. My critic was correct: Muller was very important in the history of dose-response and risk assessment. In fact, I learned that Muller created the term "proportionality rule" in 1930 to describe the linear dose-response and played a key supportive role in the initial creation of the LNT single-hit model in the mid-1930s. The LNT dose-response model assumes that the response is directly proportional to dose down to a single molecule. In marked contrast, the threshold dose-response assumes that there is a safe level of exposure as long as the exposure is below the threshold dose.

Manhattan Project and Dose-Response

While doing this historical digging, I noticed a potential disparity between what Muller stated in his Nobel Lecture and what I had come to learn about key findings in the mutation study of Caspari and Stern, on which Muller was a paid consultant. In his Nobel Lecture, Muller was quite emphatic that the threshold dose-response model was not scientifically credible and needed to be replaced by the LNT model for risk assessment. I found this very curious, since in August 1946 Caspari finished his major study on the effects of chronic ionizing radiation on mutations in Drosophila and found a threshold response.

The genetic damage component of the Manhattan Project was conducted at the University of Rochester under the direction of Stern. It represented the most significant research ever in this area. It had a very strong research team, improved quality control, large-scale studies, and excellent technical support, among other factors. While Stern, Muller, Caspari, and the rest of the Rochester team

were expecting that Caspari would confirm their belief in linearity, he didn't. In fact, just the opposite happened. His data demonstrated a threshold dose-response.

This was the proverbial fly in the ointment. Had Caspari's data supported a linear dose-response, it would have provided a major boost for the goal of replacing the threshold model with LNT held by Muller, Stern, and most others in the radiation genetics community.

This made me wonder whether Muller had seen the Caspari findings prior to giving the Nobel Lecture. I figured that he probably had *not* seen them since he never could otherwise have made the statement that he did about the lack of possibility of there being a threshold. Here was the best study to date, one in which Muller was an active and influential consultant and knew the quality of the people and research effort.

How could he ignore it, or worse still, dismiss it?

I needed to find out what Muller knew and when he came to know it. I contacted some historians of science and they had no insights on this question, so I ended up purchasing all the communication I could identify between Muller and all the Stern team members. Late one afternoon I received between six hundred and eight hundred pages of correspondence and related material.

I reviewed all the material that evening and found the so-called smoking gun. I learned that Stern had sent Muller the manuscript that he and Caspari had prepared on the study on November 6, 1946, after having alerted Muller in September to expect it. Muller acknowledged receipt of the Caspari manuscript and offered preliminary comments on it in a November 12, 1946, letter to Stern.

In the letter Muller acknowledged that these findings seriously challenged the LNT model, that the study needed to be replicated, that Stern needed to get the funds to do this, and that Caspari was a very competent researcher and that Muller could not dismiss the study due to inexperience or other reasons. Thus I knew for the first time that Muller had seen the Caspari findings one month prior to giving his Nobel Lecture and had an excellent sense of its significant implications, and that it could not be dismissed but needed to be repeated.

This new information troubled me. I put myself in Muller's position: If I were about to receive the Nobel Prize, could I ever state that there was no possibility that the threshold model was biologically plausible after seeing the Caspari study findings? In fact, his recommendation for a major replication directly contradicted this comment. The replication was not trivial and would take a year and require the help of multiple technicians, plus one as experienced as Caspari or Stern to direct it. I felt that the best I could do on this matter, if I were in Muller's situation, would be to acknowledge that the shape of the dose-response in the low dose zone remained a viable research question and needed to be resolved. I might have stated that while I believe that the

linear dose-response is most likely the correct view, this needed to be assessed further. And yet, while Muller acted like a scientist in his communications with Stern, in his public demeanor he was deceitful and very ideological—everything a scientist should not be. To act this way during the most significant moment in his professional life revealed important character traits in Muller, including those of dishonesty, risk-taking, manipulation, and arrogance.

I held out hope that he may have had new insights that led him to criticize the study and that would provide an explanation for his rejection of Caspari's threshold conclusion. However, a detailed seven-page letter to Stern dated January 14, 1947, reaffirmed the November 12, 1946, letter. With this now in hand I came to the firm but unsettling conclusion that Muller was deliberately deceptive in his Nobel Lecture and used this opportunity to achieve a long-dreamed-of goal to have LNT as the default model for cancer risk assessment. This was his chance and, apparently, the ends justified the means—again, a rationalization that scientists should never accept.

In 2012, I published this Muller Nobel Lecture story in the toxicological literature.[1] It quickly generated a series of criticisms, mostly ad hominem attacks on my character and research achievements. These were in part related to the fact that Muller could not defend himself along with other earlier defenders of the LNT model. These critics may not have been aware that Muller had himself criticized the work of a deceased scientist, Lewis J. Stadler, who had challenged Muller's gene mutation interpretations from 1931 until his death in 1954 and likewise could not respond to Muller's criticisms in 1956.

Dose-Response and Deception

The deception issue would not end with Muller's Nobel Lecture, but would serve as the tip of even more troubling revelations. My initial follow-up was to make a detailed evaluation of the Manhattan Project's genetics/radiation research and see what I could learn from it. With respect to the Caspari research, I learned that Stern at first refused to accept the validity of these findings, claiming that the only reason that Caspari observed a threshold was due to a control group that had aberrantly high mutation rates that led to the threshold rather than linearity. To his credit, Caspari dug into the literature and presented convincing evidence that the control group was not aberrant but normal. To *his* credit, Stern backed

[1]Edward J. Calabrese, "Muller's Nobel Prize Lecture: When Ideology Prevailed over Science," *Toxicological Sciences* 126, no. 1 (2012): 1–4; "Muller's Nobel Lecture on Dose-Response for Ionizing Radiation: Ideology or Science?" *Archives of Toxicology* 85, no. 12 (2011): 1495–98; and "Key Studies Used to Support Cancer Risk Assessment Questioned," *Environmental and Molecular Mutagenesis* 52, no. 8 (2011): 595–606.

down—that is, the Caspari control was now considered normal. Did this mean that Stern gave up the effort to minimize the influence of the Caspari findings? Not in the least—but how did he do this?

It was subtle and it took both Stern and Caspari to do it, the latter oddly cooperating with efforts to undermine his own study, perhaps due to his sensing of what was important to Stern, his influential supervisor. First, a detailed reading of the paper revealed that essentially the entire discussion centered on why their data should not be accepted until it could be learned why this study showed a threshold, while a companion acute study lead by Warren Spenser completed a year before showed a linear dose-response. In many ways this was a false argument, since the two studies had more than twenty-five methodological differences and the issue could never have been practically resolved. They had to know this.

Second, the Caspari study was superior to the Spenser study in multiple ways: it was performed second, used better equipment and facilities, and improved temperature controls, among other features. In addition, much was learned during the Spenser study that was transferable to Caspari's efforts. Further, a detailed review of the Spenser study revealed a long list of problems that Stern, Muller, and others apparently never detected. All of these issues have now been documented, and some are serious.

The bottom line is that Stern and Muller did not want the Caspari paper to see the light of day, and if it did, they wanted to seriously compromise its impact. This view is actually reflected in Muller's January 14, 1947, letter to Stern.

The story gets even more intriguing as we now consider the attempt to replicate Caspari's findings. In fact, it gets much worse, as the historical record shows to what lengths Stern and Muller and others under their influence, or spell, would go to twist the truth to advance their ideology. Sometimes this resulted in direct lies, other times in data manipulation, censoring, and other forms of obfuscation and misleading behavior.

In the first replication study paper, for example, Stern and Delta Uphoff, a master's student at the University of Rochester, concluded that her control was aberrantly low and that this led to data that could not be properly interpreted. This was based on extensive written communication with Muller. Muller had a massive amount of control mutation data in studies dealing with the aforementioned dispute with Lewis Stadler on the nature of gene mutations. In multiple letters that I obtained, Muller unequivocally supported the Caspari control as normal and the Uphoff control as aberrant. This write-up was sent to the Atomic Energy Commission by Stern and was classified. When Stern published the

findings a year later, he and Uphoff neglected to inform the scientific community that one year earlier the data that they were now publishing had been uninterpretable (their own written characterization) and that her control group was aberrant based on the data in the published literature and in Muller's massive database.

A second example involved Muller writing in the scientific literature that the study by Caspari that challenged LNT should not have credibility because of its aberrantly high control group values. Of course, he had the data to support the Caspari findings and had done so in writing in a series of letters with Stern. Despite the duplicity of Muller on this issue, he was never challenged by Stern or Caspari—even though they knew that Muller had directly contradicted his letters to Stern and his publications.

The National Academy of Sciences and LNT

It would be bad enough if the story stopped here, but it didn't. It became even worse. The next noteworthy developments occurred when the National Academy of Sciences (NAS) created its Biological Effects of Atomic Radiation (BEAR) I Committee in 1955 and announced its seminal recommendation to switch to linearity in June 1956. This was actually the big ideological payoff for all the past efforts to ensure the success of the LNT. It represented collusion, I should say, inbreeding at the highest levels: the Rockefeller Foundation funded the BEAR committee; Detlev Bronk, president of the NAS, was also president of the Rockefeller Institute for Medical Sciences (later Rockefeller University); and Bronk chose the chairman of the Genetics Panel from the Rockefeller Foundation.

Transcripts reveal that the chair was enticing the panelists with more Rockefeller grant money. The goal was to get the scientific community and the public to go linear, simple as that. For this to happen, data had to be censored. In addition, the Genetics Panel had to show that it was in close agreement on the scientific basis of radiation-induced mutation risks, which their individual estimates were designed to show. However, the panel was so split in their scientific conclusions of radiation-induced mutation risks that if they were shared with the public, the policy recommendations of the panel would have no credibility—or so the panel members, such as Jim Crow, a University of Wisconsin professor of genetics, strongly believed and wrote about in correspondence with Chairman Warren Weaver.

My Conclusions and Their Consequences

The findings to support my conclusions have been published in considerable detail.[2] They reveal that the Genetics Panel misrepresented the research record in the journal *Science* on several key matters, all of which were needed to get their policy views accepted. The panel voted on these matters, including deciding not to show their data and not to provide any written justification for their conclusions. Thankfully, these highly prestigious scientists preserved their correspondence reports and notes, which permitted me to discover their deceptions—both as individuals and, more surprising, as an NAS committee—and eventually piece this story together. The 1956 NAS BEAR I Genetics Panel report and its LNT recommendations would become the most significant document in the seventy-year history of cancer risk assessment. The acceptance of their guidance is the historical basis of why the U.S. and numerous other countries adopted the LNT. As the twig is bent so grows the tree.

Two years ago Jerry Cuttler, an active researcher on LNT and radiation, wrote to Marcia McNutt, editor-in-chief of *Science,* to request that the 1956 article of the BEAR I Genetics Panel be retracted due to my documentation of its deliberate misrepresentation of the scientific record and the major and continuing historical significance of this paper.[3] The situation was complicated from the start, since McNutt was also a finalist to become the next president of the NAS, and her name was already posted on the NAS website as such.

In such a situation, McNutt should have recused herself from deciding on this issue. Since the then-outgoing NAS president Ralph J. Cicerone was strongly disputing my challenging papers at the time, McNutt's conflict of interest with deciding upon the retraction request and her desire to become the next NAS president is obvious. Yet despite her finalist status—and she did become NAS president—McNutt did not recuse herself. Her decision was to deny the request. (The appendix to this article contains three key e-mail exchanges on this issue.) It was also disturbing that no apparent set of checks and balances existed within *Science*'s organization to ensure proper oversight on such matters.

The story of LNT, therefore, is one of leading scientists, from the time of Muller's Nobel Lecture in 1946 to today, being driven by ideology and/or self-interest. This should not be who we are as scientists, nor what we should accept.

[2]Edward J. Calabrese, "On the Origins of the Linear No-Threshold (LNT) Dogma by Means of Untruths, Artful Dodges and Blind Faith," *Environmental Research* 142 (2015): 432–42.

[3]Edward J. Calabrese, "LNTgate: How Scientific Misconduct by the U.S. NAS Led to Governments Adopting LNT for Cancer Risk Assessment," *Environmental Research* 148 (2016): 535–46.

APPENDIX

Marcia McNutt, e-mail message to Jerry Cuttler, August 11, 2015
Subject: Science Paper, Genetic Effects of Atomic Radiation; Evidence of Scientific Misconduct

Dear Dr. Cuttler:

We considered carefully your concerns about the controversy with respect to the linear no-threshold (LNT) dose-response model for assessing the risk of radiation-induced cancer. You have requested that *Science* retract a 1956 paper that takes a position on this issue. Standard practice in *Science* and other journals would be not to consider the retraction of an artiele more than just a few years old except in extraordinary circumstances. New discoveries are constantly advancing the frontiers of science, and unless we had some statute of limitations on retractions, we would be constantly retracting old articles after the field has moved on. We can imagine certain exceptions in cases of papers that are still highly influential. In considering this specific request to *Science*, we asked the following questions:

(i) Is the 1956 *Science* paper trustworthy? We concluded that we cannot produce the information we need to answer this question 60 years post publication to the standards that would be required to consider a formal retraction. The authors are no longer living. We do not even have a record of the *Science* editorial standards of that era, much less a review jacket for that paper. This case is so old we would never be able to reconstruct the evidence from all parties involved in our editorial decision.

(ii) If the paper is not trustworthy, is the matter a problem of scientific quality or scientific integrity? Because we cannot answer (i), we cannot answer (ii). However, I will note that many of the concerns raised in the Calabrese paper would fall under the classification of science quality, not science integrity. They would not be grounds for retraction of a paper 60 years after the fact.

(iii) Does this *Science* paper still have the "pervasive influence" claimed in the article by Calabrese? We consulted an independent expert whose positions indicate that s/he has no extreme positions on this matter, one way or another. His/her considered view is that the 1956 *Science* paper was one of hundreds of papers over the past half century on this broad topic, and certainly the use of the LNT model by almost all the regulatory agencies, world wide, is now based on a lot more than the NRC report and Dr. Muller's work. For example,

> if you take a look at the series of NRC "BEIR" [Biological Effects of Ionizing Radiation][4] reports, in the more recent ones there is no particular emphasis on Muller's work, with the arguments now more based on endpoints that more directly relate to radiation-induced cancer.

Based on this analysis, we do not see any reason to consider revising our policy for this paper. *Science* considers this case closed and will not reconsider the decision.

Dr. Marcia K. McNutt
Editor-in-Chief, *Science* family of journals
American Association for the Advancement of Science
1200 New York Avenue N.W.
Washington, D.C. 20005

Edward A. Calabrese, e-mail message to Marcia McNutt, August 19, 2015
Subject: NAS 1956 Paper Retraction

Dear Dr. McNutt:

I read your e-mail letter to Dr. Cuttler, rejecting his request (and others) to retract the NAS BEAR I, Committee Genetics Panel published in *Science* in June, 1956, due to its multiple incidents of serious falsification and fabrication. I have carefully studied your five reasons for this decision.

While I commend you for your directness and transparency in sharing the basis of the decision, I have concluded that your analysis of the issue was faulty on each of the five reasons (see attached or below) and contradicted by the factual record in a number of cases. While I know you wrote that the decision was "final," I hope that you will be open to the new analysis and that you will reconsider this issue.

Sincerely,
Edward J. Calabrese, Ph.D.
Department of Environmental Health Sciences
School of Public Health and Health Sciences
University of Massachusetts
Amherst, MA 01003

[4]See, for example, National Research Council of the National Academies, *Health Effects of Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2* (Washington, DC: The National Academies Press, 2006).

Issue #1: Is the situation extraordinary given the 60 year time lag?

The situation is extraordinary because the LNT model for cancer risk assessment continues to dominate all regulatory agencies, affects clinical treatments, environmental regulations, clean-up costs, medical treatment strategies, all needlessly wasting massive resources. In fact, it is widely believed that the recommendations by the NAS BEAR I Committee, Genetics Panel to switch from threshold to the LNT model was the most significant event in the history of risk assessment. It is also extraordinary because substantial contemporary toxicological discoveries have revealed serious failings with the LNT model with findings more consistent with the threshold and hormesis models.

Issue #2: New discoveries are constantly advancing the frontiers of science:

Contrary to your statement, my letter did not challenge an older paper (i.e., NAS Genetics Panel *Science* paper, 1956) based on new discoveries such as DNA repair, adaptive responses, apoptosis, and hormesis that could create non-linear dose-responses. It is, however, challenging this paper because it falsified and fabricated the research record and it continues to affect, in significant ways, the beliefs and actions of regulatory agencies, influential governmental and non-governmental organizations, educational institutions, materials and practices, and leaders in the risk assessment field—all without their knowledge that the Genetics Panel paper in *Science* is now recognized as being based on fraud and deception.

Issue #3: Is the *Science* paper trustworthy? You claim that this is not knowable because: new standards for evaluation; because the authors are not alive; and the 1950s recordkeeping is poor and without knowledge of how this paper was reviewed.

The issues of falsification and fabrication are historically founded and have long been addressed by professional standards in the sciences and their journals. My published articles have shown that the research record was deliberately altered in the *Science* paper by the Genetics Panel and I possess and cited the text of letters and memos documenting the scientific misconduct and the reasons why the falsification/fabrication was done. The fact that none of the Panel members are alive is adequately compensated by the factual record which is substantive and unequivocal, with high internal and external consistency. It is not significant to the present case whether the Genetics Panel paper in *Science* received a peer review, as most reports by high level advisory committees are usually stand-alone and not subject

to standard peer-review processes, as are papers of individual scientists. Nonetheless, all papers need integrity and honest reporting. My published papers have shown that the BEAR I Genetics Panel failed in this regard in multiple and critical ways, affecting key conclusions and acceptance of their findings by the scientific community, governmental agencies, and the general public.

Issue #4: Is the problem one of scientific quality or integrity?

You do not provide any specific evidence, but offer a general statement that many examples cited in the Calabrese (2015) paper concerned scientific quality rather than integrity. The fact that there were important issues raised about scientific quality (e.g., the obvious description of Jim Crow's research method) does not detract from the integrity issue. The key point is that it was *because* of the poor data quality that the Panel decided to *cover up* their scientific weaknesses (i.e., poor quality) so that their goal of a switch to LNT could occur. The central issue is that the Panel was not honest and altered the research record to promote this goal. I suspect that if the data quality were good, they would not have "needed" to lie and deceive. However, their LNT goal was more important than truth.

Issue #5: The continuing "pervasive influence" of the 1956 paper:

You cite an unnamed knowledgeable independent consultant who told you that the LNT is now based on many more papers than the NRC report and Muller's work. First, the Calabrese (2015) paper never states that the LNT was based on Muller's research. It states that Muller used his influence to promote acceptance of the LNT by being dishonest in his spoken and written words, all of which were documented. The paper traced the initial acceptance of the LNT to the work of Curt Stern and his students and these were highly criticized in the Calabrese paper. It was the Stern papers that the BEAR I Genetics Panel based their beliefs upon and cited in subsequent Congressional testimony (1957). You stated that the more recent BEIR reports do not base their recommendations on Muller's work and focus now on cancer. In multiple papers I show that within one year of BEAR I, that major advisory groups had generalized the Genetics Panel recommendation from genetic risk to cancer risk assessment. We have also documented that the U.S. EPA in the late 1970s specifically relied on the BEAR Genetics Panel 1956 recommendation when it adopted LNT, showing clearly that your assertions are incorrect. More specifically, Roy Albert, Chair of the EPA Carcinogen Group, in his 1994 paper in *Critical Reviews in Toxicology*, has reported that EPA adopted the LNT model of the Atomic Energy Commission (who

adopted the BEAR I, Genetics Panel report) that had been applied to estimating risk for fallout from atomic weapon tests. He stated that it was clear, simple, and easily understood and was plausible based on the linearity of the mutation response (see BEAR I) within the framework of target theory. He then noted that "any difference between chemical carcinogens and ionizing radiation could be waved aside as both cause genetic damage." Thus, the BEAR I report in *Science* served as the critical foundation for the current EPA LNT cancer risk assessment.

A vast number of published papers with experimental data contradict the LNT model. In fact, the mega-mouse (24,000 mice) study of the FDA to estimate the shape of the dose-response in the low dose zone showed a striking hormetic dose-response for bladder cancer as emphasized by a 14-member expert panel of the Society of Toxicology. Detailed Japanese studies with DDT showed clear hormetic dose-responses for carcinogenicity. Numerous whole animal cancer bioassays with ionizing radiation show reduced cancer risks and life extension at low doses in multiple models. These and numerous other findings, along with the above conceptual developments (DNA repair, adaptive response, etc.) all happened after BEAR I. If anything, the LNT model decision should have been reversed except for the ideological grip that has long enveloped this field.

In summary, this response addresses each issue that your letter used to support your rejection of the request to retract the NAS 1956 *Science* paper due to research misconduct. The evidence presented here provides an objective basis for you to reconsider the proposal to retract the 1956 NAS Genetics Panel *Science* paper. The evidence is convincing that misconduct did occur, and the issue is too important to continue to ignore. *Science* has a professional and moral responsibility to correct this continuing scientific deceit.

Marcia McNutt, e-mail message to Edward A. Calabrese, August 19, 2015
Subject: NAS 1956 Paper Retraction

Dr. Calabrese:

I happened to be at a large gathering of distinguished scientists today, most of whom have published in *Science,* and I asked them the following question:

"Do you believe it would be permissible for *Science* to retract your paper (or any other researcher's paper) based on evidence put forth by a third party claiming

scientific misconduct, without allowing you the opportunity to rebut the claims?"

There was not a person who believed that it would be appropriate or ethical for *Science* to retract a paper under those circumstances. Examples that were given by this distinguished group for why due process needed to be given to both sides before action is taken included:

- Possibility of conflict of interest on the part of the third party;
- Situations in which so-called "evidence of misconduct" was taken out of context and either misinterpreted or purposely misrepresented;
- Limited knowledge of third parties as to the entire story; e.g., believing that a result was based on X when it was based on Y.

You obviously answer "yes" to the question above, otherwise you would not continue to press this issue, but you are the only person I have encountered so far of that opinion. *Science* will not be changing its policy.

Please respect that the matter is closed.

Sincerely,
Marcia McNutt
Editor-in-Chief, *Science* family of journals
American Association for the Advancement of Science
1200 New York Avenue N.W.
Washington, D.C. 20005

The Honorable John A. Barrasso
Chairman
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Chairman Barrasso:

On October 3, 2018, the Senate Committee on Environment and Public Works Subcommittee on Superfund, Waste Management, and Regulatory Oversight held a hearing entitled, "Oversight of the Environmental Protection Agency's Implementation of Sound and Transparent Science in Regulation." During the hearing, Senators Booker and Carper recommended that EPA release a chemical assessment of formaldehyde generated by EPA's Integrated Risk Information System (IRIS) program. EPA has a duty to ensure its regulatory decisions are grounded in a thorough and objective review of the best available and most relevant scientific evidence. A public release of the draft formaldehyde IRIS assessment would be premature and would circumvent EPA's current review practices, which include a multi-step intra-agency review by other EPA programs as well as an inter-agency review by other interested federal agencies in advance of any public release. This review process is particularly important because, numerous stakeholders, including the National Academy of Sciences (NAS),[1] have repeatedly raised concerns about the scientific quality of assessments generated by the IRIS program.

The American Chemistry Council's Formaldehyde Panel (the Panel)[2] has continued to have concerns about the EPA's draft formaldehyde IRIS assessment. In a January 2018 meeting between the Panel and EPA to discuss the formaldehyde science, EPA staff specifically stated that the revised IRIS assessment of formaldehyde would not rely on a mode-of-action framework to integrate the available science, a direct contradiction to the recommendation of the NAS in its 2011 report.[3] In the past, IRIS assessments have relied heavily on epidemiological data to draw conclusions, while sometimes ignoring or discounting relevant toxicological and mechanistic, or mode of action, studies. This approach is outdated and inconsistent with currently accepted risk assessment practices regarding the necessity of integrating all lines of scientific evidence to reach scientifically-

[1] National Academy of Sciences (NAS). National Research Council (NRC). 2011. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Committee to Review EPA's Draft IRIS Assessment of Formaldehyde. Board of Environmental Studies and Toxicology. Division of Earth and Life Sciences. Available at http://www.nap.edu/catalog.php?record_id=13142.

[2] The Formaldehyde Panel represents U.S. producers, suppliers and users of formaldehyde and formaldehyde products.

[3] The NAS 2011 report recommends that EPA *"Select outcomes on the basis of available evidence and understanding of mode of action"* and the report also notes *"A clearer presentation of information with more tables that summarize available studies, figures that synthesize related effects from multiple studies (see Figure 6-2), and greater integration of information about mode of action and potentially susceptible populations during study selection and assignment of uncertainty factors would improve the assessment's ability to make a compelling case....."*

defensible conclusions. It also fails to meet the scientific standards required by the Lautenberg Chemical Safety Act.[4]

EPA's Acting Administrator Wheeler has prudently decided to conduct an internal review of the IRIS program to ensure the substances being evaluated reflect the priority regulatory needs of the EPA program offices. The Panel hopes that this review will be broadened beyond priority-setting to also include a review of the scientific rigor employed by the IRIS program, including the program's application of science-based safe thresholds for chemical exposures.

As evident in the October 3rd hearing, transparency and application of current scientific knowledge are critical for effective regulation. A scientifically-flawed IRIS formaldehyde assessment could lead to unwarranted concerns regarding exposure. EPA must not take such an outcome lightly. Given the previous concerns raised about the IRIS program, the Committee should endorse the efforts by Acting Administrator Wheeler to review the formaldehyde assessment to confirm the scientific basis of the assessment before releasing it publicly. Acting Administrator Wheeler should be commended for his efforts to ensure the best available data are used to draw conclusions about potential health risks to avoid creating unfounded consumer fear and prevent undue economic impacts. EPA must be allowed to conduct its full internal review without being constrained by artificial deadlines or having to truncate its review unnecessarily.

Sincerely,

Kimberly Wise White, Ph.D.
American Chemistry Council (ACC)
Senior Director, Chemical Products and Technology Division
On Behalf of the ACC Formaldehyde Panel

[4] Section 6(b)(4)(F)(i) of the Lautenberg Chemical Safety Act requires risk evaluations to integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance. Additionally, Section 26(i) requires EPA to make decisions using a weight of scientific evidence approach.

BEFORE THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

STATEMENT FOR THE RECORD OF THE
AMERICAN CHEMISTRY COUNCIL

October 3, 2018

The American Chemistry Council (ACC) appreciates the opportunity to provide this statement to the Senate Environment and Public Works Committee regarding EPA's proposed rule, "Strengthening Transparency in Regulatory Science." ACC and its members have a strong interest in EPA's adoption and implementation of the proposal that will strengthen the science EPA uses to make decisions.

ACC believes that EPA's proposal correctly codifies an important good governance principle: that government agencies should be as transparent as possible, within the bounds of the law, about scientific information they rely on and the justifications for the significant regulatory decisions they make.

EPA's proposal builds on the principles underlying the Administrative Procedure Act (APA), Executive Orders 12866, 13777, and 13783, and guidance developed by the Office of Management and Budget (OMB). In our view, the proposal is consistent with these foundational elements.

In particular, ACC supports the proposed expansion of the Office of Science and Technology Policy's (OSTP) 2013 memorandum entitled "Increasing Access to the Results of Federally Funded Scientific Research." The proposal directs federal agencies and offices to develop and submit plans to OSTP, which ensure that, to the extent practicable, peer-reviewed publications and digital scientific data resulting from federally-funded scientific research are accessible to the public, the scientific community, and industry.

The 2013 OSTP directive requires each agency to develop a public access plan that maximizes access to federally-funded "digitally formatted scientific data"[1] while also protecting confidentiality, personal privacy, confidential business information (CBI), intellectual property rights, and U.S. competitiveness.[2] In 2016, EPA issued its Plan to

[1] As defined in OMB circular 110 as "the digital recorded factual material commonly accepted in the scientific community as necessary to validate research findings, including data sets used to support scholarly publications. . ." It is a definition consistent with that of "research data" in the regulatory text of EPA's proposal.

[2] More than 20 federal agencies have developed and implemented Data Access Plans, including EPA, the National Institutes of Health (NIH), the Center for Disease Control (CDC), and the Food and Drug Administration (FDA).

Increase Access to Results of EPA-funded Scientific Research in response to the OSTP directive.[3] Importantly, EPA's proposal on Strengthening Transparency extends these commitments beyond the government-funded requirement of the OSTP directive to "dose response data and models underlying pivotal regulatory science regardless of the source of funding or identity of the party conducting the regulatory science."[4]

EPA's focus on dose-response data and models appropriately reflects the evolution of toxicology from a largely observational science to a discipline that applies advanced scientific techniques and knowledge. Research programs within academia, government, and private sector labs have greatly improved our ability to investigate and understand the underlying biological mechanisms, modes of action, and dose responses of toxicants. We can now evaluate biological events leading to toxicity and consider how (in a dose-response manner) these biological events relate to potential risks to human health. This was not possible 10-to-20 years ago.

Importantly, these improvements should translate to:

- The application of transparent weight-of-the-evidence approaches to the assessment of human relevance
- The development of points of departure
- The derivation of protective human health equivalent dosages that minimize the use of uncertainty factors and variability.

EPA's proposed rule will promote the application of this knowledge to improve the scientific basis of government regulatory policies and industry product stewardship.

For environmental concerns, exposure-response is the more appropriate relationship to evaluate because most of the environmental test guidelines require quantifying concentrations in media external to the organism for use as the exposure metric. Toxicity information, and — when available — knowledge of mechanisms, are integrated with exposure-response models for risk-based environmental safety decision making.

ACC encourages EPA to implement best available scientific procedures under this rulemaking. The Agency should move away from the outdated linear concept of how biology operates toward biologically-based mechanisms, i.e., mode of action (MOA) and adverse outcome pathways (AOP) for both cancer and non-cancer effects, that clearly establish the threshold nature of toxicological endpoints for derivation of points of departure for establishing regulatory values and making regulatory decisions.[5, 6]

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[3] Plan to Increase Access to Results of EPA-Funded Scientific Research (USEPA, November 29, 2016) https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

[4] ACC suggests improvements to EPA's terminology in the preamble that are described later in these comments in sections VI and VII.

[5] Critics of this proposed policy appear to overlook the fact that the call to evaluate different dose response models is entirely consistent with the Agency's Cancer Guidelines, which have been in place since 2005. See Guidelines for Carcinogen Risk Assessment https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3038594/

As we noted earlier, EPA's proposed rule is consistent with and builds on policies implemented by previous administrations. In our comments to EPA on the proposal, we noted in particular that implementation would be aided by a policy statement or guidance that commits the Agency to afford greater weight to studies using validated test methods and procedures, models, and approaches, when and where those data are based on publicly accessible data, and transparent computer algorithms. Guidance to assist implementation of the rule should include specific examples and/or case studies, perhaps drawing from recent EPA rulemakings, to demonstrate what constitutes regulatory science that is material to EPA's significant regulatory decisions. Other scientifically relevant and reliable studies and data should not be eliminated from consideration, but rather, accorded less weight when integrating evidence from multiple studies within and across different lines of evidence.

We believe the proposal is consistent with the relevant provisions of Section 26 of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, approved by an overwhelming Congressional majority in 2016.[7] EPA's proposed rule is an important step toward ensuring that the science the Agency relies on in decision-making is transparent and accessible.

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[7] TSCA Section 26(h)-(k) (15 U.S.C. §2625(h)-(k)) provides:

(h) Scientific Standards.—In carrying out sections 2603, 2604 and 2605, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed in a manner consistent with the best available science, and shall consider as applicable—

(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

(2) the extent to which the information is relevant for the use of the Administrator in making a decision about a chemical substance or mixture;

(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

(i) Weight of Scientific Evidence.—The Administrator shall make decisions under sections 2603, 2604, and 2605 based on the weight of the scientific evidence.

(j) Availability of Information.—Subject to section 2613, the Administrator shall make available to the public—

(1) all notices, determinations, findings, rules, consent agreements, and orders of the Administrator under this title;

(2) any information required to be provided to the Administrator under section 2603;

(3) a nontechnical summary of each risk evaluation conducted under section 2605(b); and

(4) a list of studies considered by the Administrator in carrying out each such risk evaluation, along with the results of those studies;

(5) each designation of a chemical substance under section 2605(b), along with an identification of the information, analysis, and basis used to make the designations.

(k) Reasonably Available Information.—In carrying out sections 2603, 2604, and 2605, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

Commentary

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The EPA Cancer Risk Assessment Default Model Proposal: Moving Away From the LNT

Edward J. Calabrese[1], Jaap C. Hanekamp[2], and Dima Yazji Shamoun[3]

Abstract

This article strongly supports the Environmental Protection Agency proposal to make significant changes in their cancer risk assessment principles and practices by moving away from the use of the linear nonthreshold (LNT) dose–response as the default model. An alternate approach is proposed based on model uncertainty which integrates the most scientifically supportable features of the threshold, hormesis, and LNT models to identify the doses that optimize population-based responses (ie, maximize health benefits/minimize health harm). This novel approach for cancer risk assessment represents a significant improvement to the current LNT default method from scientific and public health perspectives.

Keywords

cancer risk assessment, model uncertainty, LNT, hormesis, threshold, dose–response, US EPA

Linear Nonthreshold—Its Corrupt History and Scientific Flaws

The proposal by the Environmental Protection Agency (EPA)[1] to no longer use the linear nonthreshold (LNT) as the default model in cancer risk assessment is long overdue. It has been extensively documented that: (1) The LNT model has been based on flawed science (ie, Hermann J. Muller never induced point mutations but rather large gene deletions and other gross chromosomal aberrations[2]; (2) the LNT model has incorrect scientific interpretations (ie, Muller incorrectly assumed that his transgenerational phenotypic changes in Drosophila were due to gene mutations)[2]; and (3) the LNT single-hit theory has been formulated under the incorrect assumption that the, Muller X-ray induced gene mutation theory was sound.[3]

Further, the history of LNT has been ripe with deliberate misrepresentations of the scientific record, including (1) the incorrect dismissal of the Caspari threshold findings by Stern and Muller (see study by Calabrese[4]) contradicting a copious research record and substantial private correspondence between Muller and Stern[4]; (2) Muller's powerfully influential comments in his Nobel Prize Lecture were deliberately deceptive[5,6]; (3) scientific misconduct by the entire membership of the US National Academy of Sciences (NAS) Biological Effects of Atomic Radiation (BEAR) I Genetics Panel which lead to governmental adoption of the LNT (ie, publishing deliberately false information in the journal *Science* to enhance the acceptance of LNT; NAS BEAR I Genetics Panel, 1956[4,7]); and (4) serious errors on mutation risks that were introduced into the key Biological Effects of Ionizing Radiation (BEIR) I Report in 1972[8] which were adopted by the EPA in 1975 to justify the adoption of LNT for chemicals and radiation.[9,10]

It is only recently that the BEIR I mistakes and their perpetuation to the present by other US NAS BEIR Committees and their risk assessment implications were reported. The LNT cancer risk assessment policy, procedures, and belief system are based therefore upon a newly recognized series of corrupt actions and mistakes by key national leaders principally in the radiation genetics domain. These controlling deceptions and

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errors have guided the US cancer risk processes from the mid-1950s to the present. As important as these documented errors and deceptions for the LNT model are, a vast scientific literature exists that refutes the low-dose predictions of the LNT model.[11-13,22] Also, LNT fails outside the empirical, as no experiment would actually be possible to causally connect the perturbation of some part of the DNA by 1 ionizing photon/1 genotoxic molecule that subsequently would develop, over the organism's lifetime, into some disorder such as cancer. Linear nonthreshold simply assumes this by default.[14]

Given the present EPA proposal, its major challenge is whether a cancer risk assessment default model is needed, and, if so, what should it be? A default model in cancer risk assessment gets around the practical impossibility of testing agents for cancer risk over a large number of doses and with very large number of animals. This issue was well demonstrated in the now famous Food and Drug Administration ED-01 study that utilized some 24 000 mice.[15] Such studies take too long, are too costly, and they reduce the possibility that other agents get tested, since vast resources would be directed to the massively larger study(ies). In addition, the ED-01 study still could not explore the potential of very low risks without even a more substantial addition of mice.

Based on the history of chronic animal testing and the realization that large experiments were not practical, the National Toxicology Program (NTP) adopted the long-standing historical modus operandi of using the simple few/high doses approach to hazard assessment based on the inadequate assumption that the LNT model could make accurate predictions in the low-dose zone. These few and excessively high doses, however, made it impossible to challenge the LNT predictions as a cancer risk assessment model. Thus, the NTP and the EPA worked together to create a system of evaluation in which the LNT model would become the default for essentially all animal model cancer risk assessments.

