ENSURING ACCURACY AND ACCOUNTABILITY IN LABORATORY TESTING: DOES THE EXPERIENCE OF MARYLAND GENERAL HOSPITAL EXPOSE CRACKS IN THE SYSTEM?

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

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ENSURING ACCURACY AND ACCOUNTABILITY IN LABORATORY TESTING: DOES THE EXPERIENCE OF MARYLAND GENERAL HOSPITAL EXPOSE CRACKS IN THE SYSTEM?

TUESDAY, MAY 18, 2004

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:36 a.m., in room 2154, Rayburn House Office Building, Hon. Mark E. Souder (chairman of the subcommittee) presiding.

Present: Representatives Souder, Cummings, Ruppersberger, and Norton.

Staff present: Marc Wheat, staff director and counsel; Roland Foster, professional staff member; Malia Holst, clerk; Tony Haywood, minority counsel; and Jean Gosa, minority clerk.

Mr. SOUDER. Good morning, and thank you all for being here.

Today's hearing will examine the investigation of lab deficiencies at the Maryland General Hospital in Baltimore, MD.

Upon learning of these serious problems, Congressman Elijah Cummings, the ranking Democrat member of this subcommittee, immediately requested the subcommittee to hold a hearing on this troubling situation.

During a 14-month period between June 2002 and August 2003, the hospital issued more than 450 questionable HIV and hepatitis test results.

In July 2003, during this period, the hospital lab was inspected and accredited by the College of American Pathologists. CAP officials have ensured the subcommittee that their inspection standards were even more stringent than those required by the Federal Government. Yet, the inspection did not identify the ongoing deficiencies in lab testing.

Despite instrument readings showing that the test results might be inaccurate managers at the hospital failed to act.

Similarly, State inspectors did not respond to a 2002 letter from lab workers who warned of serious and longstanding testing problems that put patients and employees at risk.

These problems weren't taken seriously until this year, when State inspectors investigating a similar warning letter in December from a former employee, Kristin Turner.

State officials have confirmed the existence of the 2002 letter. They said they took the allegations seriously but found them vague and did not discover the serious problems until this year.

Subsequent investigations by State officials, prompted by the whistleblower, show that the laboratory was in the midst of serious problems at the very time the accreditation inspection was conducted.

State inspectors concluded the lab was understaffed and "rife with equipment malfunctions," and State and Federal inspectors later turned up pages and pages of violations of testing standards.

CAP has also since suspended its approval for two key laboratory divisions.

The complaint that led to these findings alleged that machinery used in HIV and hepatitis testing was not adequately maintained and that possibly erroneous test results were provided as a result. In all of these inspections, similar issues were identified concerning the management and quality assessment processes of the laboratory that were found to be deficient. Each oversight entity addressed these issues but did not inform all the remaining involved parties of their findings. Therefore, each oversight entity did not have the benefit of the findings of the others.

Only after the December 2003 complaint to the State survey agency that pinpointed a specific problem area to investigate did the entities involved begin to communicate their findings to each other.

Fortunately, the hospital has retested many patients and found the original results were mostly accurate, and steps have been taken to ensure patients are now receiving reliable test results.

Yet many questions remain about the full scope of this particular situation, as well as the potential for similar problems to occur elsewhere.

The purpose of this hearing, therefore, is to gain a better understanding of all of the issues that led to the deficiencies at MGH and how these problems went undetected and not addressed for such a long period of time despite inspections and warnings from lab personnel.

Our goal is to make sure that a similar situation never happens again at other hospitals and that patients can be assured that when they visit a hospital and have tests taken, that the results they receive are accurate and reliable.

We also want to be sure that all those adversely impacted by the problems at MGH are identified and given proper test results.

Our first panel will include Dr. Steven Gutman, the Director of the Office of In Vitro Diagnostics Device Evaluation and Safety of the Food and Drug Administration, and Dr. Sean Tunis, the chief clinical officer and director of the Office of Clinical Standards and Quality at the Centers for Medicare and Medicaid Services.

Our second panel will be Ms. Teresa Williams, a former employee of the Maryland General Hospital. Ms. Kristin Turner, another former employee of Maryland General Hospital, was also invited to attend but is unable to attend today's hearing due to illness.

And our final panel will feature Mr. Richard Eckloff of Adaltis US Inc.; Dr. Ronald Lepoff, Chair of the Commission on Laboratory Accreditation at the College of American Pathologists; Mr. Edmond

Notebaert, president of the University of Maryland Medical Center; and the Honorable Nelson Sabatini, secretary of the Maryland Department of Health and Mental Hygiene.

Thank you all for being here today. We look forward to your testimony and insights on this very important issue.

[The prepared statement of Hon. Mark E. Souder follows:]

Subcommittee on Criminal Justice,
Drug Policy and Human Resources

Opening Statement of Chairman Mark Souder

Ensuring Accuracy and Accountability in Lab Testing: Does the Experience of Maryland General Hospital Expose Cracks in the System?

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Thank you all for being here today. We look forward to your testimony and insights on this very important issue.

Mr. SOUDER. Now I yield to Mr. Cummings for his opening statement.

Mr. CUMMINGS. I want to thank you, Mr. Chairman, for your cooperation and assistance in holding this hearing today. I must say that when this hearing was requested, you immediately agreed that we should hold this hearing, and we were both of the agreement that this is neither a Republican nor a Democratic issue, but this is one that concerns the safety of Americans when they go to visit a hospital and, particularly in this case, receive laboratory testing.

One of the things that I do want to mention, Mr. Chairman, before I get started here, is I want to recognize my colleague from the State of Maryland's Senate, Senator Verna Jones, who has been a strong advocate of health care in our State and one who lives in the district where Maryland General is located and certainly is my neighbor.

So I want to thank you, Senator Jones, for being here.

I requested this hearing in March so that the subcommittee could explore important issues raised by a deeply troubling set of revelations concerning health care delivery in my congressional district. On March 11th, the Baltimore Sun reported that, from June 2002 to August 2003, Maryland General Hospital in Baltimore City had released more than 450 invalid HIV and hepatitis test results, despite error messages from the testing instrument indicating that the test results might be incorrect.

Today's hearing is an important opportunity to examine the factors that led to this unconscionable situation in which lives were endangered by the actions or inactions of persons charged with protecting the public health.

It is critical that we understand what caused the testing problems to occur, whether the health of any patients has been adversely affected, and why testing and related problems were not uncovered and addresses sooner by the State. Whether there are basic problems with the equipment used to run the tests and whether the instruments should have been used for HIV and hepatitis C testing are also important questions, as the instruments may still be in use in other laboratory facilities throughout the United States. My hope is that by airing and understanding these issues from all sides, we can help to ensure that nothing like this ever happens again in my congressional district or anywhere in the United States.

Although most of this hearing will be focused on what happened at one laboratory in Baltimore, this controversy has potential implications for laboratories everywhere. Clinical laboratory regulation is comprised of a multifaceted network of State and Federal governing entities. When Congress enacted the Clinical Laboratory Improvement Amendments [CLIA], Act in 1988, it did so with the goal of ensuring that all labs across this country would adhere to stringent quality standards. Additionally, Food and Drug Administration laws and regulations are designed in part to ensure the safety and effectiveness of medical devices marketed in the United States. The severity and duration of the problems at Maryland General call into question the adequacy of the regulatory regime established to ensure compliance with Federal standards. States

and private accreditation organizations also play important roles in what is a rather complex network that relies upon communication in order to be effective. The system must be attentive and responsive to the concerns of laboratory employees. This controversy was an unnecessary one that could have been avoided entirely if the concerns of employees had been listened to and taken seriously at all levels.

We will hear today from the major entities in this controversy. Hearing all of their perspectives in the context of this hearing will help us to understand the dimensions of the problem and what, if any, changes to the current regulatory regime may be necessary and appropriate to prevent such problems from occurring in the future.

On the first of our three panels, representatives from the Food and Drug Administration and the Centers for Medicare and Medicaid Services will testify concerning their respective roles in the regulatory regime that governs device safety and effectiveness in laboratory testing. On the second panel we will hear testimony from two former employees of Maryland General Hospital whose complaints helped bring this unfortunate situation to light. On the last panel we will hear from the representatives of Adaltis US, Inc., the manufacturer of the laboratory equipment that generated the suspect tests; the College of American Pathologists, the accrediting body for the Maryland General Hospital laboratory; the Maryland Department of Health and Mental Hygiene, the State regulatory agency responsible for ensuring compliance with State laboratory licensure law; and the University of Maryland Medical System, the parent company of Maryland General Hospital. I want to thank all of our witnesses for appearing before the subcommittee today to discuss some very difficult issues.

As you know, Mr. Chairman, this subject matter strikes a very deep chord because Maryland General is a very familiar place for me. I live only seven or eight blocks from the hospital, and I have received excellent health care from that facility. But the health care that I received must not be the basis of policy for this hospital or any other. With nearly 1,800 employees, Maryland General is a significant source of employment for my constituents, and it serves as a safety net hospital to many patients in my community. The lives endangered in this episode belong to the people with whom I share that community. From the outset, I have been concerned primarily about the imminent life and death consequences of the testing problems, but also about the message this whole affair sends to people served by Maryland General, as well as communities like it around this country.

All patients, all patients are entitled to full faith and confidence in the accuracy of medical test results they receive. This is the fundamental promise of CLIA. In this instance, it was not kept, and that broken promise has an impact beyond the individuals who received questionable test results.

Maryland General Hospital's efforts to respond to all dimensions of the problem are an important part of this story. Fortunately, their retesting efforts have shown, thus far, that the vast majority of the initial 460 test results were correct. Preliminary fears that hundreds of thousands of people might have received incorrect test

results have been largely alleviated. That number remains below 2,500, and I say that we are fortunate. But, Mr. Chairman, luck cannot be the foundation of our public health system. The need for answers and accountability from all parties is no less compelling today than it was 2 months ago.

The issues we are discussing today have life and death implications. I look forward to getting to the heart of these matters during this proceeding, and again I thank you, Mr. Chairman, for your cooperation in calling this hearing so rapidly. I also thank staff of the Republican side and the Democratic side who worked so hard to interview so many witnesses so that we would be prepared for this hearing today.

With that, I yield back.

[The prepared statement of Hon. Elijah E. Cummings follows:]

Opening Statement of

Representative Elijah E. Cummings, D-Maryland
Ranking Minority Member

Hearing on "Ensuring Accuracy and Accountability in Laboratory Testing: Does the Experience of Maryland General Hospital Expose Cracks in the System?"

Subcommittee on Criminal Justice, Drug Policy, and Human Resources
Committee on Government Reform
U.S. House of Representatives
108th Congress

May 18, 2004

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answers and accountability from all parties is no less compelling today than it was two months ago.

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Again, I thank you Mr. Chairman for your cooperation in convening this critical hearing.

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Mr. SOUDER. Thank you very much.

I ask unanimous consent that all Members have 5 legislative days to submit written statements and questions for the hearing record, and that any answers to written questions provided by the witnesses also be included in the record. Without objection, it is so ordered.

I also ask unanimous consent that all exhibits, documents, and other materials referred to by Members and the witnesses may be included in the hearing record, and that all Members be permitted to revise and extend their remarks. Without objection, it is so ordered.

It is our standard practice to ask witnesses to testify under oath, so if the first panel would rise and raise your right hands.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that each of the witnesses responded in the affirmative.

We thank you both for coming, and I will now yield to Mr. Gutman.

STATEMENTS OF STEVEN I. GUTMAN, M.D., DIRECTOR, OFFICE OF IN VITRO DIAGNOSTICS DEVICE EVALUATION AND SAFETY, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND SEAN TUNIS, M.D., CHIEF CLINICAL OFFICER, CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AND DEPUTY DIRECTOR, OFFICE OF CLINICAL STANDARDS AND QUALITY, CMS, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY VIRGINIA WANAMAKER

Dr. GUTMAN. Good morning, Mr. Chairman, and members of the subcommittee. I am Dr. Steven Gutman, Director of the Office of In Vitro Diagnostic Device Evaluation and Safety in the Center for the Devices and Radiological Health at the FDA. I am pleased to speak about FDA's role in regulating medical devices and to provide information regarding the Adaltis Labotech device.

FDA is responsible for protecting the public health by ensuring the safety and effectiveness of drugs, biologics, food, cosmetics, medical devices, and products that emit radiation.

This hearing specifically touches on FDA's medical device regulatory authorities. Among the broad menu of device products that FDA regulates are commercialized analytical tests and laboratory equipment intended for use in clinical laboratories. FDA refers to these as in vitro diagnostic devices.

The Medical Device Amendments of 1976 gave FDA specific authority to regulate medical devices. FDA places every medical device into one of three classes depending on the degree of control needed to provide reasonable assurance of safety and effectiveness. Devices posing the lowest risk are placed in Class I and are subject to general controls. These include company registration, quality system requirements for manufacturing, provisions regarding adulteration and misbranding, recordkeeping, and reporting of adverse events. FDA refers to these adverse event reports as medical device reports, or MDRs. Class II devices, such as instruments for measuring glucose or hemoglobin, generally pose higher risks than Class I devices. In addition to general controls, they are subject to one

or more of a wide range of special controls that the agency may designate. Class III devices are subject to pre-market approval. Examples of Class III devices include new tests for diagnosis of cancer or serious infectious diseases such as SARS. Pre-market approval requires manufacturers to submit an application which is subject to careful scientific review by FDA.

A general control applicable to all classes of devices is adverse event reporting. Under FDA regulations, user facilities are required to report device-related deaths to FDA and device-related serious injuries to manufacturers. Of course, FDA encourages anyone with knowledge of a device-related problem, even a less serious one, to report it to us through our MedWatch system.

The agency uses MDRs to help provide signals of device problems so it can determine whether followup is necessary. If FDA does followup and discovers a problem with a device, there is a broad menu of actions that can be taken depending on the problem. FDA inspects device manufacturing facilities to ensure conformance with requirements. The responsibility for inspection and oversight of clinical labs that use those devices lies with CMS under the CLIA program.

As the focus of this hearing is the erroneous test results at Maryland General, I would like to discuss the Labotech device used there. The Labotech device is an automated device intended for use in performing controlled chemical reactions that are the basis of a variety of lab tests. This device can be programmed by each individual lab to run up to 400 test assays. The lab development or modification of these assays is performed subject to regulations under CLIA.

The Labotech is considered a Class I device and is subject to general controls. FDA first cleared the Labotech device for marketing in 1992 and has only received one MDR, the Maryland General report of injury to an operator of the machine. It is believed that approximately 2500 of these devices have been placed in labs worldwide. FDA takes seriously and investigates MDRs reported to the agency. We are continuing to evaluate whether there are systemic problems with the Labotech.

FDA first became aware of the problem with test results generated at Maryland General when our press office received an inquiry on March 19, 2004. We contacted our colleagues at CMS, who indicated test results had been reported without following usual quality procedures. FDA has remained in contact with both CMS and the Maryland Department of Health to share information and see what we can do to assist in investigating this problem.

As an independent measure, FDA conducted an inspection of the Allentown, PA facility of the US distributor of Labotech. No serious problems were identified. Since this US site is only a distribution center, FDA is also scheduling a full inspection of the manufacturing site in Italy this summer.

Two adverse reports about Labotech have appeared in European data bases. FDA is still investigating whether these reports should have been submitted to our data base. There is no evidence of continued problems in the European Union, but FDA expects to followup on this issue during the inspection this summer.

FDA has recently initiated mechanisms for working with Europe to monitor post-market device performance. Problems identified in European Union data bases are now being shared with FDA.

Mr. Chairman, FDA will continue to advance our mission to protect the public health by staying abreast of this unfortunate situation through continued communication with both CMS and the Maryland Department of Health. We will be following up on device performance issues with a planned inspection in Italy this summer. After that inspection we will determine if further investigations or actions are needed.

I am happy to answer any questions. Thank you.

[The prepared statement of Dr. Gutman follows:]

STATEMENT BY

STEVEN GUTMAN, M.D.

DIRECTOR

OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

MAY 18, 2004

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, Mr. Chairman and Members of the Subcommittee. I am Dr. Steven Gutman, Director of the Office of *In Vitro* Diagnostic Device Evaluation and Safety in the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). I am pleased to speak today about FDA's role in regulating medical devices and to provide information regarding the Adaltis Labotech device.

REGULATORY BACKGROUND

FDA is responsible for protecting the public health by assuring the safety and effectiveness of drugs, biological products, food, cosmetics, medical devices, and products that emit radiation. We do this by keeping abreast of public health issues, developing regulations that further protect the American people, and enforcing the regulations and the statutes that govern these products.

This hearing specifically touches on FDA's medical device regulatory authorities. As defined by Federal law, the term "device" covers several thousand health products, ranging from simple articles such as tongue depressors and heating pads, to cutting-edge and complex devices such as pacemakers, lasers, and imaging technologies. The definition of device specifically includes articles intended for use in the diagnosis of disease or other conditions as well as *in vitro* reagents. Therefore, among the broad menu of device products that FDA regulates are commercialized

analytical tests and laboratory equipment intended for use in clinical laboratories. FDA refers to these as *in vitro* diagnostic devices (IVDs).

The Medical Device Amendments of 1976 amended the Federal Food, Drug, and Cosmetic Act to give FDA specific authority to regulate the safety and effectiveness of medical devices. Using a risk-based classification framework, FDA places every medical device into one of three "classes" depending on the degree of regulatory control needed to provide reasonable assurance of safety and effectiveness of the device for its intended use. Devices posing the lowest risk, such as bandages, are placed in Class I and are subject to general controls. These general controls include manufacturing establishment registration, Quality System Requirements for manufacturing, provisions regarding adulteration and misbranding, record keeping, and reporting of adverse events. FDA refers to these adverse event reports as Medical Device Reports (MDRs).

If general controls alone do not reasonably ensure the safety and effectiveness of a device, but FDA can identify an additional measure or measures that would provide that assurance, the Agency places that type of device into Class II. Class II devices are subject to special controls. Examples of Class II devices include instruments for measuring glucose or hemoglobin. Class II devices generally pose higher risks than Class I devices. They are subject to the general controls that also apply to Class I devices, plus one or more of a wide range of special controls that the Agency may designate. These special controls may include guidance documents, performance standards, post-market surveillance, patient registries, and/or labeling, which, taken together with the general controls, are sufficient to provide a reasonable assurance of safety and effectiveness of the device.

When FDA cannot be assured that the combination of general controls and special controls is sufficient to reasonably ensure safety and effectiveness of a medical device, FDA will place the device into Class III, which are subject to premarket approval. Examples of Class III devices include new tests for diagnosis of cancer or serious infectious diseases such as SARS. Pre-market Approval (PMA) requires manufacturers to submit an application, which is subject to careful scientific review by FDA to provide reasonable assurance of the safety and effectiveness of the device. FDA approval of a PMA application is necessary before a manufacturer may market a Class III device. Once approved for marketing, Class III devices also remain subject to the general controls already described.

As I already mentioned, one of the general controls that is applicable to all classes of devices is adverse event reporting. Under FDA regulations, manufacturers and importers of devices are required to report deaths and serious injuries to FDA that their device may have caused or contributed to, as well as certain malfunctions ("near misses," which are malfunctions of a type that is likely to cause or contribute to a death or serious injury). User facilities are required to report device-related deaths to FDA, and to report device-related serious injuries to manufacturers. (If the manufacturer is unknown, they should report the serious injuries to FDA). Of course, FDA encourages anyone with knowledge of a device-related problem -- even a less serious one -- to report it to us, through our MedWatch system.

FDA has developed special databases to ensure simplified and standardized reporting of adverse post-market events to the Agency and currently has regulatory staff with specific expertise in IVDs monitoring reports for these products. The Agency uses MDRs to help provide signals of

device problems so it can determine whether follow-up is necessary. If FDA does follow-up and discovers a problem with a device, there is a broad menu of actions that can be taken depending on the nature and severity of that problem. These include issuing public health information to alert users on how to avoid the problem; requiring corrective actions such as recalls, repairs and notifications; and taking various actions to stop further distribution of the affected devices until the problems are corrected.

Thus, FDA has a range of authorities that apply to IVDs and other devices. While FDA inspects device manufacturing facilities to assure conformance with these requirements, particularly requirements for good manufacturing practices and adverse event reporting, the responsibility for inspection and oversight of clinical laboratories that use those devices lies with the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

LABOTECH

As the focus of this hearing is the erroneous test results at Maryland General, let me now tell you about the Labotech device used there. The Labotech device is an automated device intended for use in performing controlled chemical reactions that are the basis of a variety of laboratory tests. The system includes a sample identification station, pipets for applying chemicals needed for the test being performed, incubators and washers, and an electronic eye to read chemical results. This device is considered an open system. That means its manufacturer does not specify the tests that may be performed using it, nor does the manufacturer provide instructions for specific test

procedures. Instead, the device performs functions that are useful in running numerous different assays, but for each specific assay the individual laboratory must program the machine with specific test conditions and procedures. Development or modification of these assay procedures is performed subject to regulations developed under CLIA a program administered by CMS.

The Labotech is considered a class I device, and is subject to general controls. Because of the configuration of this device, it must be manufactured under FDA quality system regulations with design controls. These manufacturing requirements are spelled out in FDA regulations (the quality system regulations) and include requirements for a controlled production environment, production by trained personnel, the presence and use of production and process controls, the implementation of a corrective action and preventive action system, and the need for product verification and validation. The product must be also labeled appropriately with adequate directions for use. This device is also subject to adverse event reporting.

