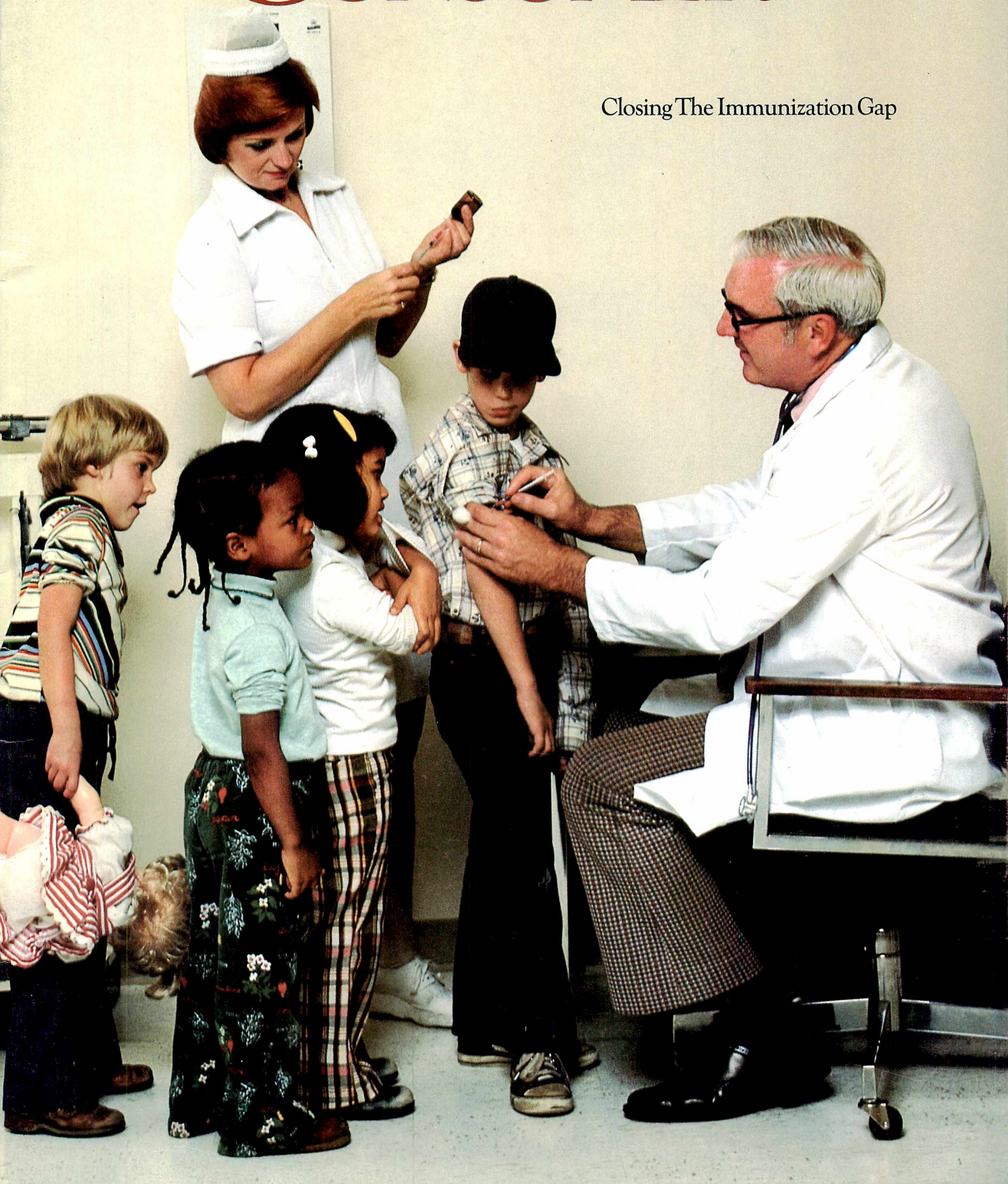