The history of EPA risk assessment regulations has been based either on epidemiological or on animal model studies. In either case, knowledge of the nature of the response at low doses affecting normal humans is limited. For most regulated chemicals, adequate epidemiological studies don't exist, and even "adequate" studies have important limitations. The reality of this situation has resulted in regulatory agencies, such as EPA, basing their human exposure standards on high dose/few dose animal studies with mice and rats, needing to extrapolate to humans, often across many orders of magnitude of dose (eg, the history of volatile organic contaminants regulation illustrates this point). The question is how does the EPA find a way out of this regulatory quagmire of using the historically corrupt and scientifically flawed LNT model? The answer is not in basing regulations on mechanistic in vitro studies as helpful as they are, nor on limited and inadequate epidemiological studies as useful as they are, nor on the few/high-dose animal model approach. None of these approaches individually or collectively can offer a solution to the issue of cancer risk assessment.

An Improved Default Model Approach: Model Uncertainty

The best answer, for the foreseeable future, from theoretical data support and public health perspectives is the use of dose–response model uncertainty, that is, using the leading dose–response models and determining where they optimally converge to yield the so-called regulatory sweet spot. This "sweet spot" is the dose where health benefits are optimized, and risks are minimized. The resultant of these converging science-driven processes will yield the optimal public health dose, with changes in dose going either up or down yielding less benefit/more public health harm, thus the sweet spot concept (note 1). In practice, this involves finding a practical and scientific means to integrate the thresbold, LNT, and hormetic dose–response models, the 3 models with the most toxicological gravitas based on the peer-reviewed published literature. Each model has its strengths and limits, its advocates, and its detractors. In the interest of full disclosure, the authors strongly favor the hormesis model and feel it is far superior to the threshold model and even more so to the LNT model.[16-18] Nonetheless, it is argued here that the combination and integration of these 3 most substantial dose–response models into a dynamic risk assessment framework works best because it has the potential to integrate the best scientific features of the 3 models while limiting/minimizing the possibility of error.

This process describes/predicts what happens if hormesis is correct or incorrect and the same for the LNT as these 2 models provide the bounds of harm or benefit. The case for this integrated dose–response approach has been published in several peer-reviewed chemical and radiation health risk assessment publications.[4,19,20] Attractive features of this integrative approach are that the nadir of the hormetic dose response, based on a large number of studies in the hormetic database,[11] and the "safe" exposure estimate using the threshold dose–response model with a standard 100-fold uncertainty factor yield essentially the same value. Thus, these 2 models provide an agreement, although they offer a different toxicological interpretation (ie no effect/safe threshold interpretation versus beneficial hormetic interpretation). At this same dose, the LNT model was found to yield a cancer risk approximately 10^{-4} (or 1 per 10 000 people over an 80-year lifespan). This value represents a low risk within society, which is not detectable via epidemiological evaluation under the best of research conditions. It is also about 500-fold lower than the cancer risk from background (ie, spontaneous tumors). Figure 1 provides a description of the integration of the threshold, LNT, and hormesis models within a model uncertainty framework, showing the optimized dose (ie, the regulatory sweet spot). If the hormetic dose–response model predictions are correct, then the benefits to society in terms of disease reduction would be substantial. However, if hormesis was wrong and LNT is correct, the effects would be undetectable, again showing the regulatory sweet spot.

The integration of the 3 most credible scientific models within a model uncertainty suggests that more research still

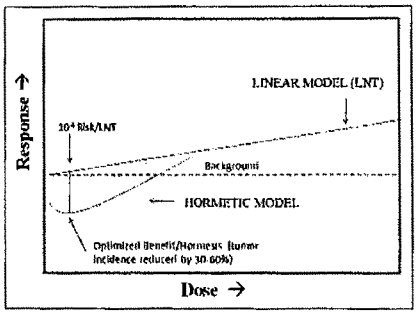

Figure 1. Integration of hormesis and LNT for risk assessment. LNT indicates linear nonthreshold.

needs to be undertaken to improve the reliability of model-based, low-dose estimates. It also raises the possibility that this general approach might be able to be refined and fine-tuned so as to be applied to specific agents. For example, it is possible/likely that the hormetic optima may vary somewhat depending on the specific agent. Despite the remaining uncertainties of this proposed model uncertainty and dose optimization regulatory sweet spot approach, it offers considerable scientific and societal advances over the present LNT model and should be adopted by the US EPA and other environmental regulatory agencies in other countries. It offers a strong scientific foundation, the integrated estimates of the 3 most evaluated models and it errs on the side of safety, while allowing society to capitalize on the potential of significant public health benefits. This perspective is far superior to the current LNT-default risk assessment both from scientific and from public health perspectives. The EPA proposal should be accepted and implemented across all programs involving risk assessment as soon as possible.

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Note

1. It is worth noting that the "optimal dose" or the "sweet spot" proposed in this article is only based on the dose–response science in cancer risk assessment. A work in progress by Dima Shamoun and Richard Williams expands on this idea of optimal dose by marrying economic analysis (in the form of benefit–cost analysis) with dose–response modeling. The idea is that the optimal dose occurs where the marginal cost is equal to the marginal benefit of the reduction in dose. This *economically* optimal dose would take into account regulatory costs, various administrative costs, compliance costs, and risk–risk trade-offs and health–health trade-offs. As a result of this comprehensive calculus, the economically optimal dose may occur at a dose higher than the optimal dose proposed here yet maximizing the net benefits of a risk-based regulation. See, for example, Keeney.[21]

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From Muller to mechanism: How LNT became the default model for cancer risk assessment*

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ABSTRACT

This paper summarizes the historical and scientific foundations of the Linear No-Threshold (LNT) cancer risk assessment model. The story of cancer risk assessment is an extraordinary one as it was based on an initial incorrect gene mutation interpretation of Muller, the application of this incorrect assumption in the derivation of the LNT single-hit model, and a series of actions by leading radiation geneticists during the 1946–1956 period, including a National Academy of Sciences (NAS) Biological Effects of Atomic Radiation (BEAR) I Genetics Panel (Anonymous, 1956), to sustain the LNT belief via a series of deliberate obfuscations, deceptions and misrepresentations that provided the basis of modern cancer risk assessment policy and practices. The reaffirming of the LNT model by a subsequent and highly influential NAS Biological Effects of Ionizing Radiation (BEIR) I Committee (NAS/NRC, 1972) using mouse data has now been found to be inappropriate based on the discovery of a significant documented error in the historical control group that led to incorrect estimations of risk in the low dose zone. Correction of this error by the original scientists and the application of the adjusted/corrected data back to the BEIR I (NAS/NRC, 1972) report indicates that the data would have supported a threshold rather than the LNT model. Thus, cancer risk assessment has a poorly appreciated, complex and seriously flawed history that has undermined policies and practices of regulatory agencies in the U.S. and worldwide to the present time.

1. Introduction

While a role of the environment in affecting the occurrence of cancer has long been known (e.g., the occurrence of testicular cancer in chimney sweeps) (Pott, 1775), transitioning this recognition of concern into an experimental science proved to be difficult as seen in the series of failures to induce skin cancer in animal models during the early years of the 20th century. Finally, after many failed attempts, in 1918 Japanese researchers made the experimental breakthrough by the repeated administration of coal tars to the ears of rabbits to produce papillomas and carcinomas (Yamagiwa and Ichikawa, 1918). This seminal finding paved the way for experimental research to assess possible environmental causes of cancer.

In a similar manner, researchers early in the 20th century began to explore whether it was possible to induce mutations in plants and animals (Campos, 2015). While it took nearly three decades, Muller (1927a) reported that X-rays induced gene mutations in fruit flies, narrowly beating three independent teams of botanists who likewise reported inducing transgenerational phenotypic changes with X-rays/radium.[1] Muller's findings, like that of the Japanese cancer researchers, quickly transformed the field. For his discovery, Muller received the Nobel Prize in 1946. The current paper clarifies the historical foundations of the LNT single-hit dose-response model, its unique dependence upon the gene mutation interpretation of Muller in 1927, and how this interpretation became accepted by the scientific community and regulatory agencies. Most importantly, it will be shown that: (1) Muller's claim that the X-ray-induced transgenerational phenotypic changes were due to gene mutations was an interpretation lacking convincing evidence; (2) the induced transgenerational phenotypic changes

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[1] In January 1927, in the *Proceedings of the National Academy of Sciences* (Communicated January 14, 1927), Gager and Blakeslee (1927) were the first to report cases of gene mutations. Thus, Muller's July 1927 publication was the second to report the gene mutation phenomenon. Muller gained acclaim because he produced many mutations quickly. However, Gager and Blakeslee repeatedly reminded the field of their primacy. In his effort to secure scientific honors, Muller (1927a, 1928a) failed to cite the earlier work of Gager and Blakeslee (1927).

were due to chromosomal deletions and aberrations, not Muller's proposed gene "point mutations"; (3) these developments undermine the historical and scientific foundations of the LNT single-hit model since it was built upon Muller's gene mutation interpretation (see Calabrese, 2017a for a significantly expanded analysis of this issue); (4) Muller and other leading U.S. radiation geneticists would collude in a series of articles to promote acceptance of the LNT, making deliberate deceptions and misrepresentations of the scientific record; (5) the deceptive practices would infiltrate and culminate in the actions of the U.S. NAS BEAR I Genetics Panel that recommended adoption of the LNT model by regulatory and public health agencies in 1956 (Anonymous, 1956) (See Calabrese, 2015a, b, c); (6) the mouse data used to provide the experimental basis for the subsequent reaffirmation of the LNT for cancer risk assessment was similarly problematic, that is, the BEIR I NAS/NRC (1972) Committee used a flawed historical control group that significantly overestimated risk in the low dose zone, yielding a linear dose response (see Calabrese 2017b, c); (7) use of a corrected historical control value yields a threshold rather than the linear dose response and; (8) this new assessment indicates that the LNT has been flawed from the start, yet national and international regulations have continued to be based upon it (Calabrese, 2015a, 2017d).

2. Muller and mutation

Hermann J. Muller, a radiation geneticist at the University of Texas/Austin, truly burst upon the national and international scene following his presentation at the 5th International Genetics Congress in Berlin during September 1927. His highly anticipated presentation convincingly demonstrated to an eager and massive grouping of geneticists from around the world that X-rays could induce transgenerational phenotypic changes in *Drosophila* perhaps providing a mechanism for evolution. Muller claimed that these changes were the result of induced gene mutation, tiny genomic changes, with Muller coining the term "point mutation". Muller not only claimed to be the first to ever artificially induce gene mutation, he produced copious numbers of them. Muller's presentation drew especially great anticipation since his article in the journal *Science*, published about three months earlier, only discussed some of the new findings, inexplicably failing to show any data. Thus, Muller, with a flair for the dramatic, disproved the doubters and set himself on a path that 19 years later would result in another trip to Europe, Stockholm, to receive the Nobel Prize in Biology and Medicine.

Muller's stunning results soon inspired: (1) numerous laboratories to redirect their research to the assessment of ionizing radiation induced mutations (Campos, 2015); (2) the creation of the Genetics Society of America (GSA) (1931) a few years later, bringing zoologists and botanists who were researching genetics under one integrated professional society; (3) the concept of a Proportionality Rule that describes the linear dose response for the ionizing radiation induced mutation response (Muller, 1930a); (4) the interdisciplinary collaboration of leading physicists and radiation geneticists to create the first mechanism-based cancer risk assessment model (LNT single-hit model) using target theory (Timoféeff-Ressovsky et al., 1935) and (5) the discovery of chemically induced mutations by Charlotte Auerbach in the 1940s (Auerbach and Robson, 1946). The reach of Muller was long and influential, inspiring the focus of Carson (1962) in her seminal book *Silent Spring*, that is normally given credit for starting the environmental revolution of the late 1960s and 1970s and continuing to the present. Muller wrote a powerfully supportive review of *Silent Spring* in the New York Herald Tribune published on the Sunday prior to the book's publication four days later (Muller, 1962). Thus, the X-ray induced "gene" mutation findings of Muller and his leadership over the next 40 years would profoundly affect the environmental movement and the fields of genetic toxicology, cancer risk assessment and numerous medical, radiation and public health practices.

There is therefore little question that Muller had a major influence on the scientific community and the general public, originating from the belief that he had actually demonstrated that X-rays produce gene mutations in the fruit fly. While the above summary highlights some of the societal impact of Muller, there are important parallel concerns with Muller's scientific legacy. In brief, Muller (1927a) made the critical assumption that the numerous X-ray induced transgenerational/heritable phenotypic changes that he reported were the result of induced gene mutations. Muller knew that transgenerational/heritable phenotypic changes via X-ray-induced chromosomal aberrations was not a significant finding (Muller, 1928b). This had been reported previously and would not affect an understanding of basic biological themes such as evolution and its potential mechanism. This was why Muller (1927a) entitled his groundbreaking July 22, 1927 article in *Science* "The Artificial Transmutation of the Gene".

3. Point mutations vs gene deletions

Within three months of his presenting these findings at the Genetics Congress[2] in Berlin (September, 1927) (Muller, 1928a), Muller (1927b) would publically express concerns that some might think that all he had done was to shoot large holes (i.e., deletions) throughout the genome with the high doses of X-rays used, noting that such concerns/questions were initiated by his longtime friend, close colleague, collaborator and confidante, Edgar Altenburg, a professor of genetics at Rice University. Within this anticipatory defensive context, at the December 1927 AAAS meeting at Nashville, Tennessee and in an April 1928 presentation to the U.S. National Academy of Sciences (NAS) Muller (1928b) tried to discount the possibility that his reported transgenerational phenotypic changes were due principally to heritable chromosome changes, suggesting as proof observations of reverse mutations (e.g., X-ray-induced reversible changes in eye color – red to white). Patterson and Muller (1930) would subsequently publish a massive 82-page paper supporting his argument. This was proof enough for Muller that X-rays induced small mutations in genes rather than vast and large deletions as suggested by Altenburg. Muller used apparent reverse mutation findings to preempt potential challenges to his gene mutation interpretation. Muller argued further that the assumed point mutations closely mimicked the type of gene mutation changes underlying the mechanism of evolution as might be seen with spontaneous gene mutations, spending much of the next

[2] The proceedings of this Congress contains Muller's paper, which included the data used for the basis of the Nobel Prize in 1946. The Congress proceedings paper of Muller had substantial limitations, being somewhat sloppily written, having three experiments, each with important weaknesses. It also lacked a methods section and provided no references, including no acknowledgement of the report by Gager and Blakeslee (1927) that preceded his *Science* paper (Muller 1927a) for the reporting of ionizing radiation induced gene mutation by six months. The general substandard quality of the manuscript made me wonder whether the Nobel Prize paper of Muller from the Congress proceedings had ever been peer-reviewed. A July 8, 1946 letter from Muller to Altenburg (Muller 1946a) revealed that the manuscript that he read at the Congress was exactly the same as published in the subsequent proceedings. Thus, it is virtually certain that the Nobel Prize research of Muller was not peer-reviewed (Calabrese, 2018). However, Muller had been acculturated into the need for and process of peer-review by Thomas Hunt Morgan, his Ph.D. advisor at Columbia University. Morgan helped to create the *Journal of Experimental Zoology* in 1903, which had a modern peer-review process from the start. In fact, Muller would publish several articles in this journal by 1920 (Harrison, 1945). Thus, Muller was part of a culture of peer-review as a necessity and expectation. Yet, he avoided it for the seminal findings for which he would be honored with the Nobel Prize.

Table 1
Stadler's challenge to Muller, quotes from Stadler (1932, 1954).

Stadler (1932). **Proc 6th Intern Cong Genet 1:274–294**
"To state that an induced variation is a gene mutation is not to explain it but merely to label it."
Page 274-275
"We do not demonstrate that a chemical change has occurred; we simply infer, since no mechanical explanation can be found, that the variation must be due to this invisible mechanism."
Page 275
"We may define mutation as a transmissible change in the gene. But we identify mutation by experimental tests, and these tests are not such as to establish conclusively, in specific instances, that a change within the gene has occurred."
Page 275
"In effect, any Mendelizing variation which cannot be shown to be due to a change involving more than one gene is a mutation."
Page 275
"... the occurrence of reversion is not proof that the original mutation could not have been due even to a deficiency."
Page 292
Stadler (1954). **Science 120(3125):811–819**
"But there was no test to identify mutations due to a change within the gene; it was simply inferred that the mutants that could not be identified as the result of specific mechanical causes were, in fact, due to gene mutation in the ideal sense (11)."
Page 813

40 years in this quest for a mechanism for evolution.

While these findings would temporarily satisfy the questioning and doubtful Altenburg and others, supporting the X-ray-induced point mutation interpretation, this concern would not go away but actually grew principally due to the persistent questioning and new research insights of the plant radiation geneticist Stadler (1932, 1954), Muller's most staunch, yet objective, respected, competitor and critic (Calabrese, 2017e).

4. Stadler challenges gene mutation interpretation

4.1. Cytogenetic advances

At the time of his groundbreaking mutation publication, Muller's (1927a) research suffered from an acknowledged limited cytogenetic evaluative capacity which prevented fine structure chromosome resolution ("... Drosophila cytology is elusive in its finer details" – page 721, Muller, 1928b), and thereby a reduced capacity to detect chromosomal deletions. Markedly improved chromosome cytogenetic resolution capacity was developed by the Cornell plant cytogeneticist, Barbara McClintock, in the prophase stage of meiosis with maize (McClintock, 1929). Two years later she would apply this novel technique to Stadler's X-ray treated corn in the summer of 1931. It revealed that what was once believed to be X-ray induced "gene" mutagens were sizeable chromosomal deletions. While these findings would force Stadler to re-evaluate and challenge his previously published X-ray induced "gene" mutational findings in barley (Stadler, 1928), they would make him raise the question of whether Muller's gene mutation interpretation with fruit flies was also incorrect. While Stadler would cautiously share his new doubts with the research community in several 1931 publications (Stadler, 1931a,b) and in private correspondence with leaders in plant genetics research like Karl Sax (Stadler, 1931c), Stadler (1932) would finally challenge the Muller gene mutation interpretation in a very public manner during his Plenary Address at the Sixth International Genetics Congress at Cornell University in the presence of Muller (Table 1).

From this opening round of public debate, Muller and Stadler would challenge each other over whether Muller had induced true gene mutations in his highly publicized high dose X-ray experiments. This research-generated debate would continue until the death of Stadler in 1954 (Stadler, 1954), involving numerous radiation geneticists trying to resolve this fundamental question (Calabrese, 2017a ; Lefevre, 1950; Voss and Falk, 1973). Copies of Stadler's research grants and interim reports to the U.S. NRC that describe his progressive series of multi-year research plans, research methods and experimental developments reveal a focused, high quality and productive research activity with numerous publications that challenged Muller's gene mutation interpretation (State Historical Society of Missouri, Stadler Papers). An extensive review of Muller's gene mutation hypothesis along with supportive and non-supportive literature findings is provided in the dissertation of Lefevre (1949), Stadler's Ph.D. student. In this instance Stadler would show his flair for excitement and self-confidence by directing his student (with the assistance of *Drosophila* specialists and with some formal assistance of Muller) to challenge Muller's gene mutation interpretation with Muller's own biological model. In this extensive study, Lefevre (1949, 1950) found no support for Muller's gene mutation interpretation based on reverse mutations.

To the outside viewer it suggested two outstanding scientists locked in a scientific dispute, with Muller compelled to protect his reputation, future, and legacy. These longstanding competitive research activities of Stadler and Muller were much like a high-level chess match in which all moves (e.g., research publications, professional society presentations) contributed important information. By the late 1930s and/or early 1940s Stadler and others had methodically shown that Muller lacked the needed proof for his gene mutation assertions (Calabrese, 2017a). The subsequent development of improved cytogenetic staining for *Drosophila* chromosomes by Painter (1934) would reveal that the use of the very high X-ray doses and dose rates similar to Muller's key findings, like that of Stadler's research with barley and corn, produced copious chromosome aberrations including a high proportion of deletions, along with few, if any, possible gene (i.e., "point") mutations.

Muller's use of the reverse mutation concept was also found unconvincing as multiple papers showed several mechanisms (e.g., position effect) by which reverse transgenerational phenotypic traits could occur without any change in the gene[3] (Bedford and Dewey, 2002; Lefevre, 1950). Thus, every move that Muller made was seemingly countered by the research of Stadler or spin-off ideas his research had inspired. Furthermore, Stadler's and related publications would yield insights that were incrementally more definite, insightful and over time, more convincing than Muller's, much like forcing Muller into a corner.

[3] See the discussion from Lefevre (1949) dissertation for a detailed assessment of reverse mutation and position effect as related to Muller's gene mutation interpretation.

4.2. McClintock's new X-Ray induced mutation mechanisms

Complementing the Stadler gene mutation criticism were new mechanistic findings of Barbara McClintock's study with her breakfusion-bridge-cycle model of X-ray induced genetic damage (Comfort, 1987, 2001) which then led to strikingly new and transformative transposable element induced mutational insights. Her novel mutable gene concept was particularly attractive to Muller's University of Indiana Colleague and future Nobel Laureate Salvadore Luria (McClintock, 1948; Muller, 1948) as well as Muller's closest colleague and friend, Edgar Altenburg. In the case of Altenburg, he would devote much effort to understand the scientific foundations of McClintock's findings and its role in spontaneous and exogenously induced mutations. The McClintock discovery had very broad biological and biomedical implications. However, it would also take Altenburg back to his 1927 suggestion that Muller had been blasting large holes in *Drosophila* chromosomes by high dose X-ray treatments. Extensive and detailed correspondence between Altenburg and McClintock in the early 1950s reveal the significance that Altenburg placed on her findings and how it stripped much significance from Muller's gene mutation model.

Altenburg would repeatedly encourage Muller to study and assimilate the findings of McClintock (Altenburg, 1952a,b,c, 1953a). Altenburg would provide Muller with a 25-page manuscript on McClintock's transpositional element concept and its relationship to X-ray-induced mutations (Altenburg, 1953a,b). However, Muller (1953) claimed he was too busy to read the manuscript while also being dismissive, claiming that no one could understand the "jumping gene" (i.e., transposable element) concept (Altenburg, 1953a; Muller, 1953), a common technique to distract attention from a perceived competitor while protecting one's legacy. However, Muller was not successful in drawing Altenburg back into his sphere of dominance, but rather, Altenburg (1957) would devote an entire chapter to McClintock's mutable gene (transposable element) concept in the second edition of his Genetics textbook. Altenburg, an excellent writer, made the challenging writings of McClintock readily understandable for geneticists and interested biologists. In this chapter, he claimed that a substantial proportion of high dose X-ray-induced mutations are due to chromosome deletions/rearrangements rather than Muller's "point mutations" and that such genetic damage was likely mediated by transposable elements (Table 2). The profound intellectual transformation of Altenburg to the McClintock model was a significant sign that the era of Muller was waning. During this same period Russell et al. (1958) would publish his highly influential dose rate challenge to Muller. With multiple scientific challenges facing him, Muller would transform his laboratory into one that would try to extend the findings of Russell into *Drosophila* rather than exploring the dramatic and more complex new ideas of McClintock. Within a month of the Russell et al. (1958) publication Muller was exploring dose rate. In the six years of redirected and intense research on this topic Muller's laboratory was plagued with a series of apparent false starts and a generally ambivalent finish. Thus, the final years of Muller's laboratory productivity were weak, perhaps a function of aging and health deterioration (Calabrese, 2017b).

Of further importance, as suggested above, was the discovery by McClintock (1950, 1951, 1953) that transposable chromosomal elements affected the occurrence of both spontaneous and exogenously induced mutations, including mutations induced by ionizing radiation and chemical mutagens such as mustard gas as used by Auerbach with *Drosophila*. Subsequent findings indicate that the early X-ray-induced transgenerational phenotypic findings of Muller (1927a) and Timofeeff-Ressovsky et al. (1935) were likely the result of X-ray activation of McClintock's transposition element process which induced massive chromosomal damage, such as small to massive deletions and other types of chromosomal aberrations (Ratner et al., 2001). These collective developments served to strongly reinforce the fundamental criticisms by Stadler of Muller's gene mutation interpretation, while supporting the McClintock transpositional element mediated mutation model.

5. LNT single-hit model, dose rate and the Manhattan Project

While Muller was in serious dispute with Stadler throughout the 1930s for his gene mutation interpretation, there was nonetheless a worldwide mesmerizing euphoria of Muller's mutation discovery (see Campos, 2015), one element of which resulted in a unique interdisciplinary collaboration between leading physicists and radiation geneticists as led by Delbruck and Timofeeff-Ressovsky, respectively. From the mid-1930s their research provided the LNT model with a hypothetical mechanistic basis via the use of target theory (Timofeeff-Ressovsky et al., 1935). This concept was then transformed into a biostatistical model (i.e., LNT Single-Hit model) which revealed that the shape of the dose response in the low dose zone was largely a function of the assumed number of target hits required to produce a gene mutation (Zimmer, 1941). The fewer the hits needed to produce gene mutations the closer the linear dose response for gene mutation was approached.

Since his X-ray induced gene mutation interpretation had experienced serious scientific challenges and setbacks through the 1930s, Muller needed another approach to redirect the mutation debate to restore support for his gene mutation interpretation and low dose linearity model and their integrative linkage. Muller's idea was an intriguing one that served, at least in part, both purposes, with a new application of a "dose x time = constant" experiment as seen in the Bunsen-Roscoe Law or with Haber's Law. Over the decade of the 1930s using his Proportionality Rule Muller had asserted that X-ray induced mutation damage was progressively cumulative and could not be repaired. As a result of these characteristics the damage should be predicted by the total dose, not by dose rate. If the total dose hypothesis were true, then the dose response for mutation should be linear at low dose, all the way down to a single ionization. Muller would test this idea in a

Table 2
Quote from Altenburg E. (1957). Genetics. Holt, Rhinehart and Winston, New York, NY.

Are all mutations due to chromosomal rearrangements?

... The possibility, therefore, arises that mutations might often be due to invisibly small deletions, rather than to an actual change in a gene–a change that we refer to as a "point" mutation. We cannot be sure, for example, that the yellow body-color mutant in Drosophila has a "yellow" gene in place of a "gray" (the normal allele of yellow). For all we know, the body color of the mutant might be yellow because the normal allele has been deleted. In fact, yellow mutants of independent origin differ somewhat in the intensity of their yellow pigmentation and, in the case of certain "extreme" yellow, it is very likely that the mutation is due to a very small deletion. In general, there is no way of telling from the outward appearance of a mutant what sort of genetic change caused the mutation. Inversions and duplications are also known to have mutant effects–inversion because of a "position" effect, and duplications either for the same reason or because of the genic unbalance they cause. Now deletions, inversions, and duplications are all the results of chromosome breakage and rearrangement. Therefore, in the present state of our knowledge, all mutations might conceivable be due to such rearrangement and not to any actual alteration in the gene itself."

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dissertation by Ray-Chaudhuri at the University of Edinburgh using X-rays and mature spermatozoa of *Drosophila*. The findings of this dissertation matched up very well with Muller's predictions supporting the total dose/LNT hypothesis. These results provided support at a critical stage to Muller's gene mutation theory. In fact, during Muller's (1946b) Nobel Prize lecture, he cited the research of Ray-Chaudhuri (1939, 1944).

The problem with this newly adopted dose-rate vs total dose strategy to defend the gene mutation interpretation was that the study of Ray-Chaudhuri had a series of important design and execution limitations, requiring corrections, improvements and replication (Calabrese, 2011, 2017a). In fact, there were so many limitations (e.g., limited sample size, quality control issues, changing animal models during the experiment, lacked documentation of essential methods, major statistical errors, failure to collect critical information), it suggested that the normally critical Muller might have lowered his academic standards in order to provide support to his sagging gene mutation interpretation.

The Ray-Chaudhuri dissertation in some ways served as a pilot study for the far more substantial efforts lead by Curt Stern, University of Rochester, during the Manhattan Project starting in 1943. Stern would initially direct an acute study by Warren Spencer, a highly regarded *Drosophila* specialist who was on leave from his faculty position at the College of Wooster (Ohio, USA). While the Spencer part of the study went as planned, a significant problem for Muller, a paid consultant on this project, occurred when the data from the low dose chronic genetic toxicity study, led by Ernst Caspari, revealed a significant dose-rate effect and a threshold for mutagenicity, contradicting the Ray-Chaudhuri (1939, 1944) conclusions. These findings by themselves had the potential to land a severe blow to the LNT single-hit theory. These findings were just preceded by 15 years of research lead by Stadler that successfully weakened the plausibility of Muller's gene mutation interpretation and now along with new mechanistic insights of McClintock on X-ray-induced mutations. This situation became sufficiently threatening to the policy goals of key leaders of the radiation genetics community such as Muller and Stern who strongly advocated the adoption of the LNT single-hit model. What happened next to the field of radiation genetics could not have been predicted.

The above set of events, which collectively placed the LNT single-hit model at risk, set the stage for what is referred to as "LNTgate" (Calabrese, 2015c, 2016, 2017d), a series of obfuscations, deceptions, and misrepresentations of the scientific record all designed to ensure that the LNT single-hit theory would replace the threshold model for cancer risk assessment. This sequence of events has been reported in detail over the past seven years via a series of progressively informed historical discoveries (Calabrese 2011, 2013, 2015a,b,d, 2016, 2017b,c,e).

The LNTgate actions were mediated via the leadership of Curt Stern and Hermann J. Muller during the second half of 1946, continuing for more than a decade. These efforts lead to the actions of the NAS BEAR I Genetics Panel to sustain and integrate these successful manipulations into the scientific record and government regulatory policies. These ideologically directed activities would be guided by the academic "offspring" of Muller and Stern, such as Jim Crow, Bentley Glass, and other esteemed leaders of the radiation genetics community. The process became fully successful when the next generation uncritically accepted as scientific fact, the mistakes, deceptions, and misrepresentations handed down by the icons of the field. This is, in fact, the domain where key features of the fields of regulatory policy and cancer risk assessment are today.

6. Saving the hit model

The LNTgate process had an unexpected spontaneous origin. It began when Ernst Caspari informed Stern, his supervisor, that his dose-rate findings contradicted those of Ray-Chaudhuri (total dose). As noted above, the observation of a threshold response for mutation was not only not expected but, as it turned out, actually "not permitted", resulting in Stern refusing to accept the Caspari findings (Calabrese, 2011). Giving the appearance of objectivity, Stern blamed Caspari's threshold "discovery" on the use of a faulty control group that he insisted was aberrantly high. Stern did not provide any evidence to support this critical judgment. However, Stern was aware of earlier publications with control group responses for this model that supported the Caspari interpretation based on prior correspondence (Stern, 1938), but he either forgot this or refused to share it. Regardless, the Caspari year-long study had reached an impasse with the Stern judgement, a major crisis.

Showing some degree of independence, Caspari would not accept Stern's judgement that his control group displayed aberrantly high values. He dove into the literature and found a series of papers, which explicitly addressed the control group question, with all supporting his position (Calabrese, 2011). When Caspari assembled these findings, Stern withdrew the control group criticism. During this period, Caspari informed M. Demerec, head of the Genetics Department for the Carnegie Institute, of his mutation threshold dose-response findings and the problems it was creating. This prompted the influential Demerec to write Caspari asking "what can be done to save the hit model" (Caspari, 1947). This statement seemed to express what Stern and Caspari might well have been thinking. With the control group issue no longer a viable means to discredit the Caspari findings, the "save the hit model" strategy of Stern became publishing the manuscript, but framing the discussion to prevent the data from being accepted/used, while still showing competence of the research team, thereby securing the LNT/Ray-Chaudhuri framework. This seemed like the best possible outcome for Stern and Caspari.

The strategy adopted was to assert that the Caspari data could not be accepted or used until it could be determined why he obtained a threshold in the chronic study, while Warren Spencer obtained an apparent linear dose response a year earlier in an acute study with the same fruit fly model while working under Stern. This created a false standard, as the two studies had more than 25 methodological differences; there would be no possible practical means to determine why the studies differed (Calabrese, 2011). The only way that this highly nuanced perspective (i.e., the recommendation not to use the Caspari findings until it resolved the differences with the Spencer study) could have been published was if Stern was the journal (i.e., *Genetics*) editor and there was no peer-review, and this was most likely just what happened (Calabrese, 2017)! In fact, even though Stern proposed this unrealistic situation, no one, of course, ever explicitly accepted this challenge over the next 70 years, including himself, Caspari or Muller. It was a tactical move in the broader strategy to "save the hit model". So Caspari and Stern prepared this manuscript with this obfuscation and sent it to Muller for review on November 6, 1946 with Muller answering on November 12, 1946 (Calabrese, 2011). Muller indicated that he was upset that Caspari found a threshold since this could be a serious problem for LNT acceptance and Stern needed to replicate the study (not to explain why the Caspari study differed from the Spencer study as emphasized in the discussion as this was impossible to do). Thus, Muller was fully informed that the strongest study (i.e., chronic exposure to ionizing radiation) to date (i.e., Caspari experiment) showed a threshold for mutation one month prior to the Nobel Prize lecture of December 12, 1946 (Muller, 1946b). The linearity supporting acute exposure experiment of Spencer had a series of methodological limitations (e.g. inadequate temperature control, inexplicably combining different dose-rate groups with the same total dose, inadequate X-ray machine

calibration) that affected the reliability of the low dose study results (Calabrese, 2011). Yet Stern, Muller and others never identified such limitations, even in Muller's detailed review of this research (Muller, 1946c). These criticisms of the Spencer study (Spencer and Stern, 1948), were first reported more than six decades later (Calabrese, 2011).

In his crucial moment of making scientific history, Muller (1946d) deceived the world with his statement that there is no possibility for a threshold response ("no escape from the conclusion that there is no threshold") to ionizing radiation induced mutation and that risks needed to be assessed via the LNT single-hit model (Nobel Prize lecture, Dec 12, Muller, 1946b). Muller made this statement having seen the Caspari study and not offering any technical or other criticism (Muller, 1946e). Thus, a type of collusion began to take shape between Stern, Caspari, and Muller to do as Demerec urged. In a follow up letter to Stern (Muller, 1947) Muller supported publishing of the Caspari paper since there were enough caveats (i.e., obfuscations) and restrictions to make the paper non-threatening to the LNT acceptance.

In 1949 Stern manipulated or colluded with the leadership of *Science* to ensure LNT would be strongly promoted (Uphoff and Stern, 1949). This was similar to how Muller (1927a) was treated two decades earlier showing no data on his Nobel Prize experiments nor seven years later (1956) in the journal's dealings with the fraudulent NAS BEAR I Genetics Panel publication (Anonymous, 1956). Here is how it happened. While the Stern research team hoped that the follow-up replication studies would put an end to the Caspari study-created crisis, it simply created a new one. The first replication experiment (i.e., led by a new master's student Delta Uphoff) was unacceptable to Stern, this time because the control group was aberrantly low. The control group's values were so outside the norm that Stern had to check with Muller who strongly affirmed (in writing) that the Caspari control group values were appropriate while rejecting Uphoff's (see Calabrese, 2015a,b for the letter correspondence documentation). The troubled Stern would go so far as to blame her for having been biased [i.e., "may reflect a personal bias of the experimenter" (Uphoff and Stern, 1947)], with this leading to the low control group values (Calabrese, 2015b). This phrase was stated in the Discussion of the manuscript that was sent to the Atomic Energy Commission (AEC) (and which was immediately classified). This amazing statement should have raised a plethora of questions by the scientific community for Stern and Uphoff but it was hidden from view. For example, how did the alleged bias start? How long did it continue? How might it have affected other experiments, other team members and others, the data analysis and manuscript write up? A follow-up experiment by Uphoff also suffered the same fate with an aberrant control group value. This situation was turning into a professional disaster. So the question was not just what could be done to save the hit model but also the reputations of Stern, Caspari, and Uphoff and other members of the Manhattan Project at the University of Rochester. Stern would again show his creativity (or deviousness). Since essentially no one had read the classified material discounting the results and blaming Uphoff and her alleged biases leading to the uninterpretable findings, Stern used his contacts with the journal *Science* to publish a one page technical note of the experiments of Spencer, Caspari, and Uphoff. In this limited technical note, Stern showed no transparency, neglecting to inform the reader that he had found the low control studies of Uphoff unacceptable less than a year before and now he concluded these findings were fully acceptable. No criticisms of the Spencer study were mentioned despite its obvious significant limitations (Calabrese, 2011). Stern also reintroduced criticism of the Caspari study without evidence. In this mini-meta analysis, Stern restored the LNT model, literally "saving the hit model". In the final paragraph, Uphoff and Stern (1949) promised the *Science* readers to provide a comprehensive paper with methods, materials, missing data and other relevant information. Yet, they never did.