FDA first cleared the Labotech device for marketing in 1992. Since the product was cleared, FDA received one MDR in 2004. An employee of Maryland General Hospital was splashed with patient samples due to a falling wash head. This incident was reported by Maryland General Hospital to the company in 2003. Since there was no indication at the time that the employee had contracted any disease or suffered any other serious injury from the incident, the company judged the event to be one that it was not required reporting at that time. Upon learning in 2004 that the employee now alleges that this incident resulted in her contracting hepatitis and HIV, the company filed an adverse medical event report with FDA about this incident. It is believed that approximately 2500 of these devices have been placed in laboratories worldwide and the device

does appear to provide safe and effective results when used appropriately. FDA takes seriously and investigates MDRs reported to the Agency, however, the nature of this MDR does not lead us to believe that this instrument is unsafe.

FDA first became aware of the problems with test results generated at Maryland General Hospital when our press office received an inquiry about the Labotech device, on March 19, 2004. Shortly thereafter, we contacted our colleagues at CMS, and they reported that they believed this was a laboratory problem, not a problem with the Labotech device.

Since that time, FDA has remained in contact with both CMS and the Maryland Department of Health to share information and see what we can do to assist in the ongoing investigation and correction of the problems observed at Maryland General. We do not have enough information at this time to make further statements about device performance at this site.

Despite our preliminary conclusion that the problems at Maryland General stem from the actions of the laboratory, we have undertaken our own investigation to determine whether the problems at Maryland General might indicate a general problem with the Labotech device itself. That assessment is ongoing, but I can share with you some of the steps we have taken and plan to take. Soon after learning of the problems at Maryland General, we scheduled an inspection of the Allentown, Pennsylvania facility of the U.S. distributor of the Labotech, Aldaltis US, Inc. The device is manufactured by Aldaltis' parent company, Aldatis Italia, S.P.A., an Italian firm. Our U.S. inspection, which was conducted from April 12 though 14, 2004, focused on whether Adaltis U.S. was aware of the problems and took corrective action. No serious problems were identified.

Since this U.S. site is only a distribution center, FDA is also scheduling a full inspection of the manufacturing site in Italy to include an evaluation of the quality systems in place and the complaint files.

As a result of questions raised at a briefing with this Subcommittee's staff on April 29th, we became aware of two adverse reports about the Labotech that appeared in European databases in 1996 and 1999. The 1999 report resulted in a public health notice in the United Kingdom. FDA is still investigating whether these reports should have been submitted to the FDA MDR database and whether they are related to the problems that were reported to FDA in MDRs. There is no evidence that continued problems have been observed in the European Union since the 1999 report, but FDA expects to follow-up on this issue during the planned company inspection in Italy this summer.

FDA has recently started developing mechanisms for working with Europe to monitor post-market device performance as part of initiatives in the area of global harmonization of device regulation. Problems with device performance that have been included in the European Union databases are now being shared with FDA regulatory staff.

FDA has checked for more informal signals of potential problems with the Labotech in addition to our review of the more formal modes of MDR reporting. We searched published literature for reports of problems. That search revealed no problems but did find two reports of successful research using the device. We also observed that the American Society cited the problems at

Maryland General on the listserve run for Microbiology. No other facilities mentioned problems with the device after seeing this report.

CONCLUSION

Mr. Chairman, FDA will continue to advance our mission to protect the public health by staying abreast of this unfortunate situation through continued communication with CMS and the Maryland Department of Health. And, despite preliminary findings that the Labotech device was not the cause of the problems at Maryland General Hospital and appears to continue to be a safe and effective diagnostic device, we will continue to investigate this issue. I am happy to answer any questions you might have.

Mr. SOUDER. Thank you.

Dr. Tunis.

Dr. TUNIS. Chairman Souder and Representative Cummings, my name is Sean Tunis. I am the chief clinical officer for CMS, and I am accompanied today by several staff who have direct oversight of the CLIA program who may be able to answer additional technical questions that you have.

I thank you for the invitation to appear here this morning to discuss the efforts to ensure quality lab services at Maryland General Hospital and to find ways to prevent similar problems in the future.

CMS is responsible for ensuring that all laboratories in the United States meet quality standards established under CLIA. We understand that Maryland General Hospital's lab has not fully complied with these standards and is now under new management, and they are sending HIV and hepatitis lab services to an outside lab.

This morning I would like to discuss CMS's general efforts at ensuring laboratory quality and then the specifics of this case in question.

The 1988 CLIA legislation establishes standards for laboratories performing tests on human specimens. CLIA regulations are based on complexity of test methods; thus, the more complicated test, the more stringent the compliance and oversight requirements.

Laboratories performing tests covered under CLIA must register, pay fees, and if they are performing moderate and high complexity tests, be surveyed by one of the State agencies working under contract with CMS or by one of the private accrediting bodies whose standards CMS has accepted as being equal to or more rigorous than those established under CLIA. These labs continue to be subject to a biennial CMS survey process and data show that since CLIA was implemented in 1992, quality deficiencies in clinical labs have decreased from 35 percent of labs with quality problems to under 10 percent with quality problems in recent years. And just to give you an idea of the magnitude of the accrediting process, in 2003, 19,000 labs in the United States were surveyed for compliance with CLIA.

When CMS finds problems during the survey, the lab is generally provided an opportunity to correct those problems prior to enforcement actions. Over the past 5 years, CMS has proposed 6,084 actions and carried out 487 compliance and enforcement actions. Overall, CLIA oversight of labs works extremely well, but obviously the system can be improved.

The State surveyor for CMS in Maryland is the Maryland Department of Health and Mental Hygiene. Labs may also choose to be approved by private accrediting organizations, as was the case with Maryland General Hospital, who chose the CAP accreditation. The surveyor determines, based on observation of the laboratory's practices, interviews with lab personnel, and review of the lab's relevant documents, whether the lab is meeting the requirements of CLIA. Emphasis is placed on overall lab performance and the structures and processes contributing to the reliability of testing.

Since it would be impossible to review every test and every document in the lab, the surveyor reviews the selected cross-section of

information to see if the laboratory has established and implemented appropriate mechanisms for monitoring and evaluating its practices. If problems identified during the survey or as a result of a complainer are not remedied in a reasonable amount of time, CMS can impose various sanctions, which may range from onsite monitoring to fines to loss of Medicare reimbursement.

Maryland General's lab is accredited by the College of American Pathologists and is located in a State with a laboratory licensure law. Labs must meet both CLIA and State requirements. The routine biennial inspection was performed by CAP in April 2003. The State of Maryland had also conducted a CLIA survey based on a compliant in November 2002. In both of these inspections, similar issues were identified concerning the management and quality assessment processes of the laboratory that were found to be deficient.

Each oversight entity addressed these issues but did not inform all of the remaining involved parties of their findings and did not followup to ensure that these problems were resolved. In retrospect, this was clearly a serious problem. Only after the December 2003 complaint did the State survey agency that pinpointed a specific problem area to investigate, and CMS recognized the severity of the issue, did all of the entities involved communicate their findings to each other.

It should be noted that Maryland General stopped HIV and hepatitis testing in August 2003, a few months after the CAP survey, having recognized problems with their tests. In March 2004, the Maryland General Hospital lab was surveyed by CMS, the State of Maryland, the Joint Commission on Accreditation of Health Care Organizations, after CMS was notified of serious problems with the lab.

Because of these problems with Maryland General's lab, CMS notified the hospital that the lab was no longer deemed to meet the CLIA conditions by virtue of its accreditation by CAP. CMS placed the lab under the jurisdiction of the Maryland State agency and the hospital was given 10 days to respond with a plan of correction. Maryland General has submitted a 400 page plan of correction that is currently under review by CMS.

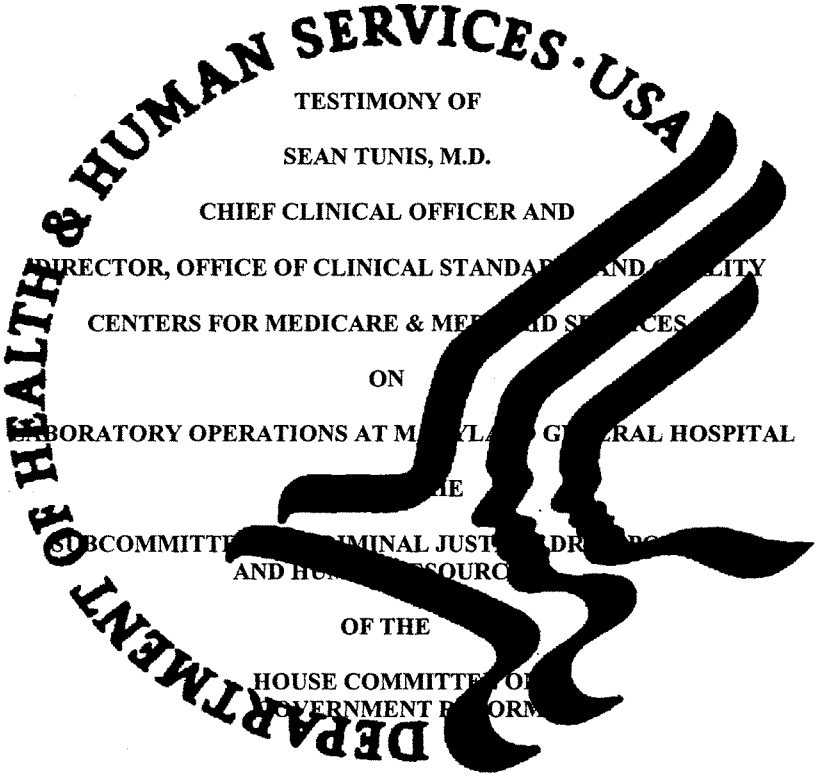
When viewed in the larger context of CLIA survey work and enforcement, the problems at Maryland General Hospital are fortunately atypical. Typically, the clarity of the hospital regulations, coupled with regular oversight, has resulted in high quality lab services in the United States. However, as a result of this experience at Maryland General, CMS is developing a plan for tighter communication protocols to coordinate activities among the State agencies surveying on behalf of CMS, the CMS regional offices, and the accrediting organizations. CMS is also specifically addressing the communications process for complaints and accreditation organization validation surveys through its State agency Performance Review Program.

These strengthened processes will be communicated through training and the pre-approval process. This improved communication will ensure that entities performing reviews of lab services are aware of complaints and deficiencies that each has found so that a pattern of problems over time can be readily identified and a re-

occurring of a situation like that occurring at Maryland General can hopefully be avoided.

Thanks for the opportunity to appear before the committee, and I am available to answer any questions that you have.

[The prepared statement of Dr. Tunis follows:]



TESTIMONY OF

SEAN TUNIS, M.D.

CHIEF CLINICAL OFFICER AND

DIRECTOR, OFFICE OF CLINICAL STANDARDS AND QUALITY

CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

LABORATORY OPERATIONS AT MARYLAND GENERAL HOSPITAL

BEFORE

THE

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CMS

CENTERS for MEDICARE & MEDICAID SERVICES

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MAY 18, 2004

Chairman Souder, Representative Cummings, distinguished members of the Committee: I thank you for your invitation to appear here this morning to discuss efforts to ensure quality results from the Maryland General Hospital laboratory. The Centers for Medicare & Medicaid Services (CMS) works with a number of different entities, including state government agencies, professional associations and independent survey groups, to ensure that entities receiving Medicare payments comply with established conditions of participation for their provider type and that all laboratories in the U.S. meet Clinical Laboratory Improvement Amendments (CLIA) standards. We understand that Maryland General Hospital's lab has not fully complied with these conditions of participation. This morning I would like to first discuss CMS' general efforts at ensuring laboratory quality and then the specifics of the case in question.

CLIA BACKGROUND

In 1988, Congressional hearings concerning deaths of women from erroneously read Pap smears, and the proliferation of bench top laboratory technology into non-traditional testing sites, led to passage of CLIA. CLIA established quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. A laboratory is defined as any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, and treatment of a disease or impairment, or to assess health. CLIA is user fee funded; therefore, all

costs of administering the program must be covered by the regulated facilities, including certificate and survey costs.

Final CLIA regulations were published on February 28, 1992 and are based on the complexity of the test method; thus, the more complicated the test, the more stringent the compliance and oversight requirements. Three categories of tests have been established: waived complexity; moderate complexity, including the subcategory of provider-performed microscopy (PPM); and high complexity. CLIA specifies detailed quality standards for the latter two categories. Waived laboratories must enroll in CLIA, pay the applicable fee and follow manufacturers' testing instructions.

CMS is charged with the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, approving entities that test laboratory proficiency, selecting accrediting organizations and identifying states exempt from CLIA as a result of their licensure requirements. The Centers for Disease Control and Prevention (CDC) is responsible for the CLIA studies, convening the Clinical Laboratory Improvement Amendments Committee (CLIAC) and providing scientific and technical support/consultation to DHHS/CMS. The Food and Drug Administration is responsible for test categorization.

LABORATORY ENROLLMENT AND PERFORMANCE STANDARDS

To enroll in the CLIA program, laboratories must register by completing an application, pay fees, be surveyed, if applicable, and become certified. CLIA fees are based on the certificate requested by the laboratory (that is, waived, provider performed microscopy (PPM), accreditation, or compliance) and, for moderate and high complexity laboratories, the annual volume and types of testing performed. Waived and PPM laboratories may apply directly for their certificate as they aren't subject to routine inspections, unless there is a complaint. Laboratories that must be surveyed routinely; i.e., those performing moderate and/or high complexity testing, can choose whether they wish to be surveyed by CMS or by a private

accrediting organization. The biennial CMS survey process is outcome oriented and utilizes a quality assurance focus and an educational approach to assess compliance.

Labs subject to routine biennial surveys must comply with a number of CLIA requirements, including:

- Personnel: CLIA sets minimum qualifications for all persons performing or supervising moderate or high complexity lab tests.
- Proficiency testing: Labs must also participate in an approved proficiency testing program, that provides an external evaluation of the accuracy of the lab's test results. Under this requirement, three times per year, labs purchase samples from an external source (the proficiency testing provider), whose characteristics are not disclosed to the lab. The lab tests the samples with their routine patient testing and the results are returned to the testing provider to be graded. If the lab passes, they have met the CLIA standard. The results of proficiency testing for all labs in CLIA are transmitted to CMS and are monitored and maintained in a database. Proficiency testing providers are private companies, or state lab departments, that must meet certain CLIA requirements to provide testing samples to labs, and are approved by CMS annually.
- Quality control: Labs must have a process for monitoring personnel, testing equipment and the testing environment to ensure proper operation and accurate results each day.
- Quality assessment: Labs must have and follow a plan to monitor, on an ongoing basis, the overall operation of the laboratory, provide communications, and resolve problems that affect the quality of their testing.
- Cytology testing: CLIA sets special rules for cytology testing including workload limits, individualized proficiency testing and personnel standards, and quality control.

Data show that these regulations are helping. Since CLIA was implemented in 1992, quality deficiencies on clinical labs have decreased significantly. The first onsite surveys of labs revealed that up to 35 percent of labs had quality issues. At this time, less than 7 percent of 12,000 labs surveyed by CMS in a year have quality problems. We believe that our educational rather than punitive approach has facilitated improvement in lab quality. Data from our Survey

Evaluation Form show that most laboratories respond very positively to the educational, information-sharing approach to oversight and correct their problems before any deficiencies are cited or prior to imposition of enforcement actions. The quality assurance approach encourages labs to develop a plan to monitor their entire operation to identify and resolve their quality-related problems. Because survey data and proficiency testing data reflect that lab performance has improved over time, it demonstrates that labs are being accountable for preventing and correcting identified issues. When CMS finds problems during the survey, the lab is generally provided an opportunity to correct these problems prior to enforcement actions. Over the past five years, CMS has proposed enforcement action in 6,084 cases, and carried out such action in 487 instances.

OVERSIGHT AND SURVEYS

CMS contracts with state government entities to perform lab surveys. The state surveyor for Maryland is the Maryland Department of Health and Mental Hygiene. CMS' objective in developing an outcome oriented survey process is to not only determine the laboratory's regulatory compliance, but to assist laboratories in improving patient care by emphasizing those aspects that have a direct impact on the laboratory's overall test performance. CMS promotes the use of an educational survey process. The surveyor determines, based on observation of the laboratory's (past and current) practices, interviews with the laboratory's personnel and review of the laboratory's relevant documented records, whether the laboratory is meeting the requirements of the CLIA regulations to produce accurate, reliable and timely (quality) test results. The surveyor meets the objectives by employing an outcome-oriented/quality improvement type of survey process or approach, the intent of which is to focus the surveyor on the overall performance of the laboratory and the way it monitors itself, rather than on a methodical evaluation of each standard level regulatory requirement.

The quality assessment (QA) requirements of the laboratory regulations (42 CFR Part 493, Subpart K) are the appropriate guide that surveyors use for organizing their review. The surveyors select a cross-section of information, tour the facility, and observe testing and all aspects of the laboratory operation to assess the laboratory's ability to produce quality results as well as its ability to identify and correct problems. Emphasis is placed on overall laboratory

performance and the structures and processes contributing to the reliability of the testing. Since it would be impossible to review every test and every document in the laboratory, the surveyor reviews the selected cross-section of information to see if the laboratory has established and implemented appropriate mechanisms for monitoring and evaluating its practices and solving its problems. The surveyors investigate further any test areas identified as a problem but not addressed by the laboratory's QA program and any new testing and personnel since the last visit. If the laboratory is failing to monitor (or effectively monitor) its own systems, the surveyor can direct the laboratory to the requirements and the relevant sections for its particular setting, thereby accomplishing the educational aspect of the survey process.

If, however, problems identified during the survey, or as the result of a complaint, are not remedied in a reasonable amount of time, CMS will impose various sanctions against the labs. These may range from onsite monitoring, fines, or loss of Medicare reimbursement, to revocation of their certificate, depending on the seriousness and pervasiveness of the problem. Most laboratories correct their problems as a result of the education they receive following the survey, prior to having sanctions imposed. Only about one percent of laboratories surveyed each year have had enforcement actions taken against them. The names of these labs and the laboratory director are compiled annually and this list is placed on the CLIA web site at: www.cms.hhs.gov/clia. The 2002 registry (the most current available) lists 133 entities, 7 of them hospitals. The bulk of laboratories experiencing enforcement actions that year were physician office labs (74) and independent labs (39). The numbers of labs experiencing enforcement actions are proportional to the total number of labs of that type that are enrolled in the CLIA program.

As mentioned previously, labs that are subject to biennial surveys can choose to obtain CLIA certification by the State agency, as an agent of CMS, or by an approved private accreditation organization. Accrediting organizations with standards that are equivalent to, or more stringent than CLIA, currently approved by HHS for this purpose include: the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the College of American Pathologists (CAP), COLA (formerly Commission on Office Laboratory Accreditation), the American Association of Blood Banks (AABB), the American Society for Histocompatibility and

Immunogenetics (ASHI), and the American Osteopathic Association (AOA). States that have lab licensure program standards equivalent to, or stricter than those of CLIA can apply for "approval" or "exemption." Then the labs in these states that meet state licensure requirements are deemed to be in compliance with CLIA. There are only two exempt states at this time – New York and Washington. Additionally, there are 13 states that have a state laboratory licensure program and in these cases, laboratories within the state must comply with both CLIA and their state requirements. Maryland is one of these 13 states.

On an annual basis, CMS, through the state agencies, surveys approximately 5 percent of accredited and exempt laboratories using CLIA standards to validate that these laboratories are in compliance with CLIA by meeting the accrediting organization's standards. After surveying the accrediting organization's laboratories, CMS compares the results of the state survey to the accrediting organization's, to determine the level of disparity. The rate of disparity is the percentage of all sample validation surveys for which a State survey agency finds non-compliance with one or more CLIA conditions and no comparable condition level deficiency was cited by the accreditation organization. As set forth in regulation at 42 CFR 493 Subpart E, an accreditation program with a disparity rate of 20 percent or more is subject to a review to determine if that organization has adopted and maintains requirements comparable to those of CMS. No accrediting organization has even approached the maximum threshold of 20 percent disparity.

Complaints alleged against accredited laboratories from any source are either addressed by the accrediting organization or by the State agency in conjunction with the CMS Regional Office.

OVERSIGHT OF MARYLAND GENERAL HOSPITAL

Maryland General Hospital's laboratory is accredited by the College of American Pathologists (CAP) and is located in a state with a laboratory licensure law. Since 2002, the laboratory has had several inspections, both routine and complaint in nature. The routine biennial inspection was performed by the accrediting organization, CAP, in April of 2003. The State of Maryland conducted 2 complaint surveys, the first, for an unrelated issue, in November of 2002 as a CLIA survey for CMS and the second in 2004 as a complaint survey under their state licensure law.

The 2004 complaint survey resulted from a December 2003 complaint from a laboratory employee who alleged that machinery used in HIV and hepatitis testing was not adequately maintained and that possibly erroneous test results were provided as a result. In all of these inspections, similar issues were identified concerning the management and quality assessment processes of the laboratory that were found to be deficient. Each oversight entity addressed these issues but did not inform all of the remaining involved parties of their findings. Therefore, each oversight entity did not have the benefit of the findings of the others. Only after the December 2003 complaint to the State survey agency that pinpointed a specific problem area to investigate, and CMS recognized the severity of the issue, did all of the entities involved communicate their findings to each other. Because the exact flow of events is somewhat complex, I have included a timeline at the end of my testimony, outlining what has transpired since late 2002.

To its credit, in August of 2003, the laboratory ceased testing HIV and hepatitis C using the instrument specifically identified in the December 2003 complaint. In response to the complaint inspection conducted by Maryland under their licensure law in January 2004, the hospital began to notify several thousand patients of the need for retesting and hired a consultant firm to address the management issues in the laboratory. Testing for these conditions has not yet resumed at the lab. Specimens are being sent out to another laboratory for testing.