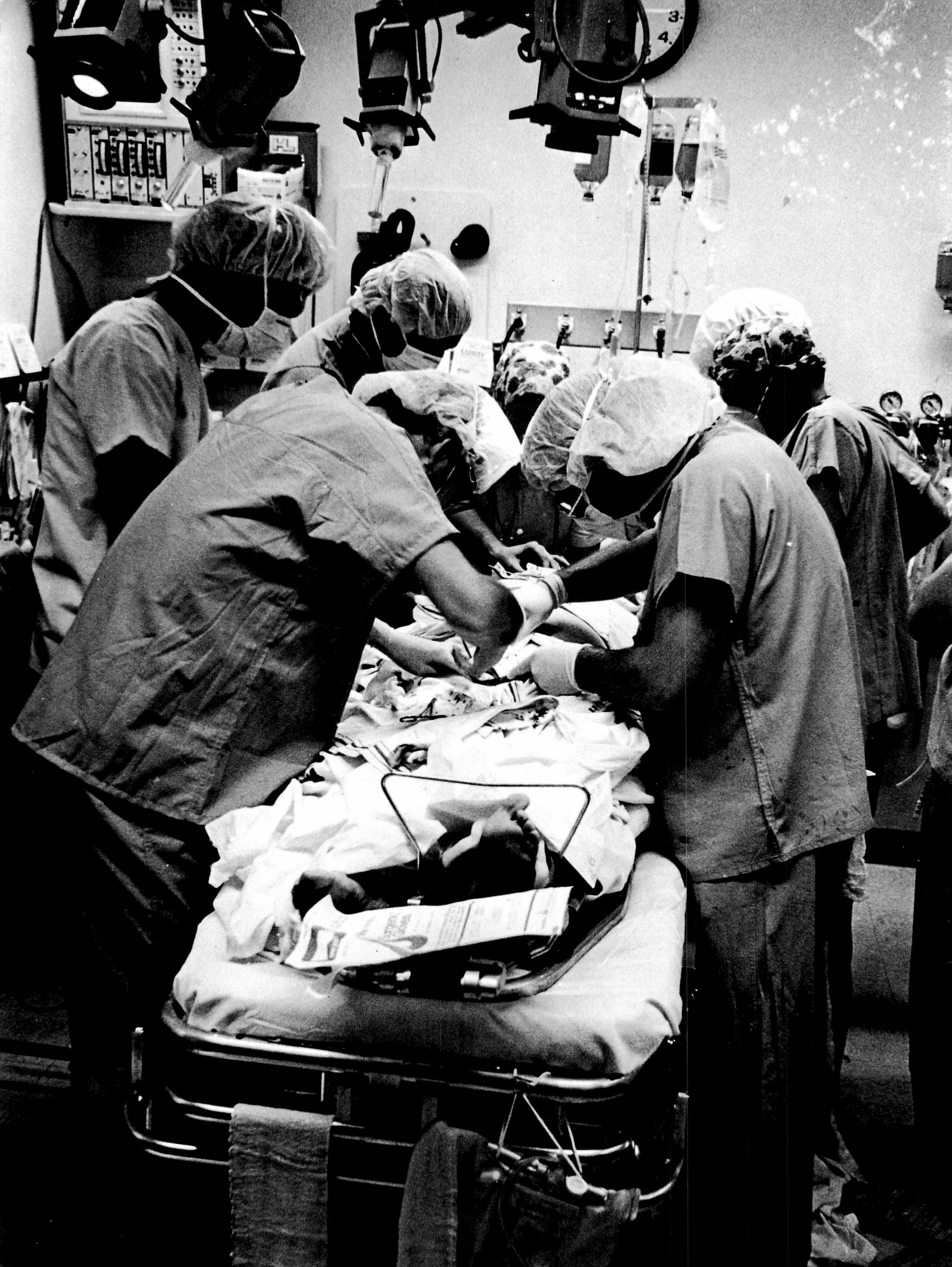
FDA
CONSUMER
November 1977