Muller and Stern actually promoted the discredited findings of Uphoff while marginalizing the Caspari paper. More specifically, at the time Stern asked Muller to help resolve the Caspari-Uphoff control group issue, Muller had been studying spontaneous mutations in the fruit fly in his ongoing disputes with Stadler concerning whether he induced gene mutation (Calabrese, 2017a). Thus, Muller was sitting on a treasure trove of control group spontaneous mutation data. As noted earlier, in multiple letters to Stern, Muller unequivocally sided with the Caspari findings while rejecting those of Uphoff (Calabrese, 2015a, b). With this as prologue we now fast forward a few years and find Muller (1950, 1954a) rejecting the Caspari study based on this control group being abnormally high, contradicting the literature, his own data/publications and his multiple letters to Stern, while never providing proof for his statements. The evidence reveals Muller dishonestly strove to discredit the Caspari study, and preserve LNT, while protecting himself from being accused of lying during his Nobel Prize Lecture. The 1950 paper of Muller was just preceded and perhaps inspired by an article by MIT's Robley P. Evans in *Science* (Evans, 1948) criticizing the LNT model, using the threshold findings of Caspari (Caspari and Stern, 1948). After Muller read the Evans article, he wrote to Stern criticizing the paper of Evans, blaming the criticism of LNT on the findings of Caspari (Muller, 1949). Muller urged Stern to contact Evans and discredit the Caspari work. No evidence has yet been found that Stern communicated with Evans on this matter.[4] However, shortly after that letter exchange with Stern, Muller published his false criticisms of Caspari's control group. Furthermore, on August 10, 1949 Altenburg (1949) wrote Muller about the Caspari threshold findings, acknowledged the reliability of the findings yet in search of a mechanistic explanation. Apparently, Muller had thought that Stern and his efforts had fully neutralized the threshold findings of Caspari, but this was not apparently the case.

7. LNT and the NAS BEAR Genetics panel

The next stage of the LNT story would take place with the NAS BEAR I Genetics Panel which first convened in early November, 1955 at Princeton University. As Muller had learned from many earlier frustrations, success within Advisory Committees is highly dependent upon who is selected. In the case of the BEAR I Genetics Panel, the answer was clear from the start, as the Panelist Tracy M. Sonneborn, a Muller colleague at the University of Indiana, read their radiation geneticist mantra into the recorded proceedings with no debate or dispute. All firmly believed that mutational damage was cumulative and irreversible with the dose response being linear down to a single ionization. Multiple notable radiation geneticists at that time were not advocates of the Muller perspective but they were either directed to other NAS BEAR I panels such as was the case of Ralph Singleton (agriculture panel) or not selected as was the case of McClintock. In retrospect, the deck was stacked along with an administrative leadership that would keep the panel focused on the big picture goals of the Rockefeller Foundation (RF) that both funded and directed the Panel while in

[4] The papers of Evans have been preserved at MIT. However, they have yet to be organized for scholarly use and it is unknown when they will be available. Of interest would be whether Stern ever sent Evans the letter Muller suggested. A check of the Stern files at APS revealed no record of a letter of Stern to Evans.

the administrative structure of the NAS.[5]

Despite the endorsement of the LNT single-hit model by leading research geneticists and physicists it was widely recognized that the fundamental data to support the LNT single-hit model was inappropriate. The model was dependent on point mutations, not large deletions, gene rearrangements, and other gross aberrations. In his final and masterful paper, published posthumously in *Science*, Stadler (1954) would illustrate how Muller's mutational data could not provide a credible biological basis for the LNT single-hit model. Despite the prominence of the journal *Science*, the stature of Stadler and the timeliness of the article, this criticism of the LNT single-hit model was never discussed by the NAS BEAR I Genetics Panel. In fact, not once in the transcribed pages of the Panel meetings were Stadler or McClintock's research on gene mutation ever mentioned.

At the second meeting of the Panel (in Chicago), Warren Weaver, Chair of the Genetics Panel and Director of Research for RF, tried to entice members of the Panel with RF funding if the Panel Report would support RF initiatives (e.g., LNT). Weaver indicated he would "try to get a very substantial amount of free support for genetics if at the end of this thing we have a case for it. I am not talking about a few thousand dollars, gentlemen, I am talking about a substantial amount of flexible and free support to geneticists" (Anonymous, 1956 - BEAR I Genetics Panel Transcript, February 5, 1956, page 35).[6] Weaver would further state that "There may be some very practical results – and here is the dangerous remark – don't misunderstand me, we are all just conspirators here together". The Weaver remarks obviously link the Panel deliverables to RF funding for geneticists, including those sitting in the room. Further discussions of the Panel during the February 5/6, 1956 meeting would reveal that to be successful in the eyes of Weaver, the Panel would need to present strong agreement/consensus for the estimation of genetic risks to the U.S. population assuming a linear dose response. However, an unanticipated problem came about 4–5 weeks later (March 1956) when the Panel members displayed multiple profound disagreements: they argued about whether it was possible to even estimate population risks, how to derive the estimations, how any derived estimates of damage related to true (real) risks, and what the risks actually were. With this confusion, the highly divergent results of the independent risk estimates that were carried out over 10 generations were seen as an unusable scientific "mess", such that Panel member, Jim Crow, would claim that no one would believe the policy recommendations of the Panelists since they could not agree amongst themselves. In a March 29, 1956 Letter to Warren Weaver, Crow (1956) stated that:

> "The limits presented on our estimates of genetic damage are so wide that the readers will, I believe, not have any confidence in them at all."

Lacking authority to do so, Crow, who was to organize the technical reports for Panel discussion, decided to arbitrarily drop the three lowest estimates of risk; by so doing he markedly reduced the variation, giving the false impression of more expert Panelist agreement than was the case. Even after dropping the three, there remained considerable uncertainty, being still too large to show to the scientific community and general public. One might have thought that the Panelists whose estimates were dropped would have strongly fought to have them retained. There is some evidence of significant disputes between Demerec and Muller on this matter based on a letter from Muller to Beadle in August 1956 (Muller, 1956) indicating that Muller did not want to be part of writing a scientific justification for their LNT recommendation. He indicated that he was already too frustrated with his debates with Demerec over the value of *Drosophila* versus bacteria in their risk estimations and did not want to air the so-called dirty laundry in public. He had thought that they had agreed to disagree. However, the available record does not reflect the details of this matter, as it likely occurred in the March 1956 meeting once Crow received the detailed write-ups for which there was no meeting transcript. Muller also noted his unresolved debates with the human geneticists of the Panel further confirming his unwillingness to seek a consensus report justifying their scientific recommendations. This lack of blatant open dispute/rebellion suggests that the group consensus was to present a united front that Weaver had earlier pointed out was necessary, perhaps using this funding carrot to achieve agreement. However, panelist James Neel, who refused to provide an estimate, strongly disputed the legitimacy of the proposed genetic damage estimation activity (Neel 1956 a, b). He argued that any consensus agreement was an illusion based on a self-fulfilling decision to reduce variability by forcing the use of similar models with similar process assumptions. Even with Crow stacking the deck, the risk estimates were still too variable, leading Weaver and Crow to encourage/coerce the Panel not to show their range of estimates to the outside world since it would destroy their credibility. The Panel would keep it private. There was no "minority" report nor leaking to the media. The "control" of the group was evident as those such as Demerec and Neel would not publically challenge the group view despite fundamental differences.

8. The NAS BEAR I Committee Genetics panel *science* publication story

The BEAR I Genetics Panel published a major article in *Science* (Anonymous, 1956) on their findings and recommendations. This paper had three significant misrepresentations of the Panel's research record. The first involved the Panel stating that the 12 geneticists of the Panel were invited to provide estimates of genetic risks for the entire U.S. population exposed to a certain dose of ionizing radiation, but only six accepted the challenge and provided the write up. Yet, nine of the 12 actually did, with Crow dropping three estimates as noted earlier.[7] In fact, I had obtained the nine detailed assessments. Second, the *Science* paper indicated that the minimum and maximum estimates of genetic damage range was ±10 or 100 fold. However, the actual average minimum-maximum damage range was about 750 fold. Third, the Genetics Panel *Science* paper neglected to report that three Panelists refused to participate, principally because they believed that such estimates could not be reliably done.

A written record exists that documents that the NAS BEAR I Committee Genetics Panel voted not to share their data with the scientific community and others (Calabrese, 2015a). After the Panel's publication in *Science* it was specifically challenged by

[5] Dr. Detlev Bronk was President of the Rockefeller Institute for Medical Research (later named Rockefeller University) and President of the National Academy of Sciences (NAS) during this time, confusing the roles of the Rockefeller Foundation and the NAS in this BEAR I Genetics Panel process.

[6] The concept of self-interest science (i.e., exaggerating fears of radiation to enhance research funding) of some members of the BEAR I Genetics Panel was documented via uncovered correspondence (Calabrese, 2014).

[7] It is interesting to note that the three estimates that Crow dropped (i.e., Demerec, Wright, and Kauffmann) were the areas with which Muller (1956) acknowledged serious issues in his letter to Beadle. Since Muller and Crow had a very close professional and personal relationship, it is tempting to speculate that Muller may have influenced Crow to drop the three estimates. This perspective is attractive since it is doubtful that Crow, one of the youngest members of the Panel, would have acted so precipitously without significant senior backup support. This would have been especially the case if he were doing Muller's bidding. Further documentation will be need to evaluate this hypothesis.

several leading U.S. academic researchers to share the scientific basis for the report and again the Panel formally voted not to do this as well (Calabrese, 2015a). Of significance is that the Panel had never even written such a scientific basis for their LNT recommendation. This should be seen as failed leadership by the NAS President Detlev Bronk and Chairman Weaver, a sign of scientific arrogance, or a type of defense posture. The Panel vote during August, 1956 not to provide a scientific basis for this major recommendation to adopt the LNT single-hit model for risk assessment was then passed on to NAS president Bronk, who accepted their decision. The NAS administration was therefore fully complicit in this process (Calabrese, 2015a).

The NAS BEAR I Committee Genetics Panel therefore falsified the research record, creating a significant cover up. Providing a detailed write up of their process would have revealed the deliberate misrepresentations of the research record. It would also have revealed a highly embarrassing fundamental lack of competence by such prestigious leading geneticists who simply could not properly address this risk estimation problem, as highlighted by Crow's amateurish and incorrect response (Calabrese, 2015a, b). It would also have taken considerable effort to complete such a report, something that should have been done during the activity of the Panel.

The goal of the NAS BEAR I Genetics Panel was to recommend adoption of the LNT in the U.S. and worldwide. Within about two years the LNT recommendation was adopted by national and international advisory committees, eventually becoming worldwide policy for cancer risk assessment. Thus, the most significant policy recommendation for cancer risk assessment lacked a written scientific basis. Most striking is that the Panel, including Muller, and the president of the NAS made this decision. It is ironic that the U.S. National Committee for Radiation Protection and Management (NCRPM) adopted LNT for cancer risk assessment in December 1958, based on the documentation-lacking NAS BEAR I Genetics Panel report days prior to the publication of Russell et al. (1958) demonstrating the existence of dose rate for ionizing radiation in the mouse model. Apparently, the status of the Genetics Panel and the NAS was so high that no documentation was needed for governments worldwide to adopt their transformative recommendations. As recently noted by Calabrese (2017a), seven of the members of the highly prestigious NAS BEAR I Committee Genetics Panel had no research experience with the effects of ionizing radiation on mutations. In fact, Crow, who had never published on the topic, made the decision on which estimates to retain. It is also ironic that Demerec and Neel, who were amongst the most appropriately experienced, did not contribute to the radiation risk estimates. Thus, the vision that the country was being guided by the most prestigious and experienced grouping of geneticists on the matter of radiation induced genetic damage was yet another myth to enhance acceptance of the LNT.

9. LNT, William Russell and the dose rate challenge

Within 2.5 years of the June, 1956 NAS BEAR I Genetics Panel *Science* publication, another *Science* publication would challenge one of the basic tenets of the BEAR I, Genetics Panel's recommendations. The paper was by William L. Russell of the Oakridge National Laboratory, also a member of the NAS BEAR I Genetics Panel. During June and July of 1958 Russell's group (Calabrese, 2017a, b) made a major discovery, that dose-rate, not total dose, was the key predictor of ionizing radiation induced mutation for mouse spermatogonia and oocytes. The Oak Ridge group kept this breakthrough discovery quiet, not presenting the findings at the International Genetics Congress in Burlington, VT in the middle of August. Russell did share the findings with a New York Times reporter during the Conference who wrote an article (Schmeck, 1958). The breakthrough paper was published on December 19, 1958 and with it was a timed release front page story by a Pulitzer Prize journalist (i.e., Nate Finney) for the Buffalo Evening News who specialized in atomic energy (note that the NY Times was then on strike) (Finney, 1958; Russell et al., 1958).

The Russell research revealed that damage from ionizing radiation was not cumulative, but reversible and had the potential to yield a threshold, suggesting the existence of DNA repair, a possibility that Altenburg shared with Muller soon after publication of the paper (Altenburg, 1958). In effect, Russell had discredited the mantra of the radiation geneticist community, creating a major problem. His strategy would be to promote the acceptance of his research while, at the same time, creating an impression of adhering to the radiation geneticist mantra. Russell did not want to be ostracized and marginalized from his field by his ideological radiation geneticist peers. Russell had seen the dominating and uncompromising personality of Muller in action many times while a member of the Genetics Panel (Crow, 1995) and with James Neel, whose paper Muller tried to prevent from being presented at an international genetics conference during the summer of 1956. In fact, Russell's supervisor, Alexander Hollaender, negotiated a follow up "reconciliation" meeting between Neel and Muller (January 1957) at Oakridge, essentially in the presence of Russell (Neel, 1956a, b; Neel, 1957a, b; Nowitski, 1956) (Table 3). Thus, Russell knew only too well how hostile Muller could get if one deviated from the radiation genetics ideology. Russell would walk this dose-response tight rope until after the death of Muller in April 1967, after which Russell would unleash a profound set of criticisms of the radiation genetics mantra and the LNT concept (Russell, 1969, 1973).

Despite these findings, their massive expansion by Russell and their powerful challenge to the LNT single-hit recommendation of BEAR I, it would take some 14 years before a new powerful NAS Committee, now called the BEIR I Committee with the Genetics Subcommittee being chaired by Muller's protégé Jim Crow to reconsider the LNT recommendations of BEAR I. During this process the BEIR I Genetics Subcommittee re-examined the BEAR I report and made two clear initial determinations (Calabrese 2017a,b). The first was that the risk assessment recommendation of BEAR I (Anonymous, 1956) needed to be based on a mammalian model rather than on a fruit fly. The second factor was their acknowledgement that the BEAR I Genetics Panel (Anonymous, 1956) made a mistake in denying dose-rate. The recognition that dose-rate rather than the total dose best predicted mutation damage, meant that the radiation geneticist belief of cumulative and irreversible damage with each dose would be replaced. This finding also meant that linearity may be at risk of being replaced by the threshold dose response, reversing the 1956 position of the BEAR I Genetics Panel. However, despite these new challenges to the LNT model, the Genetics Subcommittee still had a strong disciple of Muller in charge with Crow[8] and would find some rationale to keep the linear dose response model as the default if possible.

Even though the findings of Russell revealed a true threshold for oocytes, the same could not be said for spermatogonia, where the dose-rate related damage, which was mediated by DNA repair, was only able to reduce total mutations induced acutely by 70% and not the 100% needed to achieve a threshold (Figure 1). The BEIR I Genetics Subcommittee therefore concluded that even though it was now known that an ionizing radiation threshold existed for mouse

[8] Toward the end of his career, Crow would acknowledge that Muller and he were amongst the strongest advocates of LNT and that they were too extreme in their views and actions (Crow, 1995).

Table 3
Quote from Neel (1959); letter to Beadle, September 14, 1959.

"There is no mind in science today for whose brilliance I have greater respect than that of Dr. Muller. In the first upsurge of concern concerning the effects of the increasing exposure of the human species to the radiation which followed World War II, it was Muller who had thought most about the problem, and Muller whose point of view dominated the picture. When Jack Schull and I pulled together our monograph on the findings in Japan, we felt obligated to try to fit these findings into the context of present knowledge. The outgrowth of that attempt, our Chapter 15, was a number of questions concerning Muller's argument. We couldn't prove that he was wrong, but we didn't feel he could prove that he was right. In other words, we felt that there were a number of unvalidated assumptions behind a good many of his points. One aspect of this evaluation of ours was a little critique of the significance of mutation rate studies. This critique I delivered at the WHO Study Group on the Effect of Radiation on Human Heredity which met in Denmark in the summer of 1956. I regarded it as part of the normal scientific interchange, but Dr. Muller apparently regarded it as an attack upon his life's work. There developed a rather strained relationship which persists until the present day, I am afraid, and keeps coming back to me in small ways which I consider beneath the dignity of a great man. Be that as it may, Alex Hollander was Chairman of that meeting in Denmark. Muller apparently insisted to Hollander that my statements were unacceptable and should be modified, to the point where Hollander arranged a meeting between Muller and myself at Oak Ridge, in an effort to reconcile the differences of opinion. At this point a number of the British participants in the WHO Study Group got wind of what was afoot, through no efforts of my own, and got their own backs up. It so happened that they agreed with my point of view and in effect transmitted the message that if any pressure were brought upon me, they would withdraw their own papers."

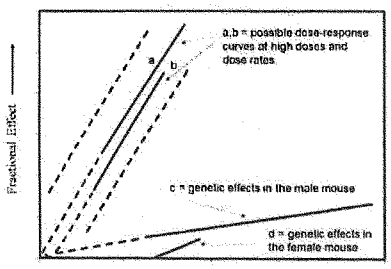

Figure 1. With new age graph 1972. Hypothetical dose-response curves for leukemia and genetic effects [illegible] – page 88, radial line = observed. Dashed extension of solid line = undetected. The "a" and "b" curvilinear dose-response curves at high doses and dose rates. Parallel dashed lines = extrapolations of risk for lines a and b. Lines c and d = equivalent genetic damage in the male and female mice, respectively.

oocytes, the LNT would be based on responses of the mouse spermatogonia. While this logic was convincing to the Genetics Subcommittee one would have to wonder why this didn't require further evaluation. Could there be an evolutionary explanation for why oocytes might show a threshold while spermatogonia didn't? Do oocytes have a more efficient DNA repair system than spermatogonia? Are responses of reproductive cells directly applicable to somatic cells?

These above noted questions were not explored or debated by the BEIR I Genetics Subcommitee. The point here is that the Genetics Subcommittee failed to broadly consider the question and were directed by the Crow leadership to obtain the desired outcome. Thus, Crow and his Genetics Subcommittee retained the LNT based on the non-threshold mutation data of the mouse spermatogonia. These views were accepted by a non-inquisitive U.S. EPA in 1976 and reaffirmed in 1977 all with reference back to the Russell research (Calabrese, 2017c).

The findings of Russell were critical for modelling cancer risk assessment for ionizing radiation based on the Atomic Bomb Survivor data for cancer outcomes. However, these epidemiological findings have limited detectability at low doses (Taubes, 1995), and findings need to be extrapolated toward background exposure. In this key low dose extrapolation process the assumption of linearity was made by the BEIR I Genetics Subcommittee (NAS/NRC, 1972) with the findings of Russell serving as the biological dose-response "homing" device for the LNT model. In the late 1970s the U.S. EPA directly extended this linearity model based on ionizing radiation to chemical carcinogens (Albert et al., 1977). The EPA linear cancer risk assessment policy would be challenged in 2017 when Calabrese (2017b,c) reported that the Russell historical control had been found in error (Selby, 1998a, b), and had been corrected for a massive error in 1996 by the Russells (Russell and Russell, 1996). Calabrese showed that if the corrected historical data had been used by the BEIR I (NAS/NRC, 1972) Genetics Subcommittee the male mouse would have shown a threshold while the female would show an hormetic response. These findings indicate that the basis for the LNT assumption was incorrectly formulated and that the adoption of LNT for risk assessment was incorrect.

10. Discussion

The present paper reveals that Muller did not discover what he claimed, that is, the "artificial transmutation of the gene" and this finding challenges the validity and application of the LNT single-hit model for cancer risk assessment (Calabrese, 2017a; Crow and Abrahamson, 1997). Muller was also incorrect on the issue of dose-rate (Russell et al., 1958) which had a significant impact on acceptance and promotion of the LNT single-hit theory (Calabrese, 2017b,c). Although complex, Muller's career was fundamentally centered on his quest to be the first to produce gene mutations, and then to defend this interpretation the rest of his life, against the findings of Stadler (1931a, b, 1932, 1954) and others and then over the remaining six years of his research career (1959–1964) on the issue of dose-rate (Calabrese, 2017a, b), while trying to avoid the alternative gene mutation model of McClintock (1950, 1951, 1953) and its advocacy by Altenburg (1957).

Current scientific understandings, therefore, reveal that Muller could not sustain the conclusion that his high dose X-ray induced artificial transmutations of the gene were "real" gene mutations. The strong preponderance of evidence in the 1930s suggested chromosome level heritable genetic changes based on advances in cytogenetic staining, findings that have been confirmed with nucleotide sequencing technologies (Calabrese, 2017a). Since Muller was incorrect with his gene mutation interpretations the LNT single-hit theory of Timoféeff-Ressovsky et al. (1935) lacked a scientific relationship with the data that was used as its foundation (as pointed out by Stadler, 1954). Despite being wrong on the fundamental biological issues, the Muller-led faction of the radiation genetics community was successful in achieving the adoption of LNT worldwide. This was largely due to its highly organized radiation geneticist network focus, profound exaggeration of risks, and collusions with the Rockefeller Foundation and the U.S. NAS (Calabrese, 2013, 2015a,b,d), and their massive LNT-promotion campaign immediately following BEAR I which affected

government, the scientific community, the media and the general public.

Since the deceptions (e.g., BEAR I) and significant errors (e.g., BEIR I) can be traced back to major scientific historical figures, Nobel Prize winners (i.e. Hermann Muller, George Beadle and Max Delbruck), prestigious U.S. NAS Committees (i.e. BEAR I and BEIR I) and at least one past NAS president (i.e. Detlev Bronk) (Calabrese, 2015a, b), it is important that the ideological history of cancer risk assessment in the U.S. be documented and become a part of the scientific and regulatory agency historical record to help ensure that vital public health policies and practices do not continue to be the offspring of a scientifically incorrect and dishonest past.

This historical assessment reveals a complicated dynamic amongst researchers, their colleagues, and rivals, all within a framework of politics, policies, social philosophies and personalities. Hermann Muller led the field, starting with redefining the concept of mutation and finding improved ways to assess it. Muller worked on these matters within a framework of wanting to be first, gaining recognition and its benefits and pushing this to extremes. One example of this obsession is seen when Muller claimed credit for an important discovery (i.e., first reported in *Drosophila* in which both genetic and cytological evidence of translocation were combined) that Curt Stern had made (Muller, 1929a, b; Muller and Painter, 1929; Stern 1926, Stern, 1929a, b). This resulted in getting the normally reserved Stern to confront Muller via correspondence. Muller was forced to publically apologize and correct the matter. However, symptomatic of this behavior and in this same general period, Muller would apparently manipulate an editor at *Science* to publish his discussion on X-ray induced mutation without providing any data, simply doing so as a means to ensure that he would be first - a tactic that was enormously rewarded.

Much of what Muller did over the next four decades was to preserve and defend the legacy of his breakthrough gene mutational findings/interpretation and the formulation of the Proportionality Rule (the LNT concept). In so doing, Muller would become the intellectual leader of the radiation genetics community, helping to ensure its importance and create new professional and funding opportunities. The principal challenge for Muller was the thoughtful reflections of Stadler and his capacity to create and test key hypotheses, the data from which would challenge Muller's interpretation of his "groundbreaking" findings. Stadler, who was unrelenting, objective and insightful, seemed to follow in the footsteps of Muller's Ph.D. advisor T.H. Morgan. These researchers, according to Muller (1946f), "abhorred what they termed "speculation", that they even distrusted the validity of the most essential lines of reasoning." Stadler and Morgan were leaders in that wave of skepticism whose participants "doubted the doubt 'til they doubted it out." (Muller, 1946f). In the end, Muller's interpretations were revealed via such follow up experimentation to be incorrect, that is, the very high doses he used produced heritable chromosomal, not gene, phenotype changes. More than 50 years later, with advances in nucleotide assessment methods, it would be shown that ionizing radiation could produce some gene mutations but at far lower doses (Asakawa et al., 2013; Colussi et al., 1998; Colussi and Lohman, 1997; De Serres, 1991; De Serres et al., 1967; Fossett et al., 1994; Furuno-Fukushi et al., 2003; Liu et al., 2003; Mognato et al., 2001; Nakamura et al., 2005; Nelson et al., 1994, 1995; Nohmi et al., 1999; Okudaira et al., 2010; Park et al., 1995; Russell and Hunsicker, 2012; Schwartz et al., 2000; Sokprasert et al., 2006; Thacker, 1986, 1992; Thacker et al., 1990; Toyokuni et al., 2009; Webber and De Serres, 1965; Yamada et al., 1996).

Muller loyalists, such as Charlotte Auerbach (1976) and others, would strain the limits of credibility by arguing that Muller was proven to be correct. These examples of revisionist history were based on an incorrect interpretation of his findings. Muller would excite the world with the claim he produced 40 gene mutations one weekend afternoon, more than the entire field had produced in a decade (Carlson, 1981). Yet, we now know that he was not producing gene mutations. In fact, Auerbach (1978) would eventually support Stadler noting that "Stadler tested many X-ray mutations of a particular gene in maize and found that all of them were deficiencies. Not long ago this conclusion was confirmed by experiments on a different gene in maze. Muller's evidence, gained from work with *Drosophila*, was less direct ..." (Auerbach, 1978). While Auerbach (1978) gave the proverbial nod to Stadler's perspective, this was done even more emphatically by two very close colleagues and friends of Muller. Crow and Abrahamson (1997) acknowledged that Stadler's deletion interpretations had been convincingly supported with modern analytical methods and that Muller was simply too stubborn, holding on too long to a discredited position. However, old deeply held and self-serving beliefs such as Muller's original error of interpretation, would mesmerize the scientific community making it impossible to change, as it became an accepted myth leading to the creation of the LNT single-hit model for cancer risk assessment, affecting vast changes in public health risk assessment policies and risk communication strategies, while being susceptible to political and ideological manipulation.

The Muller story reveals a conflicted character, the discoverer of an apparent major breakthrough, something that he greatly desired. At the same time, Muller was tortured with the possibility that he was wrong, spoke too soon, that his mutations were really only holes that the X-rays had poked in the chromosomes. He knew only too well that if his mutations were really only poked holes there really wasn't much new or great with his "breakthrough" discovery. Thus, we have a life that sought to "hold on", while trying to prove that he actually had produced "real" mutations.

Eventually the scientific story of Muller's chromosomal rather than gene mutations would progressively emerge, even if it would take up to five decades after he received his Nobel Prize. The influence of Muller continues to be dominantly reflected in current regulatory policy, which was based on poorly formulated science, in need of corrective transformation by major agencies, such as the U.S. EPA, which however have been unable or unwilling to do.

The story of Muller's discovery of gene mutation also speaks to the broader issue of science being self-correcting. Due to the courage and focus of Stadler, Muller's interpretations were challenged and tested in the laboratory. This inspired others, including perhaps a desperate Muller, to seek the truth.[9] These challenges would be tested in the domains of cytogenetics, position effects, transpositional elements, reverse mutations, and eventually with the use of the Southern Blot, PCR and other DNA technologies. We now know that Stadler was correct when he said that it was critical for the scientific community not to confuse the observation of transgenerational phenotypic changes at high doses with its unknown mechanism(s). In the end, Muller was trying in 1927 to discover the mechanism of evolution, and he "knew" that it must be gene mutation. However, he convinced the world (at least for a while), and maybe himself, that he had done so with his high dose *Drosophila* experimentation. However, the scientific community can thank Stadler and his collaborator McClintock for creating the necessary doubt that would eventually lead to science displaying a self-correction for Muller's claim. An important follow up question is whether regulatory agency "science", like that of experimental science, can be self-correcting. Now many years after Muller's

[9] In private letters with Altenburg (Altenburg, 1933c; Muller, 1933a), Muller would acknowledge problems with his reverse mutation explanation, the significant role of position effect and the influence of the mutable genes of McClintock.

incorrect interpretations were revealed, society still lives with a risk assessment model based on a mistaken set of Muller's interpretations. In 1995 Crow would reflect upon the impact of his generation of radiation geneticists in estimating ionizing radiation induced risks. With his then 20-20 hindsight Crow stated that Muller's leadership and action "oversold the dangers, and should accept some blame for what now seems, to me at least, to be an irrational emphasis by the general public and some regulatory agencies on low-level radiation ….."

In the aftermath of the BEIR I (1972) recommendation and the adoption of the LNT perspective for regulatory agency policy and practice came a spate of biostatistical models offering estimates of cancer risk in the low dose zone following the linearized perspective. The broad range of linearized models were highly speculative attempts to estimate risks at very low doses often using some feature of enhanced biological plausibility, such as the number of theoretical stages in cancer development, the role of interindividual variation, the incorporation of carcinogen bioactivation and DNA repair and other approaches (Cornfield, 1977; Crump et al., 1976; Hoel et al., 1975; Krewski and Brown, 1980; Rai and Van Ryzin, 1981). This type of modeling started, for the most part, in 1961, with the Mantel and Bryan paper, based on the carcinogen contamination Cranberry scare during the Kennedy-Nixon election of 1960 followed by a hiatus until the mid-1970s after the creation of EPA and OSHA when legislative and regulatory activities intensified. These models were constrained by linear assumptions as provided by the BEAR I Genetics Panel, the BEIR I Committee and the official adoption of LNT from BEIR I in 1975 by EPA [see recommendation to support the LNT single-hit model by a subcommittee of the U.S. Department of Health & Welfare (Hoel et al., 1975)]. In between these two NAS committees there were many advisory groups of a national and international nature that followed BEAR I (Calabrese, 2013, 2015a). The linear assumption of these models in the mid-1970s and later were based on the predecessor NAS committees, with BEIR I having the latest and most direct impact since it was based on mice rather than fruit fly model of BEAR I. Given the above historical reconstruction, the risk assessment modeling activities would have been considerably different had EPA determined that the default should be a threshold or hormetic model. The rapid dominance of linear cancer risk assessment modeling in the late 1970s would not have occurred without the recommendations of the two NAS committees. These modeling activities were derived from biostatisticians who tried to derive more biologically motivated linearized models, not being aware of the plotting, scheming, deceptions, misrepresentations and mistakes of the two NAS committees. In the end, the real leaders were Muller, his radiation geneticist followers and their institutional partners. The subsequent linearized modeling was simply the following of the linearity script as written by the NAS BEAR I Genetics Panel.

These convergent entities reached a type of critical mass during the NAS BEAR I Committee Genetics Panel, facilitating no less than a scientific, social, psychological and politically-based risk assessment revolution within the U.S. and essentially all other countries adopting the LNT model for cancer risk assessment.

11. Conclusions

1. Muller incorrectly assumed he induced gene mutations in 1927 when he demonstrated that X-rays induced transgenerational phenotypic changes in *Drosophila* (Calabrese, 2017a).
2. The Muller findings had a major impact on the scientific community. His non-peer-reviewed data (Calabrese, 2018) and incorrect interpretations were widely accepted (Campos, 2015).
3. This incorrect gene mutation mechanistic interpretation lead to the development of the "Proportionality Rule" for dose response in 1930 by Muller and the LNT single-hit dose response model in 1935 by Timofeeff-Ressovsky et al. (Calabrese, 2017a).
4. Muller's gene mutation interpretations were strongly challenged in the genetics community, especially by Lewis J. Stadler and Barbara McClintock, who showed that Muller's gene mutation interpretation lacked scientific proof and could be explained by other mechanisms (Calabrese, 2017a).
5. Limited research directed by Muller supported a conclusion that X-ray induced mutations were best explained by total dose, not dose rate and the genetic damage was cumulative, irreversible and the dose response was linear (Ray-Chaudhuri, 1939,1944)
6. Muller's total dose findings were strongly challenged in Manhattan Project research with far stronger studies (Calabrese, 2011a). These findings were improperly marginalized by leaders of the U.S. radiation genetics communities including Stern and Muller who misrepresented the data via deceptions, false statements and obfuscations (Calabrese, 2011a, 2015b, 2016).
7. The inappropriate awarding of the Nobel Prize in 1946 to Muller for producing "gene" mutations gave an enormous credibility to the LNT risk assessment model, facilitating its acceptance within the scientific, medical, regulatory and political communities. It is likely that the award had long lasting societal impact that facilitated worldwide acceptance of LNT.
8. It was incorrectly assumed by the scientific/regulatory communities and prestigious advisory groups (e.g. U.S. NAS BEAR I Committee, Genetics Panel) (Anonymous, 1956) in the late 1950s that the responses of mature spermatozoa to ionizing radiation induced "gene" mutation which were linear at high doses and independent of dose rate and such doses could be generalized to all cell types, doses and dose rates (Calabrese, 2015b, 2016).
9. These assumptions were incorrect because it was later (i.e. early 1960s) determined that mature spermatozoa lacked DNA repair, thereby preventing its capacity to repair radiation and chemically induced mutation as could occur in somatic cells (Calabrese, 2017b, c).
10. The NAS BEAR I Genetics Panel deliberately misrepresented their own research findings and hid their contradictory findings to promote the acceptance of the LNT model for regulatory agency risk assessment (Calabrese, 2015b, 2016).
11. William L. Russell at the Oak Ridge National Laboratory starting in late 1958 demonstrated that ionizing radiation induced mutations in mouse spermatogonia and oocytes were dependent upon dose-rate, not total dose as had been assumed, due to their capacity to repair DNA damage (Calabrese, 2017b, c).
12. The BEIR I (NAS NRC, 1972) Genetics subcommittee acknowledged the "mistake" of the NAS BEAR I Genetics Panel on dose-rate but still retained the LNT recommendation because the significant reduction in mutation rate in the spermatogonia as shown by Russell et al. had not regressed to control values as in oocytes. Nonetheless, the BEIR I Genetics Subcommittee suggested that findings from spermatogonia had greater capacity for generalization to somatic cells, due to repair capacities, as compared to mature spermatozoa. Russell referred to failed DNA repair capacity as an "odd phenomenon, restricted to spermatozoa and

occasioned by the peculiar nature of the specialized spermatozoan cell." (Calabrese, 2017b,c)

13. Selby (1998a,b) in 1995 detected a significant error in the Russell mouse specific locus test historical control group. This error was subsequently acknowledged and corrected by Russell and Russell (1996) along with Selby (1998a,b). If this error had not been made or had been corrected prior to the creation of BEIR I the mouse spermatogonia data that was used to support continuance of the LNT model would have supported a threshold or hormetic model based on the Russell and Selby corrections, respectively (Calabrese 2017b,c).
14. Summary: The LNT for cancer risk assessment originated due to (1) a critical mistake by Muller that he had discovered X-ray induced "gene" mutation, (2) the adoption of the LNT single-hit model was based on this assumption, (3) a mistake in generalizing the use of the DNA-repair deficient mature spermatozoa for somatic cells by BEAR I (4) deceptions and misrepresentations of the scientific record by leaders of the radiation genetics community, including the NAS BEAR I Genetics Panel and (5) failure to detect the error in the Russell Mouse Specific Locus Test control group, which would have precluded support for LNT. EPA then extended the error by adopting LNT for cancer risk assessment, stating in 1975 and 1977 that it was based on the now recognized erroneous dose rate findings of Russell as cited in BEIR I (1972).
15. It is ironic that the misrepresentation of the scientific record by this NAS BEAR I Genetics Panel to promote their ideological agenda stands in sharp contrast to the memorialized quote on the Einstein statute on the very grounds of the U.S. NAS in Washington, DC. It states: "The right to search for truth implies also a duty; one must not conceal any part of what one has recognized to be true." As the historical record shows the NAS BEAR I Genetics Panel did not follow the guidance of Einstein.

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Conflict of interest

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On the origins of the linear no-threshold (LNT) dogma by means of untruths, artful dodges and blind faith

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ABSTRACT

This paper is an historical assessment of how prominent radiation geneticists in the United States during the 1940s and 1950s successfully worked to build acceptance for the linear no-threshold (LNT) dose–response model in risk assessment, significantly impacting environmental, occupational and medical exposure standards and practices to the present time. Detailed documentation indicates that actions taken in support of this policy revolution were ideologically driven and deliberately and deceptively misleading; that scientific records were artfully misrepresented; and that people and organizations in positions of public trust failed to perform the duties expected of them. Key activities are described and the roles of specific individuals are documented. These actions culminated in a 1956 report by a Genetics Panel of the U.S. National Academy of Sciences (NAS) on Biological Effects of Atomic Radiation (BEAR). In this report the Genetics Panel recommended that a linear dose response model be adopted for the purpose of risk assessment, a recommendation that was rapidly and widely promulgated. The paper argues that current international cancer risk assessment policies are based on fraudulent actions of the U. S. NAS BEAR I Committee, Genetics Panel and on the uncritical, unquestioning and blind-faith acceptance by regulatory agencies and the scientific community.