In addition to state licensure and CLIA requirements, hospitals that participate in Medicare and Medicaid must meet a set of conditions of participation (CoPs) in order to bill for services to these beneficiaries. The CoPs are intended to protect patient health and safety to ensure that high quality care is provided to all patients. A joint survey conducted in March 2004 by the Maryland State Agency, JCAHO, and CMS found that Maryland General Hospital was out of compliance with the CoPs for Governing Body, Quality Assessment and Performance Improvement (QAPI), and Laboratory Services.

The Governing Body CoP requires hospitals to have an effective governing body legally responsible for the conduct of the hospital as an institution. Specifically, the governing body is accountable for requirements related to medical staff, care of patients, and the institutional plan and budget.

Surveyors found that the governing body of Maryland General was not aware of problems with malfunctioning equipment, possible invalid test results, and other quality issues in the laboratory. The hospital administration failed to take any action despite events that signaled problems in the laboratory, including complaints, lost contracts with external customers, occurrence reports, and an employee blood exposure.

The Quality Assessment and Performance Improvement (QAPI) CoP requires hospitals to develop, implement, and maintain an effective, ongoing hospital-wide, data-driven QAPI program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

Surveyors found that Maryland General failed to implement and maintain an effective hospital-wide QAPI program and failed to provide adequate oversight of laboratory services. As required by CLIA, the laboratory had its own quality assurance program that reported to the hospital's QAPI program. However, hospital leadership did not provide oversight necessary to monitor the laboratory's activities and improve its performance. In fact, the hospital did not monitor the laboratory's implementation of a plan of correction based on an October/November 2002 survey by the Maryland State Agency that found numerous problems in the laboratory.

The Laboratory CoP requires hospitals to maintain, or have available, adequate laboratory services to meet the needs of their patients. The hospital must ensure that all laboratory services provided to its patients are performed in a CLIA certified facility.

Surveyors determined that Maryland General's laboratory did not meet the needs of patients. The hospital failed to follow its own procedures for ensuring safety and quality when the laboratory purchased three Adaltis Labotech™ analyzers that were used in the laboratory from June 2002 through August 2003. Surveyors found no records to show that the laboratory

informed the hospital's Clinical Engineering Department of the numerous failed runs, numerous service calls, excessive downtime, or the need for repeated training.

Because of the condition-level noncompliance, CMS notified Maryland General that the lab was no longer deemed to meet CLIA conditions by virtue of its accreditation by CAP. CMS placed the lab under the jurisdiction of the Maryland State Agency. The hospital was given ten business days to respond with a plan of correction and credible allegation of compliance (a statement that indicates a resolution of the condition-level deficiencies). Maryland General Hospital submitted the plan of correction on day 11. CMS staff is evaluating the acceptability of the plan.

Since the hospital is sending its HIV and hepatitis lab services out to a reputable party, and has addressed the management weaknesses in the lab by removing the laboratory's technical supervisor, the most serious of the condition level findings have been addressed.

If CMS is not satisfied with the plan of correction, CMS can initiate principal sanctions like revocation of the lab's CLIA certificate and cancellation of its approval to receive Medicare payment. Alternative sanctions include civil monetary penalties, a directed plan of correction, or State on-site monitoring. CMS will follow up for appropriate correction of these laboratory deficiencies through the state agency by re-visiting the laboratory on site to verify compliance.

CMS COMMUNICATION PLANS AND EFFORTS TO PREVENT RECURRANCE

When viewed in the larger context of CLIA survey work and enforcement, the problems at Maryland General Hospital are unusual in nature. Typically, the clarity of the hospital and laboratory regulations coupled with regular oversight by State surveyors, private accrediting bodies and CMS have resulted in positive results. However, as a result of this experience at Maryland General Hospital, CMS is developing a plan with tighter communication protocols to coordinate activities among the states with licensure programs, the state agencies surveying on behalf of CMS, the CMS regional offices and the accrediting organizations. CMS is also specifically addressing the communication process for complaints and accreditation organization validation surveys through its State Agency Performance Review program. These strengthened processes will be communicated through training and the re-approval process for accreditation

organizations and reflected in the State Operations Manual for the CMS regional offices and state agency surveyors. With such a plan, CMS anticipates that all parties involved in the oversight of a specific laboratory will have the benefit of the activities and timely information acquired by any of the other parties involved. This improved communication will ensure that entities performing CLIA surveys, state licensure, and private accreditation organizations are aware of complaints and deficiencies that each has found within a timeframe to prevent further exacerbation of identified problems. CMS is also considering augmenting the validation process for oversight of approved accrediting organizations to include specific data-related performance measures, and is reviewing the protocols for follow-up surveys to laboratories with significant deficiencies.

TIMELINE OF EVENTS

November 8, 2002	The State of Maryland completed a focused CLIA complaint survey from an unrelated issue that resulted in two CLIA condition level deficiencies, laboratory director responsibilities and quality assurance.
April 2003	The College of American Pathologists (CAP) conducted an accreditation survey finding minor deficiencies related to laboratory management and quality assurance.
August 2003	Hospital discontinued HIV/hepatitis testing.
December 2003	The state received a written complaint specifically addressing problems with HIV and Hepatitis C testing.
January 23, 2004	The state completed a complaint survey under their state licensure law that resulted in condition level deficiencies specific to quality control testing for HIV and Hepatitis C well as general quality assurance. The laboratory sent a plan of correction to the state.
March 8, 2004	The state notified the Philadelphia Regional Office (RO) of press interest in problems at Maryland General. The RO gave the state agency authorization to conduct a CLIA laboratory survey and a hospital Medicare investigation.
March 12, 2004	The state provided a copy of the state laboratory licensure survey performed on January 23, 2004 to the RO.
March 16-24, 2004	A joint federal CLIA and state licensure survey was conducted. The CLIA survey team, consisting of state and RO representatives, identified 6

	CLIA condition level deficiencies: bacteriology, general immunology, analytic systems, technical consultant, laboratory director and technical supervisor. The state survey agency conducting the hospital Medicare investigation and a simultaneous state licensure investigation found non-compliance with the Hospital Conditions of Participation for Governing Body, Laboratory Services and Quality Assessment and Performance Improvement Program.
April 2, 2004	The state (under their state licensure law) sent the laboratory survey findings to the laboratory.
April 5, 2004	The RO sent the survey findings and a letter to the hospital removing its hospital deemed status, placing it under state agency monitoring and requiring the hospital to submit a plan of correction for the deficiencies cited.
April 6, 2004	The Philadelphia RO sent the CLIA laboratory survey findings to the laboratory. The State and RO prepared the survey findings together, but sent separate reports. The state report was sent in response to Maryland's laboratory licensure requirements and the RO report was sent in response to the CLIA requirements. The RO report included a notice that the laboratory's accreditation deemed status had been removed and the laboratory must report directly to the state until the condition level deficiencies were removed.
April 20, 2004	Maryland General sent a plan of correction to the state.
April 22, 2004	Maryland General sent a plan of correction to the RO. The RO is currently reviewing that plan of correction. If it is not acceptable, the RO may impose civil money penalties, suspend the laboratory's CLIA certificate and/or cancel Medicare payment.
April 26, 2004	CAP conducted an inspection of the laboratory and had findings similar to CMS and the State. CAP has removed accreditation of the laboratory in the affected areas.

FUTURE EVENTS

Date TBD	State agency will perform a follow up CLIA survey to determine compliance after receiving and reviewing the laboratory's plan of correction.
Date TBD	CAP will re-visit the lab to follow-up on deficiency correction and periodically thereafter.

Mr. SOUDER. Thank you very much.

Maybe I could start with Dr. Gutman. As I heard both your testimonies, my understanding is that you don't believe it was predominantly caused by poor equipment, it was caused by poor management?

Dr. GUTMAN. That is correct.

Mr. SOUDER. Were the problems that you saw in the European examples similar?

Dr. GUTMAN. No. I didn't see a similarity between the issues that were going on in this particular episode.

Mr. SOUDER. Were you aware of any other circumstances where the lab equipment utilized at Maryland General Hospital had produced faulty results, or was it just limited to HIV and hepatitis?

Dr. GUTMAN. I was aware only of those two.

Mr. SOUDER. Has there since been any checking to see if there was anything else?

Dr. GUTMAN. We have looked in our data bases and found no other reports.

Mr. SOUDER. One suggestion was that the lab equipment used at the hospital may have been manipulated to disguise deficient test results. Is this possible? And, in general, are diagnostic tools vulnerable to manipulation?

Dr. GUTMAN. It is possible, and, actually, it is acceptable practice to modify products. That is not unusual. It is unusual, however, to do it and not to be on top of it, not to do it well.

Mr. SOUDER. So what are you saying?

Dr. GUTMAN. Laboratories have a fair amount of freedom in modifying or in establishing variations to tests. There is nothing wrong with that, but it should be done in a high quality system.

Mr. SOUDER. If they modify a machine that has been cleared by you for safety purposes, when they modify it, do they have to go through FDA?

Mr. GUTMAN. I am sorry, I didn't mean that they would modify the machine. They could modify the assay. The machine can't be modified.

Mr. SOUDER. So they can modify the results that come to you? I didn't understand the word.

Mr. GUTMAN. They can set up the parameters. This machine is an open system that actually encourages you to set up parameters for a particular assay, so they can set the way in which the electric eye reads or they can set the incubation time for an assay, or they can set the amount of chemical delivered for an assay. This machine lends itself to those kinds of modifications.

Mr. SOUDER. And can those kinds of modifications give substantially different results that can lead to people being—in other words, if you are clearing—pardon me, because this is a new area for me.

Dr. GUTMAN. Sure.

Mr. SOUDER. I wouldn't say I am medically stupid, just medically ignorant, which amounts to about the same thing in asking the questions.

But if you are clearing the machine to see that it gives accurate readings, and we have a problem that the readings are coming back and we have concluded that it is the lab making the mistakes,

in effect, could these machines actually be not working around the country, but people modifying those parameters to give false readings that would make you think all the machines are working?

Dr. GUTMAN. Well, that, I think, is what happened in this case, that is, a deviation from normal laboratory practice, which would preclude that from happening.

Mr. SOUDER. And so when you audit—and maybe Mr. Tunis could respond to this. When you audit, are you looking to see whether they have altered parameters, when you are checking? Because you have confused me as to we have a Federal standard, but then we have to see how they are using that standard and what they are doing in the results. Otherwise, it wouldn't do any good to have a machine if there are flexibilities that can make the machine's data inaccurate if you manipulate it.

Dr. TUNIS. I think the survey process is generally reliant on, as I said, more of the integrity of the process in place in the lab to identify problems and correct them, and also reliant on the document that is provided. So if there are in fact alterations in the documentation to hide errors, there truly is no way for the survey process to detect those kinds of changes. So there is a presumption made that, in a well-managed laboratory, the information provided about the performance of the machinery accurately reflects the experience with those devices.

Mr. SOUDER. In your testimony you said they have now contracted this out to a well-managed laboratory. Is that another independent hospital? Do you certify that? Have you worked with them before?

Dr. TUNIS. It is an independent laboratory that is accredited and approved and has had no history of problems, so there is no reason to believe that there are issues with that laboratory.

Mr. SOUDER. Thank you.

Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

Mr. Gutman, tell me how this Labotech became classified as a level I, low level. And what does that mean?

Dr. GUTMAN. This is a Class I because it is used as a general purpose instrument or tool. And what it means is that it is a general instrument that operates according to certain specifications; that it can pipet a certain amount of reagent, that it can incubate or heat the reaction for a certain amount of time, that it has an electronic eye that will read chemical reactions. So it is a general purpose instrument. But its specific use is determined by the lab that would put chemicals onto that machine and would use that machine, and it is largely regulated through the quality requirements that would indicate that if in fact it is pipetting, dispensing one milliliter of material, that it actually does dispense one milliliter of material within a reasonable specification. If it reads chemical reactions in a particular wavelength, that it actually reads them at that wavelength.

So it is viewed sort of like a surgical scalpel. It is more complicated, but it is like a surgical scalpel; it can be used to remove a wart, it can be used for open heart surgery, but it has sort of a general purpose use. And the person who is manning the scalpel

or who is using the instrument makes a lot of determination in how that is actually used.

Mr. CUMMINGS. Does FDA have a recall process? At some point, when you see certain problems that you can recall?

Dr. GUTMAN. Absolutely. We have a recall process that allows us to work with companies to—we actually have a very broad menu of regulatory choices when problems occur. Sometimes you simply send out safety notices or labeling corrections; sometimes you would actually recall and have the product physically removed; sometimes you would have some kind of software or instrumentation fixed. If the company is cooperative, we like to try and work with the company to deal with the issue. If the company is non-cooperative, we have a wide variety of enforcement choices: seizures and injunctions and fines and criminal penalties. So there is a very broad menu of things we can put on the table hopefully to collaborate with companies to resolve problems, but, if necessary, to lean on them a little bit to solve problems.

Mr. CUMMINGS. I think that you said, with regard to Labotech, you had received a complaint in the United States, and that was from Maryland General, is that right?

Dr. GUTMAN. That is correct.

Mr. CUMMINGS. What was the date of that?

Dr. GUTMAN. I am sorry, I don't know the exact date.

Mr. CUMMINGS. Was it this year?

Dr. GUTMAN. Yes.

Mr. CUMMINGS. And where is that; where does that stand right now? In other words, when you receive a complaint, what do you do?

Dr. GUTMAN. We would evaluate the complaint and make a decision whether further action is necessary. We would look to see if it is the only complaint; we would look to see the severity of the complaint; we would look to see the circumstances of the complaint; and then we would determine appropriate followup based on that.

Mr. CUMMINGS. Can you tell us the status of that complaint?

Dr. GUTMAN. That complaint has been reviewed and is being held while we continue to gather information. We are very interested in seeing, when we go to visit the Italian firm, if that is an isolated complaint or if there are other complaints like it.

Mr. CUMMINGS. You said when you visit the Italian. Tell me, where are you going to go in Italy?

Dr. GUTMAN. I don't know the location of the company.

Mr. CUMMINGS. In other words, you are going to the company. OK.

Dr. GUTMAN. We have plans to actually have an inspection of the quality system for this company. It is scheduled for either late June or early July.

Mr. CUMMINGS. So it is quite possible that you may recall this machine?

Dr. GUTMAN. Anything is possible, but there have been very few signals that would suggest this is actually a systemic problem. So I don't want to speculate on how the outcome will be.

Mr. CUMMINGS. And I don't want you to. I just want to see exactly where you are. The thing that we are concerned about is trying to figure out whether or not our controls at FDA are sufficient

and the regulations are sufficient to make sure that you can do the job that you need to do. And I am just curious as to how you feel about your tools for making sure that these kind of things don't happen.

Dr. GUTMAN. I think we have good tools. They are not perfect tools and there are opportunities for people to under-report or to misreport, but I think in general our tools are appropriate and, in general, effective.

Mr. CUMMINGS. Let me ask you, Mr. Tunis. You said something that I found on page 9 of your testimony, I think. You talked about changes that need to be made and what you all were looking at as far as changes, and I took it that it is as a result of this episode. Do you have your testimony there? On page 9 it says: "However, as a result of this experience at Maryland General Hospital, CMS is developing a plan with tighter communication protocols to coordinate activities among the States with licensure programs, the State agencies surveying on behalf of CMS, the CMS regional offices, and the accrediting organizations."

I guess what I am trying to get to is does that—why don't you go ahead and explain why you are doing that and why does it come as a result of this episode. I assume that is what you were saying.

Dr. TUNIS. That is correct. And I think the explanation, in part, emerges from the timeline that you can see on the next page of the testimony, which sort of outlines surveys that have been done, back to November 2002, of the Maryland General Hospital lab. And in November 2002 there were some issues identified in terms of the lab director responsibilities and quality assurance. When the College of American Pathologists surveyed in April 2003, found similar deficiencies, and in the absence of having these entities able to communicate more freely about patterns of deficiencies over time, it is less easy to identify those laboratories that have a single deficiency that they correct versus ones that may have a pattern over time of having had deficiencies and not correcting those deficiencies. In fact, the plan of correction that was proposed by Maryland General in November 2002, my understanding is that the plan of correction was never implemented. The hospital did not ensure that the implementation occurred, and none of our organizations also took the step of ensuring that those changes had been made. It is possible that some time could have been saved by better communication about what was going on.

Mr. CUMMINGS. So you had a situation where the right hand didn't know what the left hand was doing and the head didn't know what either hand was doing. That is what it sounds like to me.

Dr. TUNIS. Well, again, there are an extraordinarily large number of these labs that are being surveyed. There are a fair number of quality problems that are of a minor nature that are identified, so there is potentially a lot of information that needs to flow. But you would certainly want to be able to extract out of all of that information the patterns of recurring problems that would separate out true potential for patient injury from minor deficiencies that can be corrected. And in this case one would hope that we could set up some form of communication such that if a problem is identified in November of a given year, 4 months later similar problems are identified by another organization that is trying to do the same

thing of ensuring lab quality, that information comes to people's attention and the kinds of intensive survey that we actually did in March 2004 would have occurred much earlier and potentially have prevented some poor lab results.

Mr. CUMMINGS. Well, our job here is to try to come up with solutions to problems, and we want to make sure that if there is something that the Congress needs to be doing to help you accomplish what you just said, that we do it. Do you need any regulatory authority for you to be able to accomplish what you just talked about?

Dr. TUNIS. My understanding at this point is that we have existing regulatory authorities through which a significant amount of this can be accomplished, but we are fairly early in the problems-solving stage in terms of what we need here. And if there are in fact some barriers in terms of information sharing between the organizations that need to share information, I would suggest that would be a place where we would advise you that there are limitations on regulatory authority that need to be addressed. What those are right now, I can't identify for you, but our plan would be to do that.

Mr. CUMMINGS. Thank you.

Mr. SOUDER. I'd like to ask a couple more questions on how whistleblowing works. In effect, is the only way you learned about this because of a type of whistleblowing complaint, in other words, an employee went outside the normal system to complain?

Dr. TUNIS. Well, there are existing mechanisms for employees to register complaints with the State agency as well as with CMS, including the opportunity when lab personnel are actually interviewed during surveys there is an opportunity to raise any issues that the lab personnel may have encountered. There is also lots of information on the Web site that provides contact information where problems can be reported. In fact, my understanding is that in this case problems were reported through existing channels and simply not acted on at the hospital level, at the laboratory level. So I am not sure that it is an absence of ability to report problems to places they can be acted on, but obviously failure to act will not lead to the correction of those problems.

Mr. SOUDER. Well, Dr. Tunis and also Dr. Gutman, my question would be, I think it was in Dr. Gutman's testimony that the first complaint you didn't know the level of the complaint or how serious it was. What triggers a fast response from the FDA's side of this could be a device problem that could be in every lab in the United States, or it could be a Maryland lab problem where people are either being told they have HIV or told they don't have HIV, could be dying as a result of that decision? What gravity, what level triggers a response?

Dr. GUTMAN. Certainly the information that we have based on that single event, which appears to have been difficult for the company to duplicate when they did their health hazard analysis or their design analysis, and which appears to have perhaps occurred under conditions of use that would not actually normally be expected. Based on the information we have now, we have not taken action. The fact that we have not taken action would suggest that at least, based on the information that we have now, we don't think

that it would be appropriate to take action. As we gather more information, that assessment may change.

Dr. TUNIS. And on the CLIA regulatory side, as well as the State side, you know, the November 2002 survey was triggered by a complaint and, in fact, that survey did identify some problems; a plan of correction was developed and proposed; it simply wasn't implemented. So there was, I think, a pathway by which the complaint could have been addressed and resolved at that point in time. Similarly, although much later, in December 2003, a complaint was filed with the State. The State actually undertook, in January 2004, a survey and identified additional problems. It is my understanding that the full extent of the problems, which gradually emerged, was somewhat difficult to determine based on the records that were available to review. So in terms of being able to identify the urgency of the situation, again, some of that goes back to the integrity of the information that is available on this.

Mr. SOUDER. So if you would have had the information you had toward the end at the beginning, you would have acted to discontinue their testing more rapidly? Or would you have had not to have that authority? In other words, looking at this just from a layman's standpoint, for people who are watching or just a Member of Congress who is looking at this, we are obviously going through a similar question like this in Iraq right now, that somebody does a complaint, people look at it, they try to decide how quick they are going to respond, they learn there is a picture, then they do a report. What about if the local guy doesn't do it?

At what point do you say this is grave enough that we are going to shut it down right now? And do you have the authority to override the State to do that? If you had known what you know now, would you have acted immediately or would you have waited from April to August, waited until the next year? I don't understand what the trigger is. Is this always going to be, even if it is a test that could put people's lives at risk, something that is going to take us a year to get to the shutdown of the testing?

Dr. TUNIS. This is Virginia Wanamaker.

Mr. SOUDER. I need to have you state your name and spell it for the record, and I need to swear you in.

Ms. WANAMAKER. Virginia Wanamaker, W-A-N-A-M-A-K-E-R.

Mr. SOUDER. Would you raise your right hand? I need to give you the oath.

[Witness sworn.]

Mr. SOUDER. The record will show the witness responded in the affirmative.

Ms. WANAMAKER. I am going to speak to your question about when we would have reacted with the information. Back in 2002, the type of information that was available did not speak to the specific issue. In December 2003, when the information that spoke specifically to the issue of the type of testing, which pinpointed the area to look—had we or had the State or had the accrediting body or CMS had that information in 2002, yes, the answer is we would have acted immediately to cease that testing in that laboratory, had we known what was going on at that time.

Mr. SOUDER. And you could override the State and do that?

Ms. WANAMAKER. CMS has the ultimate authority for the CLIA survey.