Closing The Immunization Gap





This Month

If there is a safe and simple way to protect children from getting a potentially serious disease, it seems logical that most parents would take advantage of it. But human behavior doesn't always follow what seems to be a logical course. There are safe and effective vaccines for polio, measles, and a number of other potentially dangerous childhood diseases. Yet a substantial and growing number of children are inadequately immunized against these diseases. In the face of this apparent contradiction, the logical course is to devise a program that will bring the unprotected children and the vaccines together. A program for *Closing the Immunization Gap* is under way, and it's the subject of our cover story this month.

Some of the devices and treatments advocated by the promoters of health quackery seem logical; others are absurd. But logical or absurd, quackery is alive and well in America today. Why quackery thrives, the forms it takes, and what the average consumer can do to avoid being taken in are some of the questions discussed by Dr. Stephen Barrett, an authority on questionable health practices, in an interview beginning on page 12.

The practice of transfusing blood from a donor to a sick or injured person is a legitimate and often lifesaving medical procedure. It is not without its dangers, however. The chief hazard in blood transfusions is that hepatitis virus may be transmitted from the donor to the recipient. This risk is known to be much greater if the blood comes from a paid donor than from a volunteer. To make sure physicians are aware of the source of any blood they use for transfusions, FDA is requiring that each container of whole blood be labeled as to whether it came from a paid or volunteer donor. The hepatitis risk raises the question whether the Nation might be better served by an all-volunteer blood donor system. This issue, as well as FDA's new labeling requirements, is examined in *Paid Blood: The Hepatitis Connection.*

This month's editorial fare also includes a report on a new type of food container that we've labeled *Canless Canning With Food Pouches* and an article describing how the *Good Advice* FDA gets from its science advisers helps the Agency do a better job of protecting consumers.

Inside Front Cover Photo: *The availability of blood for transfusions can make the difference between life and death in hospital emergency rooms and operating rooms. But transfused blood can be a mixed blessing if it carries the virus that causes hepatitis. For a report on this problem and what is being done about it, turn to page 8.*

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Section 705 [375] of the Food, Drug, and Cosmetic Act:

(a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of charge and the disposition thereof.

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

Cover Photo: Dan O'Toole

Update

FDA Acts on Estrogen, Progestin Labeling

Concern about the extended use by women of drugs containing estrogens before and after menopause led FDA to propose regulations last year calling for stronger physician labeling as well as a brochure for patients. What the proposed labeling would tell a woman and her physician was spelled out in an article in the November 1976 FDA CONSUMER, *entitled* Informing Patients About Estrogens. *Here's an update.*

Women who receive prescriptions for drugs containing the female sex hormone estrogen must now be given a special lay-language brochure explaining the benefits and risks of the drug.

The brochure requirement went into effect October 18, 1977.

About five million women in the United States use estrogen-containing prescription drugs each year to treat menopausal or postmenopausal problems. The most commonly prescribed brand is Premarin. Other brands are Hormonin, Estratab, Evex, Menest, Femogen, and Ogen.

Donald Kennedy, Commissioner of Food and Drugs, said: "Estrogens are valuable drugs, with many beneficial medical purposes. But we at FDA are increasingly concerned that estrogens are used too frequently and for too long, especially since their use for extended periods is associated with a 5 to 10 times higher risk of cancer of the uterus.

"Our goal is that the information to be supplied to patients with every prescription will lead to better use of these drugs, including less pressure on physicians to prescribe them."

Dr. Kennedy continued: "The right of patients to know what to expect from the drugs they use is especially critical for estrogen drugs, since a woman today may be exposed to estrogens her entire adult life—first for birth control and then both during and after menopause."

The brochure, to be printed and supplied by manufacturers of the drugs, notes that estrogens are associated with cancer of the uterus when used for extended times.

It also advises women to take estrogen drugs for the shortest time possible and in the lowest effective dose for treatment of menopausal symptoms. The risk of cancer increases the longer the drug is used and the higher the dose, the brochure says. Women also are advised in the brochure to evaluate, with their doctors, the need for estrogen every six months, and to be examined at least once a year while taking the drug.