1. Introduction

In the course of recent assessments of the historical and scientific foundations of dose responses models, it was learned that the linear dose response model was deliberately promoted to advance ideological agendas of some of the world's most prestigious radiation geneticists (Calabrese, 2008; Calabrese, 2013a, 2015a, 2015b). These individuals intentionally misled/deceived the scientific and world communities at the highest possible levels, including in a 1946 Nobel Prize Lecture (Calabrese, 2011a; Calabrese, 2012), in their scientific publications (Calabrese, 2011b; Calabrese, 2013b; Caspari and Stern, 1948; Muller, 1950a, 1954; Uphoff and Stern, 1949), in their role as members of the U.S. NAS (Calabrese, 2013a; Calabrese, 2015b, 2015a) and in publications of the NAS [BEAR Committee, Genetics Panel – (Anonymous, 1956a; National Academy of Sciences NAS)/National Research Council NRC, 1956). Collectively, these deceptive actions became highly significant when they facilitated an unchallenged and blind-faith adoption of the Linear Dose Response (LDR) model for cancer risk assessment of ionizing radiation and later of chemical carcinogens (Calabrese, 2011b, 2013b, 2009a). The adoption of the LDR model affected the magnitude of financial resources involved in regulatory actions, toxic tort decisions and medical practices; it also affected risk communication messages to the general public, educational practices, governmental research funding priorities, as well as decisions related to lifestyle and child rearing.

The impact of these deceptions has been substantial and, to this day, they significantly affect and dominate regulatory policies and risk assessment practices. Since these disturbing findings were published as a series of separate papers in diverse scientific journals, (e.g. mutation, radiation and toxicology journals) (Calabrese, 2015b, 2015a, 2011c, 2012, 2011b, 2013b, 2009a, 2014a, Calabrese, 014b), it has become necessary to develop an integrated and holistic version of this complex story. In addition, newly unearthed materials on key individuals have been discovered and incorporated herein to clarify previous historical frameworks. Finally, critical feedback recently received from reviewers, editors and others in the research community has proven invaluable in tempering the perspective and improving the content and context of this assessment.

This paper follows an historical timeline, starting with the professional/scientific relationship between Hermann Muller and Curt Stern and their subsequent collaborations on ionizing radiation during the Manhattan Project. The many, and, at times, bizarre ways in which Stern tried to prevent acceptance of the threshold model supportive findings of Ernst Caspari, a member of

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the Manhattan Project team, in order to promote the LNT model, are detailed. Muller's Nobel Prize Lecture with emphasis on his assessment of the nature of the dose response in the low dose range, especially in light of the Caspari findings, is critiqued, leading to an assessment of how he and Stern acted to cover up Muller's Nobel Prize Lecture deceit via obfuscation of the Manhattan Project findings and the strikingly false subsequent statements of Muller in the scientific literature. The paper then assessed how the leadership of Muller and Stern profoundly affected beliefs on dose response within the genetics community during the 1950s, especially seen through the actions of the NAS BEAR I Genetics Panel in 1956 which assured the acceptance of the LNT by falsifying and fabricating the research record, thereby constituting scientific misconduct at the highest possible level.

2. The Curt Stern–Hermann J. Muller connections

Previously, this author had extensively researched the history of the non-linear (hormetic) dose–response model, its scientific foundations and its failure to thrive and out-compete the linear no-threshold (LNT) dose–response model during the first half of the 20th century (Calabrese, 2011b, 2005, 2009b; Calabrese and Baldwin, 2000a, 2000b, 2000c, 2000d, 2000e). As a continuation of this research activity, efforts have been exerted to assess in detail the historical and scientific origins that have resulted in the validation and acceptance of today's LNT model. During this investigation, it became evident that the role of Hermann J. Muller was essential to the adoption of the LNT model and needed greater clarification.

During this assessment of Muller, interest grew in the research activities of the Manhattan Project at the University of Rochester, especially those under the direction of Curt Stern who employed the fruit fly to investigate the nature of the dose response in the low dose range. Stern was of particular interest because he had a long personal and professional relationship with Muller that would markedly impact the LNT deception story. Stern had helped to organize the Fifth International Genetics Congress in Berlin during the fall of 1927 (Carlson, 1981). It was at this meeting that Muller first presented his landmark findings on X-ray-induced mutations in fruit flies (Muller, 1927, 1928), research that would eventually lead to his Nobel Prize in 1946 (Muller, 1946a). Later, Muller and Stern would have a conflict over Muller's deliberate failure to acknowledge a prior discovery by Stern that provided proof for the linear arrangement of genes, an issue that was then a very significant question in biology. Stern would challenge Muller on this point directly via a carefully documented letter dated August 8, 1929 [American Philosophical Society (APS) (American Philosophical Society, 1929a). Stern informed Muller that his earlier publication in Biologischen Zentrablatt (September, 1926) addressed the "theory of the linear arrangement and have specifically stated it in the title of the paper". Stern concluded his letter to Muller with the statement that his manuscript "had been written before your [Muller's] first papers about them appeared." Nearly six weeks later, in a letter dated October 3, 1929, Muller would respond "I am very sorry to have omitted mention of your work in my discussion of translocation and not to have given you credit for having made the first cytological demonstration of a genetically demonstrated translocation and pointed out its significance for the theory of linear arrangement". He then indicated that he had enclosed a "carbon copy of a note I am sending in on the subject to the American Naturalist, which I hope you will consider as rectifying this mistake" (American Philosophical Society, 1929b). While Stern caught Muller in a significant professional indiscretion, he let Muller "control" the narrative by not objecting to Muller's version of the correction. Nonetheless, this arrangement proved to be acceptable to Stern as seen in an October 23, 1929, letter from Stern to Muller, restoring a positive tone to their relationship (American Philosophical Society, 1929c). One could speculate what might have happened to the LNT story if Muller and Stern had not reconciled, possibly preventing Muller's involvement in the Manhattan Project as described below.

3. The Manhattan Project: Curt Stern and LNT

After Stern[1] initiated research on the Manhattan Project in 1943, he contacted Muller, then a professor of biology at Amherst College (1940–1945), to serve as a consultant to the project. Under normal circumstances this might have been routine, but Muller had a questionable past, abandoning the US to live and research in the Soviet Union from about 1934–1938 (Carlson, 1981). Stern nonetheless obtained approval by the U.S. government for Muller's participation in the radiation genetics project. Muller's involvement proved to be extensive, involving detailed technical written communications with Stern and other team members, visits to the University of Rochester, and a donation of his Muller-5 strain of Drosophila (Calabrese, 2011c).

The Manhattan Project of Stern was designed to expand the study of high dose ionizing radiation on genomic mutations to include the area of chronic, lifetime exposures at relatively low doses and very low dose rates. The first experiment under Stern's direction was an acute (i.e., short duration) exposure study over a broad dose range. It was conducted by Warren Spencer, a professor at the College of Wooster with a PhD from Ohio State University in the area of Drosophila biology. Previous research by several of Muller's students (Hanson and Heys, 1929, 1932; Oliver, 1930, 1931), at very high doses and over a limited dose range, provided support for the hypothesis that the nature of the dose response for X-ray-induced mutation was linear.

In the Spencer study, the effects of X-rays were assessed on sex-linked recessive lethality using Drosophila with acute/short term (2–40 min) exposures and a dose-rate ranging from 10 to 96 r/h. This resulted in a range of cumulative doses from 4000 r down to 25 r (i.e., lowest cumulative dose yet tested). Following a data collection period from December, 1944 to June, 1955, Spencer reported that X-rays induced gonadal mutations in a manner that were linear across the dose response continuum, just as Stern and Muller had predicted (Calabrese, 2011c).

Ernst Caspari, a Ph.D. in insect behavior, directed the next study. From October 1945, to August 1946, Caspari assessed the effects of gamma rays on Drosophila sex-linked recessive lethality. In Caspari's study the females were first mated, placed on an egg laying suppression diet, and then exposed to the gamma radiation (2.5 r/day) for 21 days with sperm stored in the female's spermatheca. In the Caspari study, there was an aging component to the sperm that was not in the Spencer study. The dose rate used in Caspari's study was much lower (13,200 times lower) than that used in Spencer's acute study at the same cumulative dose (Calabrese, 2011c).

The data from the chronic exposure study of Caspari supported a threshold dose–response model. Stern initially rejected the

[1] In the case of the University of Rochester mammalian radiation geneticist Donald Charles, despite the use of over 400,000 mice, his research was largely unproductive, with no methodologically-based technical publications during the time of the Manhattan Project which ended in 1946 (see Charles (1950) for a brief descriptive paper). An additional summary paper (Charles et al., 1961) was published [after Charles's death (Anonymous, 1955a)] that tried to salvage the research effort with no obvious success. The failure of Charles to deliver a scientifically significant product for the Manhattan Project, given the level of resources directed to it, represented a substantial failing.

interpretation of Caspari as seen in written correspondence (American Philosophical Society, 1947a). Stern thought the findings were aberrant due to an unexpectedly high mutation rate of the "controls" that obscured a linear dose response, yielding only the appearance of a threshold response. Despite this rejection by his mentor, Caspari dug into the published literature and found convincing support for his rather than Stern's interpretation (Kaufmann, 1947; Muller, 1945, 1946b; Rajewsky and Timofeeff-Ressovsky, 1939). To his credit, Stern accepted the data-based argument of Caspari.

Caspari's data were unexpected and somewhat troubling to him because they challenged the linear paradigm of the radiation genetics community. Therefore, Caspari decided to send his findings to another leading researcher, Milisav Demerec, head of genetics at Cold Spring Harbor, for review and comment. Caspari was looking for a way around this problem (i.e., alternative interpretation) and hoping that the influential Demerec might offer a solution. Reflecting the bias of the radiation genetics research community at this time, Demerec wrote back to Caspari, acknowledging the problematic nature of the data, and rather than himself providing the hoped for insight, asked Caspari what could be done to "save the hit theory" (American Philosophical Society, 1947b). There was little question that the Caspari data had created a problem and, in fact, it would be referred to by Stern as a "problem" in future correspondence [Letter of Stern to Noviski – (American Philosophical Society, 1948). Demerec would later become a member of the BEAR I Committee, Genetics Panel that recommended the acceptance of the linear dose–response model.

While Stern seemed to accept Caspari's findings that supported the validity of his control data, he nonetheless challenged the authenticity of the data in other ways. The manuscript that Stern and Caspari developed in the late summer/early fall of 1946 contained a six-page discussion, mostly arguing that Caspari's (rather than Spencer's) findings should not be accepted until it could be shown why his threshold-supporting data differed from the earlier linear dose–response findings of Spencer. This position, in and of itself, was problematic in that the two papers had several dozen important methodological differences (e.g., temperature of 18 °C vs. 24 °C, egg-laying suppression vs. enhancement diets, irradiation by X-rays vs. gamma rays, young vs aged sperm, male vs female exposures and numerous other differences – [see Table 2, (Calabrese, 2011c), making it virtually impossible (if not impractical) to resolve the differences.

Even though the Caspari study adopted technical and methodological improvements over the Spencer study and had avoided serious operational errors of the Spencer study (e.g., Spencer's failure to control temperature, his combining of treatment groups with the same cumulative exposure but with dose rates that differed by up to 2.5 fold, his failure to match control and treatment groups over the same time periods, and his inconsistent calibration of the X-ray machine, etc.) and errors in the modeling of low dose responses (see detailed criticisms – (Bonnier and Lüning, 1949; Bonnier et al., 1949), it was strangely the Spencer study with its linear dose response that became the gold standard and not the Caspari study.

Discussion in the Caspari paper, as noted above, made it clear that the findings in support of a threshold should not be accepted until the differences between the two papers could be resolved. As untenable as this position was, Stern's actions were even more inexplicable as he would not place a similar constraint upon the flawed Spencer paper that supported linearity. It is bizarre, if not unheard of, for investigators to ask the scientific community not to accept the validity of their findings until it could be reliably determined why their findings differed from a study of considerably lesser quality and reliability. Moreover, not placing at least the same constraints on the weaker study, for which Stern was also a co-author, calls into question the investigator's non-biased and objective approach to research. As a very accomplished scientist, Stern should have known that resolving differences between these two studies was not realistically possible.

Stern's unusual behavior makes sense when viewed as an attempt to blunt any challenge to the linear dose–response model (i.e., by demanding that the data of Caspari not be accepted). Stern ensured the success of this strategy by sending the Spencer and Caspari manuscripts to his own journal, *Genetics*, and by fully controlling their publication, including the Caspari discussion. There is no evidence that he submitted either of the papers for an independent peer review as the papers were submitted to the journal on November 25, 1947, and published less than five weeks later in January 1948 (Caspari and Stern, 1948; Spencer and Stern, 1948).

At this point it was not clear whether Muller had seen the Caspari data prior to his Nobel Prize Lecture on December 12, 1946. During the Lecture he disavowed any possibility that a threshold dose response could occur in the induction of mutations by ionizing radiation. He demanded a switch to the linear dose–response model, stating, "there is no escape from the conclusion that there is no threshold" (Muller, 1946a). Not knowing whether Muller had seen Caspari's data in support of a threshold model prior to his Nobel Prize Lecture, several science historians with considerable knowledge of Muller and that era were then contacted. Yet, none of these attempts answered the question. Fortunately, substantial correspondence between Muller and Stern, Caspari, Spencer and others was obtained from archival libraries. The archived records revealed that Stern wrote to Muller on September 24, 1946, to request his services in reviewing the Caspari manuscript in preparation for journal submission. A follow-up letter from Muller on September 27, 1946, accepted this invitation and on November 6, 1946, Stern sent the manuscript to Muller at the University of Indiana. On November 12, 1946, Muller acknowledged receipt of both the letter and the manuscript. He also indicated that he had briefly read the manuscript and recognized that the findings supported a threshold dose response, seriously challenging the linear model. Muller strongly encouraged Stern to find the means to undertake a replication study and indicated that he would try to provide a detailed evaluation prior to his Nobel Prize trip to Europe in early December. Clearly, this November 12th letter acknowledged that Muller had seen Caspari's data, understood the challenge to the linearity model, was not dismissive of the findings and acknowledged Caspari's competence and the need to repeat the findings (see Table 1 for the series of Stern/Muller correspondence statements).

Muller's evaluation of the Caspari manuscript occurred five weeks after his Nobel Prize Lecture in the form of a detailed letter to Stern dated January 14, 1947 (American Philosophical Society, 1947c). Based on this analysis, Muller had not changed his opinion. He unequivocally stated that he could not find any meaningful criticism of Caspari's work (i.e., "I have so little to suggest in regard to the manuscript.") and he restated the need to replicate the findings (i.e., "Unfortunately, therefore a replication seems to be imperative."). Thus, the statements written in private by Muller to Stern were those of a scientist, while his unequivocal public rejection of the threshold model at the Nobel Prize Lecture was deceptive and not without ideological underpinnings. Knowing that uncertainty existed in the low dose zone and that further study was needed, Muller could have acted more forthrightly by pronouncing his conditional rather than categorical support of the LNT model in Stockholm. Even four months later he remained steadfast and continued to advocate his unqualified support for the linear dose–response model. In a presentation to the New York Academy of Medicine in 1947, he stated that "there is then absolutely no threshold dose…and even the most minute dose carries a

Table 1
Letter correspondence demonstrating that Muller had seen and considered Caspari's threshold supportive findings prior to his Nobel Prize lecture on December 12, 1946 (American Philosophical Society, 1946-1947; Calabrese, 2011c).

September 24, 1946 – Stern to Muller:
"Dr. Caspari's report on his work is now being typed and I wonder whether we could bother you with sending you a copy for your new comments."

September 27, 1946 – Muller to Stern:
"Also, I'd be glad to see Caspari's paper too."

November 6, 1946 – Stern to Muller:
"Caspari's manuscript has finally been typed and we would appreciate very much your critical reading of it."

November 12, 1946 – Muller to Stern:
"I have just arrived from an absence of over 2 weeks and find the Caspari manuscript here waiting for me. Unfortunately, it catches me again when I am in a tremendous pressure of work, trying to make up both the trip just passed and for another one to come in a few weeks. However, I see that it is very important and shall do all I can to go through it in a reasonable time, surely before I leave again early in December. I hope that Caspari can wait that long if necessary. In the meantime I wonder whether you are having any steps taken to have the question tested again, with variations in technique. It is of such paramount importance, and the results seem so diametrically opposed to those which you and the others have obtained, that I should think funds would be fourth coming for a test of the matter. It is not, of course, that I doubt Caspari's reliability at all, but only that I naturally share the same doubts which he himself expressed. Of course, I am only judging by the summary and a quick glance through the paper, and have not had the opportunity to read the details."

definite chance of producing a change exactly proportional to the size of the dose" (Muller, 1948).

Muller's statement in a letter to Stern (American Philosophical Society, 1947c) about having "so little to suggest in regard to the [i.e., Caspari] manuscript" may not have been quite truthful, as Muller himself was most likely responsible for the only two changes introduced to the paper prior to its submission to the journal Genetics. With the exception of these two changes, the published study in Genetics was identical in every way to that paper which was sent to both Muller for his pre-submission review and to the Atomic Energy Commission (AEC) in 1947. In the journal version, the first and most significant change was the deletion of a key sentence in the Conclusion of the 1947 AEC version (Caspari and Stern, 1947). The deleted sentence is as follows: "From the practical viewpoint, the results presented open up the possibility that a tolerance dose for radiation may be found, as far as the production of mutation is concerned" (page 15). This statement indicated support for the threshold dose–response model. The second change was significant in that it added the name of Hermann J. Muller to the Acknowledgments of the published paper. It seems more than just coincidence that the only two changes imparted to the journal version consisted of (1) the deletion of a concluding statement in support of a threshold dose–response model and (2) the simultaneous addition of Muller's name to the acknowledgment section. There should be little doubt that removing the threshold conclusion statement was of profound benefit to Muller as it would help him sustain the ideological dominance of his favored LNT model. Muller clearly had the means, motive and opportunity to mitigate the threat imposed by Caspari's paper on the LNT model. So, was Muller responsible for deleting the key concluding sentence in support of a threshold model? Well, we may never know for sure, but strong circumstantial evidence seems to point in that direction.

In the aftermath of the Nobel Lecture, Stern followed Muller's suggestion to repeat the findings of Caspari. However, his two experienced doctoral researchers, Spencer and Caspari, had left for the College of Wooster and Wesleyan University in Middleton, Connecticut, respectively. Consequently, Stern tapped a new Master's student, Delta Uphoff, a recent graduate of Russell Sage College of Albany, New York, to replicate the Caspari research (Calabrese, 2011c). Data from her first experiment piqued Stern because her control values for mutation rates were about 40% below those found in the literature, including Caspari's study. Stern expressed his concern to Muller and also asked Muller to share his largely unpublished data with him on variation among controls for the mutation rates of aging sperm in the fruit fly. In a series of letters between Muller and Stern, Muller confirmed that the findings of Uphoff were not reliable and that the unpublished (and published) data were supportive of the Caspari control results. Muller's data led to an acknowledgment in the discussion section of the Uphoff and Stern manuscript (Uphoff and Stern, 1947) that the control group data were not interpretable and that the low control group value was most likely due to investigator bias. Thus, in a rather unprecedented move, Stern was quick to place blame on the inexperienced Uphoff. This manuscript, which importantly acknowledged the assistance of Muller, was sent to the Manhattan Project/AEC where it became classified and publicly unavailable. Thus, the acknowledgment by Stern of Uphoff's unreliable control data, together with the letter exchanges between Muller and Stern regarding the reliability of Caspari's control data, clearly indicated that Muller had strong confidence in the Caspari and not the Uphoff control data (Calabrese, 2011b).

Stern then had Uphoff undertake a follow up replication study. She again reported a similar unacceptably low control group response. As in the first case, the findings were again not interpretable. Finally, in a third experiment that was undertaken, another problem arose. This time it was not the control group, which seemed to respond as expected, but the treatment group whose response far exceeded that predicted by a linear dose–response model. At this point, Uphoff had finished her degree and eventually joined the National Institutes of Health (NIH) as a staff researcher. However, the damage was done to the Stern initiative regarding the Manhattan Project/AEC. Each attempt to replicate the Caspari findings had significant problems. Could anything be salvaged?

In January of 1949, Stern decided to submit a technical note to the journal *Science*, integrating the five major experiments conducted under his direction for the Manhattan Project/AEC. These involved the studies of Spencer and Caspari and the three Uphoff replications. In this *Science* paper, Stern attempted to rescue the first two Uphoff experiments that he already knew had aberrant control groups (Uphoff and Stern, 1947) and, according to multiple letter exchanges (Table 2), Muller also knew. Stern also chose to ignore certain data that were not in support of the linear model (Caspari and Stern, 1947) and, again attacked the Caspari study as aberrant even though nothing had changed except for the occurrence of even more data supporting the reliability of Caspari's

Table 2
Stern–Muller temporal letter exchange concerning the aged-stored sperm control mutation rate [see (Calabrese, 2013a) – supplement for a more complete letter exchange].

Curt Stern wrote a letter to Hermann J. Muller on January 22, 1947 (American Philosophical Society, 1947d) informing him that "At the present time it looks as if our new control data [probably the results of the first three months of the first Uphoff experiment; note that her first month's reading was an especially low mutation rate of 0.005%] for aged sperm are considerably below those of Caspari's." He then asked Muller to "send me your figures on rate of sex-linked lethal in sperm aged several weeks, (most desirably, if you have them, data on three weeks), in comparison to control data from non-aged sperm?"

On February 3, 1947 (Lilly Library, 1947) Muller answered by stating that "... sperm of males which are about a week old and have been copulating freely [as in Caspari's experiment] during that period have only about 0.07 or 0.08 per cent of lethal. Thus the latter sperm, after three weeks, should contain something like 0.28 per cent of lethal."

control group. These multiple flip–flops by Stern were befuddling and surely required explanation, yet none were provided. The inferior Spencer study continued to receive strong support from both Stern and Muller even though, as noted above, it had very significant problems, none of which was noted by Muller in his letters to Stern regarding the research of Spencer, September 13, 1946 (American Philosophical Society, 1946) and Caspari on January 14, 1947 (American Philosophical Society, 1947c).

The *Science* paper of Uphoff and Stern (1949) was beneficial both to the LNT model and to Muller himself as its chief advocate. Stern was successful in artfully molding the interpretations of experimental data to fit the LNT mantra. He achieved this goal while the scientific community remained unaware that he and Uphoff (with Muller's support) had acknowledged just a year earlier that their own findings were not interpretable. Now, in the absence of any new data, these same findings were not only acceptable but also argued in support of the LNT model. And Caspari, who had successfully challenged Stern earlier, now remained silent as his findings in support of a threshold model were being undercut in favor of Muller's LNT model. As for Muller, he must have surely felt relief as he was spared the trouble of having to defend his highly deceptive comments at the Nobel Prize Lecture. Since the *Science* paper (Uphoff and Stern, 1949) was only a short one-page note, consisting mostly of a single table, Stern and Uphoff promised the science community a more detailed follow-up paper that would provide important methodological information and other relevant data. However, Stern and Uphoff never did publish the promised follow-up study and there exists no evidence that their colleagues in radiation genetics ever requested them to do so.

The strategy of Muller and Stern to deceive and obfuscate on the nature of the dose response in the low dose zone was successful. This is evidenced by the fact that the Spencer and Stern paper (Spencer and Stern, 1948) and the *Science* technical note by Uphoff and Stern became the highly influential and commonly cited papers. These "flawed" papers provided the scientific foundations upon which the linear dose response model was justified to the science community and, nearly a decade later, to the U.S. Congress at hearings (Congressional Hearings of 1957) partially inspired by the NAS report of the BEAR Genetics Panel (Calabrese, 2013a; Crow, 1957; Glass, 1957; Joint Committee on Atomic Energy, 1957; Muller, 1957). On the other hand, the technically superior and more relevant paper by Caspari in support of a threshold interpretation received virtually no attention; it was, in essence, unfairly but successfully marginalized. Various leaders in the field repeated false limitations of the Caspari study (Higgins, 1951; Jolly, 2004; Singleton, 1954) that were inspired by the deceptive comments of Stern and Muller e.g., (Muller, 1950b, 1954; Uphoff and Stern, 1949). For example Singleton (1954) echoed that Caspari's study could not be accepted because it had an aberrantly high control group. Ironically, this was Stern's original challenge that already had been so effectively rebutted by Caspari and Muller's own data (see Table 2 for letter exchange between Stern and Muller).

After the *Science* paper, Muller published several papers that repeatedly criticized Caspari's study as being too unreliable because of its high control group data. For example, in his 1950 article entitled "Some present problems in the genetic effects of radiation" in the *Journal of Cellular and Comparative Physiology*, Muller (1950a) provided an explicit characterization of the findings produced by Caspari and Stern (1948). Muller states on page 10 "A recent paper by Spencer and Stern....extends the principle (i.e., one-hit principle) down to total doses of 50 r and 25 r". In the next paragraph, he states: "It is true, in a parallel paper....Caspari and Stern have reported results somewhat deviating from the above." In footnote 1 on page 10 of the article cited above, Muller adds "Uphoff and Stern have published a report of further work, with doses as low as 50 r, given an intensity as low as 0.0165 r per minute. The results obtained are entirely in conformity with the one-hit principle. A consideration of these results, together with the early work, leads to the conclusion that the deviation first referred to (the Caspari and Stern (1948) findings) was caused by a value for spontaneous mutation rate that happened to be unusually high." Although this repeatedly false criticism by Muller was indeed highly disconcerting, other geneticists seemed too willing and ready to accept it, more or less on 'blind faith" and without proper review and verification. If they had chosen to follow the data originating from Muller himself (Muller, 1945) and his own graduate students (Byers, 1954; Byers and Muller, 1952) as well as others (Graf, 1972; Rinehart, 1960) then perhaps the findings of Caspari, and not of Uphoff, would have received public attention and support. Thus, Muller continued to perpetuate a false view that was discredited by his own statements/data. Shamefully, there is no evidence that anyone challenged Muller on these contradictions. Furthermore, Muller claimed that the research of Delta Uphoff and Curt Stern was "entirely in conformity with the one-hit principle" (Timoféeff-Ressovsky et al., 1935). What Muller neglected to state was that Uphoff's first two experiments displayed an aberrantly low control group responses based on Muller's own extensive data involving some 200,000 fruit flies (Muller, 1946). A letter from Curt Stern to Ernst Caspari (fall 1947) (American Philosophical Society, 1947a) addressed the control group issue. It states: "The radiation data continues to be puzzling. Delta's difference between control and exper[imental group] appears to be due mainly to a much lower control group value than yours. However, Muller informs me that this data give an aged control value close to yours. Thus, my first idea that your results could be "explained away" by assuming that your control value happened to be unusually high, seems unlikely. Rather does Delta's control appear too low". Muller's false and self-contradictory statements about Caspari's findings may be understood within the context of his ideological focus on establishing the LNT model for risk assessment and in the preservation of his legacy – a legacy that would have been severely tarnished if the deceptive remarks he made during his Nobel Prize Lecture had been discovered.

A further example of Muller's duplicity in promoting the LNT concept was his inaccurate characterization of the dose-rate used in the Uphoff experiments (Uphoff and Stern, 1949), which was 0.00165 r/min, i.e., 50 r in 30,240 min or in 21 days) (Uphoff and Stern, 1949). In his paper entitled "Radiation Damage to the Genetic Material" in the *American Scientist*, Muller (1950b) indicated that their research extended "the principle of proportionality of mutation to doses down to doses of 50 r and 25 r and of less than 0.001 r/min with a time–intensity relation differing by over 400,000 times from that of our high intensity dose." By using the incorrect dose-rate of <0.001 r/min (instead of 0.00165 r/min) Muller (1950b) extended the linear extrapolation over 400,000-fold, some 150,000-fold greater than what the correct dose-rate would have predicted. Just as in the case of validating the Uphoff control groups (discussed above), no one challenged Muller on this point. It is doubtful that Muller's actions was a simple editorial-typo as it involved two discrete changes, removing a 65 and adding a $<$ sign. Furthermore, Muller (1950b) had correctly cited the value as 0.00165 r/min in a previous paper.

4. The NAS BEAR I Committee Genetics Panel

The actions of Muller and Stern (cited above) were critical in persuading the radiation genetics community to adopt the LNT perspective, which was reinforced at multiple levels. By the early 1950s, according to Crow (1995), LNT had become the dominant

view of this group, despite having little support elsewhere. This timing is important as it set the stage for the actions of the NAS Genetics Panel on the Biological Effects of Atomic Radiation, which issued its landmark report on June 12, 1956, and published its technical report in the journal *Science* (Anonymous, 1956a) later that month.

Since the nature of the dose response in the low dose range was a critical issue, it would be important to know how the Genetics Panel debated this issue, what the nature of the debate was, what votes were taken on the general dose response issues, and who were the leading participants in the discussions. The Genetics Panel formally met on November 20 and 21, 1955, at Princeton University and on February 5 and 6, 1956, in Chicago. Transcripts were obtained for both of these meetings. The Panel had a follow up meeting March 1, 1956, with partial attendance and only a meeting summary (i.e., no transcript was taken). Intermeeting communications among Panel members were encouraged via the exchange of working documents and draft materials. These communications were typically preserved in the historical record, and it was generally possible to obtain copies of papers and correspondences of the Panel members on BEAR I from their respective institutional libraries. Although that which was archived varied according to each person, an effort was made to obtain complete sets of information on all Panel members. As a result, copious files on Panel members were obtained, enabling the reconstruction of Panel activity to a high degree.

The transcripts of the Genetics Panel indicate that the members debated neither the nature of the dose response at low doses, the expectations of a linear or a threshold dose response nor any other dosimetric issue. Dr. Tracy Sonneborn from the University of Indiana, a Panel member and colleague of Hermann Muller, wrote a general guiding statement of principles for the Panel to follow; see (Calabrese, 2015a) – Supplementary material. The basic framework consisted of four principles, i.e., that all doses of ionizing radiation were (1) harmful, (2) irreversible, (3) cumulative, and (4) displayed a linear dose–response relationship. No member of the Panel challenged these perspectives. In fact, at the Princeton meeting of the Genetics Panel, Professor Alfred H. Sturtevant from California Tech asserted his disdain for the medical profession that still adhered to an anachronistic belief in the threshold dose response model. Sturtevant stated that he had "no doubt about the correctness of the linear dose response" and that any effort to further document support for it would only be for the "propaganda value" needed to educate and convince the non-geneticists; see (National Academy of Sciences (NAS), 1955) – Transcription, November 21, 1955.

The Panel's single-minded uniformity of belief regarding the nature of the low-dose response was profoundly significant as it tended not only to limit discussion and preclude debate but also to ensure adoption of their preconceived notions. Due to this lack of discussion and absence of debate, the Panel was challenged to identify other activities that could productively fill its meeting times. The Panel Chair, Dr. Warren Weaver of the Rockefeller Foundation, forged ahead and challenged the 13 geneticists on the 17-member Panel to provide estimates of genetic damage to the U.S. adult population given a specific exposure to the gonads. The purpose of this exercise was to see how closely individual estimates of damage might converge among a blended mix of high level expert geneticists who had collective experiences studying an array of diverse populations, including fruit flies, bacteria, paramecia, yeast, human populations and clinical patients, among others. Weaver argued that a greater convergence (i.e., agreement) among individual damage estimates would tend to yield a greater confidence by society in the Panel's scientific conclusions and recommendations. Although one geneticist resigned from the Panel due to overriding academic commitments, the remaining 12 considered the challenge and the need to independently complete the assignment within about one month following the meeting of February 5–6, 1956. Of the 12 geneticists three (Tracy Sonneborn, Clarence C. Little and James V. Neel) eventually decided that there was too much uncertainty for the question to be quantitatively addressed with any degree of accuracy or reliability and that any population-based estimates would simply be misleading. For example, Neel stated that the scientific foundations needed to make such estimates of genetic damage were so uncertain that providing them would be a violation of his obligation to society as a scientist; see the April 6, 1956 letter from Neel to Weaver, cited in Jolly (2004). After the refusal of these three Panel members to participate in the exercise and provide estimates, the nine remaining geneticists may have had similar misgivings, at least to some extent, but nonetheless provided quantitative estimates of genetic damage within the prescribed time; see (Calabrese, 2015a) – Supplementary material.

When the Panel finally published its paper in *Science*, it indicated erroneously that six (instead of nine) geneticists took up the challenge and provided such estimates (i.e., "Six of the geneticists on this committee considered the ....problem."). This apparent discrepancy triggered a more extensive assessment of communications among panel members and related information regarding the estimates of damage. Chairman Weaver gave James Crow the task of organizing the submitted material and integrating tables listing the damage estimates of each participating geneticist. As a result of this process, it quickly emerged that there was considerable disagreement among Panel members concerning the identity and appropriate use of methods and assumptions in conducting the assignment. Thus, as one can imagine, confusion about the assignment and the lack of a clear protocol yielded estimates of extreme variability. Panel members were highly uncertain of their own estimates, which often radically disagreed with the estimates of fellow Panel members. In spite of the fact that each geneticist employed the linear dose–response assumption, the results of this exercise led to anything but a convergence. A close reading of all the contributions reveals that some of the "experts" had little idea how to approach the problem. This can be highlighted in the case of James Crow, the last surviving member of the Panel, who died in 2012. For example, on March 29, 1956, Crow stated (Crow, 1956): "I shall use as a minimum estimate a direct extrapolation from Drosophila and as a maximum some calculation from the sex-ratio in the Japanese cities. An estimate from mouse data turns out to be just about half way between these, so I shall use it as the most probably estimate." The non-sequiturs inherent in such biological reasoning demonstrate how poorly some of the leading experts addressed this issue. As the other geneticists expressed similar levels of uncertainty and disagreement, it is not surprising then that the Panel would share their documentation with neither external reviewers nor the interested public.

A major problem arose as a result of the extreme variability among the individual estimates. That is, the uncertainty of these estimates would erode public confidence in the Panel's pronouncements. Crow perceived the problem and memorialized his concern in a letter to Chairman Weaver of March 29, 1956: "The limits presented on our estimates of genetic damage are so wide that the reader will, I believe, not have any confidence in them at all." Thus, Crow believed that if the Panel shared its uncertainty with the public then the likelihood of winning their acceptance of any scientific and policy guidance would be seriously threatened. Crow then made a unilateral decision to exclude the estimates of three of the geneticists (i.e., Kaufmann, Wright and Demerec), the three with the lowest estimated damage values; see (Calabrese, 2015a) – Supplementary material for a detailed assessment for each of these three excluded values. Although Crow's decision

markedly reduced the amount of variation within the group, this initial "adjustment" was simply not enough to solve the variability problem. Crow then strongly urged the Panel not to share the six remaining and highly variable assessments with the scientific community and public. The Panel eventually voted on Crow's recommendation, and the majority decided in favor of it, thus essentially eliminating anyone from the interested public or the science community from critically examining the data or the process by which these estimates were derived. While a copy of the voting tally was obtained, specific information on votes of individual members was discovered for four members. Based on their preserved correspondence, (Calabrese, 2015a) – Supplementary material, Crow, Glass, Muller and Sonneborn all voted not to share the data.

The aforementioned analysis reveals that the Genetics Panel deliberately falsified the research record in the *Science* article by reporting that only six geneticists provided estimates of radiation induced genetic damage. This was patently false as nine geneticists provided detailed estimates within the prescribed period of time. There was no expectation and no established protocol for the exclusion of estimates as each geneticist on the Panel was considered an independent world-class expert in his own area of genetics. The person who excluded the three estimates was Crow, who lacked the authority to do so. In fact, the exercise on estimating risk of genetic damage was designed to develop a gage of expert agreement or lack thereof. Removing the three estimates was a deliberate act to obscure and mitigate the magnitude of disagreement and uncertainty that existed among the experts. Furthermore, the report did not even acknowledge that three other Panelists refused to participate in the exercise because too much uncertainty precluded the possibility of making any reliable estimates, (Calabrese, 2015a) – Supplementary material. Finally, the *Science* article contained an inaccurate estimate of response variability in the range of plus or minus ten-fold on either side of the mean. More specifically, the *Science* paper states, "These six geneticists concluded, moreover, that the uncertainty in their estimation of the most probable value was about a factor of 10. That is to say, their minimum estimates were about 1/10, and their maximum estimates about 10 times the most probable estimate". This 100-fold uncertainty markedly misrepresented the range of uncertainty of the six remaining Panel geneticists for estimating the next generation, which had a mean uncertainty value of 756 (312.5 median). See Table 1 of identified individual values in Calabrese (2015a) – Supplementary material.