Now, the State of Maryland has a separate State licensure law. They could do the same thing or different things under their State licensure law, but as far as the CLIA aspect and the State working for CMS under the CLIA survey, yes, the regional office has the authority to call what we phrase an immediate jeopardy, an immediate threat to public health and safety, and we can have a laboratory cease testing.

Mr. SOUDER. So as I understand it, and see if I have kind of the basic layout as we move into this hearing, the FDA clears the equipment that as you hear of complaints or things, you will check that, decide whether the equipment is being used properly and basically whether the equipment is safe. And in this case you decided, thus far, you are continuing to investigate it, but it was primarily a technician failure.

From Mr. Tunis' standpoint, that with the parameters of the equipment, it is possible that people can report false results and, basically, while you will followup on complaints and you will check the surveys, that basically phony data will lead to phony conclusions, and you are really dependent upon whistleblowers and complaints somewhere in the system, either to the hospital, to the State, or to the Federal Government to stop that. But if the complaints are serious enough, the Federal Government has the ability to step in and override the local.

Dr. TUNIS. That is correct. And I would also make the point that if there is that kind of activity going on in the laboratory, it may very well be detectable through the other aspects of the survey process, which look at the quality assurance activities of the laboratory, other aspects of laboratory process, interview with personnel. So even though you may not be able to identify a specific issue with a specific device, there usually would be other clues about overall laboratory management and processes that would also be triggers for action.

Mr. SOUDER. If people manipulate results, are there criminal sanctions?

Dr. TUNIS. I don't think we have the answer to that question.

Mr. SOUDER. Thank you.

Mr. CUMMINGS. Would you recommend that there be criminal sanctions, particularly in an instance where people may be getting the wrong results and may be going out and spreading disease, thinking that they don't have the disease?

Dr. TUNIS. You know, I think I honestly can't make a judgment about the appropriateness of criminal sanctions.

Mr. CUMMINGS. Well, let me ask you this way. Do you consider such actions, that is, when people manipulate results, do you consider that to be a very serious situation?

Dr. TUNIS. You know, obviously from a clinical perspective, the reliability of laboratory test results in important clinical problems like HIV and hepatitis are of very high level of significance, so it is obviously a non-trivial problem.

Mr. CUMMINGS. That means it is a serious problem.

Dr. TUNIS. Yes, sir.

Mr. CUMMINGS. And so how soon can you all get us information with regard to that question of criminal penalties for this? I would think that you would know that, by the way.

Dr. TUNIS. For violation of the accreditation, we have the ability to impose civil money penalties. I have not head of any authority to impose criminal penalties under the CLIA regulations. But we can verify that for you probably very quickly, within a day or two.

Mr. CUMMINGS. Let me ask you this. Mr. Sabatini, the Secretary of Health, said in a Sun paper article in an interview, something to the effect—and he is here, so he will correct me if I am wrong—he said something to the effect that the Feds never close down anybody anyway, as if to say that the Federal Government just doesn't close down labs. And I am just wondering is that accurate? Have you ever done it?

Ms. WANAMAKER. Yes, we have closed labs. In fact, there have been sanctions against 45 labs in 2002. So there are, from time to time, labs that are closed, labs that cannot respond or do not respond, do not send an appropriate plan of correction, just can't seem to get beyond their problems. And, yes, we take sanctions or actions against those laboratories.

Mr. CUMMINGS. I am going to come back to you all. I want to go back to Mr. Gutman.

Mr. Gutman, tell me something. Are you aware of any FDA problems experienced with Labotech in other countries?

Dr. GUTMAN. I am, actually. I am aware that there were problems reported in the UK in 1996 and in 1999. I am not aware of any more recent reports.

Mr. CUMMINGS. And I take it the 1999 report, which I have a copy of, it says, in part, "We have considered the risk assessment together with the possible implications of a false negative result for clinical management and have a number of recommendations on the need to repeat testing." And it goes on to talk about the problems with this machine.

You are familiar with that?

Dr. GUTMAN. I am familiar with that report.

Mr. CUMMINGS. As you go through and try to determine whether there was a major problem with this machine and whether it should continue to be used, do you take that into consideration when you are looking?

Dr. GUTMAN. Absolutely. We would be very interested in understanding why that was not reported to FDA, it actually should have been, and what actions were taken to correct that problem.

Mr. CUMMINGS. I want to go back to something the chairman said to all of you. At what point does this matter become an urgent situation? In other words, if you have people walking out of a hospital who are told that they don't have HIV/AIDS and they do have it, and then you are getting information in, at what point? It sounds to me, Mr. Gutman, like this may be a decision that might be made next year.

Dr. GUTMAN. Well——

Mr. CUMMINGS. No, let me finish. I am almost finished. And the thing I don't understand is do we need to put some urgency into your regulations so that you all can act much more quicker? Because that person who is suffering and that person who is told that

they do have AIDS and they don't, or vice versa, that is a major problem, and it is an urgent situation. It seems like we are just kind of sitting around, watching things go by, and people could be possibly going out there spreading this disease and bringing harm to other people and not even know it, and it is not their fault.

Dr. GUTMAN. Yes. I guess we do take this very seriously, and we have scheduled this foreign inspection as quickly as we can; it is the highest priority we were able to take. I must say that although we take it seriously, and I don't wish to prejudge, the fact that there have been no European reports since 1999, the fact that there have been no adverse reports to FDA, the fact that we have actually looked at the published literature and seen reports, but they seem to suggest the device works fine; we have monitored list service; this event was reported, there were no additional complaints. We actually don't have a signal to suggest that—and based on the information that this appears to be a quality lapse of the lab, not a problem of the machine, although we are taking this very seriously, we do not have actually the expectation that this is fundamentally an instrument failure. We would argue, actually, the fact that the instrument was providing information suggesting it was out of control, it was giving quality control error signals, that the instrument was doing what it was supposed to do, which is signal that something was wrong.

Mr. CUMMINGS. Same urgency question, Mr. Tunis.

Dr. TUNIS. Some perspective on that question, obviously, is the laboratory did, as I mentioned earlier, in August 2003, discontinue use of this machine. At that point in time there was no information that we had had from either the State survey in November 2002 or the CAP survey in April 2003 that problems of this seriousness and significance existed. And, again, I would go back to saying that you can only do as good a survey as the documentation allows you to do. So by the time the additional complaint was made in December 2003, and a great deal of attention was focused on that and a lot of things have rolled out since then, the immediate peril associated with the machine had been addressed by discontinuing the use of the machine.

But I think you ask a very valid question, which is, is there something more we should have known in November 2002, April 2003 that would have given us a greater ability to look more closely and identify this problem at those points in time. And, again, I can say that is something we are looking at very closely and trying to answer exactly that question.

Mr. CUMMINGS. Just one real quick question, Mr. Chairman.

Do you have faith in the College of American Pathologists to do this job? Mr. Sabatini had expressed to me in a conversation that he was concerned about whether we are getting valid results from the college. Do you have faith?

Dr. TUNIS. I do, and it is not just based on a general feeling, it is based on that every year we do a validation survey of our own, checking on 5 percent of the labs that are accredited by the private accrediting organizations and look for any systematic deviations in the results that they get and the results that we get independently. And we have not found reason to have any systematic problems with the College of American Pathology accreditation process.

Mr. SOUDER. I want to thank our first panel.

We have four votes going on, so we are going to take a recess. Hopefully it will be no longer than 20 minutes, but it could be as long as 30 minutes.

With this, we stand in recess.

[Recess.]

Mr. SOUDER. The subcommittee will come to order.

Ms. Williams, will you stand and raise your right hand?

[Witness sworn.]

Mr. SOUDER. Let the record show that she responded in the affirmative.

Thank you for your patience, and we will now hear your testimony.

STATEMENTS OF TERESA WILLIAMS, FORMER EMPLOYEE OF MARYLAND GENERAL HOSPITAL; AND KRISTIN TURNER, FORMER EMPLOYEE, MARYLAND GENERAL HOSPITAL, AS DELIVERED BY MALIA HOLST, SUBCOMMITTEE CLERK

Ms. WILLIAMS. Good morning, Mr. Chairman and Mr. Cummings. My name is Teresa Williams, and I am a health care worker. I come here today to represent the voice of the countless victims of the atrocities that took place at Maryland General Hospital. I speak for the patients, the public, and the workers.

I am here to put a face to one of the many who came forward then and now, who look beyond job security and stepped outside their comfort zone and was willing to fight for those who were unaware that their health was at stake, for those who deserved so much better.

In light of all the information that has been uncovered by the State and other government investigators, does it frighten you that only Kristin and I have come forward publicly? If it doesn't, it should. The information that we were privy to pales in comparison to the information that others could and should have come forth with. I suppose that is a cross that they will have to bear.

I don't have to argue as to whether there were problems with the quality of care at Maryland General Hospital; you know that. I don't have to argue as to whether the patients, public, and workers were put at work; you know that. I don't have to argue as to whether the instrumentation malfunctioned and had problems; you know that too.

I am hoping that my experiences, Kristin's experiences, along with a few others who are now willing to come forward to speak of what they witnessed at Maryland General Hospital will once and for all bring closure to the Maryland General Hospital event and will help to prevent this from happening anywhere ever again.

Hopefully, after this collective body has adjourned, there will be a clearer understanding of the culture and mind-set that existed 2 years at Maryland General Hospital when I worked there.

There are certain assumptions that we all make on a daily basis. When we board a plane, we assume that the engine is working properly, or the airlines wouldn't let it off the ground. We assume that when we eat at a restaurant that the food is safe for human consumption.

As a health care worker, when you work for an organization and you recognize, identify, and inform your superiors of impending danger, the assumption is that something will be done to correct the problem. As a patient, you assume and trust that your doctor, the hospital, and all those involved with your health care will do their best to make sure that you are provided the treatment necessary to enhance your lives. As a public, you assume that there are practices, policies and safeguards in place to prevent harm to you as an unsuspecting public.

As a new lead tech at Maryland General Hospital, I listened to the voices of those who worked diligently alongside me. After working there and through my own observations, I found that their concerns and complaints were not without merit.

As a new employee and someone who has worked in an environment that encouraged problems to be reported so that the necessary changes could be made to prevent further harm to those who we were being paid to serve, I found this very troubling. One of the documents that I submitted was my March 2004 letter is one from an employee to the then-director, which speaks of her frustrations and despair. She and I, along with others, talked about the problems and ways to correct them, but felt as though no one cared or listened.

My feeling was, and still is, if you have legitimate concerns and can prove them, and can assist in providing solutions, then there is someone out there who does care, who will listen, who has to act.

We took our concerns to our superiors individually and collectively to make them aware of the conditions in the lab and to let them know that this was not fair to the patients. We let them know the problems with the controls. We complained of our fears about the questionable results, the dangers of the Labotech and other instruments, and how we were fearful of patient harm. This happened on m any occasions during my employ at Maryland General.

As time went on, I realized that this disorder and resultant desperation was so entrenched and had become a culture, a mind-set that was resigned to the fact that nothing will change and this must be the norm.

Many said, "don't make a fuss, just do your job and leave at the end of the day." How could I do my job? How could any of us do our job? Our job was to serve our patients. Our job was to provide them the type of care that any one of us would have demanded.

There were many who truly believed that things could be better, so we continued to voice our concerns and to fight.

Kristin, who is not here, and I are just two faces, two lives, and two souls committed to quality health care at Maryland General Hospital.

If some bushes have been shaken, then let the bad fruit fall where it may.

I find solace in the fact that it is now in the hands of those who do care. The public's health is in the hands of those who are committed to fixing the problems. The public can now rest assured that their welfare and health is not being protected by those who are willing to take whatever steps are necessary to protect them.

I applaud Maryland Secretary of Health Nelson Sabatini for his relentless efforts to uncover, investigate, and eradicate the "broken systems," at Maryland General Hospital. If the State had been furnished all the necessary information and were informed of all the problems when they made their 2002 inspection of Maryland General Hospital, there wouldn't be thousands of questionable results, retests, and loss of public confidence, and I feel that Kristin Turner would not be HIV-positive today.

My understanding of what takes place when the State comes in to inspect was that everyone had to provide everything and anything necessary to uncover problems; that workers were automatically protected from retaliation, therefore, they were free to speak about their concerns with immunity. If the hospital had taken the lead in being forthcoming when the State came to inspect in 2002, then that would have set the stage for the workers to follow suit. This awful cycle of improper health care would have halted 2 years ago, well before Kristin Turner was infected. The assistance and guidance that is now being provided by the State would have put in place the proper systems of checks and balances that were not in place then.

But because Maryland General Hospital chose to tie the hands of the State and not ask for the much-needed help that was required to correct the problems, they have created a climate of public distrust and loss of confidence in the health care system as a whole. I would just ask everyone here today to take a moment and think of someone that you truly love, a parent, spouse, child, other family member or friend. Would you have allowed that loved one to be treated at Maryland General Hospital if you knew what was taking place?

Isn't it a blessing that you have the luxury of being able to make that decision? Unfortunately, there are thousands that didn't have that option.

I have to grapple with this every day. What more could I have done? Maybe if I had fought harder, fought longer, screamed louder, maybe it would have made a difference. But the ability to exact change was beyond my reach. When I left, I was discouraged, distraught, and broken.

This is a golden opportunity for Maryland General to do the right thing now. If they are truly committed to correcting the problems, then provide a forum whereby no one is afraid to expose all their concerns; allow them to be questioned by State and government agencies without the presence of hospital administration or hospital lawyers. Take this opportunity to fix the problems that plague the hospital once and for all.

The following is a list of some recommendations that I have made. Should I present those also?

Mr. SOUDER. Why don't you go ahead and read them?

Ms. WILLIAMS. OK.

No. 1 is to make patient, public, and employee safety a No. 1 priority; devise a system that demands and encourages the bottom line to be health care-driven as opposed to dollar-driven; institute a system of checks and balances on all levels, where there is a direct accountability for problems and for their resolution; create a citizen review board that includes people from all sectors of the

community that has some oversight over the hospital operations; employ a risk management representative in each department who is available to address any complaint or concern at the root level, and let this person be accountable and report directly to the risk management director; have focus groups where employees can discuss their concerns openly; develop a problem-tracking system that documents a problem and tracks it from the initial complaint to its resolution; use a SIX SIGMA program as a template for health care excellence. This program was started by General Electric in the 1990's and was designed to address and improve issues that are critical to quality. It has already been adopted in the health care industry. Include your "ground troupes," the people who actually are responsible for carrying out the duties, in the decisions made regarding each department; ensure that continued monitoring and recordkeeping of OSHA reportables is present so that problem areas can be easily identified, addressed, and resolved in a timely manner.

These recommendations are easily achieved and extremely cost-effective; they will save millions of dollars in litigation, retesting, and costs incurred to restore public confidence.

[The prepared statement of Ms. Williams follows:]

Good morning ladies, gentlemen and distinguished panel.

My name is Teresa Williams, and I am a Health CARE worker.

I come here today to represent the voice of the countless victims of the atrocities that took place at MGH. I speak for the patients, the public and the workers.

I am here to put a face to one of the many who came forward, then and now. Who looked beyond job security and stepped outside their comfort zone and was willing to fight for those who were unaware that their health was at stake, for those who deserved so much better.

In light of all the information that has been uncovered by the State and other Government investigators does it frighten you that only Kristin and I have come forward? If it doesn't, it should. The information that we were privy to pales in comparison to the information that others could and should come forth with. I suppose, that's a cross that they will have to bear.

I don't have to argue as to whether there were problems with the quality of care at MGH, you know that. I don't have to argue as to whether the patients, public and workers were put at risk, you know that. I don't have to argue as to whether the instrumentation malfunctioned and had problems, you know that too.

I am hoping that my experiences, Kristin's experiences along with a few others who are NOW, willing to come forward to speak of what they witnessed at MGH, will once and for all, bring closure to the MGH of then, and will help to prevent this from happening anywhere, ever again.

Hopefully, after this collective body has adjourned, there will be a clearer understanding of the culture and mindset that existed two years ago at MGH, when I worked there.

.....

There are certain assumptions that we all make on a daily basis. When we board a plan, we assume that the engine is working properly or the airlines wouldn't let it off the ground.

We assume that when we eat at a restaurant that the food is safe for human consumption.

As a healthcare worker, when you work for an organization and you recognize, identify and inform your superiors of impending danger, the assumption is that something will be done to correct the problem.

As a patient you assume and trust that your doctor, the hospital and all those involved with your healthcare will do their best to make sure that you are provided the treatment necessary to enhance your lives.

As a public you assume that there are practices, policies and safeguards in place to prevent harm to you as an unsuspecting public.

As a new lead Tech at MGH I listened to the voices of those who worked diligently along side me. After working there and through my own observations I found that their concerns and complaints were not without merit.

As a new employee and someone who has worked in an environment that encouraged problems to be reported so that the necessary changes could be made to prevent further harm to those who we were paid to serve, I found this very troubling. One of the documents that I submitted with my March 2004 letter is one from an employee to the then, director, which speaks of her frustrations and despair. She and I along with others talked about the problems and ways to correct them but felt as if no one cared or listened.

My feeling was and still is, if you have legitimate concerns and can prove them and can assist in providing solutions, then there is someone out there who does care, who will listen and who has to act.

We took our concerns to our superiors, individually and collectively, to make them aware of the conditions in the lab and to let them know that this was not fair to the patients. We let them know of the problems with the controls. We complained of our fears about the questionable results, the dangers of the Labotech and other instruments, and how we were fearful of patient harm. This happened on many occasions during my employ at MGH.

As time went on, I realized that this disorder and resultant desperation was so entrenched and had become a culture, a mindset that was

resigned to the fact that nothing will change and this must be the norm.

Many said, "don't make a fuss, just do your job and leave at the end of the day." How could I do my job? How could any of us do our job? Our

job was to serve our patients. Our job was to provide them the type of care that any one of us would have demanded.

There were many who truly believed that things could be better. So we continued to voice our concerns and to fight.

Kristin and I are but two faces, two lives and two souls committed to quality healthcare at MGH. My question is where are the others? I can only close my eyes and ponder: y tu Brutus?

If some bushes have been shaken, then let the bad fruit fall where it may.

I find solace in the fact that the matter is now in the hands of those who do care. Their health in the hands of those who are committed to fixing the problems. The public can now rest assured that their welfare and health is now being protected by those who are willing to take whatever steps are necessary to protect them.

I applaud Maryland Secretary of Health, Nelson Sabitini, for his relentless efforts to uncover, investigate and eradicate the "broken systems" at MGH. If the State had been furnished all the necessary information and were informed of all the problems, when they made there 2002 inspection of MGH, there wouldn't be thousands of questionable results, retests and loss of public confidence, and I feel that Kristin Turner would not be HIV positive today.

My understanding of what takes place when the State comes to inspect, was that everyone HAD to provide everything and anything necessary to uncover problems. That workers were automatically protected from retaliation, therefore they were free to speak about their concerns with immunity. If the hospital had taken the lead in being forthcoming when the State came to inspect in 2002, then that would have set the stage for the workers to follow suit. This awful cycle of improper healthcare would have halted two years ago, well before Kristin Turner was infected. The assistance and guidance that is now being provided by the State would

have put in place the proper systems of checks and balances that were not in place then.

But because MGH chose to tie the hands of the State and not ask for the much-needed help that was required to correct the problems, they have created a climate of public distrust and loss of confidence in the healthcare system as a whole.

I would just ask that everyone here today take a moment and think of someone that you truly love, a parent, spouse, child, other family member or friend. Would you have allowed that loved one to be treated at MGH if you knew this was taking place?

Isn't it a Blessing that you have the luxury of being able to make that decision? Unfortunately there are thousands that didn't have that option.

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I have had to grapple with this everyday? What more could I have done? Maybe if I had fought harder, fought longer, screamed louder, maybe it

would have made a difference. The ability to exact change was beyond my reach.

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Recommendations:

1. Make patient, public and employee safety a number one priority.
2. Devise a system that demands and encourages the bottom line to be healthcare driven as opposed to dollar driven.
3. Institute a system of checks and balances on all levels. Where there is direct accountability for problems and their resolution.
4. Create a citizen review board that includes people from all sectors of the community that has some oversight of the hospital operations.
5. Employ a risk management representative in each department who is available to address any complaint or concern at the root level, and let this person be accountable and report directly to the risk management director.
6. Have focus groups where employees can discuss their concerns openly.
7. Develop a problem tracking system that documents a problem and tracks it from the initial complaint to its resolution.

8. Use the SIX SIGMA program as a template for healthcare excellence. This program was started by G.E. in the 1990's and was designed to address and improve issues that are critical to quality. It has already been adopted in the healthcare industry.
9. Include your "ground troupes", the people who actually are responsible for carrying out the duties, in the decisions made regarding each department.
10. Insure that continued monitoring and record keeping of OSHA reportables is present, so that problem areas can be easily identified, addressed and resolved in a timely manner.

These recommendations are easily achieved and extremely cost effective. They will save millions of dollars in litigation, retesting and costs incurred to restore public confidence.

May 16, 2004 Incident

More extensive than uncovered.

Surgical patients, ER patients, nursing homes, treatment centers.

Total CK (cardiac screen) ....The instrument could not detect value because specimen needed to be diluted causing a delay in patient

medical treatment and was the result correct since the controls had failed

Drugs of Abuse .....did this cause someone not to be considered for a job, or lose their job. Were those results used to render a decision in a court case.

Therapeutic Drugs.....Were the patients' dosages correct? Were they under medicated or over medicated?

Mr. SOUDER. Thank you. Next we are going to do something a little unusual.

If Malia Holst could come forward. She is the subcommittee's clerk. It is M-A-L-I-A H-O-L-S-T. She is going to read Kristin Turner's statement, who was referred to in the last testimony, and who is ill and could not come to read her statement.