The brochure also states that these drugs should not be used to treat simple nervousness and depression during menopause because they have not been shown to be effective for these purposes, and also that they have not been shown to be effective for keeping the skin soft or for helping women feel younger after menopause.

The original effective date scheduled for the brochure requirement was September 20, 1977. The date was changed to October 18 because FDA was requested almost immediately by the Pharmaceutical Manufacturers Association (PMA) and the American College of Obstetricians and Gynecologists (ACOG) to stay the requirement pending the completion of court challenges. FDA rejected the PMA and ACOG petitions, but had previously agreed to delay the effective date of the regulation by as many days as it took to rule on them (28 days).

Following FDA's denial of the petitions, PMA and other groups asked the U.S. District Court in Delaware to issue a preliminary injunction preventing the regulations from taking effect October 18. On October 5, the court denied the preliminary injunction request, clearing the way for the regulations to take effect.

Following the court's denial of the preliminary injunction, FDA surveyed principal wholesalers and producers of estrogen drugs and was assured that every attempt was being made to make the patient package inserts available to pharmacies by the October 18 deadline.

The estrogen brochure is part of FDA's program of requiring lay-language inserts for selected prescription drugs and other products.

In a second action to inform women about the use of prescription drugs containing hormones, FDA has proposed that a brochure similar to the one now required for estrogens be given to women taking another class of hormone-related drugs, the progestins. These drugs are used primarily to treat menstrual disorders. They have also been used in pregnancy tests and to prevent miscarriages, although there is no adequate evidence they are effective for the latter purpose.

The proposed brochure would point out that progestins, when taken in early pregnancy, can increase the risk of birth defects in the offspring, such as heart defects and deformed limbs. Women would be advised that there are safer and more rapid pregnancy tests.

The proposed regulations also would require that physician labeling for progestins warn that use of these drugs in early pregnancy is not recommended and make clear there is no adequate evidence that they prevent miscarriages.

FDA is encouraging progestin manufacturers to publish and distribute the brochure even before the regulations are put into final form. The most common prescription drugs containing progestins are Delalutin, Duphaston, Norlutate, Norlutin, and Provera.

The estrogen and proposed progestin regulations were published in the July 22 FEDERAL REGISTER.

FDA Acts to Bar 8 Medical Test Products

The history and responsibilities of FDA's Bureau of Biologics was the subject of an article in the July-August 1977 FDA CONSUMER. *The article,* Making Sure Biologicals Are Safe, *pointed out that when the bureau became a part of FDA in 1972 one of its first undertakings was to begin a systematic review of all previously licensed biological products. Here's an update.*

The Food and Drug Administration has moved to revoke the licenses for the marketing of eight skin test products used to detect a variety of diseases or other medical conditions.

The products have been used to test for past or present infection by tuberculosis, lymphogranuloma venereum (a bacterial venereal infection), or mumps, and for susceptibility to diphtheria.

Skin tests are administered by physicians who inject a drop of the liquid testing substance under the skin with a needle and syringe or a multiple-puncture device. The patient's reaction, which is "read" usually 24 to 48 hours later, indicates the status of immunity to the disease for which the test is being given.

The action to revoke the licenses for the eight skin test products is based on an evaluation of them just completed by an FDA advisory panel made up of experts from outside the Government. The panel reviewed 23 tests and found that 12 lacked evidence of effectiveness. The licenses for four of these—one of which was used to test for trichinosis—already have been revoked by FDA.

FDA has published formal notices of intention to revoke the licenses for the eight other products. Manufacturers may request a hearing. Some of these test products already have been removed from the market voluntarily by the manufacturers on the basis of discussions at the panel meetings.

In addition to recommending the removal of 12 products, the panel also found that:

- Five products for testing for tuberculosis are safe and effective.
- Additional effectiveness studies are required for six other skin test products. FDA intends to require that manufacturers conduct these studies within two years.

There are no other skin test products on the market to replace those for lymphogranuloma venereum, trichinosis, and mumps, but physicians can use other diagnostic methods which are more reliable to detect these infections.