The Genetics Panel of the NAS, as a group, therefore deliberately sought to misrepresent the research record in their landmark *Science* publication on three distinct aspects. These included: the incorrect statement that only six geneticists provided genetic damage estimates when nine did; the failure to report that three other geneticists refused to provide any estimates at all because of the high level of uncertainty of this exercise; and, finally, the uncertainty range for the six geneticists was given as 100 fold when the mean value was actually 756 fold. These actions of fabrication and falsification by the Genetics Panel were undertaken to ensure that governmental agencies, legislative bodies and the general public would be more likely to accept the Panel's LNT-derived policy recommendations for assessing the risk of ionizing radiation.

5. BEAR I Genetics Panel report – fallout

Following its acts of falsification and fabrication of the research record, the Genetics Panel continued to show its arrogance in the aftermath of the BEAR I Panel and at the start of BEAR II (fall, 1956). In this case, several leading biologists had requested that the Genetics Panel provide documentation that would explain/support its decision to recommend the adoption of the linear dose–response model for risk assessment purposes, (Calabrese, 2015b) – Supplementary material and Glass (1956). The biologists noted that the BEAR I Panel had proclaimed the correctness of the LNT model, but it failed to provide any written scientific basis for its decision. Since providing documentation to support major decisions is the main mission of any NAS Committee, the BEAR I Genetics Panel, by this standard, clearly failed to perform its mission. However, in a decision that may be difficult to understand, the Panel actually refused to do so, deciding instead to redirect its efforts to identifying research areas for future funding. Furthermore, it is highly unusual, if not astonishing, that the Panel actually informed the President of the NAS, Detlev Bronk that it had decided not to provide documentation to support the LNT recommendation. In fact, no documentation in support of the LNT decision ever existed at the time of the BEAR I Genetics Panel report on June 12, 1956, and now it would have to be written well after the fact – a serious problem in and of itself. Secondly, the Panel members openly noted that they preferred to spend their time identifying research priorities for funding opportunities, some of which would be of interest to their own research laboratories. No evidence has been found to suggest that President Bronk ever objected to the Panel's no documentation decision, which was shared with him in a letter from George Beadle, Chair of the BEAR II, Genetics Panel (Beadle, 1957) on September 11, 1957. Thus, the President of the NAS was complicit in the decision not to require the BEAR Genetics Panel to document its support of the LNT model.

The BEAR I and II Panels consisted of essentially the same individuals except for two changes. The Chair (i.e., Warren Weaver) stepped down so he could award grants from the Rockefeller Foundation to Panel members without an obvious conflict of interest, and one new person (TG Dobzhansky) who had been invited for BEAR I, but was unavailable at the time.

The BEAR I, Genetics Panel released their report amongst a flurry of media attention with front page stories in the *New York Times* (Laviera, 1956) and *Washington Post* (Haseltine, 1956). Other leading venues, including *US New and World Report* (Anonymous, 1956b), *The Saturday Review* (Muller, 1956), *Time Magazine* (Anonymous, 1956c, 1956a), *Science* journal (Anonymous, 1956c), *The Lancet* (Anonymous, 1956f, 1956g) and others, also had articles on the BEAR I Genetics Panel report. The *New York Times* called it the most extensive study ever conducted by such a leading group of experts. Yet, in retrospect the evidence shows that the effort failed in critical ways, especially in not even debating the key question concerning the nature of the low dose zone in the dose–response paradigm. The Panel proclaimed the validity of the linear model at the start and never felt the need to justify this fundamental decision, even following a subsequent challenge by leading biologists. Such inappropriate actions of the Panel continued, as it even deemed it necessary to fabricate and falsify the record in their key *Science* publication to ensure that their views would be accepted. All this was clearly expressed in newly unearthed records of the Panel's correspondence. The dishonesty of the Panel was nothing new as it was simply carrying on a tradition seeded a decade earlier by Hermann J. Muller at his Nobel Prize Lecture.

The explicit deceptions of some Panel members continued even some 35 years after the fact. For example, Panel member and geneticist Bentley Glass (Glass, 1991), in a book review about the Rockefeller Foundation, retold the BEAR I, Genetics Panel story reported in the 1956 *Science* article concerning how the Panel obtained its estimates of genetic damage in the U.S. population. Glass wrote that Chairman Weaver sought to overcome vast disagreements among Panelists by instructing them to return to their hotel rooms and work out their damage calculations individually.

The following day, Glass reports, the disagreements were profoundly diminished and a strong consensus emerged. The story by Glass may well be how he remembered the event but his memory is strongly contradicted by the factual record. The fabrications of Glass started with his "authoritative" quote from Weaver that inspired the geneticists to return to their rooms. The quote does not exist in the meeting transcripts. The story of Weaver sending Panelists to their hotel rooms to work on their estimates and of their returning the next day in triumphal consensus likewise never occurred. In fact, Weaver charged them to return to their respective homes and gave them about a month to work on the estimates. Thus, once again, based on the transcripts and substantial subsequent written communications, Glass bears false witness. Glass's most significant fabrication is that the Panelists actually reached a strong quantitative agreement. The consensus story was not real but faked by Weaver and the Panel as discussed above and detailed elsewhere, (Calabrese, 2015a) – Supplementary material.

The highly regarded Glass, among whose honors included being a President of the AAAS and Phi Beta Kappa, amongst numerous other honors, repeated, therefore, the long established false narrative, reinforcing the LNT mantra well into the modern era of risk assessment and doing so with great appeal to his authority. This is therefore the story of not only how the U.S. and world governments came to adopt the linear dose response for risk assessment but also how its origins were forged by deception, artful dodges and blind faith to become established, preserved, protected and reinforced by those very people (e.g. Genetics Panelists) and organizations (e.g. NAS) that society is supposed to trust.

6. The Rockefeller Foundation and the LNT

In 1954, the Board of Trustees of the Rockefeller Foundation (RF) developed the proposition that it was necessary for the United States (U.S.) to undertake a major assessment of ionizing radiation on humans and the environment. One of their Board members was Dr. Detlev Bronk, who was also serving at that time as the President of the Rockefeller Institute for Medical Research (which would become Rockefeller University in 1965) and President of the U.S. National Academy of Sciences (NAS). Prior to this time, Dr. Bronk had also been the President of Johns Hopkins University and the President of the American Association for the Advancement of Science (AAAS) in 1952. Bronk took the proposal of the RF Board of Trustees to the NAS and received permission to undertake this project as an official NAS activity (Hamblin, 2007). This new project was called the NAS Biological Effects of Atomic Radiation (BEAR) Committee. The project involved six independent technical panels for different areas of concern (e.g., genetics, pathology, oceanography and fisheries, agriculture, meteorology, and waste disposal and dispersal). The panels were created by Dr. Bronk and administratively overseen by the RF.

All six BEAR Committee expert panels were chaired by renowned experts in their respective fields except for the Genetics Panel, which was chaired by Warren Weaver, a mathematician and long-time administrator at the RF (Rees, 1987). Interestingly, Bronk selected Weaver to chair the Genetics Panel and, as such, this selection represented a striking deviation in panel construction and leadership. Although multiple individuals with considerable relevant scientific expertise and strong leadership skills were already on the Genetics Panel, none of them would be selected as Chair. Overlooked in the selection process were: George Beadle, the future President of the University of Chicago (and 1958 Nobel Prize winner); Alexander Hollender, the highly regarded scientific administrator at Oak Ridge; Clarence C. Little, the past President of the Universities of Maine and Michigan; and Milislav Demerec, Head of Genetics at Cold Spring Harbor.

In the selection of panel members, one suspects that Bronk and Weaver may have intended to "stack the deck" with radiation geneticists who supported the LNT. For example, Ralph Singleton was a radiation geneticist at the Brookhaven National Laboratory who at the time, questioned the linearity hypothesis and reported a non-linear relationship between mutation rate and dose rate, with disproportional increases at higher doses (Singleton, 1954; Richter and Singleton, 1955; Sparrow and Singleton, 1953). In an April 17, 1955 article in the *New York Times*, (Anonymous, 1955b) Singleton challenged the linearity concept for genetic damage stating "there probably is a safe level of radiation, below which no genetic changes occur." Singleton's expertise and the timing and topic of his publications would seem to have easily qualified him for membership on the Genetics Panel, assuming of course that the key objective was to form a panel representing diverse viewpoints to encourage discussion and thoughtful consideration. As it turns out, Singleton was not appointed to the Genetics Panel but to the Agriculture Panel of BEAR I.

The BEAR Panels were the creation of the RF, fully funded by the RF, administered by RF staff and directed by a member of the RF Board of Trustees, who was also President of the NAS. Not only did Dr. Bronk help to conceptualize the project, but he was also part of the organization that funded the project and led the organization that received the funding and oversaw the project, including guiding the selection of panel chairs and their members.

For a long time, the RF was a major funding organization for radiation geneticists, including members of the Genetics Panel. The funding of such members extended over three decades, much of which was during the employment of Weaver and also under his direction. As noted in Wynchank (2011) and prior to the creation of the Genetics Panel, the RF had funded nearly four million dollars to the University of Indiana for research in the area of radiation genetics alone. Such funding supported the research activities of Professors Sonneborn and Muller, both members of the BEAR Genetics Panel.

Weaver was clearly aware of the importance of RF funding to radiation geneticists and showed no reluctance in connecting the Panel's success to opportunities of lavish funding for its members. Weaver specifically stated at the February 5, 1956 meeting of the Genetics Panel that he would "try to get a very substantial amount of free support for genetics if at the end of this thing we have a real case for it. I am not talking about a few thousand dollars, gentlemen. I am talking about a substantial amount of flexible and free support to geneticists", (National Academy of Sciences (NAS)/National Research Council (NRC), 1956) – NAS transcripts, February 5, page 35. As part of his interaction with the Genetics Panel, he prefaced his funding remarks with the statement that "There may be some very practical results – and here is the dangerous remark – don't misunderstand me. We are just all conspirators here together." The remarks of Weaver were blunt and remarkably focused linking the project outcome to the funding interests of the geneticists on the Panel. Such a blatant coupling of funds and outcome were highly manipulative.

Could such an inducement, as grant support, really be persuasive enough to affect the performance, judgment or integrity of esteemed scientists on an NAS Panel? In his 2007 dissertation (Seltzer, 2007), Seltzer sheds some light on this question. He concluded that members of the Genetics Panel saw themselves as funding advocates for radiation genetics (p. 285 footnote 208). Furthermore, it was hoped that the Genetics Panel, which would continue into the foreseeable future, would affect the directions and priorities of funded research in genetics. Seltzer (2007) also further showed that such expectations were in fact evidenced in correspondence between members of the Genetics Panel, i.e.,

Beadle, Dobzhansky, Muller and Demerec. In a letter to Beadle, Demerec (American Philosophical Society, 1957a) offered a funding plan that could be achieved by "setting aside a fund (let us say, one hundred million dollars), to be administered by some competent organization (such as the National Academy of Sciences) and used during a period of 20 or 25 years to fund already functioning research centers so as to attract and train first rate scientists". Dobzhansky (American Philosophical Society, 1957b) responded to this proposal by stating that he would "needless to say, be all in favor (of) $100,000,000 for research in general genetics.... but I would find it hard to keep a straight face arguing that they (general genetics) must be studied to evaluate the genetic effects of radiation on human populations". This evoked from Demerec (American Philosophical Society, 1957c) the statement that "I, myself, have a hard time keeping a straight face when the talk is about genetic deaths and the tremendous dangers of irradiation. I know that a number of very prominent geneticists, and people whose opinions you value highly, agree with me". Finally, Dobzhansky (American Philosophical Society, 1957d) responded by saying "Let us be honest with ourselves – we are both interested in genetics research, and for the sake of it, we are willing to stretch a point when necessary. But let us not stretch it to the breaking point! Overstatements are sometimes dangerous since they result in their opposites when they approach the levels of absurdity. Now, the business of genetic effects of atomic energy has produced a public scare, and a consequent interest in and recognition of (the) importance of genetics. This is to the good, since it will make some people read up on genetics who would not have done so otherwise, and it can lead to the powers-that-be giving money for genetic research which they would not give otherwise" (American Philosophical Society, 1957d).

These shared comments by key members of the Genetics Panel provide previously unknown insights into motivations of the leading radiation geneticists of that era and the group that legitimized LNT for use by society. According to Seltzer (2007), these letters made two points: (1) that the geneticists were quite focused on the viability of their discipline and (2) that they were cognizant of and acted upon opportunities to manipulate the current situation (e.g., to stretch a point) for the purpose of increasing the likelihood of greater funding, it seems as though the persuasiveness of grant funding is more powerful than one could have imagined, even for esteemed scientists.

When viewed from a grander perspective, the RF displayed an undue and unheard of influence over the course of cancer risk assessment within the United States and throughout the world. The RF directed and funded the entire process that resulted in the adoption of the LNT, all hidden within the prestige of the U.S. NAS due to the multiplicity of roles played by Bronk. Weaver used his long-honed knowledge and skills concerning the vulnerability of academics for external grant funding and lured Panel members with funding possibilities on the basis that their area would be seen as important to society. Such manipulations raise serious ethical issues. In fact they paved the way for the very activities that occurred within the Genetics Panel, that is, misrepresenting the research record to enhance its policy recommendations. To ensure a "proper" narrative, Weaver the mathematician, and not one of the geneticists, drafted the final report of the Genetics Panel (Glass, 1991). At an organizational level, the RF manifested hegemony over the BEAR Genetics Panel, warping and corrupting a risk assessment process that had lasting, social and economic public policy consequences. At an individual level, Bronk's failure to require the panel to document the scientific basis for the LNT recommendation and the Panel members' self-serving decision to identify funding opportunities instead of writing the report, together represent unscrupulous behaviors that enabled them to establish the legitimacy of the LNT model without having to defend their position and, at the same time, optimizing their future funding options.

7. Conclusions

- The recommendation by the U.S. NAS in 1956 to adopt the LNT model was rapidly accepted by governments worldwide and provided the basis for estimating cancer risks from ionizing radiation and chemical carcinogens over the past six decades.
- The recommendations of the U.S. NAS BEAR I Committee, Genetics Panel were ideologically-driven with no written scientific basis provided by the Panel.The Genetics Panel explicitly refused to provide a written documentation when formally challenged to explain their recommendations. Moreover, the President of the NAS became complicit in the Panel's questionable and irregular actions by taking no corrective action, even after receiving notification by letter of the Panel's refusal to provide such a report.
- Studies under the direction of Curt Stern at the University of Rochester/University of California-Berkley using Drosophila provided the scientific basis for the LNT of the BEAR I Genetics Panel. Detailed re-analyses of these studies has revealed serious flaws in the acute study by Warren Spencer and in key follow up chronic exposure experiments by Delta Uphoff. Curt Stern intentionally concealed critical limitations of the Uphoff findings which had Stern and Uphoff characterize these findings as "uninterpretable". Stern, in cooperation with Hermann Muller, deliberately misrepresented and marginalized the findings of Ernst Caspari which supported a threshold model.
- The NAS Genetics Panel committed scientific misconduct by falsifying, fabricating and then publishing in the journal Science its doctored estimates of human genetic risk to radiation exposures. The Panel's deceits were designed to prevent the scientific community and the general public from knowing the profound uncertainties entailed in its genetic risk estimates, thereby insuring the ready acceptance of its policy recommendations.
- Current cancer risk assessment policy and practices are based on fraud and deception by key leaders of the radiation geneticist community and by the U.S. NAS, BEAR I, Genetics Panel. Their deceptions were uncritically adopted by regulatory agencies and the scientific community worldwide and provide the foundation of cancer risk assessment and risk communication messages. The implications of such fraudulent actions are profound and likely to affect: human health risk assessment, adoption and use of new technologies, cost benefit assessments at multiple societal levels, toxic tort actions/decisions, and in the education of the public on vast areas of environmental health and medical treatment practices.

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Toxicology rethinks its central belief

Hormesis demands a reappraisal of the way risks are assessed.

Edward J Calabrese and Linda A Baldwin

How clean is clean? Billion-dollar arguments on this question are common in the United States, as agencies — such as the Environmental Protection Agency (EPA) — face the need to remediate sites of uncontrolled or abandoned hazardous waste, Ground Zero being the foremost example in many minds. Likewise, debates rage about 'safe' levels of compounds in the body, for example lead-associated cognitive deficits in children, which are claimed to occur at blood lead levels lower than previously thought. In addition, the US Congress is exploring whether low doses of organic mercury preservatives are contributing to an apparent marked increase in childhood autism.

These, and numerous other examples, illustrate the central role that toxicology and the knowledge of the dose–response relationship play in a vast array of critical environmental, medical and public-health issues. As regulatory and public-health agencies base their decisions and policies on toxicological predictions, they are therefore of considerable importance to vast numbers of people as well as to national economies.

We believe the predictive models that all regulatory agencies use are based on a fallacy in the toxicological models used to predict and extrapolate dose responses from chemicals, pharmaceuticals and physical stressor agents. Here, we clarify the basis of this fallacy and advocate a more predictive model that will revolutionize public attitudes towards risk.

Traditional models

The most fundamental concept used in toxicology to determine risk assessment and regulation is the dose-response relationship, for which two models have traditionally been used. The threshold model (Fig. 1a) is used in the assessment of risks for non-carcinogens, and the linear non-threshold (LNT) model (Fig. 1b) to extrapolate risks to very low doses of carcinogens. But we believe the most fundamental shape of the dose response is neither threshold nor linear, but U-shaped (Fig. 1c), and hence both current models, especially the linearity model, provide less reliable estimates of low-dose risk.

This U-shape is commonly called hormesis — where a modest stimulation of response occurs at low doses and an inhibition of response occurs at high ones[1]. The stimulation is often (but not always) observed following an initial inhibitory response, appearing to represent a modest overcompensation to a disruption in homeostasis[2]. Depending on the endpoint that is measured, the hormetic dose response is either an inverted U — the endpoints being growth (such as the effects of low doses of various toxic metals, herbicides and radiation on plant growth) or survival (such as the effects of low doses of gamma rays on longevity in rodents) — or a J — the endpoint is the incidence of disease (for example, mutation, birth defects, cancer; Fig. 1c). Yet virtually all the leading toxicology textbooks consider only the traditional threshold and linear models.

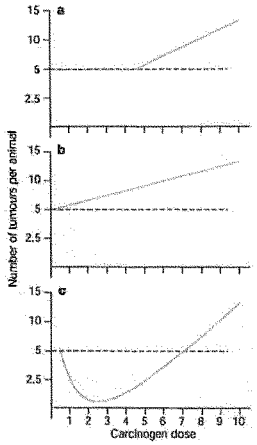

Figure 1 Hypothetical curves depicting (a) threshold, (b) linear non-threshold, and (c) hormetic dose-response models using cancer (number of tumours per animal) as the endpoint. The reduction in number of tumours per animal at the lower doses (1–5) compared to the number of tumours per animal (5 tumours per animal) in the control indicates a reduced risk of cancer.

The toxicological community made an error of historic proportions in its formative years (the 1930–40s) in buying into the threshold model[3]. Once accepted, this model became dogma, providing the basis for subsequent progress and confusion — despite toxicologists, radiation biologists, pharmacologists and others regularly pointing out unmistakable exceptions to the so-called threshold rule, such as the effects of saccharin, dioxins, cadmium, mercury, numerous insecticides/herbicides, and numerous pharmaceutical agents. These unexpected results were generally written off either as reproducible but 'paradoxical' phenomena with no apparent capacity for generalization, or as biologically irrelevant random variation.

The implications of this systematic error are immense, not least in toxicological risk assessment. The *a priori* criteria we developed to assess whether experiments displayed evidence of hormesis based on study design, magnitude of the stimulatory response, statistical significance of the stimulatory response and reproducibility of findings, revealed up to 5,000 examples of hormetic responses independent of chemical class/physical agent, biological model and endpoint measured. Low levels of agents such as cadmium, dioxin, saccharin, various polycyclic aromatic hydrocarbons, X-rays and various gamma-ray sources reduce tumours in some species. Low doses of X-rays enhance life span in male and female mice and guinea pigs; ethanol and acetaldehyde enhance longevity in fruit flies; multiple stressor agents extend longevity in nematodes; numerous toxic substances (for example, cadmium and lead) enhance growth in various plant species. Low or modest consumption of ethanol reduces total mortality in humans, while increasing it at higher levels of consumption. The hormesis concept is thus highly generalizable and far-reaching.

Yet the vast majority of toxicological experiments are not designed to evaluate the hormetic hypothesis, assessing doses that are too high for the hormetic domain. Of those experiments that do have adequate study designs, a substantial proportion demonstrates hormesis. Using a database with rigorous and clearly defined entry and evaluative criteria, the hormetic model strikingly outperforms the 'dominant' threshold model[4]. The hormetic model is not an exception to the rule — it is the rule.

Overlooking hormesis

So how did the field of toxicology get its most fundamental tenet, the nature of the dose response, so wrong? One reason is that, as mentioned above, most toxicological experiments lack the capacity to assess possible hormetic dose responses. Yet even when they do have potentially adequate study designs, the hormetic response can still be missed because at the assumed toxicological threshold dose (called NOAEL, for no observed adverse effect level), there is often evidence

of a low degree of toxicity, even if the response is not significantly different from the control group. As the dose below the standard threshold becomes progressively more dilute, the response becomes more likely to exceed the control value (hormetic-like). This is why mammalian toxicological studies, which emphasize high-dose toxicological responses such as those used to assess possible carcinogens in the US National Toxicology Program (NTP), are often incapable of adequately assessing the hormetic phenomenon. We believe that this combination of circumstances contributed significantly to the toxicological community overlooking the hormetic model and putting full emphasis on the threshold model for non-carcinogens and the linear model for carcinogens.

The mechanism by which hormesis occurs has also hindered its general acceptance. Toxicological researchers have rarely focused on why there are transitions (for example, stimulation followed by inhibition) in dose responses. Molecular pharmacologists, on the other hand, have focused on how such switching mechanisms work and how they affect the nature of the dose response, including hormetic-like biphasic dose–response relationships. There are more than 30 pharmacological receptor systems in the published literature that affect hormetic-like dose responses where the mechanisms that account for such responses have been clarified to at least receptor level[5]. These findings reveal that there is no single hormetic mechanism, but suggest a general strategy for resource conservation across biological systems.

Seven years ago, hormesis would not find its way into even informal conversation among toxicologists. Now, we not only know that it exists but accept its dominance over other models. The implications are enormous: they affect how toxicologists select biological models, choose endpoints to measure, design studies, assess risk and even pose the questions and the hypotheses they test. The dose response affects nearly all aspects of toxicological, pharmacological, epidemiological and clinical evaluation.

Implications of hormesis

What are the implications of the hormetic perspective? Most notably, it challenges the belief and use of low-dose linearity in estimating cancer risks, and emphasizes that there are thresholds for carcinogens. The economic implications of this conclusion are substantial. The EPA has been struggling to harmonize how it assesses risks from non-carcinogens and carcinogens, having mistakenly assumed for a long time that non-carcinogens act via a threshold model whereas carcinogens act via a linear model at low doses. As both types of biological response follow the hormetic paradigm and display similar quantitative features of the dose response, the EPA could use the hormetic model as default to assess risk in both non-carcinogens and carcinogens[6].

> Hormetic responses have equal, if not greater importance, for the biomedical and clinical sciences

The hormetic perspective also turns upside down the strategies and tactics used for risk communication of toxic substances for the public[7]. For the past 30 years, regulatory and/or public-health agencies in many countries have 'educated' — and in the process frightened — the public to expect that there may be no safe exposure level to many toxic agents, especially carcinogens such as radiation and dioxins. If the hormetic perspective were accepted, the risk-assessment message would have to change completely. Changing a dominant risk-communication paradigm is not as simple as flicking on a light switch. It changes beliefs, attitudes, and assumptions, not unlike changing from a Soviet-style society to a western one. It would certainly be resisted by many regulatory and public-health agencies as an industrial-influenced, self-serving scheme that could lead to less costly, less protective clean-up standards, reminiscent of attempts by early opponents of hormesis to link it with homeopathy.

Hormetic responses have equal, if not greater, importance for the biomedical and clinical sciences. Many antibiotics, antiviral and anti-tumour agents, and numerous other medicines display hormetic-like biphasic dose responses: one dose may be effective clinically but another may be harmful. Some anti-tumour agents (for example, suramin) that inhibit cell proliferation at high doses, where they may be clinically effective, become like a partial agonist at lower doses, where they enhance cell proliferation. This is also true for some antibacterials (erythromycin and streptomycin, for example) and antiviral agents (such as gliotoxin analogues, colanolides, adefovir and Rhamnan sulphate). In these cases, the drug may be harmful to the patient at lower than therapeutic doses and requires careful clinical supervision. Some Alzhiemer's treatments, such as the second/third-generation anticholinesterase agents, often enhance cognitive function at low doses but decrease it at higher doses. Thus, the hormetic biphasic dose response provides not only new opportunities for clinical improvements but also risks that have to be addressed.

Exercise is now being seen as a similar phenomenon, in that there may be an optimized degree of exercise that confers a wide range of benefits, whereas at higher levels (dose), the net result would be adverse. Immunology is likewise replete with examples of both chemical- and radiation-induced hormetic-like biphasic dose responses for a broad spectrum of endpoints and biological models. More than 150 endogenous agonists, drugs and pollutants induce hormetic effects in humans and other animals, affecting antibody production, cell migration, phagocytosis of microbes, destruction of tumour cells and other end-points. A better understanding of such phenomenon would have important implications for future research and biomedical development.

Paradigm shift

At a time when the human genome has dominated many aspects of the scientific literature, it is generally unrecognized that the dose response of most, if not all, peptides conform to the hormetic model. Recognition of hormetic-like biphasic dose responses is important for elucidating the bioregulatory actions of various peptides and their biomedical implications.

Yet hormesis is not easy to study, as it requires the use of more doses (especially in the low-dose zone), often including a temporal component (measurement at various times within an experiment) and using more subjects to enhance statistical power, and needs replication. These extra features often steer researchers to less resource-intensive and more readily definable phenomena.

The hormetic dose response represents a paradigm shift in the concept of the dose response throughout biological science. It is widespread and outperforms other dose-response models. A general recognition of the hormetic perspective is likely to yield a vastly improved evolutionary basis of adaptive responses, scientific foundations of risk assessment and clinical medicine, as well as a more biologically plausible framework for understanding regulatory strategies at the level of the cell and the organism.

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Senator ROUNDS. Senator Ernst.

Senator ERNST. Thank you to our witnesses today, and thanks for holding the hearing, Mr. Chair.

Mr. Hahn, in your written testimony you stated that your research found that some of the EPA's environmental assessments were not always of high quality, and these assessments went on to form the basis for major regulations.

Can you go into a little bit more detail on this or specify which regulations you found to be based on low quality environmental assessments?

Mr. HAHN. So, I did that research about 10 years ago, and I can't give you a list of a top 10, and journalists often ask me, but I can give you some examples of what the problems were.

Senator ERNST. OK. That would be helpful.

Mr. HAHN. And some of these problems have been fixed. But you get a 200-page regulatory impact assessment, which is great for insomnia, on some chemical, and frequently the Agency doesn't summarize in a very clear way what their main findings are; they don't necessarily pay attention to the alternatives which they were supposed to think about in finding the best and cheapest way of achieving the result; they don't necessarily count all the benefits they should have.

So, there were real deficiencies in the analytical rigor that was underlying these regulatory proposals. And some of the administrators at EPA and other agencies have tried to fix some of these things; I don't know how well they are doing.

But what I would say generally—and I am sorry Senator Booker had to leave—I think it is a really good idea to be able to share data and models, because even at the highest level of academia, even with peer reviewed publications there are frequently errors.

A couple of professors from Harvard, who shall remain nameless but everyone knows who they are, wrote a very influential book about how long it should take to recover after the last Great Recession, and it turns out there were some fundamental errors in their analysis that wouldn't have been uncovered but for the fact that their data was shared, which is a good idea. So, I think it is a really good idea to be thinking about sharing data.

At the same time, I agree with you that we don't want to necessarily eliminate, by law or regulation, some very persuasive data that is published in peer reviewed journals, but my bugaboo is it is really important to share this data so other people can take a look at it in sunlight so that, when you are passing a regulation that is going to impose costs on people or make them lose their job, that you have the best available evidence upon which to make those decisions.

Senator ERNST. No, I thank you for that.

So, just going back and maybe repeating in different terms some of what you just said, it is possible, then, that some of those assessments were made, and they were the result of maybe shoddy work or perhaps errors; is that correct?

Mr. HAHN. To use a phrase that my 3 year old niece used many years ago when I was doing this research, some of it was stinky.

Senator ERNST. Well, that is a great way to describe it. Do you think that the EPA was trying to tailor the assessments to support the need for regulations in some of those cases, perhaps?

Mr. HAHN. I think it is possible. It is something that is very hard to prove, but we all live in Washington, DC.

Senator ERNST. Certainly. And that is why I think that having transparency and peer review is important; a little bit of sunlight there. If a regulation is truly needed, then you shouldn't be opposed to having other people take a look at the methodology there.

Dr. Holt, this ties into this conversation as well. Some of those regulations turned out by various Federal agencies, including EPA, do pose economic threats to certain industries, and of course, a number of those communities that rely on those industries. If you were to be an employee of one of those industries or live in a community where a lot of that economic thrust is involved, shouldn't you want to know every bit of information or data that is being used by those different agencies to develop the regulation that might threaten your very job or even your entire community?

Mr. HOLT. Surely, there are regulations that don't work well, that are improper, that even should be removed, but the approach to making regulations is not to limit bad regulations by limiting the science that might lead to regulations, which is what is going on here. The full science should be available. And this is not to make science more available; the effect is to restrict the science that is available, because the whole rule is about removing some studies that cannot be used to make regulations. So, we should ask, are we throwing out some good science here. And the answer that is arrived at by science society after science society, science after scientist, is yes, it would be throwing out good research.

Senator ERNST. Well, I certainly appreciate all of the different opinions here today.

Thank you, Mr. Chair.

Senator ROUNDS. Thank you.

Senator Whitehouse.

Senator WHITEHOUSE. Thank you, Chairman. I appreciate this hearing.

Dr. Holt, in a circumstance in which science discovers that a substance or a chemical is harmful to human health, and there is an industry involved in the manufacture or the distribution of that chemical or substance, and that industry wants to fight back against the science, what sort of an apparatus does such an industry have at its disposal to take on the enterprise of science?

Mr. HOLT. Well, let me stick to the subject at hand here. An approach that they might use is to say that their test results are proprietary. And under this rule, if it were in effect, the studies that might be available would not be available because they have a legitimate claim to keep their data proprietary, non-public; and therefore, some good science that had been verified in appropriate ways would not be available to the regulatory agency.

Senator WHITEHOUSE. Setting aside that question for a minute and back to my original question, does an industry in that predicament have access to an array of groups that have experience in trying to deprecate science and foment alternative views?

Mr. HOLT. Well, as I have heard you speak often, there is an imbalance in access to resources, access to media, and access to public persuasion, so the regulatory agencies are set up in order to try to restore that imbalance, to make sure that all parties have input to the regulatory process.

Senator WHITEHOUSE. The concern or a concern that I have about the very title of this hearing, Sound and Transparent Science—which in theory is a very good thing—goes back to a phrase that has been kicked around in this conversation called secret science, which I think is a highly misleading term. My understanding is that very often in public health, in order to get data, you look at people's public health records; you look at who got sick, who didn't. You look at the health records of human beings.

The condition of getting access to those records is that you don't give that private information out publicly. People's families might not want to know about it; people might not want their employers to know about it. There might even be cases where they don't want their insurance companies to know about it.

Will you agree with me that it should not be the price of having health records form the basis for scientific study that the individuals involved lose all their privacy with respect to their health records?

Mr. HOLT. Still directed at me?

Senator WHITEHOUSE. Yes.

Mr. HOLT. Yes. You are right. As I said earlier, there really is no secret science. There should be fully available science when it comes to making regulation, and that science——

Senator WHITEHOUSE. And the term "secret" really——

Mr. HOLT [continuing]. That science is not just the data. Some of the data must be kept non-public because of health records, because of legal proprietary information, because of a number of other things.

Senator WHITEHOUSE. But if you were an industry——

Mr. HOLT. But the science itself, the process of taking those data and verifying them should not be secret. But that is not what this rule or this legislation would deal with.

Senator WHITEHOUSE. If you were an industry that wanted strategically to knock down public health science so that the dangers of your product were not understood or made public, then this would be a pretty handy way to go about it, because you disable an entire field of legitimate public health science by calling secret science science that actually only depends on people's health records.

Mr. HOLT. I think it could be used that way.

Senator WHITEHOUSE. May I ask unanimous consent that a curriculum vitae for Dr. Calabrese dated August 2013 be put into the record? I don't know if it is in the record already, but it is a pretty good summary of some of his industry clients and how much they have paid him over the years, and I think that is important in judging the witness's conflicts of interest here. So, if I could add that to the record.

Senator ROUNDS. Without objection.

Senator WHITEHOUSE. Thank you.

[The referenced information follows:]

EDWARD J. CALABRESE, PH.D.

CURRICULUM VITAE

August, 2013

TABLE OF CONTENTS

I. SUMMARY:

- Professor of Toxicology at the University of Massachusetts, Amherst since 1976.
- Board Certified in general toxicology by the Academy of Toxicological Sciences since 1982.
- Over 750 publications in peer-reviewed journals.
- Over 600 invited presentations at major conferences and University seminars.
- Author or Co-Author of 26 books.
- Editor or Co-Editor of over 40 monographs and/or conference proceedings.
- Consultant to most environmentally oriented federal agencies.
- Consultant to numerous major U.S. corporations and trade associations.
- Extramural funding since 1976 from all sources exceeds 30 million dollars.
- Founding Editor-in-Chief Human and Ecological Risk Assessment
- Founding Editor-in-Chief Dose-Response Journal
- Honorary Doctor of Science Degree, McMaster University 2013
- Advisory Board for the first graduate training program focused on hormetic mechanisms, Friedrich-Schiller-University, Jena, Germany 2011 to present

II. BIOGRAPHICAL SKETCH:

Edward J. Calabrese is a Professor of Toxicology at the University of Massachusetts, School of Public Health and Health Sciences, Amherst. Dr. Calabrese has researched extensively in the area of host factors affecting susceptibility to pollutants, and is the author of over 750 papers in scholarly journals, as well as more than 10 books, including Principles of Animal Extrapolation; Nutrition and Environmental Health, Vols. I and II; Ecogenetics; Multiple Chemical Interaction; Air Toxics and Risk Assessment; and Biological Effects of Low Level Exposures to Chemical and Radiation. Along with Mark Mattson (NIH) he is a co-editor of the recently published book entitled Hormesis: A Revolution in Biology, Toxicology and Medicine. He has been a member of the U.S. National Academy of Sciences and NATO Countries Safe Drinking Water committees, and on the Board of Scientific Counselors for the Agency for Toxic Substances and Disease Registry (ATSDR). Dr. Calabrese also serves as Chairman of the Biological Effects of Low Level Exposures (BELLE) and as Director of the Northeast Regional Environmental Public Health Center at the University of Massachusetts. Dr. Calabrese was awarded the 2009 Marie Curie Prize for his body of work on hormesis. He is the recipient of the International Society for Cell Communication and Signaling-Springer award for 2010. He was awared an Honorary Dcotor of Science Degree from McMaster University in 2013.

Over the past 20 years Professor Calabrese has redirected his research to understanding the nature of the dose response in the low dose zone and underlying adaptive explanatory mechanisms. Of particular note is that this research has led to important discoveries which indicate that the most fundamental dose response in toxicology and pharmacology is the hormetic-biphasic dose response relationship. These observations are leading to a major transformation in improving drug discovery, development, and in the efficiency of the clinical trial, as well as the scientific foundations for risk assessment and environmental regulation for radiation and chemicals.