Ms. HOLST [reading]. Thank you for inviting me to testify at this very important hearing. I am sorry that I cannot attend in person, but I have become ill and was unable to travel to Washington. I hope these comments are of some help to you as you consider these important matters.

In March 2003 my life was forever changed because of the at best irresponsible conduct of a hospital and a biomedical equipment company. The focus of this hearing is not what happened to me, but rather why the hospital and company were allowed to engage in such dangerous practices.

There are two immediate things I hope are achieved through this hearing. First, I am not sure how much emphasis is being placed on the issues surrounding the Labotech. This is the instrument that in my view was designed poorly and dangerously, resulting in unreliability, inaccuracy, and injury. I am now aware that there have been international warnings issued regarding the lack of reliability of the results because of both mechanical and programming errors. Maryland General utilized three different Labotechs during the time of my employment, and all three consistently malfunctioned and failed runs. Adaltis, the distributor of the machines in use at Maryland General Hospital, was responsible for repairing the machines and many times each month sent people in to "fix" the machines, yet they were never able to be used for more than 2 to 3 days after each repair without having more problems.

The most frightening and consistent malfunction to occur with the Labotech was missed samples. Missed samples means that a patient's sample was not dispensed onto the test plate, and therefore a negative result was obtained. In reality, the machine never performed the test. The negative result obtained could possibly have been a "false negative." There is no way of knowing how many "false negatives" have been reported to patients. The thought of patients being delayed prompt treatment and unknowingly spreading a disease they were just tested for because of a false negative is frightening.

The problems with the Labotech are not related to any individual instrument, the problem is in the design and the programming. Adaltis must be required, since they apparently haven't taken the proper steps on their own, to remove every Labotech from service and hire an outside company to inspect each instrument for safety and reliability before it is allowed to be put back into use. There are over 2,500 Labotechs currently in use in the United States. The number of potentially inaccurate results being reported out to patients each day because of instrument malfunctions is staggering. Please take some action to protect the public from this machine. There must be more stringent requirements enforced before allowing an instrument like the Labotech to be released and put into use.

The second action I hope is taken is to make sure that better oversight is put in place for hospitals and hospital labs. The problems at Maryland General stemmed from a lack of accountability at every level in administration and a grave disregard for the health and safety of the people in the community. In the laboratory, one man was allowed to choose profit over patient safety, and his actions were never questioned by his superiors, making them just as responsible for the multitude of problems that resulted from his decision. Patients were provided less than optimal care, and were provided results from a machine that he knew was unreliable and unable to be validated. He demanded that the results be run in-house instead of sent out, even with the equipment problems, because the Labotech was the "money-maker" for the laboratory, and to send out tests would have cost the hospital money. In my view, his conduct was a betray of the community's trust which the administration allowed to continue.

He also refused to provide a safe environment for the employees in the lab. By refusing to replace a defective piece of equipment, the Labotech, and inform the employees of the seriousness and longstanding malfunctions, he knowingly placed employees in harm's way. On March 12, 2003, the instrument had a major malfunction, exposing me to blood. I did everything I was instructed to do, from the protective equipment I was wearing to how I handled the malfunction, and the treatment following the exposure. However, in June, while hospitalized for a severe flu-like illness, my blood tests came back positive for both HIV and hepatitis C. I tested negative on the day of the incident. My life has been irreversibly changed in every way imaginable. I only tell you this because this incident could have been completely prevented. I learned only after the accident that administrative director of the lab, James E. Stewart, was made aware of serious problems with the machine from the very first week it was brought into the lab. He also knew that the machine had never been safety tested or inspected by the hospital's own engineering staff. I later learned that on numerous occasions many of the laboratory staff requested that the machine be sent back and replaced by a different machine from a different company that was actually proven to be reliable and safe. Instead, another dysfunctional Labotech was brought in and put to use. If proper safety procedures were followed as set out by both the hospital and OSHA, after the extreme number of problems with Labotech, it should have been removed from service, long before I began my employment. Please don't let what happened to me happen to anybody else with this or any other dangerous and defective piece of equipment.

What is particularly disappointing is Maryland General Hospital's response to this public health catastrophe. When its laboratory practices were first called into question, the hospital circled the wagons around Mr. Stewart and the other administrators who failed to do their jobs. They denied responsibility and awareness of the serious problems their lack of action caused. Also disappointing is the fact that following my complaint, the State found many more problems in the laboratory than those I cited, yet Maryland General's lab had passed all the accreditation and certification inspections that had recently been conducted. This flies in the face of all

common sense and seriously calls into question the validity of the inspections and accreditation process established to ensure public safety. The agencies responsible to ensure the proper operation of hospital labs must also be held accountable and required to take responsibility for their failures and breach of the public trust. I fear the problem of lack of proper oversight is not a problem limited to Maryland General Hospital. New guidelines ought to be considered and/or the old ones enforced for the health and well being of every patient.

Thank you again for the opportunity to share my information with this congressional subcommittee. I have all the confidence in the world that you will take whatever action is appropriate to help prevent these messes from occurring in the future in other hospitals and with other pieces of biomedical equipment. You have the power to prevent what happened in Baltimore and to me from happening anywhere else.

Sincerely, Kristin Turner.

Mr. SOUDER. Thank you.

And to state again for the record, that was Kristin Turner's testimony. It was unsworn testimony, so we didn't have the witness here to do that. We normally don't do this in a committee, particularly when there are fairly serious charges made in the testimony, but I felt that given that it was a pivotal part of this case and given that the witness's excuse was very good, namely, that they had a health problem arising from the case, that we should break our precedent.

Mr. CUMMINGS. Mr. Chairman, just one point. I had an opportunity, Mr. Chairman, to interview Ms. Turner for 2 hours, and I found her to be a very credible person. I was extremely impressed with her concerns, and I just wanted to put that on the record, Mr. Chairman.

Mr. SOUDER. Thank you.

I yield to Mr. Ruppersberger for a statement.

Mr. RUPPERSBERGER. Mr. Chairman, thank you, and Elijah, Congressman Cummings, I want to thank you for your leadership in bringing this important issue. Congressman Cummings is always there in his community, and attempting to work as hard as he can. I also acknowledge that Senator Verna Jones is here, who also represents the district where Maryland General Hospital is located. And all of you for coming here to help us better understand the issues and responses related to the laboratory incidents at Maryland General Hospital.

First, I would like to state for the record that I am no stranger to the University of Maryland Medical System. As many of you might know, I was in a very serious accident in 1975, and as a result of the shock trauma system, I am alive here today. I am also vice chair of the Board of Visitors, which is an advocacy group, non-statutory, that promotes for the whole Maryland emergency medical system. Beyond the realities of hospitals like Maryland General Hospital, what they give to communities every day and remain important employers, health care professionals go into this line of work because they ultimately care about people; and this I know and I think we know.

I also know that Congressman Cummings is deeply engaged in this important matter, as it directly impacts so many of his 7th District constituents, but constituents throughout the Baltimore region. The impact of these laboratory issues on patients is, first and foremost, what everybody involved in this matter should be focused on. I look forward to learning from the individuals who helped bring this issue to light, from Maryland General to better understand the response, and from the involved regulatory agencies and also you, Ms. Williams. Thank you for being here so that we can get the views on what actually happened. From what I know about the situation, it is clear that mistakes were made. It also seems clear that there has been aggressive and decisive action taken to address and remedy identified problems. We need to make sure that action is on target and that it continues.

Now, of course it is easy to focus on fixing problems once they have been identified. I would expect nothing less than a tremendous response to an incident such as this, a situation that had the potential to affect so many patients. I am encouraged to hear that new tests largely confirm the results of the original tests. This is great news for patients and the community, and I hope that trend continues.

But my main interest here today goes beyond simply looking at the response to this incident at Maryland General Hospital. We need to determine whether there is any way that the many working parts in the machinery that make up our health care oversight and accreditation system are working together the way they should.

Obviously, an individual institution such as Maryland General, and in some cases a parent organization like the University of Maryland Medical System, has an obligation to make sure its laboratory is delivering test results in which patients can have confidence. But I am also concerned that, with all the other organizations involved here that were supposed to play a role in preventing situations from becoming so dire, this problem wasn't readily discovered until employees stepped forward with information.

In Maryland we have the Department of Health and Mental Hygiene, and we need to know why their inspection process didn't turn up these problems. We have CMS, who also had a role here too. So did the independent accrediting bodies like the College of American Pathologists and the Joint Commission on Accreditation of Health Care Organizations. Why didn't all of these groups and organizations work together the way they should to prevent, not just fix, this problem at Maryland General Hospital?

I am hopeful that what we hear today will help us determine whether changes need to be made at the State level or the Federal level that will prevent situations like this from arising in other communities in Maryland and around the country. With all the time, energy, and money the health care institutions and government have invested in oversight and inspection, we must find ways to prevent these kinds of problems in the future. Hopefully, we will take a few steps down that road through this process today.

Thank you.

[The prepared statement of Hon. C.A. Dutch Ruppersberger follows:]

Congressman C.A. Dutch Ruppersberger
Criminal Justice, Drug Policy & Human Resources
Subcommittee Hearing
MGH Laboratory and Testing Issues
Remarks
05.18.04

Thank you Mr. Chairman, my Maryland colleague Congressman Cummings, and all of you for coming here today to help us better understand the issues and responses related to the laboratory incidents at Maryland General Hospital.

First, I would like to state for the record that I am no stranger to the University of Maryland Medical System and Maryland General Hospital. As many of you know, I was in a horrible car accident in 1975 in Baltimore and I am only here today because of Shock Trauma and the health care professionals who saved my life that day. Today, I sit on the board of directors for Shock Trauma and I remain committed to the hospital system. Beyond the realities that hospitals like MGH give to communities everyday and remain important employers… health care professionals go into this line of work because they ultimately care about people. This… I know.

I also know that Congressman Cummings is deeply engaged in this important matter and that it directly impacts so many of his 7th district constituents served by Maryland General Hospital. The impact of these laboratory issues on patients is – first and foremost – what everybody involved in this matter should be focused on. I am look forward to hearing from the individuals who helped bring this to light, from Maryland General to better understand their response, and from the involved regulatory agencies to get their view on what happened. From what I know about the situation, it is clear that mistakes were made. It also seems clear that there has been aggressive and decisive action taken to address and remedy identified problems. We need to make sure that action is on target and that it continues.

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Mr. SOUDER. Thank you.

Mr. Cummings, do you want to start the questioning?

Mr. CUMMINGS. I just wondered if Ms. Norton had a statement.

Mr. SOUDER. Do you have an opening statement?

Ms. NORTON. Thank you very much.

I just want to thank Mr. Cummings for bringing this to the committee's attention, and you, Mr. Souder, for moving on it quickly. I don't know if I have ever heard of a more egregious situation. What particularly bothers me is the extent to which equipment, faulty equipment, was involved, given the—obviously also personnel, but particularly given how hard-pressed hospitals are these days and the financial pressures on them. I read Chairman Souder's statement, in which he says that so far as we have been able to tell, the situation at Maryland was unique. But he also says in his statement that we don't have any way of knowing whether that is the case. And, of course, this seems to have been discovered by accident, virtually.

So I am led to believe that with hospitals under great duress, that a place to skimp may be on equipment that perhaps should have been replaced. I recognize that State regulatory oversight is the first line of defense here, but it only makes me wonder about the hospitals in my own city, when I hear of mistakes like this. They have excellent reputations. We have had to close down the general hospital. I won't be able to stay for the entire questioning, but I do want to note that in Ms. Williams' testimony she says "the information that we were privy to pales in comparison to the information that others could and should have come forward with," which leads me to believe that what you have done here, Chairman Souder, calls for, at least at the State level, more investigation, perhaps using the subpoena power. And perhaps some of this will come out in Ms. Williams' testimony.

Thank you again for calling this hearing.

Mr. SOUDER. Thank you.

Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. I want to thank my colleagues for their opening statements.

Ms. Williams, first of all, I want to thank you for what you said. But perhaps more importantly, I want to thank you for standing up for others, because you didn't have to do it, but then again I guess you did have to do it, because your conscience would not allow you to do otherwise. And I just want to thank you.

Your position was what lead tech, is that what you said? What does that entail?

Ms. WILLIAMS. What it is is working the bench every day, and you have supervisory responsibilities: the scheduling, the ordering, the checking out new equipment, talking with the reps, all the normal supervisory responsibilities.

Mr. CUMMINGS. And you came to Maryland General when?

Ms. WILLIAMS. I came on full-time—I worked per diem prior to January 2001, but I came on full-time as the Infectious Disease Department Chemistry II Lead Tech January 2001.

Mr. CUMMINGS. Now, when did you leave?

Ms. WILLIAMS. I left August 2002.

Mr. CUMMINGS. And why did you leave?

Ms. WILLIAMS. Well, it is mainly because I had problems with my mother. You know, I was going back—I live in Jersey. She was sick. I had to travel back and forth. But the other issue was the fact that I couldn't fight this fight any longer by myself. There was a group of us who had rallied together and had gone to management, gone outside the laboratory and talked with the vice president of human resources and told him of the problems, and he took it to the president of the hospital.

Mr. CUMMINGS. You know for a fact that he took it to the president of the hospital?

Ms. WILLIAMS. I can only say that is what he told us.

Mr. CUMMINGS. But you know what you did.

Ms. WILLIAMS. Right.

Mr. CUMMINGS. OK, go ahead.

Ms. WILLIAMS. And as the issue regarding the controls, regarding the instrumentation. You have to understand this meeting was prior to the validation studies that I was responsible for for the Labotech, so I was addressing the other issues, the other issues that were mentioned in the article regarding the clerk being made to verify patient results, along with other issues.

We took it outside the laboratory because no one in the lab wanted to hear it. They wouldn't act upon it. When we came to them with the problems, we would look for changes, we would look for things that they had done to correct the problem. There were none. So we decided to take it outside the laboratory, and it fell on deaf ears also. We looked to see whether or not there were edited verify reports that we could check to see whether or not corrections were made to the patients that test results went out improperly on the edited verify reports. There was nothing, there were no corrections. So we knew that even though in the meeting they said we have taken care of that, don't worry about it, there was nothing that we could identify that proved that they did. So we decided that we were going to take it outside of the hospital totally and go to the State.

You have to understand the environment there was such that there was intimidation. We were afraid. And I am afraid right now, because I know that this affects a lot of people's jobs. I know that there are still friends of mine that work there that want to come forward, who will come forward now, but someone had to step forward first. But it was intimidation. You know, we were told keep it up, we could lose our jobs.

Mr. CUMMINGS. You were told that you would lose your job if you came forward?

Ms. WILLIAMS. Yes. To keep your mouth shut. I have one document that I submitted with my 2004 letter, which was an email that Jim Stewart sent to one of the group.

Mr. CUMMINGS. Jim Stewart was who?

Ms. WILLIAMS. He was the lab director. That he told her that she was the focal point of constructive criticism of the laboratory and basically to stop spreading it, to keep your mouth shut. She was one of the initial six that left the laboratory and sought help outside. Because everyone was so afraid, they didn't want to sign their name to the letter. You know, we had started the letter together,

we all had a draft of what we wanted to say and how we would do it, and then they became afraid.

Mr. CUMMINGS. Well, I am about to run out of time on my cycle here, but let me just ask you this. You said you are afraid right now, and that is always a major concern to Members of Congress. If we ask people to come or subpoena people to come in to testify, and they express fear about testifying, we want to make sure that we send a strong message out that we will do every single thing in our power and the authority of the Federal Government to make sure that you are protected. And I don't know whether that helps you or makes you feel better, but I am just saying that is a fact. We will not, under any circumstances, tolerate that kind of thing, and that is on both sides of the isle, Republicans and Democrats, because it goes against the very process that we are involved in here. Do you understand that?

Ms. WILLIAMS. Thank you.

Mr. CUMMINGS. So what are you so fearful of? I am just curious.

Ms. WILLIAMS. Well, by coming forward, I have ruffled the feathers of some very important people. Some very important people have lost their jobs. But I have to look beyond that. I have to think about there may have been four or five very important people who lost their jobs, but there were thousands of equally as important people whose lives are at stake. So, yes, I am fearful. There are others who want to come forward who have said that they will come forward if it is the proper forum, and that is why I put it in my testimony, allow them to be able to speak freely.

When the State came in in 2002, I wasn't there, but I did get panic phone calls that the employees were told don't say anything that would jeopardize the hospital. When you tell your employees, who know what is going on is not right, don't say anything that is going to jeopardize the hospital, that means you can't say anything. So they didn't. Give them the opportunity now, with immunity, to come forward and tell of everything. I mean, if you are really serious, Maryland General, of really correcting this, let it all out right now. Clean it up; correct it.

Mr. CUMMINGS. I am just curious, just one question. The chairman asked a little earlier a question of an earlier witness. I guess you have been in the room the whole time?

Ms. WILLIAMS. Yes.

Mr. CUMMINGS. About if there is a situation where people are altering tests and messing with results when these agencies come in who are supposed to address these tests, whether the folks at CLIA considered it a serious offense to have criminal penalties with regard to that. What is your view on that?

Ms. WILLIAMS. It is very serious. No. 1, I read the article, and that is what got me really outraged, that they had accused the technologists of manipulating the Labotech results. We can't manipulate them. I mean, the instrument is set up and designed where the protocol is already preprogrammed, so we will put the specimen on the instrument, but it samples it, does its calculations, and prints out a hard copy of its results. So there is no manipulation as far as us going in and changing the results, because it flows form there and then it goes directly into the hospital computer sys-

tem. So I am not sure of where that is coming from, as far as technologists manipulating results.

Now, if you are talking about documentation not being present to verify those results, I understand that was a problem. There is a law, I think it is under CLIA, that says that the patient results and control results have to be kept for 7 years. When the State went in, they could not find all the patient results and control results. That is a responsibility of the director. The techs run it, we staple it, we set it out there, it is sent down to storage. That is the responsibility that the director and the operations manager have to follow through on after we have done our job. So as far as manipulating, no.

Mr. CUMMINGS. Thank you.

Ms. WILLIAMS. That would have to be done—I am sorry, but if there were some manipulating, that would have to be done on a programming level or an engineering level, not on a tech level. We don't have that knowledge or capability.

Mr. CUMMINGS. Thank you.

Mr. SOUDER. Did you operate the machine?

Ms. WILLIAMS. I was part of the validation studies. As far as the testing that is in question right now, I wasn't there for the patient testing. I was there when the instrument came in and the validation studies were being done.

Mr. SOUDER. You heard the earlier testimony from FDA that there aren't any other machines that are malfunctioning in the United States, to their knowledge, and that the two European examples that they had didn't have the same problems, and they haven't had a problem for 5 years, that is why they came to the conclusion that there was something that could be in the programming of the parameters or in the documentation. Ms. Turner's testimony referred to the machine repeatedly breaking down. Did you see that, too?

Ms. WILLIAMS. Yes.

Mr. SOUDER. Could you describe some of what that is and in what way?

Ms. WILLIAMS. What happens, a lot of times it would fail calibrations; it would mis-step, where it goes to sample the patient specimen and it wouldn't put the specimen in the well, or else it would double another well, so there were two patients in the same well. The other thing that I have seen is that it wouldn't drop the tip. As it pipettes, it would carry over. So you would have cross-reactivity as far as the reagent boat and it going to the next patient.

Mr. SOUDER. Were the machines serviced on a regular basis? Is that something that is required to do? Because you would think that would show up in other hospitals as well as a problem, unless there was some sort of internal maintenance or less training than necessary at the hospital, some programming error in the machine.

Ms. WILLIAMS. All I can say is that this instrument—I understand that there were three ultimately, but I only worked on one—had problems from the day that it came into the lab. First of all, when it came in, it was contaminated. There was blood already in it, because it was refurbished. It wasn't a new instrument. So we had to call Adaltis to come in to decontaminate before they did their actual validation studies of the instrument itself. Once they

are finished with their validation studies of the instrument, then that is when we perform our validation studies of the reagents.

There were problems with parts malfunctioning, things that we could not troubleshoot, things that were beyond our scope in training. So we had to call them in regularly. As a matter of fact, we had to have two training sessions. The first training session we didn't get trained well enough, not all because of Adaltis, but because we were pulled away to preform other responsibilities, which interfered with us getting thoroughly trained on the instrument. So they did come in for a second session. But the instrument itself had inherent problems.

Mr. SOUDER. You said there were three machines?

Ms. WILLIAMS. That is what I have heard yesterday, that there were three, there was more than the one that I actually operated.

Mr. SOUDER. Has anybody come forth on the other machines, do you know?

Ms. WILLIAMS. I think Kristin.

Mr. SOUDER. She was on a different machine than you were?

Ms. WILLIAMS. Yes.

Mr. SOUDER. OK.

Ms. WILLIAMS. Now, I don't know if the machine that exploded on her is the same machine that I operated. I don't have any information regarding that.

Mr. SOUDER. Is part of the reluctance of some people to come forth the fact that one of the troubling things here is it the machine or is it the people, and it makes it difficult for the people to come forth if they in fact then get blamed for the problem?

Ms. WILLIAMS. No. I think that people are afraid—well, the finger has been pointed at people who did come forward, who tried to correct the problems. So, yes, of course you are going to be afraid that they are going to blame it on me when I tried to help. But I think they are afraid for their jobs. They are afraid of being blackballed. They are afraid of coming forth because they don't know—who goes to Capitol Hill? You know, we are just low-level workers here. This is a forum that we are not accustomed to, you know, so what do we say, how do we protect ourselves? You have University of Maryland and Maryland General Hospital, who have 10,000 attorneys that can come to their defense. I sit here alone today. So, yes, they are afraid for all of those reasons.

Mr. SOUDER. Well, thank you for being willing to testify.