The panel's report and FDA's proposed actions were published in the FEDERAL REGISTER September 30, 1977, with 60 days allowed for public comment.

The expert panel spent two years evaluating all data available on the 23 skin tests. It was headed by Dr. John A. Sbarbaro, director of public health for the Denver (Colorado) Department of Health and Hospitals.

The skin test panel report is the first of a series of six reports being prepared as a part of FDA's comprehensive review of all licensed biologic products. The goal of this program, initiated in 1972, is to re-evaluate all licensed biologics in light of current scientific advances to assure that they meet the effectiveness requirements of the Food, Drug, and Cosmetic Act, as well as the safety and potency requirements of the Public Health Service Act.

Biologics have been federally licensed and regulated for safety and potency since 1902 under Public Health Service authority; however, application of the effectiveness provisions of the Food, Drug, and Cosmetic Act amendments of 1962 was not made until 1972, when biologics regulation was transferred from the National Institutes of Health to FDA.

Five other expert panels are still reviewing biological products. These products are:

- Bacterial vaccines and antigens that are labeled "no U.S. standard of potency."
- Bacterial vaccines and toxoids with potency standards.
- Viral and rickettsial vaccines.
- Allergenic extracts.
- Blood and blood derivatives.

Court Approves Color Additive Timetable

Under a 1960 law, the sponsor of a color additive must submit information to FDA on the additive's safety before it can be approved for use in food, drugs, or cosmetics. Many color additives already were in use when this law was passed, however, so Congress authorized FDA to permit these colors to continue to be used on a provisional basis pending settlement of safety questions. An FDA plan to produce a final decision on all colors that have received only provisional approval was described in Countdown on Color Additives *in the November 1976* FDA CONSUMER. *Here's an update.*

The U.S. District Court for the District of Columbia has ruled in favor of FDA's decision to extend the provisional listing for 32 color additives until January 31, 1981, so that long term toxicity tests could be completed and evaluated.

A suit filed by the Health Research Group (HRG), a Washington consumer organization, contended that FDA's authority to grant extensions to the provisional list is limited to allowing ongoing studies to be completed, not to permitting the start of new ones. HRG also contended that the extension of the provisional list was arbitrary because it would extend to 20 years the transitional period permitted for these color additives under the 1960 Color Additive Amendments to the Food, Drug, and Cosmetic Act.

In ruling in FDA's favor, the court said that "the new testing assures that the Commissioner will have the most complete information possible with which to take final action on these additives."

Good Advice

Keeping up with the latest developments in science technology isn't always easy for FDA laboratory personnel who are busy analyzing samples of the products the Agency regulates. That's where FDA's science advisers come in. Their advice on analytical techniques and their assistance in research projects contribute to better consumer protection.

by James Greene

Much that was science fiction a generation ago is scientific fact today. Man has walked on the moon, performed heart transplants, and created life in a test tube. Spectacular accomplishments such as these capture headlines. Most research and day-to-day activities of scientists receive little fanfare, however, even though they may have considerable impact on the daily lives of millions of people. That certainly is true of the work of a group of university scientists who since 1966 have been helping FDA strengthen its laboratory capabilities in ways that lead to better consumer protection.

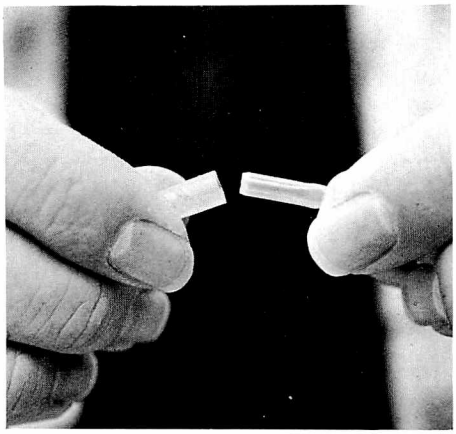
The program began with the appointment of eight chemists as science advisers to FDA district offices. It has since expanded to include microbiologists and physicists and there is now a science adviser in 18 of FDA's 20 field laboratories across the country. They are paid by FDA on a consulting basis and usually spend one day a week in FDA laboratories aiding chemists and microbiologists in laboratory analyses of products, overseeing research projects, and reviewing technical papers being readied for publication in scientific periodicals.