CURRICULUM VITAE

Name: Edward J. Calabrese
Date of Birth: August 10, 1946

Address: 60 Cherry Lane
Amherst, MA 01002
Phone: (413) 549-5264 (home)
(413) 545-3164 (work)
Fax: (413) 545-4692 (work)
E-Mail: edwardc@schoolph.umass.edu

III. ACADEMIC TRAINING

University of Massachusetts at Amherst, MA	1972-1974	Education Science Ed.	Ed.D. 1974
University of Massachusetts at Amherst, MA	1971-1973	Physiology/ Toxicology (Entomology Department)	Ph.D. 1973
State College at Bridgewater, MA	1969-71	Biology	M.A. 1972
State College at Bridgewater, MA	1964-68	Biology	B.A. 1968

IV. WORK EXPERIENCE

Graduate Program Director, Environmental Health Sciences Department, December 2003-2004.

Division Chair, Environmental Health Sciences Division, December 2003-2006.

Director - Northeast Regional Environmental Public Health Center,
October 1985-Present.

Professor - Promoted from Associate Professor, June 1982-Present.

Associate Professor - Promoted from Assistant Professor, June 1980.

Assistant Professor - September 1976 - Environmental Health Sciences Program, Division of Public Health, University of Massachusetts, Amherst, MA. Duties include: teaching introductory and advanced courses in environmental toxicology, directing thesis research.

Assistant Professor - July 1974-August 1976 - Department of Occupational and Environmental Medicine, University of Illinois, School of Public Health, and Assistant Director of the Environmental Health Resource Center. Duties included: the identification and quantification of present and potential environmental health hazards within the state, the development and review of environmental health legislation, standards and regulations, testimony at regulatory and legislative hearings on standards of environmental quality and teaching courses in environmental health.

Environmental Research Director for the Massachusetts Public Interest Research Group - December 1973-June 1974. Duties included: determination of research and educational goals of the organization, direction of student research projects, direction of Water Quality Training Institutes throughout Massachusetts.

Adjunct Professor - Southwest Residence College - University of Massachusetts. January 1974. Taught environmental science courses to undergraduate and graduate students.

Assistant Professor - Fall 1973 - North Adams State College, North Adams, MA. Biology Department - taught Ecology, Evolution, and Introductory Biology.

V. GRANTS AND RESEARCH FUNDING

Principal Investigator. Air Force Office of Scientific Research. Enhancing Biological Performance: Occurrence, Mechanisms and Applications. 2013-2018. ($1,197,558).

Principal Investigator. ExxonMobil. Hormesis Research. 2007-2013. ($150,000 per year).

Director. Hormesis Conference general support. Multiple public and private organizations. 2010-2013. (Approximately $50,000).

Principal Investigator. Air Force Office of Scientific Research. Conference on Adaptive Responses and their Biomedical Applications. 2012. ($25,544).

Principal Investigator. Air Force Office of Scientific Research. Conference on Adaptive Responses and their Biomedical Applications. 2011. ($25,580).

Principal Investigator. Lounsbery Foundation. Development of an Integrative Mechanistic Framework. 2010-2012. ($25,000)

Principal Investigator. Air Force Office of Scientific Research. Chemical/Radiation Hormesis Database, Evaluation of Hormetic Mechanisms & Their Biomedical and Risk Assessment Implications. 2008-2010. ($299,371).

Director. Hormesis Conference general support. Multiple public and private organizations. 2008-2009. (Approximately $120,000).

Principal Investigator. Air Force Office of Scientific Research. Chemical/Radiation Hormesis Database, Evaluation of Hormetic Mechanisms & Their Biomedical and Risk Assessment Implications. 2007. ($84,778).

Principal Investigator. Air Force Office of Scientific Research. Chemical/Radiation Hormesis Database, Evaluation of Hormetic Mechanisms & Their Biomedical and Risk Assessment Implications. 2007. ($199,845).

Director. Hormesis Conference general support. Multiple public and private organizations. 2007. (Approximately $150,000).

Director. Hormesis Conference general support. Multiple public and private organizations. 2006. (Approximately $100,000).

Principal Investigator. Alfred P. Sloan Foundation. Hormesis Center. 2004-2007. ($45,000).

Principal Investigator. Dow Chemical Co. Distributions for Monte-Carlo Soil Ingestion Risk Assessment. 2004-2007. ($160,470).

Principal Investigator. Lounsbery Foundation. Workshop to Create a Hormesis Institute/Center. 2005-2007. ($75,000).

Principal Investigator. ExxonMobil. Hormesis Research. 2006. ($150,000).

Principal Investigator. Air Force Office of Scientific Research. Chemical/Radiation Hormesis Database, Evaluation of Hormetic Mechanisms & Their Biomedical and Risk Assessment Implications. 2006. ($214,645).

Principal Investigator. ExxonMobil. BELLE – Chemical Hormesis Database. 2005. ($150,000).

Principal Investigator. Air Force Office of Scientific Research. Chemical/Radiation Hormesis Database, Evaluation of Hormetic Mechanisms & Their Biomedical and Risk Assessment Implications. 2005. ($211,026).

Principal Investigator. U.S. Department of Energy. International Conference – Hormesis Implications for Toxicology, Medicine, and Risk Assessment. 2005-2006. ($5,000).

Principal Investigator. Dow Chemical Co. Distributions for Monte-Carlo Soil Ingestion Risk Assessment. 2004-2006. ($160,470).

Principal Investigator. Alfred P. Sloan Foundation. Hormesis Center. 2004-2006. ($45,000).

Principal Investigator. U.S. Department of Energy. Non-Linear Dose Response Relationship in Biology, Toxicology and Medicine. 2004-2005. ($20,000).

Principal Investigator. General Electric Foundation. BELLE Initiative. 2004. ($100,000).

Principal Investigator. ExxonMobil. BELLE – Chemical Hormesis Database. 2004. ($75,000).

Principal Investigator. Air Force Office of Scientific Research. Chemical/Radiation Hormesis Database, Evaluation of Hormetic Mechanisms & Their Biomedical and Risk Assessment Implications. 2004. ($174,302).

Principal Investigator. U.S. Department of Energy. Non-Linear Dose Response Relationship in Biology, Toxicology and Medicine. 2003-2004. ($12,500).

Principal Investigator. Florida Power and Light. Assessment of Arsenic Bioavailability in Humans. 2002-2003. (~$110,000).

Principal Investigator. Air Force. Toxicological Assessment of Hormesis. 2001-2003. ($450,000).

Principal Investigator. US EPA/American Chemical Council. Soil Ingestion in Construction Workers. 2001-2003. ($750,000).

Co-Principal Investigator. Health Risks and Fish Consumption from the Pasiac River. 2001-2002. ($125,000).

Principal Investigator. CA EPA. Single Exposure Carcinogen Database Update and Evaluation. 2002. ($50,000).

Co-Director. 11th Annual Soil and Groundwater Conference. San Diego, CA. March 2002. ($100,000).

Co-Director. 18th Annual Soil, Groundwater and Sediment Contamination Conference. University of Massachusetts. October 2001. ($125,000).

Principal Investigator. Conference on Non-Linear Dose-Response. Multiple sponsors (EPA, NIEHS, AWWARF, Air Force, and other). June 2001. ($150,000).

Co-Director. International Conference on Contaminated Soil, Sediment, and Groundwater. London. August 2000. ($300,000).

Co-Principal Investigator. Soil ingestion workshop/assessment. U.S. EPA. June/July 2000. ($50,000).

Principal Investigator. Soil ingestion in construction workers. U.S. EPA/CMA. October, 1999 ($650,000).

Principal Investigator. Development of an ionizing radiation hormesis database. Nuclear Regulatory Commission. September 1997 - September 1999 ($188,000).

Principal Investigator. Biological effects of low level exposures. Three year cooperative agreement. Reviewed once, 1999. Nuclear Regulatory Commission, 1996-1998, 1999-2001. ($60,000 or $20,000/year).

Principal Investigator. Assessment of soil ingestion in children. Health Canada. January 1999 ($6,500).

Principal Investigator. Biological effects of low level exposures (BELLE). From multiple sponsors. 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004. (approx. $120,000/year from multiple sources).

Co-Principal Investigator. Florida Power and Light. Biological effects of arsenic contaminated soil. January 1998 ($100,000), March 1999 ($50,000).

Principal Investigator. ARCO. Assessment of the role of particle size on soil ingestion estimates in children. June 1997 ($150,000).

Principal Investigator. Health Research Foundation (Japan). Biological effects of low level exposures. September 1997 ($15,000).

Principal Investigator. U.S. Air Force. Assessment of the societal and scientific implications of hormesis. October 1997 - October 2000 ($345,000).

Principal Investigator. U.S. EPA. Single exposure carcinogen database. October 1997 – May 1999 ($75,000).

Principal Investigator. GE Foundation. Biological effects of low level exposures (BELLE). October 1997 ($15,000).

Co-Principal Investigator. EPA. Assessment of groundwater contamination by MTBE. September 1997 ($43,000).

Principal Investigator. Exxon. Biological effects of low level exposures. 1996-1999 $20,000/year. ($80,000).

Principal Investigator. Dow-Corning. Biological effects of low level exposures. 1996-1999 $10,000/year. ($40,000).

Principal Investigator. Canadian Electric Utilities. Biological effects of low level exposures. 1996 ($10,000).

Co-Director. Bitor-Venezuela. Evaluation of the endocrine disruption potential of surfactants. June 1996 ($447,000).

Co-Principal Investigator. Massachusetts Department of Environmental Protection. Determination of heavy metal background levels. June 1996 ($23,000).

Principal Investigator. ARCO. Assessment of the role of particle size on soil ingestion estimates in children. June 1996 ($150,000).

Principal Investigator. Radiation, Science and Health, Inc. Critical assessment of selected literature on radiation hormesis. December 1996 ($26,000).

Principal Investigator. Environmental effects of Orimulsion. December 1996 ($836,000).

Principal Investigator to support BELLE related activities. January 1995. RJReynolds, Inc., $25,000; Electric Power Research Institute, $10,000; Dow Corning, $10,000; and Canadian Electric Utilities, $10,000.

Principal Investigator. RJReynolds, Inc. The effects of low levels of chemical agents on biological responses. February 1995 ($25,000).

Principal Investigator to assess soil ingestion in children living in Northwest of the U.S. ARCO. September 1992 - June, 1996 ($748,000).

Principal Investigator. Louisiana DEQ. Assessment of soil ingestion in children. June 1995 ($50,000).

Principal Investigator. US EPA. An evaluation of gender differences in susceptibility to toxic substances. June 1995 ($55,000).

Principal Investigator. US EPA. Single exposure carcinogen database. October 1995 ($75,000).

Principal Investigator. Health Canada. Develop new methodologies to assess human high risks. November 1994 ($60,000).

Principal Investigator to direct BELLE activities. EPRI, Dow Corning, Center for Indoor Research, and EPA. October 1994 ($55,000).

Principal Investigator. Florida Power and Light. Development of a framework to conduct an ecological risk assessment on Tampa Bay. April 1994 ($140,000).

Principal Investigator. Gillette, Inc. Support of BELLE-related activities. May 1994 ($3,000).

Principal Investigator. Florida Power and Light. Assess the effects of several types of fuel oil on red blood cells. September 1994 ($31,000).

Co-Director of a series of conferences on petroleum contaminated soil. Held at the University of Massachusetts, Amherst. 1985, 1987, 1988, 1989, 1990, 1991, 1992, 1993, 1994, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002. Approximately $100,000/conference from external co-sponsors.

Co-Director of a series of conferences on soil and groundwater contamination. Held in the greater Los Angeles area. 1989-2002. $100,000/year.

Principal Investigator on a grant to assess interspecies differences in hepatic peroxisomes proliferation and its role in the development of fish tumors. Department of Defense, U.S.A. April 1988-1993 ($749,000).

Florida Power and Light. Critical Evaluation of the PM_{10} standard. November 1993 ($20,000).

Principal Investigator to direct BELLE activities: EPRI, Dow Corning, Center for Indoor Research, and others. April 1993 (approx. $50,000).
Principal Investigator to assess single exposure carcinogens. ATSDR/September 1993 ($50,000).

Principal Investigator to assess the prevalence of soil pica in children and soil ingestion in children with soil pica. State of Colorado. July 1992 ($151,000).

Principal Investigator to direct the development of a newsletter on the Biological Effects of Low Level Exposures (BELLE). U.S. EPA. September 1992 ($60,000).
Director of the Council for Health and Environmental Safety of Soils Funded by EPA, ATSDR and other organizations. 1988 – 1992 ($150,000/yr.)

Principal Investigator. U.S. EPA. Lead Training Center. March 1992 ($320,000); October 1993 ($220,000); October 1994 ($290,000).

Co-Director of National Conference on Hydrocarbon Contaminated Soils. From multiple agencies/organizations. ($70,000).

Co-principal Investigator - Development of risk assessment methods for human and ecological risks. Health and Welfare Canada. April 1 1992 ($75,000).

Co-principal Investigator for Regional Lead Training Center. U.S. EPA. April 1992 ($250,000).

Principal Investigator to conduct national conference on the Biological Effects of Low Level Exposures to Chemicals and Radiation. NIEHS. April 1992 ($10,000).

Principal Investigator to support research activities concerning the biological effects of low level exposures (BELLE). Ontario Hydro. January-May 1992 ($20,000); RJR-Nabisco ($35,000); EPRI ($10,000).

Principal Investigator to assess the effects of selected oxidant stressor contaminants on red blood cells. State of Colorado. May 1992 ($44,000).

Principal Investigator to assess factors assessing the siting of waste sites in the U.S. Waste Management Inc. June 1992 ($200,000).

Principal Investigator to assess environmental factors affecting stream health. Wyman-Gordon, Co. July 1992 ($135,000).

Co-Director of the Hydrocarbon Contaminated Soil and Groundwater Conference. Newport Beach, California. 1991 - co-sponsorship $100,000 (approx.).

Principal Investigator to unrestricted support on predictive toxicology. Proctor and Gamble. June 1991 ($5,000).
Co-principal Investigator to develop a toxicological based risk communication program for lead in water. U.S. EPA. August 1991 ($50,000).

Co-Director of the 6th Annual Hydrocarbon Conference. Sept. 1991 (combined sponsorship $100,000. From multiple agencies, federal, state and private sector).

Principal Investigator of a project to differentiate soil and dust ingestion in children. U.S. EPA. Sept., 1991 ($50,000).

Principal Investigator to support research activities concerning the biological effects of low level exposures (BELLE). Dow Chemical. November 1991 ($5,000).

Principal Investigator to support research activities concerning the biological effects of low level exposures. RJR Nabisco, Inc. July 1990 ($45,000).

Principal Investigator-Evaluation of the health basis for EPA's regulations of SOTs and IOCs in drinking water. American Water Works Association Research Foundation. July 1990 ($100,000).
Principal Investigator on contract to assess the relative potency of methemoglobin forming agents. EPA. July 1990 ($28,000).

Principal Investigator-Methemoglobin forming agents: Toxicologic and risk assessment. EPA. August 1990 ($28,000).

Principal Investigator to support research activities concerning the biological effects of low level exposures. Dow Chemical. November 1990 ($10,000).

Principal Investigator to support research activities concerning the biological effects of low level exposures. The Electric Power Research Institute. December 1990 ($10,000).

Co-Director of the Hydrocarbon Contaminated Soil and Groundwater Conference. Newport Beach, California. 1990 - co-sponsorship $100,000 (approx.).

Principal Investigator of a contract to assess the Public Health risks associated with medical waste. Funded by the Rockefeller Institute of Government, Albany, New York. January 1989 ($15,000).

Co-Principal Investigator on a grant to assess factors affecting heavy metal tissue distribution in selected fish species. General Electric. July 1989 ($112,500).

Co-Principal Investigator on a grant to assess public health aspects of soil contaminated with petroleum. U.S. EPA. July 1989 ($43,000).

Principal Investigator to continue research on how to estimate how much soil children ingest. Gradient Corporation. August 1989 ($35,000).

Director of a conference on drinking water and health. American Water Works Association Research Foundation. September 1989 ($10,000).

Principal Investigator of a contract to assess the methodological approaches for establishing an Air Toxic Programs. Rohm and Haas, Inc. Part 1 - January 1987 ($60,0000. Part 2 - January 1988 ($60,000).

Principal Investigator on a grant to develop an approach for assessing human risk for soil contamination. Hercules Corporation. January 1988 ($10,000).

Principal Investigator of a contract to assess environmental exposure from the application of lawn care chemical treatment practices. Massachusetts Department of Food and Agriculture. January 1987 - June 1987 $75,000; July 1987 - June 1988 ($75,000).

Director on a grant from Proctor and Gamble in the general area of research in animal extrapolation. July 1988 ($5,000).

Principal Investigator of a grant to assess the amount of soil children consume. Syntex, Corporation. August 1988 ($25,000).

Principal Investigator of a study to assess the environmental and public health effects of soils contaminated with petroleum products including disposal options. Mass. Depart. of Environ. Engineering. July 1986 - June 1987 ($108,000).

Director of workshop on risk assessment for aerial spraying of insecticides for control of gypsy moths. U.S.D.A. - Forest Service. January 1986 ($12,000).

Co-principal Investigator of a grant to assess the effects of acid rain on selected freshwater fish species. Massachusetts Fish & Wildlife Service. May 1986 ($7,000).

Co-principal Investigator of a contract to assess the environmental and public health implications of disposal options for petroleum contaminated soil. Edison Electric Institute. July 1986 ($50,000).

Co-principal Investigator to establish an aquatic toxicology research program in the School of Public Health. Funded by the Mass. Department of Fisheries and Wildlife. July 1986 ($100,000/year).

Principal Investigator of a study to assess the environmental and public health effects of soils contaminated with petroleum products including disposal options. Mass. Depart. of Environ. Engineering. September 1984 - June 1985 ($71,000). July 1985 - June 1986 ($76,000).

Director on a grant from Proctor and Gamble in the general area of research in animal extrapolation. August 1986 ($5,000), an additional $5,000.00 was received in July 1987.

Principal Investigator of a grant to assess the amount of soil children consume. Syntex, Corporation. August 1986 ($344,000).

Co-principal Investigator of the 3-year grant to assess the aquatic toxicity of chlorination of waste water treatment plants. Mass.Water Pollution Control Assoc. September 1986 ($90,000).

Director of EPA sponsored conference on the Environmental and Health effects of Ozone. U.S. EPA. October 1986 ($10,000).

Principal Investigator of a grant from the University of Illinois - Effects of ozone on mice with low levels of glucose-6-phosphate dehydrogenase in red cells. January 1985 ($5,000).

Principal Investigator of a study entitled "The Effect of Environmental pH and Modifying Factors on the Reproduction of Rainbow Smelt." Massachusetts Fish and Wildlife Service. January 1985 ($9,873).

Director of a contract to provide toxicological and risk assessment consultation and research to the Connecticut State Health Department. February 1985 ($90,000).

Principal Investigator of a study to assess possible reproductive hazards in the semi-conductor industry. Digital Corporation: Phase 1 - July 1984 ($244,000); Phase 2 - March 1, 1985 ($194,000).

Director of the Northeast Regional Environmental Health Center, sponsored by the six New England States. Starting October 1985 (goal of $250,000/year).

Principal Investigator on the assessment of the occurrence of biological factors affecting interindividual variation in response to toxic substances. Hercules Corporation. October 1985 ($11,000).

Director of a national conference on "Environmental and Public Health Effects of Soils Contaminated with Petroleum Products." Funded by the Massachusetts Department of Environmental Quality Engineering, EPRI, ARCO, Northeast Utilities and other companies. October 1985 ($50,000).

Director of a contract to assess the public health hazards associated with leaking underground storage tanks. EPRI. October 1985 ($20,000).

Co-Investigator of a study to assess the possibility of using surrogate parameters in monitoring for the presence of volatile organic contaminants in drinking water. American Water Works Association Research Foundation. October 1984 ($60,000).

Principal Investigator of a study to assess the effects of elevated levels of sodium in drinking water on school children. Massachusetts Department of Environmental Quality Engineering. June 1983 ($10,000).

Developed the concept and proposal for a state-supported Environmental R & D Center. It was funded by the Massachusetts Legislature in July 1983 for up to $500,000 per year.

Director of a grant from the U.S. EPA to conduct an International Conference on Cardiovascular Disease and Inorganic Constituents in Drinking Water. August 1983 ($65,000).

Director of a contract from the Massachusetts Department of Environmental Quality Engineering to assess the impact of several plastics manufacturing plants on ambient air quality. September 1982 ($5,068).

Principal Investigator of a contract to assess government policy with respect to genetic screening in the workplace. U.S. Congress' Office of Technology Assessment. January 1982 ($7,400).

Principal Investigator of a Biomedical Research Grant from the University of Massachusetts Graduate Research Council to study the development of an animal model to simulate human hereditary blood disorders (i.e., G-6-PD deficiency). April 1982 ($5,000).

Director of a quarterly newsletter entitled "Health Effects Update" for members of the American Water Works Association. May 1982 ($20,000/year).

Principal Investigator of a grant to investigate the efficacy of the guinea pig heterologous model to predict the effects of ozone on human erythrocytes with a G-6-PD deficiency. Hoffmann-LaRoche, Inc. June 1982 ($10,000).

Principal Investigator of a grant to study the effects on blood pressure of a reduction in sodium in drinking water from 120 ppm to 25 ppm. American Water Works Research Foundation. June 1982 ($29,000).

Principal Investigator on a study designed to evaluate the effect of ascorbic acid supplementation on the body burden of lead. Hoffmann-LaRoche, In. July 1982 ($14,700).

Co-principal Investigator on an unrestricted grant from the State of Massachusetts Department of Environmental Quality Engineering to study the potential of organics in drinking water as pollutants in household air. November 1981 ($600).

Principal Investigator of a grant to investigate the effects of variable dietary ascorbic acid intake on the toxicity of a proposed toxic ozone intermediate on human subjects (in vitro). Hoffmann-LaRoche, Inc., N.J. December 1981 ($10,000).

Director of a $41,000 grant from the U.S. EPA to conduct an International Conference on Cardiovascular Disease and Drinking Water during May 1979.

Principal Investigator on a contract from the U.S. EPA to provide a critical assessment of the epidemiological and toxicological studies concerning the health implications of widespread use of diesel fuel. June 1979 ($9,500).

Co-principal Investigator on a contract from the U.S. EPA to evaluate the effects of chlorite on the kidney, blood pressure, and blood parameters in adult and neonate rats and mice. December 1979 ($176,198).

Co-principal Investigator on a grant from the U.S. EPA to conduct a study on the effects of elevated levels of sodium in drinking water on cardiovascular function. March 1978 ($950,000).

Director of a $24,000 grant from the U.S. EPA to conduct an International Conference on the Effects of Pollutants on High Risk Groups during June 1978.

Principal Investigator on a grant from the U.S. EPA to conduct a study on the effects of ozone and nitrogen dioxide on mice with low levels of glucose-6-phosphate dehydrogenase in their red cells. June 1978 ($211,000).

Co-principal Investigator on a grant from the U.S. EPA to conduct a study on the effects of chloramines, chlorite, and copper on pregnant female mice with red cells having low levels of glucose-6-phosphate dehydrogenase. July 1978 ($95,000).

Co-principal Investigator on a U.S. EPA grant to evaluate the effect of chlorine dioxide disinfection on neonates born during 1946 in a community that temporarily adopted the use of chlorine dioxide for disinfection. 1978 ($50,000).

Co-principal Investigator of a grant from the Water Research Resources Center at the University of Massachusetts to investigate the effects of elevated levels of sodium in drinking water on the health of community residents. January 1977 ($4,500).

Co-Principal Investigator. Massachusetts Department of Environmental Protection. Determination of heavy metal background levels. June 1997 ($30,000).

Co-principal Investigator on a contract from the Environmental Protection Agency to conduct: (1) a study of the incidence of death from circulatory system causes between two communities with markedly different sodium levels in drinking water and (2) an analysis of the difference in drinking water quality with respect to minerals and heavy metals between these two communities. July 1977 ($10,000).

Co-principal Investigator on a grant from the U.S. EPA to conduct a study on the effects of chlorine dioxide on mice with low levels of glucose-6-phosphate dehydrogenase in their red cells. October 1977 ($50,000).

Principal Investigator of a grant from the University of Massachusetts Graduate Research Council - Biomedical Effects Section - to continue studies on the effects of ozone on mice with low levels of glucose-6-phosphate dehydrogenase in red cells. December 1976 ($5,000).

VI. CONSULTING ACTIVITY – Partial Listing

Occupational Health and Safety Administration (OSHA). Advisor and expert witness on litigation proceedings on the area of establishing health risk to workers in different occupations with particular emphasis on chemical coordinating exposure. Consultation has focused on carcinogenic risk from exposure to aromatic amines such as 3,3'-dichlorobenzidine and "MOCA."

Environmental Protection Agency (EPA). (1) Invited as a consultant to advise what EPA's research priorities should be for FY 1981. (2) Selected to critically review the development of several criteria documents for drinking water contaminants (i.e., antimony, copper, cyanide, dichlorobenzidine, nickel, and zinc). (3) Selected for a national committee to evaluate the methodology by which EPA develops health criteria from which national drinking water regulations are established. (4) Selected as a member of the solvent taskforce to assess risk to the general public from drinking water with variable levels of contamination from a variety of common solvents. (5) Invited member of a select committee to advise EPA on developing methodologies for dealing with epigenetic carcinogens. (6) Selected to chair the health effects committee on nationwide public hearings on volatile organic contaminants in drinking water. (7) Selected as a member of an advisory group to help establish methodologies for assessing risk

from carcinogens in drinking water. (8) Selected by EPA to give the principal address on health effects of drinking water pollutants at four nationwide workshops concerning the re-evaluation of the Primary Drinking Water Standards. (9) Selected by EPA to Chair a congressionally mandated study on the comparative health risks of seven different drinking water treatment technologies, (10) consultant Scientific Advisory Board (SAB) on dioxin and environmental exposures.

National Semi-Conductor Co. (Danbury, CT). Provide direction for the development of a new industrial hygiene program. Supervised the developments of risk assessment resulting from occupational exposure to arsenic, arsine, silver, gold, antimony, boron compounds, phophene, hydrofluoric acid, acetic acid, silane, and hydrazine.

North Atlantic Treaty Organization (NATO). Drinking Water and Human Health committee.

Massachusetts State Pesticide Board. Human health effects advisor to an advisory committee of the board. 1977-1981. In September 1981, invited to the State Pesticide Board by the Governor for a 4-year term, but declined invitation.

Ecology and Environment, Inc. (Buffalo, NY). This is an international consulting firm concerned with toxic substance regulation, hazardous wastes, and occupational health. I served on a health advisory board, which provides direction for their industrial hygiene program.

Department of Environmental Quality Engineering (DEQE) for the State of Massachusetts. (1) On matters pertaining to ambient air quality standards and toxic substances in drinking water. (2) Helped to create a 25-hour course on toxicology and risk assessment for DEQE staff. I co-instructed the course. (3) Ad Hoc Committee on sodium in drinking water. (4) Member of a committee to develop a statewide air toxic program.

State of California - Energy Resources Conservation and Development Commission. Provided information on human high-risk groups in a power plant setting.

U.S. Army - Division of Environmental Health and Safety (Fort Dietrick, MD). Provided guidance on the development of a program to establish permissible exposure limits to chemicals employed in various army occupations.

National Sanitation Foundation. Nominated and elected to the NSF Council of Public Health Consultants from 1980 to 1983, specializing in toxicology.

Governor's Hazardous Waste Siting Council. Advise the Massachusetts Legislature and the Governor on the public health considerations in dealing with the proper disposing of hazardous wastes in Massachusetts.

Mitre Corporation. Served on a selected committee to formulate and review methodology for establishing acceptable exposures to toxicants to U.S. Army personnel in combat and training operations.

State of Massachusetts - Department of Public Health and Department of Environmental Quality Engineering Joint Advisory Committee on Environmental Risk Assessment.

National Academy of Sciences. (1) Advised on the development of a possible national study of persons at increased risk to environmental pollutants and (2) Participated as a member of the Safe Drinking Water Committee.

Praeger Scientific Publishers (NY). Reviewer of book proposals in the areas of environmental and occupational health and toxicology.

John Wiley and Sons, Publishers (NY). Reviewer of proposed books in the area of environmental and occupational health and toxicology.

MacMillan Publishing Co. (NY). Reviewer of proposed books in the areas of environmental and occupational health and toxicology.

Sybron Corporation (Rochester, NY). To direct a human risk assessment of exposure to propylene dichloride.

Perkins-Jordan, Co. (Portland, ME). Environmental/industrial engineering company advisor in the area of toxicity of hazardous substances.

Office of Technology and Assessment for the U.S. Congress. I am advising in the area of genetic susceptibility to pollutants.

Pierce, Atwood et al. - a Portland, Maine Law Firm. I am advising with regard to risk assessment for environmental agents.

Canal Electric Co. To advise on the possible health risks of switching from 2.2% sulfur oil to 2.8% sulfur oil for the generation of electricity.

Research Foundation of the American Water Works Association. To develop and conduct courses on toxicology and environmental risk assessment.

Northeast States for Coordinated Air Use Management (NESCAUM). I have been invited to present lectures for NESCAUM staff members on high-risk groups and standard setting during their Air Pollution Health Effects Course. January 1981 (Hartford, CT); March 1982 (Durham, NH).

U.S. Consumer Product Safety Commission and their contractor, JRB Associates. To advise and critically review their studies on consumer products and high risk groups especially children.

Electric Power Research Institute. I have been invited to participate in their nationwide study on the human health effects of inhalable particles from coal-fired power plants.

Gordon A. Enk and Associates, Inc. (Medusa, NY). I was invited to advise in the area of development of toxicological assays to prevent potential human health effects for coal-fired power plants.

Geomet, Inc. (Rockville, MD). I have advised on projects dealing with toxicological hazards in the utility industry.

American Industrial Hygiene Association. Non-Traditional Shiftwork Periods Ad Hoc Committee Membership. July 1982.

Bioassays, Inc. (Woburn, MA). I have advised in the area of developing animal models for predicting the response of humans to ozone and nitrogen dioxide.

Arthur D. Little Company. I have advised on projects dealing with the role of high-risk groups in establishing ambient air standards for mobile source pollutants.

Dynamic Corporation. I advise on a project dealing with assessing the toxicological health hazards associated with the generation of electricity.

Waste Management of Wisconsin, Inc. I advise on the health effects of groundwater contamination by organic substances.

Committee on Human Health Effects and Drinking Water for the American Water Works Association.

Center for Environmental Health and Human Toxicology. Advised on the health effects of formaldehyde.

Massachusetts Railroad Association. To advise on the potential human health risks associated with herbicide spraying.

Harvard University. I advise on the carcinogenic potential of diesel emissions from power generating plants.

State of Florida. I advise the State's Department of Environment on development of a water reuse policy.

City of Los Angeles, Department of Water and Power. I advise concerning risk assessment of carcinogens in drinking water.

State of Connecticut, Preventable Diseases Division. I advise on several areas of health hazards assessment of a wide range of pollutants.

National Institute of Environmental Health Sciences. Selected for the Third Task Force for Research Planning on the Environmental Health Sciences - specialty: Role of host variations, 1984.

American Industrial Health Council. I have advised on the areas of risk assessment and in developing ways to improve scientific communication with the media.

Envirologic Data. I advise in the general area of toxicology and risk assessment.

Academy of Toxicological Sciences. Selected to peer-review the applications of those persons seeking to become board certified in toxicology.

National Science Foundation (NSF). I advise on the area of long-term environmental health research goals with particular emphasis on human high-risk groups and risk assessment.

Council for Environmental Quality (CEQ). I advise on the area of long range planning of EPA research goals as they pertain to pollutant effects on high-risk groups and research methodologies.

U.S. Forestry Service. I advise on the human health risk associated with the aerial spraying of selected pesticides.

U.S. Consumer Product Safety Commission. I was selected based on a national competition to serve as a member of the Consumer Product Safety Commission's Chronic Hazard Advisory Panel on the use of the plasticizer, di(2-ethylhexyl)phthalate (DEHP) in children's products, e.g., pacifer, rubber pants, etc.

Scientific Advisory Panel. Health and Human Services, State of Connecticut.

Media Training. I was one of three toxicologists who participated in an intensive media training program which focused on how to be interviewed by the media on environmental issues. This was sponsored by Chemlawn Inc. February 1985; I had another media training session in November 1985 sponsored by Hoffman-LaRoche, Inc.

Doctor's Data. I was invited to be on the Scientific Board of Directors of this organization. February 1985.

National Academy of Sciences. I was appointed to a special study committee commissioned to assess the health effects of pollutants in commercial aircraft. 1985 to 1986.

World Health Organization. I was invited to participate in development of basic research needs associated with toxic oil syndrome on June 27-28, 1985, in Copenhagen.

Associated Industries of Vermont. I advised on the toxicological basis of the proposed State of Vermont air toxics program.

Gulf and Western, Inc. I advise on the toxicological effects of cadmium and lead contamination of water, air and soil.

State of California - U.S. EPA. I advise on the development of methodologies for establishing a health-based air toxics program.

Rohm and Haas, Inc. I was invited to provide a one-day program on animal extrapolation and risk assessment; also, I was invited to critique their approaches for deriving air quality standards for air toxics.

Southern California Edison. I advise on the environmental and public health implications of soils contaminated with petroleum products.

Monsanto. I was selected to be a member of an expert independent panel of scientists to review toxicology data of pesticide products.

Navy. I advise the Navy on the health effects of contaminants in drinking water.

Syntex Corporation. I advise on the health effects of soil contamination with various organic contaminants.

Tambrands, Inc. I have been invited to become a member of their Institutional Review Committee.

Pacific Power and Light. I have advised in the area of assessing public health implications of PCB contaminated soil.

Digital Equipment Corporation. Assess the health implication of ozone emissions from manufactured equipment.

U.S. Justice Department. Advise on health risk assessment associated with hazardous waste sites.

Department of Defense, U.S. Army. Advise on the extrapolative relevance of alternative animal models for predicting human responses to environmental toxins.

Council for Agricultural Science and Technology. Invited to serve on national committee to assess risk from 2-4D exposure.

Alliance Technologies. Advise in the area of risk assessment and toxicology on a variety of environmental issues.

Roy Weston, Inc. Advise in the area of risk assessment and toxicology.

Colorado Department of Public Health. Advised on the development of risk assessment methodologies to estimate human health risks from possible exposure from the Rocky Mountain Arsenal.
NOITE Corporation. Denver, Colorado. Advise on the potential public health risks associated with drinking water contaminants.

Smith, Kline and Beckman. Advise on the public health risks associated with incineration of medically related waste.

Gelman, Inc. Advise on the public health implications of organic contaminants in groundwater.

GZA Corporation. Advise on the public health risks of petroleum contamination.

Gelman Sciences. Advise on the public health risk of various issues relating to risk assessment procedures to estimate public health hazards for chemical contaminants such as 1,4 dioxane.

State University at Albany - Center for Policy Research. Advise on the issue of medical infectious waste and public health.

World Health Organization (WHO). I advise on the role of genetic factors in affecting the occurrence of occupationally-induced disease.

Woodward-Clyde Consultants, Inc. Advise on the public health risks associated with exposure to toxics from multi-media.

Environ Corp. Advise on the issue of soil ingestion by children.

W.R. Grace. Advise on various risk assessment issues.

Committee on Urban Environmental Protection for the Division of Urban Affairs of the National Association of State Universities and Land Grant Colleges.

Member of the International Joint Commission, Great Lakes Science Advisory Board's Health Committee, 1991-1992.

Florida Power and Light. Advise on various risk assessment areas.

3M Corporation. Advise on environmental and occupational health issues.

National Academy of Sciences. Invited to be a member of the committee assessing the human health effects of the fuel additive MTBE.

State of Colorado. Advised on risks associated with contamination at the Rocky Mountain Arsenal. 1988-present (2002).

Journal Reviewer (examples of):

Ageing Research Reviews
Archives of Environmental Contamination and Toxicology
Biogerontology
BioEssays
BioMed Central Genomics
Chemical Research in Toxicology
Chemosphere
Drug Safety
Ecology Letters
Ecotoxicology
Ecotoxicology and Environmental Safety
Environment International
Environmental and Experimental Botany
Environmental Health Perspectives
Environmental Science and Technology
Ecperimental Gerontology
Free Radical Biology and Medicine
Fresenius Environmental Bulletin
Food and Chemical Toxicology
Frontiers in Bioscience
GLIA
Hazarouds Materials
HortScience
Human and Experimental Toxicology
International Journal of Obesity
International Journal of Toxicology
Italian Journal of Zoology
Journal of Alzheimer's Disease
Journal of Plant Growth Regulation

Senator ROUNDS. I am going to take just a little bit of liberty here. I really do appreciate the participation of all of our witnesses here today.

I look back at the time in which I have had an opportunity to serve on this Subcommittee, and the idea on it is to be able to provide oversight, and part of that is to ask questions about how the determinations are made.