We are going to run into a very tight time problem here, because we have to be out of the room in a little more than a half hour, and we have another panel.

So, Mr. Ruppersberger, if you have some questions.

Mr. RUPPERSBERGER. Sure. Real quick.

First thing, you are not alone. You have a lot of people here supporting what you are saying. We are trying to get to the facts so that we can fix the system that didn't work. One of the issues is macro and micro. The fact is this a systemic problem is affecting hospitals and testing places all over the country, really, if not the world, and we are trying to get to the facts.

Now, you said you are a low-level worker. You are not a low-level worker, you are front line. And I think you get a lot of information from front line.

Now, I am sorry I wasn't in the first panel; I had another function where I had to be. But one of my concerns is the actual testing itself. Are you familiar with CMS and what CMS does?

Ms. WILLIAMS. No.

Mr. RUPPERSBERGER. CMS is really required—let me explain what CMS really is. CMS is the Centers for Medicare and Medicaid Services. There is a law called CLIA. It was passed in 1998, Clinical Laboratory Improvements, and it really kind of controls what we do here as far as inspections. CMS is charged with implementation of the law, including laboratory registration, fee collection, surveys, surveyor guidelines, training enforcement, approving entities that test laboratory proficiency, selecting accrediting organizations, and identifying States that can be exempt from this law as a result of their own licensure requirements.

From your perspective from being on the front line, I would like to know a little bit more about the testing issue. And let me give you some background on that. From what my research has shown, you have about 180,000 labs throughout the country, such as Maryland General Hospital and all over the country. Maryland General Hospital, I think just in a year, had over 554,000 lab tests that were conducted. Now, of those, 2,000 are in question here. And we really need to focus on why, I think, that the organization whose responsibility it is to conduct these surveys and inspections would not pick this up. And that is where I really want to focus because Maryland General Hospital, they have done a lot, they have reacted to this, they have tried to fix it and they are fixing it, and that is important. We have to move on, but we have to learn from those mistakes, and for people's lives. That is why Congressman Cummings has brought this to our attention, to make sure that we fix it.

From your perspective, tell me about the survey, if you have any personal knowledge, and what you have seen. Were questions asked? Of the 2,000 test areas that we are looking at, there were subsystems that were there. Were these subsystems looked at? Because when you really look at the facts, Maryland General Hospital was accredited and considered to be one of the better labs. So there was a breakdown. Do you have any comments on that?

Ms. WILLIAMS. I think——

Mr. RUPPERSBERGER. Long question, but it is important to get that out.

Ms. WILLIAMS. I can speak to the CAP inspections. I wasn't there when the State came in. But the way it is set up is that you are given a booklet, prior to the inspection, of areas that you need to address and questions that will be asked. So I had been there 3 months, taking over the Chemistry I and II departments, to run those, 3 months before the inspection of 2001 took place. So we were just given a pamphlet. We had to address it, we had to make new procedure manuals, clean the area, make sure all the reports were up to date. But we knew what we were going to be asked.

I think what was a problem with the CAP inspection process is that the inspection team was from right there in Baltimore, from one of the hospitals that—I guess neighborhood hospitals, where people had worked there before, they knew each other. That could pose a problem. When I had talked to the screening team last

week, I felt that maybe it would be better to have an inspection team that came from out of State, where no one worked for anyone, no one knew anyone. Also, to have inspectors that were familiar with the instrumentation that you were using, because if you are using a hospital that is using a manual method to perform the same test that you are doing automated, there could be an information flow problem, because if you are doing it manually, you know how it is supposed to go from beginning to end. If you are doing it by an automated method, there are certain assumptions that are already in place because the machine does that for you. So you would have to have someone who knows your instrument, even if it meant having a team that came from several different places to do the inspection. It doesn't have to come from just one hospital and everyone from each department represents someone that inspects the other person in your department. Have someone from out of State that has no ties, nothing associated with your hospital. And let them know ahead of time, if they are going to make them aware of questioning, let them be educated in the instrument that they are coming to test for.

Mr. RUPPERSBERGER. I think your comments are extremely valid. I know my red light is on and we have to move forward, but I think if we are going to resolve the issue and look at the whole systemic problem on a national basis and a local basis, we need to talk to people such as yourself so that we know what questions to ask and where there could be breakdowns.

Thank you for coming here today.

Ms. WILLIAMS. You are welcome.

Mr. SOUDER. Thank you also for your willingness to speak out. Your recommendations are very interesting. I know sometimes whistleblowers feel like people say, oh, well, they're just a complainer. You know what? Complainers don't ask for SIX SIGMA audits. You are asking for very particular reasonable things to be done in this type of thing, and I commend you for your willingness to speak out, and the others who have also been willing to speak out.

Thank you for coming.

Mr. CUMMINGS. Mr. Chairman, just one thing. Mr. Chairman, I just hope that—you know, this witness has provided some very valuable testimony. Unfortunately, I know we are running out of time. I just want to be able to perhaps followup with some written questions, things that we may not have been able to get to today.

And I too really appreciate you doing what you are doing. You have probably affected a whole lot of people's lives that you will never hear from because they won't even know you did it. But on behalf of all of them, I just want to say thank you.

Ms. WILLIAMS. Thank you.

Mr. SOUDER. Thank you.

If the third panel could come forward. Mr. Richard Eckloff, the Honorable Nelson Sabatini, Mr. Lepoff, and Mr. Notebaert. And if you could remain standing.

Part of the problem is this is the main committee room, and they have another hearing at 2. We hadn't allowed for that many votes to intervene. So we will need to keep moving.

If you could each stand and raise your right hand.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that each of the witnesses responded in the affirmative.

I appreciate your patience. We will start with Mr. Richard Eckloff, who is Adaltis US Inc., from Allentown, PA.

STATEMENTS OF RICHARD ECKLOFF, ADALTIS US INC., ALLENTOWN, PA; NELSON J. SABATINI, SECRETARY, MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE, BALTIMORE, MD; RONALD B. LEPOFF, M.D., F.C.A.P., CHAIR OF THE COMMISSION ON LABORATORY ACCREDITATION, COLLEGE OF AMERICAN PATHOLOGISTS, NORTHFIELD, IL; AND EDMOND NOTEBAERT, PRESIDENT, UNIVERSITY OF MARYLAND MEDICAL SYSTEM, BALTIMORE, MD

Mr. ECKLOFF. On behalf of Adaltis US Inc., thank you for your invitation to testify at this investigative hearing. As the company that sold and serviced the laboratory equipment on which the tests that are the subject of this hearing were performed, Adaltis US appreciates this opportunity to assist the subcommittee with its efforts to address the serious public health concerns raised by this matter.

From late 1994 until April 8th of this year——

Mr. SOUDER. Can you raise your voice, please?

Mr. ECKLOFF. From late 1994 until April 8th of this year, I was the general manager of Adaltis US, the domestic distributor for Adaltis Italia S.p.A., which manufactures automated processors. Adaltis US also distributed diagnostic products manufactured by other companies. As general manager, I was responsible for sales, marketing, and product support for these products in the continental United States.

The equipment on which the tests at issue were performed is called the Labotech Automated Microplate Analyzer. The Labotech was cleared by the Food and Drug Administration as a Class II medical device in 1992. The Labotech is designed to robotically perform the processing steps that a medical technologist would manually perform to complete tests that are known as enzymatic immunoassays, or EIAs.

The Labotech is an "open system." This means that it is programmable to perform tests utilizing test kits made by many different manufacturers. These test kits contain samples, called calibrators and controls, that are necessary to calibrate the analyzer to perform a particular manufacturer's test properly. Adaltis did not manufacture the HIV or hepatitis kits that were used by Maryland General Hospital to perform the tests that are at issue here.

There are more than 2500 Labotechs currently in daily use at locations throughout the world. Of these, approximately 170 are currently in use in the United States, including Labotechs installed at prestigious medical institutions such as the National Institutes of Health in Bethesda, MD, Walter Reed Army Medical Center in Washington, DC, and the Cleveland Clinic.

To our knowledge, invalid test results have not been generated by a Labotech and then reported to a patient by any hospital or laboratory other than Maryland General Hospital.

We understand that the test results at issue were generated at the Maryland General Hospital between June 2002 and August 2003. We further understand that the test results were invalid because control readings were not within the ranges set by the test kid manufacturers. A review of our records indicates that, during this time period, there was a high number of service support requirements for this account. Nearly all of these support requirements, however, were responsive to maintenance, training, and operator issues unrelated to failed runs due to test kit control readings. Our records indicated that only four calls were received from the hospital due to such failed runs. Our records also indicate that all of these reported incidents were addressed by employing normal troubleshooting procedures and were satisfactorily resolved. Adaltis US was not aware that invalid test results were generated or that invalid test results were reported to patients. These facts came to our attention when they were reported by the press in or about March of this year.

Adaltis US has also learned that the Maryland Department of Health has conducted an investigation of this matter and that a report has been prepared. We were not contacted by the Department in connection with its investigation. We have, however, followed the reports on the Department's investigation that have appeared in the press.

For example, in an Associated Press article published in the Washington Times on March 20, 2004, it was reported that: "[A]ccording to the State inspection report, lab personnel manipulated and eliminated readings showing completed blood tests might be inaccurate. The report said workers at all levels allowed results to be reported even when instrumentation and quality control materials were used improperly." Similarly, on March 23, 2004, the Associated Press reported that: "[A]ccording to a State inspection report, lab workers manipulated and eliminated machine readings showing that recently completed blood tests might be inaccurate and should be discarded."

We are also aware that the College of American Pathologists, which is represented on this panel, issued a press release on May 11th stating that: "After thorough investigation, the College determined that what caused the errors appeared to have been deliberate data manipulation by laboratory employees. The employees edited the quality control reports of the testing instrument used."

Our own internal investigation, which is still underway, has uncovered no evidence that is inconsistent with the press reports.

In summary, all the information available to Adaltis US at this time indicates that the circumstances that caused invalid test results to be generated and conveyed to patients of Maryland General Hospital were related to hospital personnel and procedures, not to any malfunction of the Labotech. And we are unaware of any instances, other than those reported by Maryland General Hospital, where invalid test results have been generated by a Labotech and conveyed to patients.

Again, let me thank you for this opportunity to testify before you today. I would be happy to respond to questions you may have or to provide supplemental information you may request.

[The prepared statement of Mr. Eckloff follows:]

TESTIMONY ON BEHALF OF ADALTIS U.S. INC.

BY

RICHARD ECKLOFF

FORMER GENERAL MANAGER
ADALTIS U.S. INC.

Before The

Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources
United States House of Representatives

Investigative Hearing:

The Conditions and Circumstances That Caused Inaccurate Test Results To Be Generated and Conveyed to Patients of Maryland General Hospital

May 18, 2004
Washington, D.C.

Chairman Souder, Congressman Cummings, and Members of the Criminal Justice, Drug Policy and Human Resources Subcommittee, my name is Richard Eckloff. On behalf of Adaltis U.S. Inc., thank you for your invitation to testify at this investigative hearing. As the company that sold and serviced the laboratory equipment on which the tests that are the subject of this hearing were performed, Adaltis U.S. appreciates this opportunity to assist the Subcommittee with its efforts to address the serious public health concerns raised by this matter.

From late 1994 until April 8th of this year, I was the General Manager of Adaltis U.S. Until late 1999, when its name was changed, the company was called Biochem Immunosystems U.S., Inc. On April 8th of this year, Adaltis U.S. sold all of its assets to Trinity Biotech.

Adaltis U.S. was, at all times relevant to your investigation, the domestic distributor for Adaltis Italia S.p.A., which manufactures automated processors. Adaltis U.S. also distributed diagnostic products manufactured by other companies. As General Manager, I was responsible for sales, marketing and product support for these products in the continental United States.

The equipment on which the tests at issue were performed is called a LABOTECH Automated Microplate Analyzer. The LABOTECH was cleared by the Food and Drug Administration ("FDA") as a Class II medical device in 1992. The LABOTECH is designed to robotically perform the processing steps that a medical technologist would manually perform to complete tests that are known as enzymatic immunoassays, or "EIAs."

The LABOTECH is an "open system." This means that it is programmable to perform tests utilizing test kits made by many different manufacturers. These test kits contain samples, called calibrators and controls, that are necessary to calibrate the analyzer to perform a particular manufacturer's test properly. Adaltis did *not* manufacture the HIV or hepatitis test kits that were used by Maryland General Hospital to perform the tests that are at issue here.

There are more than 2500 LABOTECHS currently in daily use at locations throughout the world. Of these, approximately 170 are currently in use in the United States, including LABOTECHS installed at prestigious medical institutions such as the National Institutes of Health in Bethesda, MD, Walter Reed Army Medical Center in Washington, D.C., and the Cleveland Clinic.

To our knowledge, invalid test results have not been generated by a LABOTECH and then reported to a patient by any hospital or laboratory other than Maryland General Hospital.

In the Subcommittee's letter of April 29, 2004, you advised us that you are seeking to understand the conditions and circumstances that caused inaccurate test results to be generated and conveyed to patients of Maryland General Hospital. Adaltis U.S. does not have access to much of the information that would be necessary to be responsive on this issue. Other members of this panel, as well as members of the two other panels that testified today, may be able to provide far more assistance to the Subcommittee. Nevertheless, Adaltis U.S. will share what it has learned.

We understand that the test results at issue were generated at the Maryland General Hospital between June 2002 and August 2003. We further understand that the test results were invalid because control readings were not within the ranges set by the test kit manufacturers. A review of our records indicates that, during this time period, there was a high number of service support requirements for this account. Nearly all of these support requirements were responsive to maintenance, training, and operator issues unrelated to failed runs due to test kit control readings. Our records indicate that only four calls were received from the Hospital due to such failed runs. Our records also indicate that all of these reported incidents were addressed by employing normal trouble shooting procedures and were satisfactorily resolved. Adaltis U.S.

was not aware that invalid test results were generated or that invalid test results were reported to patients. These facts first came to our attention when they were reported by the press in or about March of this year.

Shortly after Adaltis U.S. first learned about this matter, the FDA conducted an investigation at our headquarters in Allentown, Pennsylvania. The FDA did not tell us why it was conducting that investigation; however, the FDA did inform us that it was well aware of what had occurred at Maryland General Hospital. We have no further information about the FDA's investigation.

Adaltis U.S. has also learned that the Maryland Department of Health and Mental Hygiene has conducted an investigation of the invalid test results generated at Maryland General Hospital and that a report on that investigation has been prepared. We were not contacted by the Department in connection with its investigation. We have, however, followed the reports on the Department's investigation that have appeared in the press.

For example, in an Associated Press article published in the Washington Times on March 20, 2004, it was reported that: "[A]ccording to the state inspection report, lab personnel manipulated and eliminated readings showing completed blood tests might be inaccurate. The report said workers at all levels allowed results to be reported even when instrumentation and quality control materials were used improperly."[1/] Similarly, on March 23, 2004, the Associated Press reported that: "[A]ccording to a state inspection report, lab workers manipulated and

1/ F. Klug, *Lab Worker says thousands of HIV tests flawed*, Associated Press, March 20, 2004, published in *The Washington Times*.

eliminated machine readings showing that recently completed blood tests might be inaccurate and should be discarded."[2/]

Adaltis U.S. does not understand precisely what Maryland General Hospital workers were reportedly found to have done or how they generated the test results at issue. The press reports do make clear, however, that the LABOTECH properly indicated that the test results were invalid but that Maryland General Hospital personnel disregarded this information. Mr. Sabatini is here today to testify, and we certainly do not mean to speak for him. Nevertheless, we are aware that the Associated Press reported on March 12 of this year that: "State health secretary Nelson Sabatini said the problem appeared to be a personnel issue and *not* an equipment issue."[3/]

We are also aware that the College of American Pathologists, which is represented on this panel, issued a press release on May 11th stating that: "After thorough investigation, the College determined that what caused the errors appeared to have been deliberate data manipulation by laboratory employees. The employees edited the quality control reports of the testing instrument used."[4/]

Maryland General Hospital did finally make a report regarding the invalid test results on April 21st of this year—nine months after the last of the invalid test results was generated at the Hospital. At that time, the Hospital belatedly filed a MedWatch report with the FDA that asserts that LABOTECH malfunctions occurred resulting in invalid test results. That report, however,

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2/ W. Hall, *Hospital Moves To Correct Problem With Test Results*, Associated Press (March 23, 2004).

3/ A. Dominguez, *Maryland Hospital Urges HIV Retesting,* Associated Press (March 12, 2004)(emphasis added).

4/ College of American Pathologists, *Update on the Maryland General Hospital Laboratory Issue* (News Release, May 11, 2004).

provides no information about any specific incidents, gives no indication of the extent of the problem, and provides no information at all about the types of tests performed or the results obtained. Nevertheless, after we received a copy of the report form on April 26, 2004, we began an internal investigation. That investigation is still underway.

In sum, all information available to us at this time indicates that the circumstances that caused invalid test results to be generated and conveyed to patients of Maryland General Hospital were related to Hospital personnel and procedures—*not* to any malfunction of the LABOTECH. And we are unaware of any instances, other than those reported at Maryland General Hospital, where invalid test results have been generated by a LABOTECH and conveyed to patients.

Again, let me thank you for this opportunity to testify before you today. I would be happy to respond to questions you may have or to provide supplemental information you may request.

Mr. SOUDER. Thank you very much.

Next is Mr. Nelson Sabatini, Secretary of the Maryland Department of Health and Mental Hygiene, Baltimore, MD.

Mr. SABATINI. Thank you, Mr. Chairman. I appreciate the invitation to testify today. I also want to thank you, Representative Cummings and Representative Ruppersberger, for holding this hearing. You are opening the public debate on what I believe is a critical health care issue that is facing this Nation.

At this point we are all well aware of the problems that occurred at the Maryland General Hospital laboratory, and while we are here primarily to talk about Maryland General, I believe it would be a terrible mistake to characterize this as an isolated event. In 1999, the Institute of Medicine published a report estimating that as many as 100,000 patients a year die from medical errors in hospitals. Let me repeat that. 100,000 patients die every year from errors in hospitals. And that is about 2,000 a week or 250 people a day across this country.

As far as we know, none of the Maryland General patients has died, so the thousand or so medical errors that we are talking about today don't even show up on the radar screen. The Institute of Medicine study focused only on medical errors with fatal outcomes.

The Institute's report should horrify all of us. The report said that these errors are caused by "systems problems" that go undetected and uncorrected by hospitals. This is certainly the case at Maryland General; the problems went undetected or ignored by the hospital for an extended period of time. But given the IOM report, I believe we can assume that Maryland General's problems are not unique in the industry.

We have to ask ourselves how can this be happening in a country that I believe provides the best health care in the world? And I would submit that what we are seeing is the direct result of a 30-year experiment in self-regulation by the hospital industry.

I believe the Maryland General experience is merely a symptom of a system failure, and I believe it calls into question the legitimacy and adequacy of the entire regulatory process. I have said publicly that the system is broken and it needs an overhaul, and I mean just that. In the case of Maryland General Hospital, the system was not equipped to address the problems at the hospital or its lab. The Federal and State regulatory agencies, which bear ultimate responsibility for ensuring quality health care, do not have the regulatory tools they need to provide any credibility of quality assurance. Let me explain why.

Federal law, and a comparable State law in Maryland, grant what is known as "deemed status" to any laboratory accredited by the College of American Pathologists or the Joint Commission on Accreditation of Health Care Organizations. Accredited facilities are "deemed" to be in compliance with all applicable Federal and State regulations, and thus are exempt from routine Federal and State surveys. In Maryland this legislation was passed about 30 years ago and embodied the logical-sounding idea that no one is better equipped to regulate doctors and hospitals than doctors and hospitals themselves. So we, the government regulators, have passed the baton to private entities like the Joint Commission,

which answers not to government, not to the public, but to the American Hospital Association and the American College of Surgeons.

We depend on these accreditation organizations to conduct their own periodic surveys, provide us with assurance that they are high standards of quality are being met and that patients can feel safe in a "deemed" facility. Patient safety is ultimately a government regulatory responsibility, but we have subcontracted it out. The Federal Government and many State agencies have abdicated, have turned over their authority to private sector organizations, which in my view have uncomfortably close ties to the industry and the people that they survey.

Accreditation surveys are generally announced in advance, and even if unannounced, they are fairly predictable. You heard that from the earlier witness. The surveys are collegial in nature and leisurely in execution, and they focus almost entirely on process instead of outcomes. This is like saying a business is doing fine as long as its books appear to be in order.

By way of contrast in Maryland, we regulate nursing homes by looking first at outcomes, not at process, and it is our consistent experience that bad outcomes are a very good indicator of systemic problems in a facility. We do care about process, but we try to care more about people. And when it comes to regulating hospitals, the liability to care about either is less than ideal.

Deeming limits the ability of government to exercise its inherent regulatory authority. Even though hospitals operate under licenses granted by the State, we have no authority to routinely inspect these facilities. We can only conduct surveys in response to specific complaints, and when those surveys do turn up problems, our ability to mandate corrective action is limited. The corrective process is slow, it is bureaucratic, and it is based on the assumption that once a hospital knows of a problem, it will fix that problem, even without the expectation of a followup survey.

There is also the issue of disclosure, of transparency. Those 100,000 deaths a year are not spread evenly among all hospitals; there are good hospitals, there are not-so-good hospitals. But the public has very little chance to know which is which. Survey reports by the private sector accrediting organizations are not routinely disclosed to the general public. In theory, some of the reports are public, but actual disclosure requires the consent of the facility. The public has no consistent and reliable way to evaluate a hospital before choosing one.