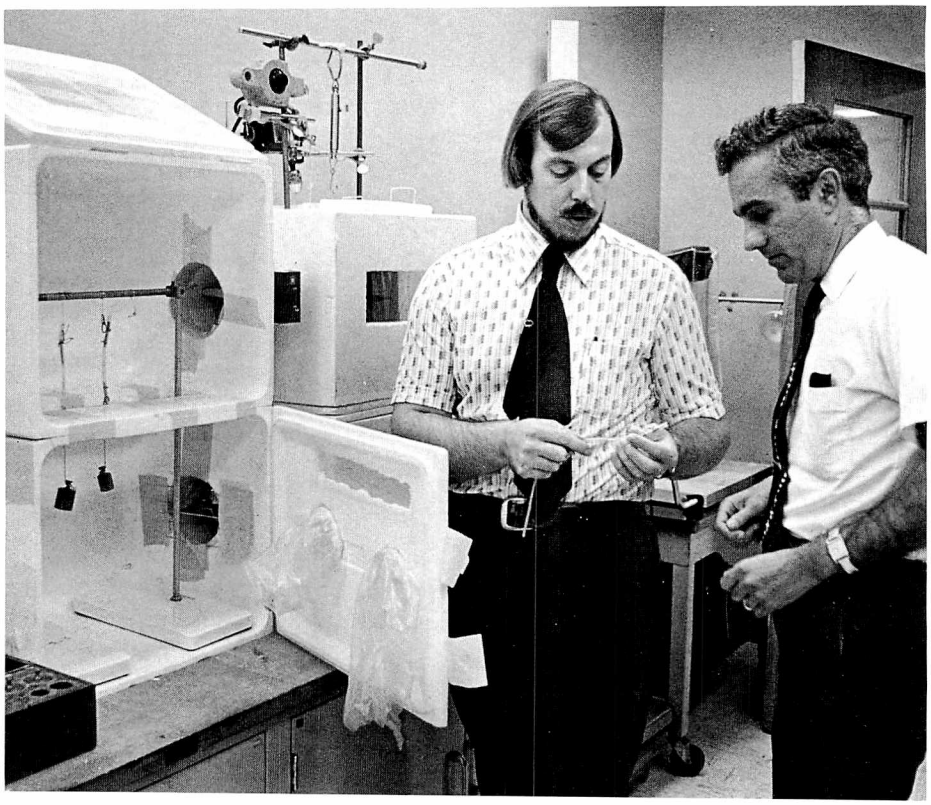
In addition, they serve as a bridge between the academic community and FDA's field science branch by conducting periodic refresher courses in chemistry or microbiology for FDA personnel to keep them abreast of new techniques of analysis, many of which are developed at university laboratories. Dr. Kenneth Stevenson, for example, an associate professor of Food Science and Human Nutrition at Michigan State University and the science adviser for FDA's Detroit District, built on work done by his university colleagues to develop an automated method of analyzing vitamin content in baby foods. The new method will allow FDA scientists to analyze a much larger number of baby food samples for riboflavin, thiamin, and other vitamins in a shorter period of time.

Stevenson knew that foods for which nutritional claims are made must carry nutritional labeling and he realized a quicker method of analysis would benefit FDA and consumers.

Dr. Edward Biehl, professor of chemistry at Southern Methodist Uni-

Thousands of gallons of oil trail over the water from a broken tanker off the coast of Puerto Rico. Thanks to a new method developed with the help of one of its science advisers, FDA now has a faster way to analyze shellfish for oil contamination resulting from such spills.