Part of the discussion on that, and I think regardless of which side of the dais you sit on, you want sound science, and you want the opportunity to be able to look at it and to ask the same questions that you would as if we all had scientific background; what would we be asking with regard to how that determination is made, and what data is available,, and how is it come up with, as much to be able to support the regulatory processes and say, look, we may disagree with the regulatory outcome, but we understand the science that was used behind it, and we can dispute it, or we can agree with it, back and forth.

It seems to me that there must be a way for an agency with regulatory oversight responsibilities to be able to share over a period of time a process that could be agreed upon very similar to, and I am thinking about the National Science Foundation, where, time and again, there are different projects that are looked at, they are peer reviewed, they are looked at objectively by outside groups who then discuss clearly how they come to a conclusion as to which way they work; what should be included, whether or not the projects meet the appropriate funding guidelines, and so forth.

Speaking from experience as a former Governor who worked on a National Science Foundation, at that point we were looking at National Science Foundation work for an underground laboratory to be located in Lead, South Dakota. Matter of fact, Princeton was one of the universities which participated in a lot of work. And we went through an extended period of time in which there were peer review processes to determine whether or not this was one of the sites at which an underground laboratory looking for neutrinos would be built, and I found it fascinating that although there was constant discussion among the different science organizations who were working on different locations, there was an acceptance that the basic process of sound science would win out.

Now, whether we use the terms of being able to replicate something or to be able to say that it is verifiable, become items that within the science community have clear and defined terms. But these are the types of discussions that we need to have if we are going to get to the point where, over a period of time, regardless of which Administration it is, they should be held accountable for using the appropriate science, year in, year out.

And an oversight committee such as this, regardless of whether there are Republicans responsible for operating as a majority or Democrats, and regardless of whether the Administration is Republican or Democrat, there should be certain accepted standards that either Republican or Democrat administrations should be held to adhere to with regard to how the regulatory processes are determined, and the accepted facts that are being used in making those regulations. That is what this is all about.

I don't think there is anything wrong with questioning the existing program which is out there, because most certainly there are questions that are raised on a regular basis. It does not mean that any one of the existing proposals is perfect, but most certainly I think the discussion that you all have held today, and the differing points of view that you have, has been very helpful to this Committee in trying to move forward, and I would just thank you all for your input today.

Senator WHITEHOUSE. Can I ask two more unanimous consents? One to put into the record a memorandum from the public relations firm of Bracewell and Patterson dating back to 1996 for the R. J. Reynolds Tobacco Company, and the other an action plan called The Secret Science Action Plan, prepared for Phillip Morris.

Senator ROUNDS. Without objection.

Senator WHITEHOUSE. Thank you, sir.

Senator ROUNDS. Thank you.

[The referenced information follows:]

From: Christopher Horner
To: Hyde, Timothy N.; Tompson, Randy
CC:
BCC:
Subject: Federal Agency Science
Date: 12/23/1996 1:56:01 PM

Attachments:

Gentlemen: The following is the document we discussed. Have a happy holiday. CCH
M E M O R A N D U M

TO: Mr. Tim Hyde
Mr. Randy Johnson
RJ Reynolds Tobacco Company

FROM: Mr. Christopher C. Horner
Bracewell & Patterson, L.L.P.

DATE: December 23, 1996

RE: Background and Proposed Program to Address Federal Agency Science

Per our earlier conversations, the following sets forth what needs to be done to reform agency science, focusing on the need based upon your interests, and how you are positioned to take a behind the scenes leadership position. It provides an overview of the issues relevant to this goal, and details a program taking advantage of the increasingly flagrant way regulators have perverted the scientific process, hiding behind a wall of selected scientists to essentially cow industry and Congress into accepting fringe scientific conclusions.

Summary

We propose creating, beginning with congressional oversight and a goal of enacting legislation, required review procedures which EPA and other federal agencies must follow in developing "extra-judicial" documents (i.e., those documents produced as guidance, science or other government products issued by regulatory agencies which are not necessarily at time of publication ripe for judicial review). This is important to your organization because, at some point in the near future, EPA will most likely be ordered to re-examine ETS. The only way to do

so on a level playing field is to construct explicit procedural hurdles the Agency must follow in issuing scientific reports.

Because there is virtually no chance of affecting change on this issue if the focus is ETS, our approach is one of addressing process as opposed to scientific substance, and global applicability to industry rather than focusing on any single industrial sector. Thus the examples of questionable science, to justify these standards. Congress must require those examples serve as the test cases.

Background

On the surface, now appears an opportune moment for addressing agency science head on, tackling the substance. This would seem the case because the first run at legislative attempts to reform the regulatory process failed and concerned Members are searching for a new mechanism to control EPA and other regulatory bodies. The landscape of the past year is littered with examples of persistent or newly-promoted "bad science," including the Mercury Report to Congress, MACT Hazardous Waste Combustion Rule, Methylene Chloride and the Dioxin Reassessment. Regarding the latter example, as you are likely aware, for the next round of EPA Science Advisory Board (SAB) review of the Dioxin Reassessment the Agency has removed any SAB members who were too vocal in their disagreement with the Agency. There will still be SAB review, but it will be an already-transparent group of "agreeable" scientists. So, in addition EPA is flagrantly "stacking the deck" with those whose conclusions are predetermined and in the Agency's favor.

Irrespective of this pattern, it is clear the 104th Congress was singularly unsuccessful in managing the Agency on a chemical-by-chemical or industry-by-industry basis. EPA actions demonstrate the it has taken measure of its legislative and industry adversaries, and decided upon aggressive campaigns on several of these issues to impose its policy-driven will upon scientific conclusions. The Agency helps create, and responds, to, the political winds, so you should anticipate no relief on re-evaluating ETS. EPA has of late played its public relations card very well, avoiding long news cycles for its proposals -- even timing them around holidays when readership is at its nadir -- while engaging the environmental press for the coming conflicts. EPA, helped by the backlash of the generally "pro-environment" public to a poorly implemented reg-reform agenda, has fostered an atmosphere where "industry" are reluctant to match the Agency's hardball tactics out of fear either that Congress would duck/mismanage the issue, or of Agency retribution. Thus, through a lack of industry support and unfavorable press, Congress has to date lacked the requisite support to effectively use the oversight powers of the legislative branch.

It is in this climate you will face a chastened but at least as aggressive EPA on re-evaluating the ETS study.

Project Approach

To improve the climate, and process, under which ETS and others are reviewed, we recommend initiating reforms by playing a strong role in molding and guiding Congress's oversight of EPA's latest Clean Air Act initiative (on PM 2.5/ozone). Such an effort would work toward requiring EPA to institute certain procedural changes to the pre-regulatory process. These would serve as a set of checks and balances to ensure a fair and equitable development and publication of scientific findings (i.e., reform the scientific process). It is that process, which is beyond the reach of the Administrative Procedure Act, which sets the stage for the rulemaking process. These procedures could then be subject to judicial review without the courts becoming involved in specific scientific issues (i.e., discern if EPA followed the requisite steps, rather than if it achieved the "right" answer).

When EPA announced its proposal to regulate particulate matter and tropospheric ozone, despite their news cycle management, the set the predicate for procedural change. These proposed regulations, based on questionable science, are not focused on those industries that comprise EPA's "usual suspects", but rather all industries including small businesses. Congress is expected to conduct heavy oversight of this process, with most leaders expressing that the actions are unnecessary and unrealistic. EPA has already signaled a desire to compromise as the process moves forward, and will start airing its options in the January 14-15 initial public hearings. It is critical to our overall goal that EPA not be allowed to change the forum into an industry-by-industry examination. Equally important, the process should not devolve into "outdoor air" interest seeking to shift the focus to "indoor air" interests. Instead, the efforts we envision focus on the process by which EPA arrived at its scientific conclusions, avoiding to the extent possible specific scientific issues, contaminants, or industries.

While some will approach these hearings as regulation-specific, as you can appreciate, from our perspective the greater problem is EPA (and OSHA) "science," encompassing all the scientific reports, studies, guidance documents and procedures produced by the nonregulatory offices of these agencies. None of these products are subject to timely challenge. In some instances, industry must wait years before regulations are promulgated, thus allowing industry to sue. Then, when industry has that opportunity, the court is faced with the ramifications of overturning years of EPA actions and policies based on this scientific document. Moreover, industry face mindsets such as "how can a

document which has been around for so long be wrong?" (the "historical credibility" argument). Finally, once industry's hands are tied in Washington, EPA or OSHA has distributed the documents or guidance to the press or states, forcing industry to face a public relations nightmare.

Thus, as we seek to create a regime where this cycle is a thing of the past while highlighting problems with contemporary studies. These studies will be the first "test cases" for the reformed process. This requires developing (1) overall criteria for a "sound science" process, and (2) a record, through congressional oversight, on how the Agency typically does not meet those criteria.

To illustrate, criteria could be as follows:

"Sound Science" Criteria - any government scientific program must have four components:

Inclusive - The scientific community, the public, Congress, and other Executive Branch agencies are given fair and timely access to review and affect change in the development of the science/document.

Transparency - the public can follow the developmental process the steps followed to develop the final science/document.

Able to be reproduced - Can the answer be reproduced from the record?

Algorithm - Given the set of all available scientific knowledge on the subject would independent groups arrive at the same answer?

[a possible fifth component which could be included as a deal closer could be:
Not judicially reviewable - This may seem counterintuitive, but one of the aspects of reg-reform which its opponents exploited to bring it down was the belief that everything would be litigated. Thus, it may be possible to achieve reforms through the principle that the scientific portions of a successful program should not be easily placed before the courts. Instead, the courts should be able to easily look at procedures followed (e.g., did the Agency follow its own procedures).]

We envision these new steps being "field tested" on, e.g., the methylene chloride study, ETS, etc. which, having been used as justification for reform would be held and reviewed under the new procedures.
To ensure Agency compliance Congressional oversight is also required. This at worst builds a record for judicial review and at best sets in

motion a set of enforceable procedures. We intend to develop for the Hill a set of scientific and procedural questions on scientific issues which different committees could then use. This requires:

Written Record - Submit lengthy, detailed questions to the agency requiring written responses. This creates a written record which the Agency often seeks to avoid, because it otherwise is permitted to develop scientific documents without responding explicitly (unlike the proposal/promulgation process) to public concerns.

Followup Hearings - Once the Agency has responded use this record both within and across an issue in oversight on how the Agency develops science. (e.g., this is an ideal place to inquire into risk assessment default values and risk criteria, which seem to change from office to office).

We envision the end results of the oversight hearings to be: (1) EPA publication in the Federal Register of a formal process for handling "extra-judicial" documents; (2) new legislation; and/or (3) inclusion in environmental or regulatory reform legislation which appears moving in the 105th Congress.

This approach merely ensures a fair hearing, but that is typically all the situations require to avoid the skewed result the federal agency prescribes. Critically, this approach also circumvents the tenuous situation you otherwise likely will face, of seeking after-the-fact, RJR-specific congressional support to undo the Agency's work.

What makes the National Association of Manufacturers a strong base for the above work is NAM's broad, yet non-specific, business base. Its one of a small handful, at best, of broad based associations not associated with particular industries. Thus, their lead on this general issue will not bog the hearings down in "anti-environmental," industry-specific rhetoric, nor create an environment where specific industries can legitimately fear Agency retaliation.

Conclusion

We envision a program, using contemporary studies and reports to illustrate how the Agency skews its results in the pre-regulation stage, to create set, reviewable science procedures. That process and its criteria will first be tested on those current examples of Agency misfeasance, which obviously must be sent back to the Agency or otherwise placed on hold in the interim. We need to meet again with you to discuss this proposal and how to best implement it, specifically beginning with the audiences with NAM and NFIB we discussed. We need another meeting, to hammer out the presentation to the two

referenced audiences, and reach consensus with you on the issues and approach we intend to pursue. Until we speak with you on this further, Happy Holidays.

CCH

/cch

SECRET SCIENCE
Action Plan

POWELL TATE
a Cassidy Company

April 9, 1998

A PUBLIC AFFAIRS CAMPAIGN MOUNTED IN THREE PHASES:

PHASE I: LAYING THE GROUNDWORK

April 1 - June 1998

PHASE II: BUILDING A CRITICAL MASS OF "OUTRAGE"

June - December 1998

PHASE III: SUPPORTING A SOLUTION

1999

PHASE I - ACTION PLAN

April - June 1998

PHASE I OBJECTIVES:

- Identify and Document the Problem
- Begin to Build a Critical Mass of Bi-partisan Support

PHASE I STRATEGY:

- Recruit Organization to Act as Initial Catalyst
- Leverage Relationships to Develop Core Alliance
  - Catalyst Organization
  - Boland & Madigan
  - Powell Tate

PHASE I EXECUTION

- Statement of Position
  - Plain Language
  - Baseline for Agreement
  - "Mantra" for Outreach

PHASE I EXECUTION

- Soft Testings: "Unofficial" Outreach to "Friends" to:
  - Assess Interest in Issue
  - Gauge Appetite For Activism
  - Identify Pitfalls and Vulnerabilities
  - Determine Potential for Additional Third-party Outreach
- Backgrounder Used as Departure Point
- Findings Compiled and Used as Departure Point For Recruitment

PHASE I EXECUTION

- Recruit Founding Member to Serve as Catalyst
  - Gma
  - Business Roundtable
  - Nam
- Create Low-keyed But Powerful Presentation to Make the "Pitch"

PHASE I EXECUTION

- Conceptual Research: Qualitative Independent Research to Determine
  - Initial Opinion Leader Reaction/response to the Issue/concept
  - Potential Fissures Within "Scientific Community"
- May Be Used Externally As Well As Internally
- Helps Solidify Strategy & Messages

PHASE I EXECUTION

- Third Party Education and Recruitment -- Two Tiers
  - Associations/public Interest Groups
    - Philosophical Support
    - Spokespeople, Especially Within State Organizations
    - Bi-partisan Appeal
  - Corporations
    - Monetary and Philosophical Support
    - Spokespeople, Especially Locally
    - Political Appeal

PHASE I EXECUTION

- Education and Recruitment Via
  - Formal Presentation
    - Power Point Presentation
    - Flip Book
    - Case Studies
    - 4-5 Page Backgrounder
  - Boland & Madigan/Powell Tate Relationships
    - Clients and Contacts
    - Ally Development Experts
  - Catalyst Organization Contacts
  - Client Contacts

- Core Group Targets:
  - Food
  - Energy
  - Communications
  - Transportation
  - Health Care
  - Waste Management
  - Labor
  - General Manufacturing
  - Government Transparency
  - Taxpayer Rights
  - "Science" (Professional Organizations)

PHASE I EXECUTION

- Strategy And Plan Preparation -- Phases II & III
  - Broadening Coalition
  - Media Outreach, National and Local
  - Fundraising
  - Additional Research For Public Consumption
  - Internet
  - Government Relations

Senator ROUNDS. With that, once again I want to thank all of our witnesses here today. You add to the discussion.

I would also like to thank our colleagues who have attended this hearing for their thoughts and questions.

The record will be open for 2 weeks, which brings us to Wednesday, October 17th.

With that, this hearing is adjourned.

[Whereupon, at 3:35 p.m. the Committee was adjourned.]

[Additional material submitted for the record follows:]

Paper

CASE-CONTROL STUDY OF LUNG CANCER RISK FROM RESIDENTIAL RADON EXPOSURE IN WORCESTER COUNTY, MASSACHUSETTS

Richard E. Thompson,* Donald F. Nelson,† Joel H. Popkin,‡ and Zenaida Popkin‡

Abstract—**A study of lung cancer risk from residential radon exposure and its radioactive progeny was performed with 200 cases (58% male, 42% female) and 397 controls matched on age and sex, all from the same health maintenance organization. Emphasis was placed on accurate and extensive year-long dosimetry with etch-track detectors in conjunction with careful questioning about historic patterns of in-home mobility. Conditional logistic regression was used to model the outcome of cancer on radon exposure, while controlling for years of residency, smoking, education, income, and years of job exposure to known or potential carcinogens. Smoking was accounted for by nine categories: never smokers, four categories of current smokers, and four categories of former smokers. Radon exposure was divided into six categories (model 1) with break points at 25, 50, 75, 150, and 250 Bq m^{-3}, the lowest being the reference. Surprisingly, the adjusted odds ratios (AORs) were, in order, 1.00, 0.53, 0.31, 0.47, 0.22, and 2.50 with the third category significantly below 1.0 ($p < 0.05$), and the second, fourth, and fifth categories approaching statistical significance ($p < 0.1$). An alternate analysis (model 2) using natural cubic splines allowed calculating AORs as a continuous function of radon exposure. That analysis produces AORs that are substantially less than 1.0 with borderline statistical significance ($0.048 \leq p \leq 0.05$) between approximately 85 and 123 Bq m^{-3}. College-educated subjects in comparison to high-school dropouts have a significant reduction in cancer risk after controlling for smoking, years of residency, and job exposures with AOR = 0.30 (95% CI: 0.13, 0.69), $p = 0.005$ (model 1).**
Health Phys. 94(3):228–241; 2008

Key words: ^{222}Rn, indoor; cancer; risk analysis; hormesis, radiation

INTRODUCTION

EXPOSURE TO radon gas has been shown to be a significant cause of lung cancer. Radon here means specifically the ^{222}Rn isotope along with its radioactive, alpha-particle-emitting progeny. ^{222}Rn arises as a decay product of ^{226}Ra, which is widely dispersed in rock and soil. Though ^{222}Rn has a half-life of only 3.8 d, its chemical inertness allows it to emerge from the rock and soil into confined spaces where it accumulates. It has been recognized as a significant lung-cancer risk for underground miners for some time. The BEIR VI report (NRC 1999) analyzed the pooled data from 11 cohort studies of the lung-cancer risk from radon exposure of underground miners using a linear, no-threshold (LNT) model of the excess relative risk. The report did recognize that a threshold at well below typical miner exposures could not be ruled out. Because miner exposures were typically 30 times larger than the residential exposures of people, the extrapolation of risk to those lower exposures involves considerable uncertainty. Nevertheless, the U.S. Environmental Protection Agency (U.S. EPA 2003) based a reassessment of lung-cancer risk from radon in homes on the BEIR VI report with only minor revisions in procedure and results.

Well over twenty case-control studies of the lung-cancer risk from radon in homes have now been reported for North American, European, and Chinese locations in order to assess more firmly the risk at lower exposure levels. While many, but not all, report an excess risk, the 95% confidence intervals (CIs) in the great majority of them include the possibility of no excess risk, which would occur if a threshold were to exist. A pooled analysis of the seven North American studies has recently appeared (Krewski et al. 2005, 2006). The data were found to fit an LNT model with "no apparent evidence of nonlinearity throughout the range of radon concentration observed." The slope of the excess odds ratio (OR) was found to be 0.10 per 100 Bq m^{-3} in fine agreement with the BEIR VI slope deduced from the pooled miners data. The 95% CI, −0.01–0.26, however, still includes tbe possibility of a threshold. A recent pooled analysis of 13 European studies (Darby et al. 2005) has also found agreement with the LNT model with a slope of 0.08 per 100 Bq m^{-3} with a 95% CI,

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0.03–0.16, that excludes a threshold with statistical confidence. Two poolings of Chinese data have been published. The earlier one (Lubin 2003) found an excess OR at 100 Bq m^{-3} of 0.139 with 95% CI of 0.01–0.37. The later study (Lubin et al. 2004) found an excess OR at 100 Bq m^{-3} of 0.33 with 95% CI of 0.01–0.36. Thus, both of the Chinese poolings exclude a threshold. A meta-analysis of seventeen case-control studies also suggested a linear dependence (Pavia et al. 2003).

In view of the unusual and unexpected trend of the adjusted odds ratio (AOR) vs. radon exposure found in this study, to wit, a protective effect, it is worth examining the literature further. First, while a number of the particular case/control studies found individual AOR values below one, that is, protective or hormetic, none found any statistically significant trends in that direction. It is, however, a curious fact (investigated in greater detail in the Discussion section) that the pooled study of Krewski et al. (2005, 2006) has *unadjusted* ORs that are strongly hormetic. Ecologic studies of lung cancer vs. radon exposure have had scattered results and, of course, lack the individual matching of case-control studies. It is interesting, however, that by far the largest and most fully analyzed such studies (Cohen 1995, 1997) found a hormetic result. These have been criticized on a number of grounds and defended. The BEIR VI report (NRC 1999) reviewed these and other ecologic studies and issued a strong judgment: They are not "informative" because of "inherent limitations of the ecologic method."

This paper presents a case-control study of lung cancer incidence vs. residential radon exposure in Worcester County, Massachusetts, carried out between 1990 and 1999 with both cases and controls from a single health maintenance organization. Each case was matched individually by age and sex to two controls. In contrast to previous case-control studies, evidence supporting a hormetic dose-response for radon exposures less than 150 Bq m^{-3} was found. This effect remains marginally statistically significant even after controlling for potentially confounding variables, including age and sex by the matching of the cases and controls, and smoking history, years of residence, income, education, and occupational exposure to suspected carcinogens in multivariable regression analyses. At a time when international consensus is being sought on the lung cancer risk of low radon exposure, it may be regarded as unfortunate to have a nonconforming study appear, but the results were obtained using objective, scientific methods and required peer-reviewed reporting. In addition, many aspects of this study rank it among the most careful ones in both data collection and analysis.

STUDY DESIGN

This study was encouraged as an adjunct study to the Connecticut Study (Sandler et al. 2006) and followed the protocol therein except for a few modifications as required by a lower budget, most significantly testing of only the current home. Approval to recruit cases and controls was obtained by the Institutional Review Board of the St. Vincent Hospital and Fallon Clinic. Both cases and controls were clients of the Fallon Clinic\Fallon Community Health Plan. Subjects of the study were residents of Worcester County, or for a handful of subjects, residents a few miles over its borders. Cases with histologically or cytologically confirmed primary lung cancer were eligible to participate in the study if they were at least 40 y of age, had the permission of their primary care physician, had lived in a radon-testable residence a minimum of 10 y, and were not cigar or pipe smokers (cigarette smoking being accepted). Among never smokers, all cases were histologically confirmed, except for unavailable path specimens in 3 of a total of 15 patients, while smokers with "non-small cell" cancer had cytological confirmation (a total of 8 cases). The pathology was not available for 20 smoking cases. All cases were confirmed by a single, blinded pathologist (Chief of Pathology, St. Vincent Hospital).

Of 580 cases considered for the study, 113 refused entry, 102 did not meet the residency requirement, 62 were not given physician approval to participate, 89 died before both the case's physician and the case subject had agreed upon participation in the study, 5 were disqualified for cigar/pipe smoking, and 209 were enrolled in the study. Radon detectors were lost for 9 of these, leaving 200 cases in the study. Males comprised 58%, females 42%. The cancer pathology of the cases indicated 59 (29.5%) with adenocarcinoma, 44 (22.0%) with small cell carcinoma, 20 (10.0%) with large cell carcinoma, 44 (22.0%) with squamous cell carcinoma, 10 (5.0%) with other, and 23 (11.5%) with no available pathology.

Controls were randomly selected by computer from the same client population. Two were matched individually to each case on sex and age to within ±2.5 y using date-of-birth (independent of year-of-participation). Of 939 controls considered for the study, 292 refused entry, 146 did not meet the residency requirement, 87 were not given physician approval to participate, 13 were disqualified for cigar/pipe smoking, and 401 were enrolled in the study. Radon detectors were lost for 4 of these, leaving 397 controls in the study. By default, 99% of the subjects were Caucasian.

A questionnaire was filled out by a trained interviewer during a face-to-face interview for every case and control. Because of illness or recent death, a surrogate (a

spouse or offspring) was interviewed for 21.5% of cases and 3.3% of controls. A detailed smoking history of the number and type (unfiltered or filtered) of cigarettes smoked per day for each year in the subject's life was obtained. The years of residency of the home and any structural changes made during that time were recorded. Previous radon testing and radon remediation were ascertained. Among cases and controls, 7.5% and 9.8%, respectively, had had the home tested, but only 0.5% of eases and 5.5% of controls could remember the result. Only one home had had any remediation, and that was minimal (crack filling). The subjects were questioned in detail concerning hours per week spent in wakeful living areas and bedroom(s) and any other level of the house, usually the basement, where the subject spent one or more hours per week. Sleep was assigned eight hours per night. This distribution of occupancy time was determined over days of the week and weekends, over seasons of the year, and for each differing lifestyle period (full-time work, part-time work, retirement, child-rearing, etc.). These questions determined the placement of detectors in the house. A job history of each subject was obtained, and corresponding years of occupational exposures to heat welding, asbestos, vinyl chloride, formaldehyde, ethylene oxide, x-rays, radioactivity, insecticides, herbicides, smelter fumes, and foundry fumes were obtained. Finally, stratified family income and years of education were requested. Table 1 summarizes many of these data.

DOSIMETRY

Radon concentrations were measured in yearlong exposures of Radtrack etch-track detectors (Tech/Ops Landauer, Inc., 2 Science Road, Glenwood, IL 60425) in the present, or for a few subjects, the immediate past residence that had been lived in for a minimum of 10 y. Before forwarding each batch of exposed detectors for reading by Tech/Ops Landauer, Inc., the U.S. EPA's National Air and Radiation Environmental Laboratory in Montgomery, Alabama, disguised "blanks" (unexposed detectors) and "spikes" (detectors given a calibrated exposure) in each batch (Smith et al. 1992). The number of spikes and blanks disguised in each batch was determined by the Montgomery EPA testing lab, and typically contained two spikes and one blank per batch. A correction factor of the calibration value divided by the

Table 1. Study population demographics, smoking status, and radon exposure.

Covariate	Controls (N = 397)	Cases (N = 200)	p-value
Mean (SD) radon exposure	66.3 (65.2)	67.5 (118.5)	0.086[a]
Same as above, one outlier removed		60.2 (59.4)	0.047[a]
Median radon exposure	50.1	43.7	0.039[b]
Same as above, one outlier removed		43.6	0.030[b]
Sex			0.966[b]
Men	229 (57.7%)	115 (57.5%)	
Women	168 (42.3%)	85 (42.5%)	
Residency (y)			0.081[d]
<20	90 (22.7%)	62 (31.0%)	
20–39	203 (51.1%)	94 (47.0%)	
≥40	104 (26.2%)	44 (22.0%)	
Mean (SD) time of residency (y)	30.6 (12.1)	28.5 (12.1)	0.049[c]
Mean (SD) time in home (h wk^{-1})	113.6 (18.2)	116.6 (17.9)	0.052[c]
Mean (SD) age (y)	67.7 (10.0)	66.6 (9.7)	0.225[c]
Smoking status			<0.001[d]
Never smoker	162 (40.8%)	15 (7.5%)	
Former smoker	196 (49.4%)	80 (40.0%)	
Current smoker	39 (9.8%)	105 (52.5%)	
Total job exposure (y)			0.112[d]
0	290 (73.0%)	134 (67.0%)	
1–9	52 (13.1%)	25 (12.5%)	
≥10	55 (13.9%)	41 (20.5%)	
Education			<0.001[d]
<High school	77 (19.4%)	67 (33.5%)	
High school	149 (37.5%)	90 (45.0%)	
At least some college	165 (41.6%)	40 (20.0%)	
Refused	6 (1.5%)	3 (1.5%)	
Income ($ y^{-1})			<0.001[d]
<30,000	159 (40.1%)	109 (54.5%)	
≥30,000	190 (47.9%)	58 (29.0%)	
Refused	48 (12.1%)	33 (16.5%)	

[a] T-test of natural logs.
[b] Kruskal-Wallis test.
[c] Two sample t-test.
[d] Chi-squared test.

Landauer reading was found for each spike, and an average of those correction factors for a particular analysis batch was applied (multiplied) to each Landauer measured value in that batch. Such corrections averaged a 19% increase. Another quality assurance procedure was to place two detectors side by side for exposure in approximately one-tenth of all homes. Sixty-four such tests were conducted. The coefficient of variation for the duplicate readings was 12%, which is thus a measure of the precision of individual radon concentration measurements.

The radon detectors were placed in the house after administering the questionnaire and thus determining the usage of various parts of the house. Detectors were always placed in the living area most often used, in the present bedroom, and in any former bedroom. Also, a detector was placed in any other level of the house that had been used on average for one or more hours per week. Typically this was the basement, but occasionally an upper story of the house when the bedroom was on the ground level.

The exposure rate was then calculated as a doubly weighted average of the various detector measurements: first, an average weighted by the fraction of hours per week usage of the particular area in a given lifestyle period, and second, an average of such averages weighted by the number of years of each lifestyle period during residency in the house (the most recent five years being excluded as a latency period). This is a more elaborate and accurate method than that used in the pooling of data (Krewski et al. 2005, 2006), where a "living area" (sometimes an average of the living area and bedroom) measurement was used. The importance of resident mobility within the house in determining the average exposure has been studied and emphasized by the Iowa group (Field et al. 2000). A sub-analysis presented below supports this thinking. Two extreme examples that occurred in this study illustrate the point. One subject with full-time employment lived in a two-story house but spent 50 h per week in the basement. Another subject lived entirely in the basement for a number of years before building the upper two floors of the house.

Several yearlong etch-track detector tests of outdoor Worcester County air yielded either below detectable, or barely detectable, concentrations (average $\sim$10 Bq m^{-3}). Thus, only in-house exposure was considered in this study. It is worth mentioning that no exposure contribution was imputed for any of this study's subjects; all contributions were measured. The few subjects for whom exposure measurements were lost (in spite of a written request on the detectors to be notified in case of death, occupancy change, etc.) were dropped from the study. For our study population of 597 subjects, we found the mean (standard deviation, SD) and median radon concentrations for the living area to be 63.5 (79.4) and 44.0, for the bedroom to be 61.6 (77.6) and 43.3, and for the basement (419 subjects) to be 176.8 (185.7) and 133, all in units of Bq m^{-3}.

One detector problem encountered in this study is worth mentioning. The EPA furnished the detectors for this study all at once, and the manufacturer did not list any shelf life for them. Thus, after six years into the study, it was a surprise to find that the "blanks" began to show small non-zero readings. A conversation with the detector maker[8] revealed several things: (1) there is an aging phenomenon in etch-track detectors which causes the background (unexposed) reading to increase with time; and (2) the reading procedure of the detector maker uses a background subtraction procedure determined from samples of the same plastic sheets (typically held for four years) that the exposed detector came from. The conversation thus affirmed a procedure of subtracting the average reading of the "blank" detectors from the readings of exposed detectors in that batch. Many "blanks" were then placed in the following batches to better evaluate the effect until new detectors were furnished. A plot of all the corrected measurements vs. the time of measurement showed no secular variation, thus supporting the subtraction procedure.

STATISTICAL ANALYSIS

All analyses were performed using the statistical software package Stata Release 8.0 (Stata Corp. 2003). As an initial step, exploratory analyses were performed on the data to summarize and quantify data spread and to look for important trends. Initial confirmatory analyses were used to investigate the statistical associations between the outcome of lung cancer (case or control) and several explanatory variables. In order to test for statistical associations, the chi-squared goodness-of-fit test was used on the categorical data, while the two-sampled t test was used for continuous outcomes. The nonparametric Kruskal-Wallis test for differences in the medians was also used. Potential outlier observations were identified using the Extreme Studentized Deviate (ESD) statistic method as described by Rosner (2000).

Conditional logistic regression was used to model the binary outcome of cancer status on radon exposure rate (in Bq m^{-3}) while controlling for potential confounders including years of residency, smoking status, education (<high school, high school graduate, and at least some college), household income ($\leq$\$30,000 vs.

[8] Private communication, Mark Salasky, Tech/Ops Landauer; 1996.

>$30,000), and total years of job exposure to known or potential carcinogens (0 y, 1–9 y, and ≥10 y). Due to the large number of respondents who refused to give their household incomes or, to a lesser extent, education level, refusals for these two variables were considered as separate categories in the regression models.

Persons were considered former smokers if they had not smoked within two years of their interview date. Current smokers were classified into categories of pack-years smoked, while former smokers were categorized by the time since last smoked. The number of filtered cigarettes smoked was multiplied by a weight factor of 0.8 compared to unfiltered cigarettes. "Filtered" cigarettes have changed with time over the decades of this retrospective study, and smokers' response to them has been found to change also, making any such factor rather speculative. The assumption of a modest reduction of inhaled carcinogens of 20% seems to be reasonable, and was used in calculating smoking intensity. Pack-years of smoking were calculated as the lifetime-averaged number of packs smoked per day multiplied by the total number of years of smoking. The number of years smoked was given to the nearest year.

Because of the importance of smoking as a potential confounder, several alternative ways of modeling smoking into the multivariable regression models were considered. Preliminary univariate analyses and log-odds plots revealed a strong positive relationship between pack-years smoked and cancer among current smokers, and an inverse, non-linear relationship between time since last smoked and cancer among former smokers. Among former smokers, initial analyses revealed no statistical correlations between pack-years and cancer. Neither age when first smoked nor age at quitting for former smokers was found to be statistically associated with cancer. In addition, no statistically significant multiplicative interaction terms between smoking and radon were found. Based on these preliminary results, it was determined that the smoking data were best modeled with categories of pack-years for current smokers, and categories of time since last smoked for former smokers.

The total job-related exposure in years to all the known and potential carcinogens, listed above, was taken as a covariate. No data were available on the intensity of the exposure. Preliminary univariate analyses on individual compounds revealed some marginal statistical associations with lung cancer; however, these results became statistically non-significant once smoking was controlled for. Nevertheless, since it is important to control for exposure to other carcinogens when looking at the effects of radon on lung cancer, it was decided that this exposure could be best quantified as an index of total, cumulative years exposed to all the compounds considered.

Log-odds plots of the data suggested that there was a non-linear dose-response relationship between radon exposure and lung cancer. Therefore, radon exposure was considered as a categorical variable to allow for this potential non-linearity. In addition, radon exposure was modeled with a smooth function using natural cubic spline terms with two degrees of freedom (Hastie and Tibshirani 1990). Natural spline terms for radon exposure were obtained from the data set using the 'ns' function from the statistical package R (R Development Core Team 2005). Since neither analysis imposed a theoretical risk-vs.-exposure functional dependence, the data thus determined their own functional shape. For comparison, a fit to the LNT model was also calculated.

RESULTS

Summaries of demographics and radon-exposure for the 200 cases and 397 controls in the study are presented in Table 1. Controls had a mean (SD) radon exposure rate of 66.3 (65.2) Bq m^{-3} and a median exposure of 50.1 Bq m^{-3}. In contrast, cases had a mean (SD) and median radon exposure of 67.5 (118.5) Bq m^{-3} and 43.7 Bq m^{-3}, respectively. However, one outlier among the cases was identified at 1,511 Bq m^{-3}. With this outlier removed, the mean (SD) and median for cases dropped to 60.2 (59.4) and 43.6 Bq m^{-3}, respectively, a difference that is statistically lower than that of the controls ($p = 0.047$ for means and $p = 0.030$ for medians via the Kruskal-Wallis test). This comparison of the simplest measure of exposure of cases and controls makes the possibility highly unlikely that these data are consistent with a linear increase in the risk of lung cancer with increasing radon exposure over the low dose region covered. Fig. 1 shows

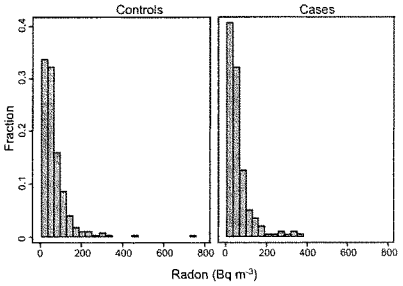

Fig. 1. Distribution of radon exposures (Bq m^{-3}) by cases and controls. One outlier at 1,511 Bq m^{-3} among the cases is not shown.

the distribution of radon exposure for both cases and controls.

Among the sample population, cases tended to have a marginally statistically shorter mean number of years of residency in their homes than controls [28.5 (12.1) vs. 30.6 (12.1) y, $p = 0.049$]. Almost 42% of controls reported having at least some college as compared to 20% of cases, a difference that is highly significant ($p < 0.001$). Controls had statistically significantly higher family incomes than cases, with almost 48% of controls reporting household incomes greater than \$30,000 y^{-1} as opposed to 29% of cases in this income category ($p < 0.001$). The percent of those who refused to give a household income was high for both groups (12% for controls and almost 17% for cases). A higher proportion of cases than controls also tended to have at least 10 y of occupational exposure to potential carcinogens (21% vs. 14%), an increase that is not statistically significant ($p = 0.112$).

Not surprisingly, cases were much more likely to be current smokers than controls. Approximately 53% of cases reported that they were smokers at the time of interview, as compared to only 10% among the controls ($p < 0.001$). Similarly, only 7.5% of cases reported being never smokers as compared to almost 41% among the controls ($p < 0.001$). The proportion of former smokers was about equal between both groups (40% for cases and 49% for controls).