In contrast, surveys we conduct at nursing homes and other long-term care facilities are periodic, unannounced, comprehensive, and public. The results of our surveys are published on our Web site. As a regulatory agency, we can't guarantee that a good facility today won't have problems tomorrow, but at least we give the public a chance to look at the track record before they pick a facility. Equally important, the reports help the public, and the legislature, judge how well we are doing our job and to hold us accountable.

When it comes to hospital laboratories, though, there are at least four different agencies or organizations involved in quality oversight, the State and Federal Government, and at least two accrediting organizations, which means, among other things, that when

something does go wrong, you see what you have seen throughout this hearing today, a reaction of this, that is who is to blame and that is who accountable.

You are going to hear a lot of people explain how someone else dropped the ball today. Let me say this as pointedly as I can: we all dropped the ball. I am not proud of the way the State acted in this situation. I am not proud of the way the State acts and reacts and fulfills its regulatory responsibility with regard to hospitals.

At Maryland General, as early as 2002, the State and Federal agencies identified potentially serious problems. There was no followup to ensure corrective actions. The hospital was to notify the accrediting organization and alert it to the Federal investigation and deficiencies. This also did not happen. There was no direct or indirect sharing of information between the government and private survey agencies. In April 2003, the College of American Pathologists conducted its routine inspection, and even though its surveys identified problems similar to those identified by us in 2002, it granted the laboratory accreditation "with distinction," and the deficiencies went on and on and were not fixed. It was only in January of this year——

Mr. SOUDER. Mr. Sabatini, are you about done? You are over time and we are going to run out of time here.

Mr. SABATINI. I will be done within 30 seconds.

Mr. SOUDER. OK.

Mr. SABATINI. It was only in January of this year that a strongly worded complaint reached both us and the local newspaper that the hospital, and its gaggle of regulatory and accrediting agencies, began to address the problem.

The current system is frightening, it is cumbersome, it is bureaucratic, and even if there were good communications among all the agencies, there are too many of them.

I am going to stop there.

Mr. Chairman, we need to and we owe it to the public who depend on us to make sure that when they enter a health care facility in this country, that they can be convinced of the safety of the care that they are getting. We are not doing that and we are not fulfilling our obligation in that regard. We need to work together and fix it.

Mr. SOUDER. Thank you. And if you have additional materials or further statement you want to submit to the record, we will put it into the full record.

Mr. Lepoff, who is the Chair of the Commission on Laboratory Accreditation at the College of American Pathologists from Northfield, IL.

Mr. LEPOFF. Good afternoon, Mr. Chairman, other members of the subcommittee, Mr. Cummings——

Mr. SOUDER. If you can bring the mic up so the full room can hear.

Mr. LEPOFF. My name is Ron Lepoff, and I am the Chair of the College of American Pathologists Commission' on Laboratory Accreditation.

In April 2003, a 13-member CAP inspection team conducted a required biennial inspection of the laboratory at Maryland General Hospital. This multi-disciplinary team used a 2100 item checklist

to guide its evaluation. The inspection team cited the laboratory with nine deficiencies, including failing to carry out its own plan for quality assurance. The CAP gave the laboratory 30 days to remedy the deficiencies or face possible revocation of its accreditation. Subsequently, the laboratory attested and provided documentation to show that it had corrected the cited deficiencies. Only after evaluating this documentation did CAP re-accredit the Maryland General Hospital laboratory.

In hindsight, however, it is clear that quality assurance issues and extensive employee complaints about Maryland General extend back to 2002, when Teresa Williams filed her formal complaint with the State of Maryland.

The complaint alleges that the laboratory routinely failed to monitor quality control and instrumentation, falsified federally required proficiency testing results, failed to follow manufacturer instrumentation protocols, and reported patient results on testing runs for which quality control checks failed. The CAP only yesterday was provided with a copy of Ms. Williams' complaint. Had the College been given this complaint in 2002, it would have responded quickly with a focused complaint investigation. If the allegations had been substantiated, it almost certainly would have led to revocation of the laboratory's accreditation, and possibly additional penalties by CMS.

The State subsequently received the December 2003 complaint from Kristin Turner that alleged multiple quality issues, including improper HIV and hepatitis testing. Again, the College was not provided a copy of this complaint until yesterday.

In response to Ms. Turner's complaint, the State inspected the MGH laboratory in January 2004 and found that laboratory personnel improperly altered quality control values on reports produced by the instrument when initial reports indicated values outside an acceptable range. This improper practice would have concealed the quality control problems from CAP inspectors. No inspection team would have uncovered the quality control issues based on a standard review of quality control records because those records had been altered.

The College commends the laboratory personnel who came forward in the MGH case. They did the right thing. This underscores the critical need for laboratory personnel to interact openly with and identify issues for inspectors without fear of retaliation from their employers.

In this case, the laboratory personnel reported working "beneath a cloud of fear" and, according to reports, remained silent during the 2002 State inspection. During the College's April 2003 inspection, no employee conveyed concerns to the CAP inspection team.

Questions have been raised about why the College awarded the MGH laboratory "accreditation with distinction." We believe this designation has been misinterpreted as being the highest rating on a multi-level graded scale from poor to excellent. The College recognizes only two accreditation levels: meeting basic CLIA standards or meeting the College's additional standards to merit accreditation with distinction. The "accreditation with distinction" designation recognizes that CPA accredited laboratories adhere to additional

College standards that exceed those mandated by CLIA and are, therefore, "distinct" from Federal standards.

In summary, the MGH case highlights the fact that no inspection can identify every possible deficiency and that Federal, State, and private accrediting bodies must promptly share complaint information. Multiple levels of oversight and review are necessary, including the laboratory inspection itself, proficiency testing, responsible laboratory quality assurance management, and self-reporting by laboratory personnel.

The College is committed to preventing events like those at Maryland General Hospital by modifying its inspection and accreditation process to enhance self-reporting by laboratory staff of quality issues.

Additionally, we recommend that Congress ensure that whistleblower protections and patient safety legislation now before Congress include worker reports to private accrediting organizations.

Finally, we recommend that governmental agencies develop and utilize clear protocols for communicating with private accrediting bodies in a timely manner regarding complaints so that private accrediting organizations can meet their obligations.

The College thanks the subcommittee for its interest in ensuring the highest quality laboratory testing. The CAP is firmly committed to working with stakeholders at all levels, public and private, to achieve that goal.

I would be happy to answer any questions the subcommittee might have.

[The prepared statement of Mr. Lepoff follows:]

Testimony of Ronald B. Lepoff, MD, FCAP, before the Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government Reform

May 18, 2004

Good morning, Mr. Chairman, Representative Cummings and other members of the subcommittee. My name is Ron Lepoff, MD, chair of the College of American Pathologists' Commission on Laboratory Accreditation.

In April 2003, a 13-member CAP inspection team conducted a required, biennial inspection of the laboratory at Maryland General Hospital. This multidisciplinary team used a 2,100-item checklist to guide its evaluation. The inspection team cited the laboratory with nine deficiencies, including failing to carry out its own plan for quality assurance. The CAP gave the laboratory 30 days to remedy the deficiencies or face possible revocation of its accreditation. Subsequently, the laboratory attested and provided documentation to show that it had corrected the cited deficiencies. Only after evaluating this documentation did CAP re-accredit the Maryland General Hospital laboratory.

In hindsight, however, it is clear that quality assurance issues and extensive employee complaints about MGH extend back to 2002, when Theresa Williams filed her formal complaint with the state of Maryland.

The complaint alleges that the laboratory routinely failed to monitor quality control and instrumentation; falsified federally required proficiency testing results; failed to follow manufacturer instrumentation protocols; and reported patient results on testing runs for which quality control checks failed. The CAP only yesterday was provided with a copy of Ms. Williams' complaint. Had the College been given this complaint in 2002, it would have responded quickly with a focused complaint investigation. If the allegations had been substantiated, it almost certainly would have led to revocation of the laboratory's accreditation and, possibly, additional penalties by CMS.

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instrument when initial reports indicated values outside an acceptable range. This improper practice would have concealed the quality control problems from the CAP inspectors. No inspection team would have uncovered the quality control issues based on a standard review of quality control records because those records had been altered.

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accredited laboratories adhere to additional College standards that exceed those mandated by CLIA and are, therefore, "distinct" from federal standards.

In summary, the MGH case highlights the fact that no inspection can identify every possible deficiency and that federal, state and private accrediting bodies must promptly share complaint information. Multiple levels of oversight and review are necessary, including the laboratory inspection, proficiency testing, responsible laboratory quality assurance management and self-reporting by laboratory personnel.

The College is committed to preventing events like those at Maryland General Hospital by modifying its inspection and accreditation process to enhance self-reporting by laboratory staff of quality issues.

Additionally, we recommend that Congress ensure that whistleblower protections in patient safety legislation now before Congress include worker reports to private accrediting organizations.

Finally, we recommend that governmental agencies develop and utilize clear protocols for communicating with private accrediting bodies in a timely manner regarding complaints so that private accrediting organizations can meet their obligations.

The College thanks the subcommittee for its interest in ensuring the highest quality laboratory testing. The CAP is firmly committed to working with stakeholders at all levels, public and private, to achieve that goal. I would be happy to answer any questions the subcommittee might have.

Thank you.

Mr. SOUDER. Thank you.

And our final witness is Mr. Edmond Notebaert, who is the President of the University of Maryland Medical System in Baltimore, MD.

Mr. NOTEBAERT. Thank you, Mr. Chairman, Congressman Cummings. It is a pleasure to appear before you this afternoon, giving me the opportunity to speak to you. My name is Edmond F. Notebaert. I am the President and Chief Executive Office of the University of Maryland Medical System, which is the parent organization of Maryland General Hospital. I have been the President and Chief Executive Officer of the University of Maryland Medical System since September 1, 2003.

When the University of Maryland Medical System first became aware of the issues at Maryland General Hospital in early March, the response was immediate, decisive, and comprehensive. On March 8th, the very first day Maryland General Hospital executives revealed this problem, the University of Maryland Medical System dispatched its top senior vice president of strategy & corporate operations to the Maryland General Hospital. This individual was assigned the responsibility to lead the System's team in understanding and addressing all of the issues identified by the regulatory agencies at Maryland General Hospital. This individual met with Maryland General Hospital's management daily and remained on the site well into the evening for the first 6 weeks of the effort to identify and remedy problems in the laboratory operations and processes. He continues to be involved with that hospital on a daily basis.

Within 5 days of learning about the situation at Maryland General Hospital, the University of Maryland Medical System elected to bring in a lab management company, and within 10 days identified and hired Park City Solutions, the leading laboratory consulting and management services provider in the United States and Canada, to provide lab management services to Maryland General Hospital. Park City Systems [sic] took over the operation of the laboratory on March 19th, 16 days after the State issued its report citing deficiencies in the laboratory. As part of the System's comprehensive approach, we hired Park City Solutions not only to fix the identified deficiencies, but to conduct a top-to-bottom review of the laboratory and fast-track the implementation of any necessary changes. We rejected taking any sort of band-aid incremental approach.

During their first week at Maryland General Hospital, Park City Solutions brought in the lab administrator and two technical experts. Shortly thereafter, they recommended additional people be brought in, and, in fact, we told them to bring in whomever they needed. We gave PCS broad authority to take all necessary actions to understand and address Maryland General Hospital's laboratory issues. In addition to providing an initial assessment of the situation and addressing problems as they were identified, PCS administers the laboratory's operations on a day-to-day, which includes placing specialists to oversee each and every section of the laboratory, implementing new procedures and policies, putting in place a system of quality, and providing training to laboratory personnel to ensure their competence. As issues are resolved and tasks com-

pleted, their presence will decrease. However, in the indefinite future, PCS will be retained as the laboratory administrator until all issues are resolved at Maryland General Hospital, and the lab staff and management has embodied the culture of quality that the University of Maryland Medical System stands for.

Quality is the most important goal of the University of Maryland Medical System. Our own review shows that there were insufficient quality controls and quality improvement processes in the Maryland General Hospital laboratory. Retesting has confirmed that the original test results were overwhelmingly accurate. The quality processes that validated the test accuracies and provided integrity to the results were below the standards that we would expect.

Over the last few weeks of the investigation, we have learned a great deal. First and foremost, we have learned that there was a breakdown in Maryland General Hospital's policies and procedures, adherence to those policies and procedures and management reporting systems. However, apparently, even when problems were brought to the attention of management, they were not sufficiently addressed. That response is unacceptable.

The University of Maryland Medical System found that the supervisory structure was poorly defined in the hospital. Certain laboratory supervisors did not take responsibility, hospital management did not sufficiently involve itself, and salaries were not competitive. We also found that the staff was not well trained in quality assurance processes.

Various steps are being taken, including working with PCS, to bring immediate and positive change to Maryland General Hospital. Sometimes bad things happen in good hospitals. Maryland General Hospital is, and will continue to be, a good hospital providing services to the citizens of the surrounding community who need and deserve quality health care. Indeed, our objective for Maryland General Hospital is to provide first-class lab services.

I can and want to assure you that the Maryland General Hospital lab is fully operational today, that its results are accurate, and that its personnel are competent. PCS is finalizing the documentation and quality improvement processes that will make this lab a model.

Maryland General Hospital voluntarily implemented a patient notification and retesting process to locate, retest, and identify every patient and employee who had been tested on the Labotech machines at Maryland General Hospital. Maryland General Hospital, in an effort to be comprehensive, responded with a sensitive approach to the community and expanded its testing well beyond anything that was required by any regulatory agencies. The Maryland General Hospital continues to go to great lengths to locate and contact all patients who were identified as having been tested on the Labotech machine.

The vast majority of these tests have been reconfirmed. In particular, 99.6 percent of the HIV test results have been reconfirmed to be consistent with the original tests. What this means is that while the quality control processes within Maryland General Hospital's laboratory were not up to our standards, this circumstance did not result in a significant set of mistakes in the actual testing or the test results thus far. In fact, we are fairly confident——

Mr. SOUDER. Mr. Notebaert, we really need you to wrap up because we are running out of time. We will insert your full statement, as well as we are inserting the testimony of Mr. Lymas' full statement.

Mr. NOTEBAERT. Thank you, Mr. Chairman. I think in light of the time I will save my remarks for submission through the written testimony. Thank you for the opportunity to appear before the committee.

[The prepared statement of Mr. Notebaert follows:]

WRITTEN TESTIMONY
BEFORE THE HOUSE
GOVERNMENT REFORM
SUBCOMMITTEE ON CRIMINAL JUSTICE,
DRUG POLICY AND HUMAN RESOURCES
REGARDING MARYLAND GENERAL HOSPITAL

BY

Edmond F. Notebaert
President and Chief Executive Officer
University of Maryland Medical System
May 18, 2004

Testimony of Edmond F. Notebaert
University of Maryland Medical System

Good morning Chairman Souder, Congressman Cummings, Members of the House Government Reform Subcommittee on Criminal Justice, Drug Policy and Human Resources, and other distinguished government officials.

Thank you for allowing me to speak with you today. My name is Edmond F. Notebaert. I am the President and Chief Executive Officer of the University of Maryland Medical System, which is the parent organization of Maryland General Hospital. I have been the President and CEO of University of Maryland Medical System, which I will refer to as "UMMS," since September 1, 2003. Prior to joining UMMS, I served as President and CEO at Children's Hospital of Philadelphia Health System for 13 years. During my tenure, The Children's Hospital of Philadelphia was transformed from a small, regional inpatient facility into the number one ranked Children's Hospital in the world. Together with my management team, the hospital developed a first-class reputation for quality and expanded its patient base and its research funding, while operating in a fiscally sound manner. I have more than thirty years of health care management experience in urban hospitals.

I would like to address the issues currently surrounding Maryland General Hospital. Specifically, I have come here today to discuss with you what we at UMMS have learned about what happened at Maryland General Hospital's laboratory, what the response has been to what happened, and what has been done to ensure that it does not happen again.

When UMMS first became aware of the issues at Maryland General Hospital in early March, the response was immediate, decisive and comprehensive. On March 8th, the very first day Maryland General Hospital executives revealed the problems, Mike Mullane, UMMS' Vice President, Strategy & Corporate Operations, one of the System's top executives, was assigned the responsibility to lead the System's team in understanding and addressing all of the issues

identified by the regulatory agencies at Maryland General Hospital. Mike met with Maryland General Hospital's management daily and remained on site well into the evening for the first six weeks in an effort to identify and remedy problems in the laboratory's operations and processes. He continues to be involved on a daily basis.

Within 5 days of learning about the situation at Maryland General Hospital, UMMS decided to bring in a lab management company, and within 10 days, we identified and hired Park City Solutions ("PCS"), the leading laboratory consulting and management services provider in the United States and Canada, to provide lab management services to Maryland General Hospital. Recognized for its innovative vision and ability to execute business solutions in the healthcare industry, PCS has supported more than 850 healthcare systems in the United States and Canada, provided services to over 1000 laboratories, conducted more than 85 compliance audits for hospitals and independent laboratories, and provided compliance training for more than 3,000 laboratories and internal auditors. PCS took over the operation of the lab on March 19th, just 16 days after the state issued its report citing deficiencies in the laboratory. As part of the System's comprehensive approach, we hired PCS to not only fix the identified deficiencies, but to conduct a top to bottom review of the laboratory and fast-track the implementation of any necessary changes. We rejected taking any sort of band-aid incremental approach.

During their first week at Maryland General Hospital, PCS brought in a lab administrator and two technical experts. Shortly thereafter, they recommended additional people be brought in and in fact, we told them to bring in whomever they needed. We gave PCS broad authority to take all necessary action to understand and address Maryland General Hospital's laboratory issues. In addition to providing an initial assessment of the situation and addressing problems as

they are identified, PCS administers the laboratory operations on a day to day basis, which includes placing specialists to oversee each and every section of the laboratory, implementing new policies and procedures, putting in place a system of quality, and providing training to the laboratory personnel to ensure their competency. As issues are resolved and tasks completed, their presence will decrease. However, for the indefinite future, PCS will be retained as the laboratory administrator until all issues are resolved and Maryland General Hospital has the lab staff and management that embody the culture of quality that we stand for.

Quality is the single most important goal of University of Maryland Medical System. Our own review has shown that there were insufficient quality controls and quality improvement processes in the Maryland General Hospital laboratory. Retesting has confirmed that the original test results were overwhelmingly accurate. Rather, it was that the quality processes that validate the tests' accuracy and provide integrity to the results that were below the standards we would expect.

Over the last few weeks of the investigation, we have learned a great deal. First and foremost, there was a breakdown in Maryland General Hospital's policies and procedures, adherence to those policies and procedures, and management reporting systems. Moreover, apparently, even when problems were brought to the attention of management, they were not sufficiently addressed. That response is not acceptable.

UMMS also found that the supervisory structure was poorly defined, certain laboratory supervisory staff did not take responsibility, hospital management was not sufficiently involved, salaries were not competitive and staff was not as well trained in quality assurance processes.

The various steps that are being taken, including working with PCS, are bringing immediate and positive change to Maryland General Hospital. Sometimes, bad things happen at good hospitals. Maryland General Hospital is, and will continue to be, a good hospital providing services to members of the surrounding community who need and deserve quality health care. Indeed, our objective for Maryland General Hospital is to provide first class lab services that will be a model not only to our other hospitals, but also to labs elsewhere.

I can and want to assure you that the Maryland General Hospital lab is fully operational today, that its results are accurate and its personnel are competent. PCS is finalizing the documentation and quality improvement processes that will make this lab a model for others.

Let me give you one example of the quality improvements that we are instituting. Federal and state regulations require quality controls to be reviewed on a periodic basis. I understand that most labs interpret this periodic requirement to mean on a weekly, monthly or even a quarterly basis. We have taken it a step further. Our lab director is conducting these reviews every single day and will continue to do so until we have absolute assurance of accountability and responsibility at all levels.

Maryland General Hospital voluntarily implemented a patient notification and retesting process to locate, notify and retest every patient and employee who had been tested on the Labotech machines at Maryland General Hospital. Maryland General Hospital, in an effort to be comprehensive, responsive and sensitive to the community, expanded its testing well beyond anything that was required by any regulatory agency. There were two "phases" in which patients were identified for retesting. Phase I began with the identification of all individuals who may have received testing on a Labotech machine on which the proper quality control measures were

not followed and who were the focus of suspected invalid runs by the state. Based on that criteria, approximately 460 patients were identified. Later in March, when PCS determined the extent of the Labotech quality control issues, Maryland General Hospital implemented Phase II and identified all individuals tested for HIV and Hepatitis during June 2002 – August 2003 on any Labotech machine. During Phase II, again in an effort to be comprehensive, approximately twenty two hundred individuals were identified, although many of those patients had test results where quality controls were not at issue.

Maryland General Hospital continues to go to great lengths to locate and contact all patients who were identified as having been tested on the Labotech machine. Specifically, for all patients identified, the Hospital sent 2 letters to these patients, one by regular mail and one by certified mail to the patient's last known address. These letters informed the patients to contact a toll free number (which was established to receive calls from anyone who had questions about a test they received at the Hospital, or from anyone who received the letters) for instructions on how to receive free testing. In addition, letters were sent to all ordering physicians and many physicians were personally contacted to explain the retesting program. The Hospital also engaged Hospital Support Services, a Medicaid eligibility service, and private investigators to assist in locating patients and to offer these patients the opportunity to be retested. Numerous newspaper and radio ads were placed in a variety of newspapers and on a number of radio stations on multiple occasions. Finally, a Community Outreach Manager was hired in March, and has made contact with many community organizations, including HealthCare for the Homeless, Total Health Care, Our Daily Bread, and Chase Brexton Health Center, to assist the Hospital in locating and notifying patients of the retesting program. We will, however, not rest until all individuals originally tested have had the opportunity to be retested.