FDA Chemist George Mack (left) and Dr. Edward Krikorian, science adviser to FDA's Baltimore District, examine a plastic medical shunt before it is placed in a box they designed to determine the minimum force required to pull the shunt apart at the connection. Shunts are used in various medical procedures to carry blood into or out of a patient or to divert blood from an organ during surgery.

versity and the science adviser for FDA's Dallas District, was instrumental in the development of an improved method for analyzing certain chemicals—some of which are known to cause cancer—that are found in shellfish contaminated by oil spills. Using a process called high pressure liquid chromatography, Biehl and FDA chemists Jim Hanus and Bert Guerrero are able to analyze shellfish and determine levels of oil contamination at less than one part per billion. The new procedure, which can be done more quickly and efficiently than the old method, helps FDA prevent contaminated shellfish from getting into the marketplace by making it possible for the Agency and industry to monitor the quality of shellfish that may have been contaminated by oil spills.

Two scientists at FDA's Baltimore District, George Mack and Bill Smith, are working with the District's science adviser, Dr. Edward Krikorian, associate professor of chemistry at the University of Maryland School of Pharmacy, on a project designed to establish quality controls on the manufacture of commercial shunts used by hospitals. Shunts are small plastic tubes doctors insert into a vein or artery through which blood is pumped into or out of a patient, or to divert blood from an organ which requires surgery. Cases have been documented by FDA where connections in the shunts leading to the vein or artery were pulled apart inadvertently by movement of the patient, resulting in a serious loss of blood and, in isolated instances, even death.

Smith, Mack, and Krikorian built a mechanical contraption to test the minimum force required to pull these shunts apart at the connection. During these tests water at body temperature was pumped through the tubing to simulate blood flow, and an electric motor or weights were used to create the continual pressure required to measure at what point the shunt connections separated. Such data will be valuable in establishing proper safety guidelines for the manufacture of shunts.

Sometimes science advisers are associated with projects at their universities which, while not directly involving FDA, produce results that aid the Agency in its work. Dr. M. K. Hamdy, a professor of Food Science at the University of Georgia and the science adviser to FDA's Atlanta District, recently completed a 5-year study on mercury contamination in aquatic environments that is of interest to FDA because of the Agency's responsibility for monitoring mercury contamination of seafood.

The comprehensive study, funded by the Department of Interior and the University of Georgia, sought to determine how mercury, which until recently was permitted to be dumped as industrial waste into waterways, is biochemically transformed into highly toxic mercury compounds in aquatic environments. Once that was established a method was needed to extract the mercury from the water. The study found that bacteria in fish transformed the mercury into highly toxic mercury compounds that could endanger consumers if the fish were used for human food. Earlier studies in Japan had established that mercury-contaminated

Dr. M. K. Hamdy, science adviser to FDA's Atlanta District, observes the behavior of a fish living in mercury-contaminated water. Hamdy's experiment, designed to study the effects of mercury pollution in an aquatic environment, is of special interest to FDA because of the Agency's responsibility for monitoring the contamination of seafood by mercury.

fish could cause illness if eaten by humans, but Hamdy's project for the first time documented the step-by-step biological process which resulted in the contamination.

Hamdy then developed laboratory procedures to withdraw the mercury from the water. He found that small glass columns filled with particles of rubber could absorb the mercury as the water passes through a series of these columns.

Mercury-contaminated waste would be channeled into the columns before it is discharged into a river or other waterway. Such a project, if successful, could go a long way in helping to control the pollution of our waterways. Manufacturers now must remove mercury from waste water before it is discharged by treating it with chemicals. These chemicals, although not as dangerous as mercury, certainly do not help the aquatic environment.

Hamdy is now trying laboratory experiments to remove the mercury from the rubber so that companies can reuse it in their manufacturing processes. In the near future, he hopes to set up a pilot project at a manufacturing plant on the Savannah River to see if the results obtained in the laboratory can be duplicated at a real plant.

In addition to working with FDA personnel on special projects and advising them on technical matters, the science advisers function as a liaison with the academic community. They are able to explain to their academic peers and students just how the Agency uses trained scientists to carry out its day-to-day regulatory responsibilities. They are able to show their students firsthand how their scientific training can be translated into usable skills outside the academic environment.