Table 2 shows the unadjusted ORs and corresponding 95% CIs for lung cancer and several predictor variables based on conditional logistic regression models. In this analysis, the radon variable was categorized into 6 exposure rate variables with the base category ranging from 0–<25 Bq m^{-3}. Other break points, 50, 75, 150, and 250 Bq m^{-3}, were chosen to roughly equalize category populations. This univariate regression analysis revealed a significant decrease in cancer rates as radon exposure increased to about 150 Bq m^{-3}. In comparison to the lowest radon category, those with radon exposures in the 25–<50, 50–<75, and 75–<150 Bq m^{-3} categories have a statistically significant lower odds of cancer with deduced ORs (95% CI) equal to 0.53 (0.32, 0.87), $p = 0.012$; 0.45 (0.26, 0.77), $p = 0.004$; and 0.44 (0.25, 0.77), $p = 0.004$, respectively. Study participants in the 150–<250 Bq m^{-3} exposure category were half as likely to be cases as controls; however, this result is not

Table 2. Unadjusted ORs (95% CI) of cancer by radon exposure (as a categorical variable), smoking status, income, education, and total job exposure.

Variable	Cases/Controls	Odds ratio[a]	95% CI
Radon exposure (Bq m^{-3})			
<25	57/70	1.00	Reference
25–<50	60/127	0.53	(0.32, 0.87)[d]
50–<75	34/89	0.45	(0.26, 0.77)[d]
75–<150	34/86	0.44	(0.25, 0.77)[d]
150–<250	8/18	0.49	(0.19, 1.28)
≥250	7/7	1.20	(0.40, 3.59)
Smoking			
Never smoked	15/162	1.00	Reference
Last smoked 3–5 y	20/13	17.66	(6.25, 49.87)[e]
Last smoked 6–10 y	22/16	19.50	(6.83, 55.69)[e]
Last smoked 11–15 y	15/31	6.12	(2.33, 16.11)[e]
Last smoked >15 y	23/136	2.09	(0.92, 4.75)[c]
Smoker 5–30 pack-y	15/12	10.75	(3.53, 32.69)[e]
Smoker 30–50 pack-y	40/12	50.23	(17.83, 141.49)[e]
Smoker 50–60 pack-y	16/7	49.26	(13.50, 179.75)[e]
Smoker >60 pack-y	34/8	68.39	(21.80, 214.56)[e]
Income[b] (\$ y^{-1})			
<30,000	109/159	1.00	Reference
≥30,000	58/190	0.37	(0.23, 0.60)[e]
Education[b]			
<High school	67/77	1.00	Reference
High school graduate	90/149	0.66	(0.43, 1.01)[c]
At least some college	40/165	0.22	(0.13, 0.38)[e]
Total job exposure (y)			
0	134/290	1.00	Reference
1–9	25/52	1.07	(0.63, 1.81)
≥10	41/55	1.74	(1.07, 2.82)[d]

[a] ORs and 95% CIs obtained from univariate conditional logistic regression.
[b] Refusals removed.
[c] $p \leq 0.1$.
[d] $p \leq 0.05$.
[e] $p \leq 0.001$.

statistically significant [OR (95% CI) = 0.49 (0.19, 1.28), $p = 0.143$]. The highest category of radon exposure (≥250 Bq m^{-3}) predicts an increase in the odds of cancer as compared to those in the base category, but the OR is not statistically significant [OR (95% CI) = 1.20 (0.40, 3.59), $p = 0.746$].

Initial regression analyses also revealed a decrease in the odds of cancer among former smokers as the time since cessation of smoking increased. Former smokers with 3 to 5 y and with 6 to 10 y since quitting were 17.7 and 19.5, respectively, times more likely to develop lung cancer as compared to the base group of never smokers, an increase that is highly statistically significant ($p < 0.001$ for both groups). Those who last smoked 11 to 15 y prior to interview were only 6 times more likely to be cases compared to never smokers, a result that is also highly significant [OR (95% CI) = 6.12 (2.33, 16.11), $p < 0.001$]. Former smokers who had not smoked for at least 15 y had an estimated increase in cancer risk that is not statistically greater than for never smokers [OR (95% CI) = 2.09 (0.92, 4.75), $p = 0.078$].

Among current smokers, there was clearly a trend toward increasing risk as the number of pack-years of smoking increased. For example, those with 5 to 30 pack-years of smoking had an estimated 11-fold risk in cancer compared to never smokers [OR (95% CI) = 10.75 (3.53, 32.69), $p < 0.001$] while those with more than 60 pack-years of smoking had a cancer risk about 68 times greater than the never smokers [OR (95% CI) = 68.39 (21.80, 214.56), $p < 0.001$]. In fact, 34 of the 42 participants with greater than 60 pack-years of smoking were cases, as compared to only 15 cases among the 177 never smokers in the study. No current smokers reported less than 5 pack-years of smoking.

Other factors that were statistically associated with cancer risk include education level, household income, and total years of job exposure to known or potential carcinogens. Those study participants who were high school graduates had two-thirds the risk of cancer as compared to those with less than a high school education, a difference that approaches statistical significance [OR (95% CI) = 0.66 (0.43, 1.01), $p = 0.057$]. Participants with at least some college had an OR of 0.22 (0.13, 0.38) of cancer, a decrease in risk that is highly significant ($p < 0.001$). Similarly, those with family incomes greater than \$30,000 y^{-1} had a highly statistically significant reduced cancer risk as compared to those making less than \$30,000 y^{-1} [OR (95% CI) = 0.37 (0.23, 0.60), $p < 0.001$]. In terms of occupational exposure, there was an almost two-fold cancer risk among those who were exposed to known or potential carcinogens for 10 or more years on the job as compared to those with no job-related exposure, an increase that is statistically significant [OR (95% CI) = 1.74 (1.07, 2.82), $p = 0.027$]. Those with one to nine years of job-related exposure had no significant increased cancer risk when compared to those with no occupational exposure.

Unadjusted ORs were calculated for the three cell types that together account for about three-quarters of the cases: adenocarcinoma (59 cases, 117 controls), small cell undifferentiated (44 cases, 87 controls), and squamous cell carcinoma (44 cases, 88 controls). The unadjusted ORs for adenocarcinoma were below unity with statistical significance between 50 and 150 Bq m^{-3}. For the five increasing exposure categories enumerated above, the ORs (95% CI) were 0.53 (0.22, 1.25), $p = 0.147$; 0.28 (0.097, 0.82), $p = 0.020$; 0.31 (0.11, 0.91), $p = 0.032$; 0.38 (0.059, 2.39), $p = 0.30$; 2.72 (0.23, 31.5), $p = 0.43$. The unadjusted ORs for squamous cell carcinoma and small cell undifferentiated were without statistical significance.

Results from multivariable regression analyses are presented in Table 3. Two logistic multivariable models were considered: model 1 which categorized radon exposure into the six separate categories cousidered in the univariate logistic analyses, and model 2 in which radon exposure was fitted by natural cubic spline terms. Natural spline terms with between 2 and 4 degrees of freedom were considered (e.g., 1 to 3 knots) in order to give the regression model maximum flexibility to fit the data. Preliminary results revealed that varying the degrees of freedom produced overlapping curves and approximately equal fits to the data. Since spline terms with 2 degrees of freedom give a more parsimonious model than models incorporating terms with higher degrees of freedom,

Table 3. AORs (95% CI) by radon categories controlling for smoking, residency, job exposure, income, and education (model 1). Model 2 gives AORs for continuous radon exposure modeled with natural cubic spline terms with 2 degrees of freedom.[a]

	Model 1 AOR (95% CI)	Model 2 AOR (95% CI)
Radon exposure (Bq m^{-3})		
<25	1.00 (Reference)	0.75 (0.55, 1.03)[h]
25–<50	0.53 (0.24, 1.13)[h]	0.39 (0.14, 1.07)[h,c]
50–<75	0.31 (0.13, 0.73)[i]	0.35 (0.12, 1.04)[h,d]
75–<150	0.47 (0.20, 1.10)[h]	0.35 (0.13, 0.99)[i,e]
150–<250	0.22 (0.04, 1.13)[h]	0.36 (0.12, 1.10)[h,f]
≥250	2.50 (0.47, 13.46)	0.47 (0.11, 2.04)[g]

[a] Reference = 4.4 Bq m^{-3}.
[b] 12.5 Bq m^{-3} v. 4.4 Bq m^{-3}.
[c] 37.5 Bq m^{-3} v. 4.4 Bq m^{-3}.
[d] 62.5 Bq m^{-3} v. 4.4 Bq m^{-3}.
[e] 112.5 Bq m^{-3} v. 4.4 Bq m^{-3}.
[f] 200 Bq m^{-3} v. 4.4 Bq m^{-3}.
[g] 880.5 Bq m^{-3} v. 4.4 Bq m^{-3}.
[h] $p \leq 0.1$.
[i] $p \leq 0.05$.

results using this fit are presented under model 2 in Table 3. The AORs for radon exposure under model 1 were calculated with <25 Bq m^{-3} as the base category of comparison, while under model 2, 4.4 Bq m^{-3} was used as the base of comparison to calculate the AORs at the midpoints of the model 1 radon categories. The value at 4.4 Bq m^{-3} was chosen as the base group in model 2 since this was the lowest radon reading observed in this study. Under model 1, those in the 50–<75 Bq m^{-3} category of radon exposure had roughly one-third the cancer risk of those in the under 25 Bq m^{-3} category, a result that is statistically significant [AOR (95% CI) = 0.31 (0.13, 0.73), p = 0.008]. However, three other categories, 25–<50, 75–<150, and 150–<250 Bq m^{-3}, demonstrate a statistical trend toward a decreased risk, giving deduced AORs (95% CI) of 0.53 (0.24, 1.13), p = 0.099; 0.47 (0.20, 1.10), p = 0.083; and 0.22 (0.04, 1.13), p = 0.069, respectively. Those in the ≥250 Bq m^{-3} category had a 2.5-fold increase in cancer risk compared to the base group, but this increase is not statistically significant [AOR (95% CI) = 2.50 (0.47, 13.46), p = 0.285]. There was less precision and hence a larger CI in the ≥250 Bq m^{-3} exposure category because of a lack of cases and controls with high exposure values. Within the study population, only 14 (2.4%) participants were in the ≥250 Bq m^{-3} category.

Modeling radon exposure as a smooth function using natural cubic splines (model 2) produces ORs as a continuous function of exposure. Model 2 results presented in Table 3 are the values of the continuous function at the centers of the exposure categories. These results indicate a decreased cancer risk for those in the 75–<150 Bq m^{-3} category as compared to the reference category that is marginally significant (p = 0.048). In addition, those in the 25–<50, 50–<75, and 150–<250 Bq m^{-3} categories have a decreased cancer risk that approaches statistical significance compared to the reference category with AORs that have associated p-values equal to 0.068, 0.058, and 0.078, respectively. Model 2 deduced an AOR for subjects in the exposure category ≥250 Bq m^{-3} that was less than one also, but with no significance [AOR (95% CI) = 0.47 (0.11, 2.04), p = 0.312]. Fig. 2 shows the AORs, on the natural log scale, and associated 95% CIs for the discrete radon categories under model 1 as well as the continuous AORs (again on the natural log scale) obtained from model 2. A model 2 curve using 3 degrees of freedom (not shown) closely follows the plotted 2 degrees of freedom curve below 300 Bq m^{-3} and then rises somewhat faster, being above 1.0 at the last plotted discrete point [e.g., deduced AOR = 1.41 (0.06, 34.23) at 880.5 Bq m^{-3}]. Model 2 gives deduced AORs that are marginally statistically significant ($0.048 \leq p \leq 0.05$) in the region of radon exposure from about 85 to 123 Bq m^{-3}. Fig. 3 shows the continuous AORs and associated 95% CIs (dashed lines) obtained from model 2 for exposures below 250 Bq m^{-3} on a linear scale.

Multivariable regression analyses also revealed that income and occupational exposure are no longer significantly associated with cancer risk after controlling for education, smoking, and years of residency. However, there is a statistical trend towards an increased risk for those with 10 y or more of job-related exposure ($p \leq$ 0.13) from both models 1 and 2. Education remains

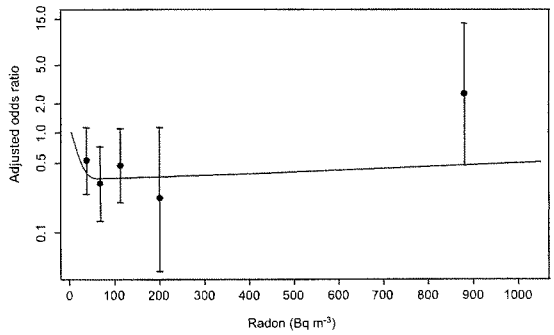

Fig. 2. Plot of AORs and corresponding 95% CIs obtained from model 1 at the midpoint of exposure and continuous AORs obtained from model 2. Odds ratios for model 2 are normalized to 1.0 at 4.4 Bq m^{-3}, the lowest observed radon exposure.

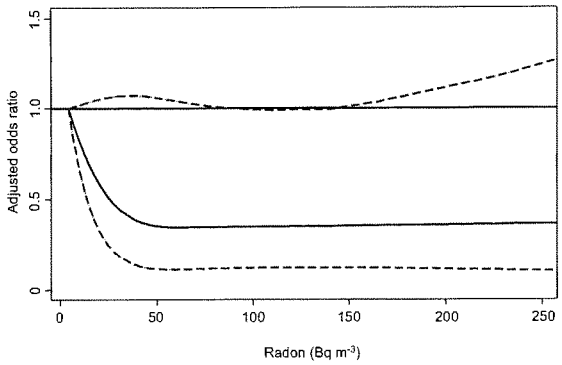

Fig. 3. Plot of AORs and corresponding 95% CIs (dash lines) obtained from model 2 for radon exposures less than 250 Bq m^{-3}. Odds ratios are normalized to 1.0 at 4.4 Bq m^{-3}.

statistically associated with cancer risk even after adjusting for the other covariates, with college-educated participants having approximately one-third the risk as compared to those with less than a high school education [AOR (95% CI) = 0.30 (0.13, 0.69), $p = 0.005$, model 1, and AOR (95% CI) = 0.31 (0.14, 0.69), $p = 0.004$, model 2]. Those who refused to give their education status and those with a high school degree had no statistically different cancer risk when compared to those with less than high school. AORs for the each of the three cell types discussed above were completely lacking in significance under either model 1 or 2.

Because other studies of lung cancer risk vs. residential radon exposure, including the pooling study, have compared their data to the LNT model, a fit to that imposed model was calculated here. A positive slope (95% CI), albeit statistically insignificant, of +0.04 (−0.20, 0.35) per 100 Bq m^{-3}, was found. The positive risk values at the higher exposure values pull the best-fit linear function upward in spite of the large hormetic dip at the lower values. The likelihood ratio test was used to determine if the regression model 2 with natural spline terms gives a superior fit to the data as compared to the linear model. This test resulted in a marginally significant result ($p = 0.0496$) that corresponds in magnitude to the p-values associated with the AORs deduced from model 2.

According to both models 1 and 2, the AOR per year of residency was very close to unity (0.99). This indicates that years of residency had little statistical effect on this study's deduced cancer risk. Nevertheless, admission of subjects with as little as 10 y of residency is a weakness of this study. To address this weakness, a sub-analysis of model 1 that included only subjects with at least 20 y of residency was performed. Because conditional logistic analysis was used, case-and-two-control triads were eliminated from the analyses if the case or both controls of the triad had a residency of less than 20 y. This cutoff at 20 y reduced the sample size from 597 to 348 subjects. Recalculating the univariate analysis of Table 2 with this data subset did not change the unadjusted ORs substantially but did, of course, expand the CIs because of the reduced statistical power. For comparison to Table 2, the new ORs and 95% CIs for the categories of increasing radon exposure were: 0.57 (0.31, 1.04), $p = 0.067$; 0.41 (0.20, 0.83), $p = 0.013$; 0.54 (0.28, 1.05), $p = 0.071$; 0.53 (0.13, 2.19), $p = 0.376$; and 1.08 (0.21, 5.68), $p = 0.926$.

When radon as a categorical variable was considered and covariates listed under model 1 controlled for in this sub-analysis, the AORs were greatly reduced for the 25–<50 and 50–<75 Bq m^{-3} categories of radon exposure as compared to the results presented in Table 3. Despite the reduced sample size, AORs for both categories were statistically less than one. Those in the 25–<50 Bq m^{-3} category gave an AOR (95% CI) = 0.24 (0.07, 0.85), $p = 0.027$, while those in the 50–<75 Bq m^{-3} had an AOR (95% CI) = 0.11 (0.02, 0.60), $p = 0.011$. The results for the 75–<150, 150–<250, and ≥250 Bq m^{-3} radon categories also differ from the results presented in Table 3, with those in the 75–<150 and 150–<250 Bq m^{-3} exposure categories having an increased risk, and those in the ≥250 Bq m^{-3} radon category having a decreased risk of cancer compared to the results using the

full data set. However, the AORs were not statistically different from one for any of these three categories in the sub-analysis, reflecting its loss of statistical power [AOR (95% CI) = 0.70 (0.21, 2.31), $p = 0.564$; AOR (95% CI) = 1.13 (0.06, 21.62), $p = 0.934$; and AOR (95% CI) = 0.73 (0.06, 8.99), $p = 0.804$ for the 75–<150, 150–<250, and ≥250 Bq m^{-3} radon categories, respectively]. While the complete loss of statistical significance in the three highest exposure categories is not surprising in view of the loss of 42% of the subjects in this sub-analysis, the lowering of the AORs in the lower two exposure categories and their increased statistical significance at being less than one is quite remarkable. These changes in AORs are difficult to explain given the nature of multivariable regression analyses. However, these results suggest the possibility that a greater nonlinear association between radon and cancer risk would have been seen if available resources had allowed for enrolling only subjects with a residency of ≥20 y, as the Iowa study (Field et al. 2000) was able to do.

A second alternative analysis based on model 1 was considered where radon exposure was calculated as a simple average of the living room and bedroom exposures, the "living area" exposure of the pooling study (Krewski et al. 2005, 2006), in contrast to the mobility-weighted average approach. Interestingly, with the exception of the highest radon exposure category of ≥250 Bq m^{-3}, this alternative model produced ORs adjusted for the covariates listed in Table 3 that were 26 to 38% larger than those obtained using the weighted average method. In addition, the p-values for the alternative AORs increased substantially in every category, with only the 50–<75 Bq m^{-3} category retaining statistical significance [e.g., AOR (95% CI) = 0.73 (0.35, 1.52), $p = 0.396$; AOR (95% CI) = 0.39 (0.17, 0.91), $p = 0.029$; AOR (95% CI) = 0.59 (0.25, 1.38), $p = 0.222$; AOR (95% CI) = 0.30 (0.06, 1.59), $p = 0.157$; and AOR (95% CI) = 2.20 (0.38, 12.77), $p = 0.381$ for the 25–<50, 50–<75, 75–<150, 150–<250, and ≥250 Bq m^{-3} radon categories, respectively]. Note that in every category this less accurate measure of exposure caused the AORs to move closer to unity, that is, to blur out the functional dependence. Also, note that in all but the highest (and least significant) exposure category the 95% CIs increased from 23 to 40%, demonstrating that the pooling study measure of exposure produces a greater randomness or misspecification in the exposure values compared to the weighted average used in this study.

Because of the substantial number of cases and controls that were interviewed by proxy (21.5% for cases, 3.3% for controls), a third sub-analysis was performed using only those data obtained from the participant interviews. The statistical results in the unadjusted case were unaffected by this analysis. However, in the multivariable model, the trends towards significance disappeared for radon categories less than 250 Bq m^{-3}, but the deduced AORs for these categories were still less than unity. A trend towards significance persisted in the ≥250 Bq m^{-3} category, giving an AOR of 9.35 ($p = 0.067$) as compared to the reference category (model 1). An investigation to understand this found only one thing: smokers interviewed by proxy had a statistically higher number of pack-years as compared to smokers interviewed in person. Whether this is proxy recall bias is unclear, and whether it alone could account for the loss of significance is also unclear. Of course, a lower statistical power from the loss of a quarter of the subjects could also contribute to the loss of statistical significance in the regression model.

DISCUSSION

The results of this study differ strongly from previous case-control studies concerning the risk of lung cancer from residential exposure to radon. The data here exhibit a striking protective or hormetic dip in the low dose rate region for both models 1 and 2. The four exposure categories between 25 and 250 Bq m^{-3} have an average AOR of 0.38 for model 1 and 0.36 for model 2. The AOR is less than 1.0 with statistical significance for model 1 between 50 and 75 Bq m^{-3} and with marginal statistical significance for model 2 between approximately 85 and 123 Bq m^{-3} (ranges below the EPA action level of 4 pCi L^{-1} = 148 Bq m^{-3}). This result was entirely unexpected. There have been many other reports in case-control studies of ORs below one in the low dose region but in all cases without statistical significance (Blot et al. 1990; Letourneau et al. 1994; Alavanja et al. 1994, 1999; Auvinen et al. 1996; Kreuzer et al. 2003; Baysson et al. 2004; Wichmann et al. 2005; Sandler et al. 2006). What reasons can be offered for this difference?

One important aspect of any radon study is careful dosimetry. Year-long measurements of radon with constant calibration of detectors using spikes, blanks, and duplicates are necessary. Equally important is the use of detectors in multiple house locations to account adequately for the subjects' mobility in the house. It is of great importance to determine this mobility, not just for the subjects' present lifestyle (full-time work, part-time work, retirement, child-rearing, etc.) but for all previous lifestyle periods in that house. This requires careful questioning of subjects and forming of doubly weighted averages. While this study was begun with this approach in 1990, more than a few studies performed since have not held to this standard. However, the Iowa study, the most elaborate one to date, did emphasize the importance

of this standard, but it did not find an OR dip below one (Fisher et al. 1998; Field et al. 1998a and b, 2000). As a test of this measurement standard, the data were reanalyzed using simply the average of living area and bedroom detector readings as the measure of exposure, as in Krewski et al.'s pooling studies (Krewski et al. 2005, 2006). There was a significant tendency for all OR values to move toward unity (from both above and below) and for CIs to enlarge and so remove statistical significance. One dosimetry difference of this study compared to the Iowa study should be noted. The high outdoor radon concentration in Iowa required assuming an exposure (35 Bq m^{-3}) of subjects outside their houses, while, as discussed above, radon concentrations in outdoor Worcester County air were sufficiently low (~10 Bq m^{-3}) as to be ignored.

Since cigarette smoking is known to be the dominant cause of lung cancer, at least ten times as lethal as radon as a national mortality cause, it is essential to account for it carefully. The year-by-year smoking histories of the subjects in this study (number and type smoked) were obtained from the interviews. This allowed exploring smoking in many statistical ways, leading to the use of nine smoking categories (Table 3) in our final analysis. Handling of this important confounder by considering both the duration and intensity of smoking among current smokers and length of time since last smoked among former smokers is in line with previously published radon studies (e.g., Wichmann et al. 2005; Krewski et al. 2005, 2006).

Under all the models that were considered, both former and current smoking greatly increased the risk of cancer with a single exception: former smokers who reported not smoking for at least 15 y prior to entering into the study had only a slightly elevated risk of cancer compared to never smokers that was not statistically greater than one (Table 3). Another major finding that was consistent across all the models considered was that those with at least some college had approximately one-third the risk of cancer as compared to those with less than a high school education. Whether this results from nature (genes) or nurture (healthier behavior) is unclear, but there is some indication of the latter. More highly educated people may have a healthier diet containing more anticarcinogens. This hypothesis is supported by findings in Italy which showed a marginally statistically significant reduced lung cancer risk of approximately one-third for those with a high consumption of carrots and tomatoes compared those with a low consumption of these vegetables (Bochicchio et al. 2005). A suggestion of reduced lung cancer risk with increased intake of vegetables, fruits, and juices was also reported for Missouri women (Wright et al. 2002). No significant protective benefit for those with a high school degree, as compared to those with less education, was found.

A rather unique aspect of this radon study design was use of the same health maintenance organization client pool (but not a hospital-based pool as in Baysson et al. 2004) for randomly choosing controls to be matched individually by age and sex to the cases. Because a control should be as identical as possible to its matched case (except, of course, for the presence of primary lung cancer), such a procedure should be superior to choosing the controls from the general population. This closer matching of cases and controls can potentially adjust for confounders that are not easily quantified or adjusted for in a regression analysis. Compared to population-based recruiting, controls in this study came from a more similar socio-economic, geographic, and medical-care stratum of the population. How much difference can that make? The only way to answer that would be to recruit a new set of 400 controls matched to the 200 cases from the general population in Massachusetts and re-analyze the data. Unfortunately, resources are not currently available for such a study.

Because our results conflict with the LNT hypothesis, it is worth reconsidering that issue. Its appeal originally stemmed from two ideas. First, a linear increase without a threshold requires but one parameter, a slope, and so is the simplest, nontrivial mathematical model. In the absence of further scientific information, this is naturally the preferred starting point. In time, a theoretical basis for the LNT hypothesis emerged: most cancers are monoclonal, and at typical residential exposures it is exceedingly unlikely that a lung cell will be struck twice by an alpha particle from radon and its progeny even in a person's lifetime. Doubling the exposure doubles the number of cells struck, and so doubles the chances of cancer. There is thus no basis for nonlinearity, and hence LNT is the logical conclusion (NRC 1999). Such reasoning assumes that cells do not communicate with each other. However, the "bystander effect," where nearby cells "know" that a cell has been damaged, is well established for in vitro cellular systems (Morgan and Sowa 2007). It undermines the theoretical reasoning for the linearity supporting LNT since nearby nontargeted cells could potentially experience either detrimental effects such as genetic damage (Morgan 2003) or non-detrimental effects such as a radio-adaptive response (Iyer and Lehnert 2002). Nevertheless, the importance of the bystander effect as a modifier on radiation responses at the tissue and organ level and, by extrapolation, on human health is unclear (Morgan and Sowa 2007). In opposition to evidence supporting nonlinearity, however, a third support for LNT has now appeared: the pooling of seven studies (Krewski et al. 2005, 2006) finds a linear

dependence of excess odds ratios [EOR (95% CI) = 0.10 (−0.01, 0.26) at 100 Bq m^{-3}, $p = 0.10$].

So what can be made of this? First, it should be said that, although BEIR VI backs the LNT hypothesis, it acknowledges the bystander effect and states, "The committee acknowledged that other relationships [than LNT], including threshold and curvilinear relationships, cannot be excluded with complete confidence, particularly at the lowest levels of exposure" (NRC 1999). The Phase I study of BEIR VII (NRC 1998) states, "Enhanced expression of p53 [gene] has also been reported in bystander cells in cultures exposed to alpha rays" (Hickman et al. 1994), and then goes on to state, "The existence of inducible repair systems that improve the efficiency of DNA repair has fueled speculative proposals that low levels of ionizing radiation actually have beneficial, rather than deleterious, effects. These suggestions of hormesis in the radiation response must be considered seriously but critically."

How could such nonlinear dependences—a hormetic dip, in this study—be missed in other case-control studies? One possible contributing effect would be that the reference category includes a substantial portion of those subjects that experience the protective effect. In that case, the reference category, normalized to OR = 1, would really contain a sizable population that properly belongs to OR < 1. An increase from such a reference category would be expected. For example, the high outdoor radon concentration in the Iowa study required using a reference category whose upper limit (corresponding to an average exposure *rate* of 58 Bq m^{-3}) covers all of the radon exposure category used here that gave an AOR = 0.53 (model 1) or 0.39 (model 2) and one-third of the next category used here that gave an AOR = 0.31 (model 1) or 0.35 (model 2). The need for a substantial number of low-exposed subjects in order to detect hormesis has been emphasized in a recent review (Calabrese 2005). A second possible contributing effect is inadequate dosimetry, particularly in not accounting properly for in-house mobility and for its differences during earlier lifestyle periods. This could cause a blurring out of an OR dip before its inevitable rise. The sub-analysis of this study using the simpler, pooled-analysis (Krewski et al. 2005, 2006) measure of radon exposure, discussed earlier, gives strong support to this conjecture.

Though the Iowa study is the most rigorous and elaborate study reported to date, the recent pooled analysis of Krewski et al. (2006) should probably be regarded now as the standard of comparison. The present study has both similarities and differences with that pooling. Some basic measures of the studies' data are surprisingly similar: from tables 3 and 5 of Krewski et al. (2006), the mean of the mean values of radon exposures reported (SD) for all cases was found to be 69.8 (46.5) Bq m^{-3} while that of controls was higher at 71.1 (43.0) Bq m^{-3}. In the present study, the mean radon exposure of all cases was 60.2 Bq m^{-3} (one outlier removed) while that of controls was higher at 66.3 Bq m^{-3}. Also, the *unadjusted* ORs (95% CI) calculated using 2-by-2 tables from data presented in table 9 of Krewski et al. (2006) yield: 0.80 (0.71, 0.90), $p < 0.001$; 0.69 (0.60, 0.78), $p < 0.001$; 0.75 (0.63, 0.88), $p < 0.001$; 0.90 (0.78, 1.05), $p = 0.178$; 0.77 (0.62, 0.96), $p = 0.02$; and 0.75 (0.61, 0.93), $p = 0.008$ for the categories 25–<50, 50–<75, 75–<100, 100–<150, 150–<200, and ≥200, respectively, all in Bq m^{-3}. With the exception of the 100–<150 category, all the unadjusted ORs were statistically less than 1.0. These values have their counterpart in the present study. For comparison on an equal footing [individual matching of cases and controls is not considered and radon exposure was determined *using the simple average living area measure* as used in Krewski et al. (2006)], the unadjusted ORs (95% CI) of the present study were: 0.70 (0.45, 1.09), $p = 0.113$; 0.54 (0.32, 0.92), $p = 0.024$; 0.52 (0.31, 0.88), $p = 0.015$; 0.59 (0.22, 1.63), $p = 0.311$; and 1.19 (0.38, 3.71), $p = 0.770$ for the categories 25–<50, 50–<75, 75–<150, 150–<250, and ≥250, respectively, all in Bq m^{-3}.

In spite of these similarities, after adjustment for confounders, this study and the pooling study arrive at strikingly different conclusions: this study finds a hormetic dip (AOR <1.0) persists over a substantial range before a positive cancer risk begins to emerge at higher radon exposure levels; in contrast, the pooling study finds a positive cancer risk throughout the range. The methods used for calculating the risk differ markedly: the present study fits cubic splines to the AOR data, letting the data determine the functional form; the pooling study fits only to chosen functional dependences with the main emphasis on the LNT function. (A forced fit of the present study data to the LNT model also gives a positive slope, albeit statistically insignificant.)

The confounders adjusted for in the final analyses of the two studies differ: the pooling study used age at diagnosis/enrollment, smoking categories, number of residences, and years of residence covered by alpha-track detector measurements; this study used smoking categories, education, and exposure to known or suspected carcinogens. The puzzle that needs to be answered then is how these differing adjustments lead to such different results for data sets that share similar simple hormetic measures of exposure.

In addition, aspects of the study designs may be important. The pooling study is hindered somewhat by having to find a "lowest common denominator" for the

data of the seven studies, while the present study is not so affected. The present study used controls individually matched to cases, not frequency matching as most of the seven studies used. The present study imputed no data while several of the seven studies used imputed exposure data. The present study used historic-mobility-weighted averages of exposure while the pooling was able to use only a "living area" measurement. The present study matched controls to within ±2.5 y while the pooling study used ±5 y. All the seven pooled studies used population-based controls while the present study used controls from the clients of same health maintenance organization as the cases were from, giving presumably a better socio-economic, geographical, and medical-care stratum match to the cases. Lastly, the present study used only face-to-face interviews for which 21.5% of case interviews were surrogates, while the pooled study included a wider range of interview techniques and had 44.1% surrogates for case interviews. It is hoped that this juxtaposition of both similarities and differences will help to resolve the puzzle posed above.

This paper's final conclusion: the possibility of a hormetic effect on lung cancer at low radiation doses cannot be excluded.

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NSSGA

NATIONAL STONE, SAND
& GRAVEL ASSOCIATION

STATEMENT FOR THE RECORD

BY

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SUBMITTED TO THE
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
SUBCOMMITTEE ON SUPERFUND, WASTE MANAGEMENT,
AND REGULATORY OVERSIGHT
UNITED STATES SENATE

"OVERSIGHT OF THE ENVIRONMENTAL PROTECTION AGENCY'S
IMPLEMENTATION OF
SOUND AND TRANSPARENT SCIENCE IN REGULATION."

OCTOBER 3, 2018

Chairman Barrasso, Ranking Member Carper, and other members of the Environment & Public Works Committee:

The National Stone, Sand and Gravel Association (NSSGA) appreciates the opportunity to submit a statement for the record of this Committee hearing and to address the importance of transparency in regulatory science.

Aggregates and the Economy

NSSGA (www.nssga.org) is the leading voice and advocate for the construction aggregates industry. NSSGA advances public policies that protect and expand the safe, environmentally responsible use of aggregates that build America's infrastructure and economy. NSSGA members—stone, sand & gravel producers and the equipment manufacturers and service providers who support them—supply the essential raw materials found in every home, building, road, bridge and public works project. The industry employs more than 100,000 highly-skilled men and women at 5,000 separate worksites, in all 50 states. Our members are committed to maintaining a sustainable environment for all, and to providing a safe and healthful work environment for their employees, whose daily efforts in today's economy provide vital support to their families and the communities in which they live.

The Need for Transparency in Regulatory Science

The aggregates industry is not opposed to sensible, evidence-based regulations. Our members are directly impacted by the Agency's regulations under a host of federal statutes. We believe that the foundations of the regulatory process will be immensely strengthened, and its benefits greatly increased, when the underlying models, assumptions, methods, and data that support regulatory research findings are made publicly available in a manner that is sufficient to permit independent validation.

We salute the leadership shown by the Environmental Protection Agency (EPA) in clarifying and proposing to codify the bedrock principles for scientific inquiry that led to a host of valid discoveries and beneficial action, but which have been deteriorating in the U.S. over time. The Agency should be congratulated for a sound and useful model that all federal and state regulatory bodies and research entities should emulate.

First and foremost, the Agency should continue to endeavor to ensure that the research methods and findings it relies on will pass rigorous scientific and legal review.

This concept has been recognized for decades in the courts and in many other contexts. The limitations of such reviews are now well documented, but they still provide a useful first-step toward valid science.

Tremendous environmental progress in the U.S. has been made in the last five decades. The Agency should be credited for its role in changing not only the state of the environment but also the way Americans think about the air, water, and land we all share.

Much environmental progress to date, however, has represented the "low-hanging fruit." We are now in a time when many regulations depend on complex, assumption-laden mathematical models or constructs and ambiguous data sets—all of which are open to various interpretations. At the same time, no attempt is made to replicate the majority of peer-reviewed scientific papers and, indeed, many or most cannot be replicated when such attempts are made. Research findings from numerous scientific disciplines are affected.

Society's need for a healthy environment must consider the needs of all those affected by its regulations. A transparent regulatory process—informed by accessible, reproducible scientific methods, data, and findings—provides the best opportunity for achieving both imperatives. That is particularly true considering the deference that courts provide to regulators' choices of research methods and models. Petitioners today cannot rely on the courts to question an agency's regulatory processes or conclusions, no matter how opaque, irreproducible, speculative, or erroneous their scientific foundation.

EPA's proposal recognizes and catalogs ample convincing evidence that the Agency's present rulemaking process is inadequate and should be modernized. The proposal lays out sensible and thoughtful steps that will vastly improve the scientific basis for technical regulations. Importantly, many of the ideas embodied in the proposal originated primarily outside the Agency before the current administration took office.

The proposal's objectives are consistent with EPA's authority under the numerous environmental statutes that it implements, which emphasize the need for regulatory decisions to be guided by sound science and informed public participation while also recognizing the need to protect important privacy interests. For example, the Toxic Substances Control Act ("TSCA") requires EPA to make regulatory decisions based on the "best available science," including the "degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented." At the same time, TSCA recognizes the importance of certain privacy interests, such as protecting confidential business information and private personal

information. Clearly, EPA must ensure that any final action it takes on this proposal continues to respect the balance between sound, transparent science and legitimate privacy interests.

Mr. Chairman, NSSGA thanks you for holding this very important hearing. NSSGA looks forward to continuing to work with the committee in doing what is right for America. If we ignore or sideline this opportunity to strengthen the science that strengthens the Nation's regulations, we put the future of our society at unnecessary and avoidable risk.

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