As of May 13, Maryland General Hospital has successfully contacted the vast majority of all Phase I patients and a significant number of Phase II patients. The vast majority of tests have been reconfirmed. In particular, 99.6 % of HIV test results have been reconfirmed to be consistent with the original tests. What this means is that while the quality control processes within Maryland General Hospital's laboratory were not up to our standards, this circumstance did not result in significant mistakes in the actual testing or the test results thus far. In fact, we are fairly confident that external factors, such as subsequent exposures, account for the different results in the few cases where there has been a difference. In addition, it is important to keep in mind that there is a margin of error rate for all laboratory tests that is generally accepted by the industry and regulatory agencies.

Our comprehensive approach to change at Maryland General Hospital goes far beyond the laboratory. It includes changing the existing culture and instituting a new management philosophy there and throughout the System overall. While we still support the important principle of keeping community orientation at each of our community hospitals, the individual hospitals will now operate more as an integral part of a larger System, creating more collaborative relationships and instituting greater accountability. This will require hospital executives to report certain identified issues to the appropriate individuals within their organization and to the System and to follow up and monitor the results to assure that issues are resolved properly within a reasonable period of time.

More specifically, we also have implemented specific changes in reporting mechanisms at the System level, Maryland General Hospital level, and the laboratory level. Specifically, at the System level we have created new reporting systems so that the System's management is

made aware of certain issues identified at a facility. For example, we now require that all surveys and reports issued by third parties, including regulators and accrediting agencies, be submitted to the corporate office for our review. We also have created and are publicizing an e-mail address that employees may use as a means to report issues directly to me if their internal reporting mechanisms have failed in some way.

We also are replacing certain members in senior management, including the CEO at Maryland General Hospital, with individuals who reflect this new management philosophy and who understand accountability. Specifically, we envision the new management personnel to be aggressive and ambitious in achieving quality outcomes, able to see the potential in the organization and anxious to facilitate that potential, and fully engaged in taking the resources available to make all of our hospitals the best they can be.

In addition, Maryland General Hospital's Board is changing in many ways. Historically, Maryland General Hospital's Board and management were proud of Maryland General Hospital's legacy. When Maryland General Hospital became affiliated with UMMS in 1999, Maryland General Hospital asked, and we agreed, in respect of Maryland General Hospital's history and professed community orientation, to maintain for three years Maryland General Hospital's existing Board and management.

Since the end of that three-year period, in an effort to accelerate positive integration between UMMS and Maryland General Hospital, as well as the Maryland General Hospital community, we have appointed a number of individuals whose main interests are improving Maryland General Hospital's service to the community. Indeed, as soon as the System could impact Maryland General Hospital's board, we appointed Jerry Lymas who is sitting here with

me today, Ken Harris, a Baltimore City Council member and H. Mebane Turner, Ed.D., the former President of the University of Baltimore. Mr. Lymas is currently serving as the Chairperson of Maryland General's Community Development Committee, and, in that capacity, has begun economic development partnerships with local minority owned financial institutions and the Coppin State College Helene Fuld School of Nursing located in West Baltimore. In addition, Maryland General Hospital has hired a new Community Outreach Manager, Keith Hobbs. Mr. Hobbs has been initiating meetings with dozens of community organizations, churches, not for profit agencies, government officials, providers and other entities to expand the dialogue with such community organizations and promote partnering opportunities, including health fairs and screening programs. Overall, we believe that these efforts are beginning to bear fruit and will prove to be the foundation for stronger ties between Maryland General Hospital and the community in the future. We believe that these changes will bring diversity and differing perspectives to Maryland General Hospital's governance and staff, and will ensure that Maryland General Hospital's focus is serving its community with the high level of quality care that it deserves.

At the Maryland General Hospital management level, in addition to interviewing for a new Chief Executive Officer who will implement the new management philosophy, we have assigned a new and well-respected Medical Director, Glenn Robbins, M.D. who we handpicked from one of our other facilities. He was the senior vice president and medical officer at another UMMS hospital and we have enormous confidence in his ability. In fact, in the past year, he has begun developing System-wide quality measures and a set of hospital-wide quality indicators. His first task is to work with Maryland General Hospital's Board to facilitate a hospital-wide assessment of all quality improvement systems and to implement immediate action to correct any

identified deficiencies. In addition, we have created new reporting relationships and data elements that must be reported in an effort to create sufficient redundancy so that identified issues are brought to the appropriate person's attention. The Maryland General Hospital Board will now receive more timely and accurate information to enable them to fulfill their oversight responsibilities.

Finally, at the laboratory level, there have been significant changes in personnel and processes to ensure that appropriate quality control is in place. As previously discussed, PCS has been engaged to enhance quality within the laboratory, operate the laboratory on a day to day basis, review and revise policies, procedures and processes within the laboratory, perform equipment validation, supervise each section of the laboratory, and train laboratory personnel. In effect, PCS will remain in charge of the laboratory until it has implemented necessary processes and trained personnel so that they are fully competent to perform their job functions. The Maryland General Hospital Board also appointed Dr. John Braun as the new Laboratory Director and Technical Supervisor. His job duties will include oversight of the quality and compliance of the laboratory. We have redesigned the supervisory structure to eliminate any structural ambiguity and ensure clear accountability.

All new laboratory personnel will be trained, and annual training will be conducted for all existing personnel. Maryland General Hospital is actively recruiting new lab personnel and is impressed with the quality and quantity of the candidates[1]. We also are implementing incentives to encourage laboratory personnel to remain at Maryland General Hospital.

[1] To date six new medical technologists and eight phlebotomists have been hired. We are also recruiting a full time quality assurance professional and a laboratory technical supervisor. This is the result of a comprehensive staffing analysis and comparison to local and national benchmarks.

As I stated earlier, what happened at Maryland General Hospital does not meet the quality expectations that we have set for the University of Maryland Medical System. A breakdown in quality control processes is unacceptable both in your eyes and mine. I assure you, however, that Maryland General Hospital is an excellent hospital whose goal is to provide quality care to the community it serves. I believe that the issues identified have been responded to in an immediate and decisive way. We have implemented, and will continue to implement, significant changes at the System level, Maryland General Hospital level and laboratory level to assure that the lab and Maryland General Hospital will be a model for the System, the state and the country and a true partner in the health and well being of the community it serves.

Thank you for allowing me to speak with you today.

Mr. SOUDER. Thank you. And I know you were making it clear that you have indeed followed up with each patient, which is important to have on the record, and I appreciate that you did that.

I wanted to ask just a brief question of Mr. Lepoff. Do you do the certification on PCS as well, the firm that came in to replace the laboratory?

Mr. LEPOFF. We continue to accredit part of the Maryland General Hospital laboratory. We have reinspected the laboratory in April, on April 26th, and we will be conducting an unannounced reinspection of the laboratory at some time between now and May 26th, an another full inspection of the laboratory in August of this year.

Mr. SOUDER. You said in your testimony that you hadn't heard the complaints until yesterday. Did the committee staff make you aware of those complaints or anybody else?

Mr. LEPOFF. Yes, sir, committee staff.

Mr. SOUDER. So no one had contacted you before our committee staff the day before the hearing?

Mr. LEPOFF. We did not receive copies of the complaints until yesterday.

Mr. SOUDER. Mr. Cummings.

Mr. CUMMINGS. I just want to say this is a mess. You know, the more I have listened to all of this, I can understand, Mr. Sabatini, why you said what you said and when you did this, saying that everybody is blaming everybody else. That is exactly what has happened, and, sadly, the people who suffer are the poor patients. In some kind of way we have to get this communication thing right. There is absolutely no reason why you should have the agency—and I am not just talking to you, I am talking to the whole panel—have the agency CAP, who is doing the accreditation, not find out about employee complaints that go to the very essence of what you are evaluating. The only way you found out was because of this hearing. That is ridiculous. That is crazy. In some kind of way in the United States, where we can send a man to the moon, we ought to be able to communicate amongst each other.

Let me just ask you this, Mr. Lepoff. Is it normal that a local group of evaluators go into a laboratory and evaluate? You heard, I think, what Ms. Williams said. She was very skeptical about that procedure. Is that accurate? Is that the way it usually happens and is that what happened here?

Mr. LEPOFF. It is true that in 2001 and 2003 the groups that inspected Maryland General were from the general Baltimore area.

Mr. CUMMINGS. But can you understand her concern about credibility?

Mr. LEPOFF. Yes. First of all, many of our inspections occur with teams from out of State.

Mr. CUMMINGS. Well, right now I am talking about Maryland General and I am talking about trying to make sure this doesn't happen again anywhere in the country. But it happened here, is that correct? We had a local team going in.

Mr. LEPOFF. We had a local team, but our experience has been that laboratorians are perfectly capable of being objective about other people's laboratories.

Mr. CUMMINGS. Now, Mr. Sabatini, let me ask you this. I heard what you just said, and, to your credit, you said everybody has a stake in this, everybody had a problem, did something or failed to do something that caused this problem. What is it that you would suggest be done? I mean exactly. Mr. Lepoff talked about layers. You sound like basically what you are saying is the less the better.

Mr. SABATINI. Well, I think that, one, there ought to be some way to identify a responsible editing for regulatory oversight, as opposed to three, four, or five.

Mr. CUMMINGS. That are not communicating.

Mr. SABATINI. That are not communicating and have no reason to communicate. I mean, it works in the nursing home industry, and it should be able to work in hospitals. Hospitals, you assume that they meet standards when they are accredited by an organization that is basically dependent upon the industry for their support. Let me just very briefly read a quote from what I think is one of the better books that has been published on medical errors. It says: "As we have described, the Joint Commission on Accreditation of Health Care Organizations has begun to call safety balls and strikes, but the Joint Commission is a voluntary organization. Hospitals aren't required to be accredited, and most of the Joint Commission's resources come from the hospitals themselves. This makes JCOA a key problem in the patient safety crusade, but one that may be inclined to back off when hospital administrators cry kill the ump."

We wouldn't allow Enron or anybody else to behave the way this industry is behaving in terms of regulatory oversight. The review process is done on a schedule. People prepare and rehearse in preparation for it, they are not unannounced surveys, and, again, there is no single accountable agency. So we can all sit here and say it wouldn't have happened if the other guy would have told me. That is not good enough.

Mr. CUMMINGS. Well, what is your relationship with the College of Pathologists?

Mr. SABATINI. None.

Mr. CUMMINGS. You have no relationship?

Mr. SABATINI. No. Other than the fact that if they accredit a laboratory, then I, by statute, have to assume that laboratory is in compliance with all of the standards and quality standards that have been set by both the Federal and State government.

Mr. CUMMINGS. Well, I see my time is up, but let me just say this. In some kind of way we have to—so many lives are at stake here. We have to find a way to communicate. I know there have been several recommendations that you all have made.

The thing that I would recommend also, Mr. Chairman, it seems like there are some State issues. We will make sure that all of this testimony gets to our State agencies, too, our State legislature.

But some kind of way we have to work through this because, as I listened to this, and if I were a patient, my confidence in getting accurate results from a laboratory in a hospital, if it is run the way this is, I would be afraid to even go in to try to get a test.

And I am not blaming that just on Maryland General, I want you to understand that, Mr. Notebaert. I think you all have done a great job in trying to correct this and address the problems, but

this is more of a bigger picture than that. The College is not just a local entity, they look at laboratories and hospitals all over the country. So it is just that Maryland General, I think what happened here may very well help us to bring some kind of revision that will benefit hospitals and laboratories all over the country.

And I want to thank all of you, and you all will hear more from us, and we really appreciate you.

Mr. SOUDER. Thank you. I am sorry, Mr. Ruppersberger, we have to leave, by agreement with the chairman. I appreciate both his leadership and Mr. Cummings' leadership in Baltimore. I know we are going to have some additional written questions. Two of you are on contradiction under oath about whether visits are unannounced or announced, and we are going to have to get that sorted out for the record that contradicted each other multiple times. I find it appalling that in the State of Maryland you do not have a procedure, when you have a certification organization, to notify. It sounds to me like the poor employees are very confused as to where they are supposed to go. Their immediate result is likely to go first to the hospital, then to the State, and somebody has to get interconnected. Maybe we can streamline the processes, maybe we won't streamline the processes, but bottom line is those individuals involved need to be sharing much better than they have been in the past.

Thank you all for coming. And if you want to submit any additional things for the record, please do so.

With that, the subcommittee stands adjourned.

[Whereupon, at 1:55 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[Additional information submitted for the hearing record follows:]

WRITTEN TESTIMONY
BEFORE THE HOUSE
GOVERNMENT REFORM
SUBCOMMITTEE ON CRIMINAL JUSTICE,
DRUG POLICY AND HUMAN RESOURCES
REGARDING MARYLAND GENERAL HOSPITAL

BY

Jerry Lymas
Member of the Board of Trustees
Maryland General Hospital
May 18, 2004

Testimony of Jerry Lymas
University of Maryland Medical System

Good Morning Chairperson Mark E. Souder, Congressman Elijah Cummings, Members of the House Committee on Government Reform-Subcommittee on Criminal Justice, Drug Policy, and Human Resources, distinguished government officials, and my fellow Marylanders.

Thank you for allowing me to speak with you today. My name is Jerry Lymas. I have been a proud and active member of the Baltimore community for over 30 years. I attended Morgan State University where I first met Parren Mitchell who was elected to Congress in 1970 representing Baltimore's 7th Congressional District. In September 1971, I attended law school at the University of South Carolina and become one of the first six African American students to desegregate that law school. I served two years in the United States Army following my graduation from law school in 1974.

When I returned to Baltimore, I served on Congressman Parren Mitchell's staff as special assistant. In that capacity, I acted as the Congressman's liaison to the community on all issues including healthcare issues. In that capacity, I regularly met with the community on organizations, churches, not for profit entities, and other groups, and became intimately familiar with the needs and concerns of the Baltimore community. During that time, among other projects, I worked with the Veterans Administration to build a hospital in downtown Baltimore and to ensure that minority owned contractors participated in the construction of that facility. I also helped to get federal HMO certification for the second African-American owned health maintenance organization in the country, Monumental Health Plan.

In 1983, I left the Congressman's staff to establish a business that focuses on neighborhood development projects. Since 1983, I have worked on the development and management of over forty such projects, examples of which include developing child care

centers, apartment complexes for churches, and other businesses in the community. One of the largest projects I helped develop involved rehabilitating a large unused building into a state office complex. This project and others brought housing, services and jobs to the community. In addition, I have come to know, and have relationships with, the community organizations and their leaders as I have negotiated the process of developing commercial establishments in a number of Baltimore neighborhoods. I see it as my personal mission to make a difference at the neighborhood level and to facilitate the connection between the needs of the community and those resources that are available in order to better the community as a whole.

Maryland General Hospital became a part of the University of Maryland Medical System (the "System") in 1999. As part of the Affiliation Agreement, the parties agreed that the System would not change Maryland General Hospital's governance structure and as a result their management structure for a period of three years. As an indication of the System's vision for Maryland General Hospital's future, one of the System's first acts after the three-year "no touch period" was to invite H. Mebane Turner, M.D., the President of the University of Baltimore, Ken Harris, City Council Member, and me, among others, to join the Board of Maryland General Hospital in 2001. At that time, I understood Maryland General Hospital's vital role in the community of providing critically needed medical care to an underserved community as well as the economic impact a hospital of its size has in terms of community jobs and overall development. I accepted the invitation to become a member of the Board because I felt I could play an important role in linking the community needs to the many and varied resources that Maryland General Hospital has to offer.

With that as a background, I would like to speak with you today not only as a member of the Board of Maryland General Hospital or as the chairperson of Maryland General Hospital's

Community Development Committee, but also as a long standing and knowledgeable member of the Baltimore community. Based upon my experience both in the community and as a member of the Maryland General Board, I know that Maryland General is currently serving the community in many important ways and will continue to serve the community with an even greater impact. Maryland General is right now expanding its important existing role in the community. Indeed, efforts are now being made to create new opportunities to bring Maryland General Hospital into the community and to bring the community into Maryland General Hospital. Most importantly, with Ed Notebaert's leadership, I see a renewed commitment at the highest levels of leadership to transform Maryland General Hospital into a true community hospital providing high quality care with a focus on being a valuable and valued member of the community.

As the ranking member of this Committee is well aware, Maryland General Hospital has a long history in Baltimore. It was established in 1881. Over that time period, it has undergone many changes. In recent years, it has served the medical needs of some of its most underserved communities when few others would do so. Maryland General Hospital is the primary health care resource for the community surrounding its facilities. Over the past year, it provided approximately $13 million (or 9% of total revenues) in uncompensated care to members of the community. In addition, Maryland General Hospital has been committed to providing preventive health services in an effort to try to tackle some of Baltimore's most difficult health problems. Maryland General Hospital provides community focused health care services including free health screening for over 13,000 people per year, as well as free prenatal care, diabetes care, addiction services, mobile mammography services, eye care screening, smoking cessation, rehabilitation services, assistance to patients to access the health care system, and transportation

services. Maryland General Hospital dedicated significant money to these services in the past year. And Maryland General Hospital has ongoing programs aimed at improving the quality of its services and gaining patient feedback. In fact, in April 2003, Maryland General Hospital stopped simply collecting patient survey cards and hired a Patient Service Representative to interview patients in person and to try to solve immediate problems on the spot. These in-person interviews demonstrate that, over the past year, more than 91% of those patients surveyed would recommend Maryland General Hospital to their friends or family members. These in-person surveys reflect the fact that the community is utilizing the hospital in even greater numbers as the number of admissions, surgical cases and ER visits are all increasing each year.

Maryland General Hospital is also a significant economic contributor to the community. For example, the University of Baltimore, June 2003, Economic Impact Study establishes that in 2002, the Maryland General Hospital directly employed approximately 1412 people and paid approximately $70.2 million in salaries. More recently in January 2004, that study published updated data that Maryland General Hospital employed approximately 1572 people and paid approximately $88.0 million in salaries. Maryland General Hospital's economic impact on the community will only increase.

Even though Maryland General Hospital has demonstrated a substantial commitment to serving the health care needs of the community, it can always do better, and changes are in the works. During my tenure as Chairman of the Community Development Committee, we have initiated several projects aimed at increasing involvement with the community. The first initiative was for Maryland General Hospital to invest locally by making deposits in minority-owned community banks. The second initiative is the development of a partnership between Coppin State College Helene Fuld School of Nursing and Maryland General Hospital. The goal

of that partnership is to provide practical training to each nursing student onsite at Maryland General, and, in turn, to integrate qualified Maryland General Hospital staff into teaching roles. This partnership gives back to the community in two important ways: 1) it provides young nurses with excellent educational opportunities at the start of their careers, and 2) it helps to fill the critical shortage of nurses in Maryland with qualified people who are interested in, and connected to, the community.

Yet another initiative is to increase community outreach. In 2004, Maryland General Hospital hired Keith Hobbs as a Community Outreach Coordinator. Mr. Hobbs is in the process of meeting with dozens of community organizations, churches, not-for-profit agencies, government officials, providers and other entities in an effort to explain how Maryland General Hospital currently serves the community, how it is changing to better serve the community, and its long term community focused vision. Mr. Hobbs is committed to a real grass roots effort, to being the foot soldier to share the message that Maryland General is bringing more health fairs and health screening programs to the community through partnership with community groups, as well as bringing community groups into the Hospital by providing meeting space within the Hospital. Mr. Hobbs is excited, as am I, about making community events and partnership opportunities a way to focus on the health care needs of the community.

For me, the most encouraging news is that the System's leadership, especially Mr. Edmond Notebaert, who has over thirty years experience managing urban hospitals, is committed to transforming Maryland General Hospital into a true community hospital, and has taken steps to achieve that goal. Recent events at Maryland General Hospital and changes in the leadership of Maryland General Hospital have served to hasten that process. A key focus for me and the System's leadership, at this time, is the recruitment of a new senior management team. I have

every confidence that all new members of that team will possess a demonstrated commitment to managing a quality and community focused hospital.

To conclude, Baltimore is my home. For over 30 years, I have been working to better this community for me, my family, and its residents. I have worked to bring jobs, housing, services, better healthcare, and, in short, a better life to Baltimore. Working as a member of the Board of Maryland General Hospital is part of that commitment. Maryland General Hospital has a long presence serving the ever changing medical needs of the community. Step by step that mission is evolving, and I am watchful of how it is progressing. I must tell you that I am reassured that Maryland General Hospital is able to provide top notch health care services to the community and that it is headed in the right direction. Finally, I am confident telling you that Maryland General Hospital and the System's top leadership share a vision and a resolve not to only provide the highest quality health care services to the community, but to truly be a part of the community and to offer hope and healing to the "faces at the bottom of the well."

I thank you very much for allowing me to speak with you today.

Transcript Questions

Hearing on
"Ensuring Accuracy and Accountability in Laboratory Testing: Does the Experience of Maryland General Hospital Expose Cracks in the System,"
before the
Subcommittee on Criminal Justice, Drug Policy and Human Resources
of the
Committee on Government Reform
May 18, 2004

From p. 40 of the transcript

Mr. Souder:

If people manipulate the results, are there criminal sanctions?

Insert at p. 40, line 905

Mr. Tunis:

CMS lacks the administrative authority to impose criminal sanctions. However, in the process of any complaint investigation or State agency survey, it is routine practice to report any possible criminal act or fraudulent practice to the appropriate enforcement agency such as the Department of Justice (DOJ) or the Office of the Inspector General (OIG). There currently is an ongoing, active DOJ case regarding the issues at Maryland General Hospital.

From p. 41 of the transcript

Mr. Cummings:

And so how soon can you all get us information with regard to that question of criminal penalties for this. I would think that you would know that, by the way.

Response: This request is addressed in the above response to Mr. Souder's question. Therefore, CMS recommends that lines 924 through 932 be removed from the transcript.