At least one adviser goes beyond just telling his students about FDA's work. Dr. Clifton Meloan, a professor of chemistry at Kansas State University and adviser to FDA's Kansas City District, often uses actual problems encountered by FDA scientists as the basis for assignments for his graduate students. He also teaches a chemistry course based on his work with FDA.

Meloan, who was one of the Agency's six original science advisers, also acts as a consumer educator for FDA by speaking before various civic, business, and educational organizations. He averages about 18 talks a year and covers a variety of topics, such as how FDA functions; what the Agency does to protect the food we eat; how FDA decides what substances are dangerous and should not be permitted in the products it regulates; and current Agency regulatory problems of wide public interest such as Laetrile and saccharin.

A different but equally important form of communication that emanates from the adviser program is publication in scientific and professional journals of reports on research carried out by FDA district laboratory personnel with help from their science advisers. These articles are a way of sharing the program's findings and accomplishments with others who might be able to use the information in the interest of consumer protection.

James Greene is a staff writer with FDA's Office of Public Affairs.

Paid Blood: The Hepatitis Connection

A number of studies show clearly that blood from paid donors is much more likely to be contaminated by the virus that causes hepatitis than blood from volunteer donors. In an effort to reduce the hepatitis hazard associated with blood transfusions, FDA is requiring that whole blood and certain other blood products be labeled to indicate whether they came from a paid or volunteer donor. The labeling issue is one aspect of a bigger question now being debated: should the Nation adopt an all-volunteer blood supply system?

by Phyllis Lehmann

"Give blood—the gift of life," the slogan urges. But sometimes the gift of life is a mixed blessing. Blood transfusions have saved the lives of many an accident victim or surgical patient only to cause disease or death later.

Contaminated blood also creates needless additional suffering for victims of such diseases as leukemia and lymphoma, who need regular transfusions to prolong their lives.

The villain is viral hepatitis, an inflammatory disease of the liver that can be fatal. Because hepatitis is grossly under-reported, national statistics on the incidence of the disease are sketchy.

"There are simply no hard figures," says Dr. Lewellys Barker, director of FDA's Division of Blood and Blood Products. "But on the basis of some very good studies of specific cities, we know there are a lot of cases out there."

According to the best estimates, somewhere between 10,000 and 30,000 people each year get sick with hepatitis after receiving blood transfusions. At least 400 and perhaps as many as 800 of them die from the disease. Incapacitated for a few weeks to several months, hepatitis victims spend an average of 28 days in the hospital. A special Department of Health, Education, and Welfare Task Force on Blood Banking has estimated that post-transfusion hepatitis costs the Nation some $86 million a year in medical costs.

In addition to these overt cases, there are probably five times as many—or at least 100,000—cases a year in which the victim does not feel sick enough to see a doctor. Even these cases cause liver damage that can lead to chronic liver problems.

A major factor in the hepatitis hazard, FDA believes, is where the blood comes from. In this country, there are two sources of blood and blood components: volunteer donors, who are not paid for their donations; and commercial donors, who receive $25 to $50 each time they give a unit (about a pint) of blood. Unfortunately, commercial blood banks often attract those types of people—derelicts and drug addicts, for example—most likely to carry hepatitis.

Although it is estimated that only 10 percent or less of the national blood supply comes from paid donors, this blood may be responsible for 25 to 45 percent of post-tranfusion hepatitis cases. Studies indicate that a patient is 3 to 10 times more likely to develop hepatitis after a transfusion of blood from a commercial donor than after a transfusion of voluntarily donated blood.

The hepatitis hazard isn't restricted just to whole blood. The disease can be transmitted by some of the products produced from blood plasma, the yellow fluid that makes up more than half the volume of human blood. In a process known as plasmapheresis, whole blood is taken from donors, the plasma is separated from the red blood cells, and the red cells are returned to the donor. The plasma then is sent to fractionation plants where it is used to produce plasma products for such things as treating shock and controlling bleeding in hemophiliacs. Although the fractionation process destroys or removes the hepatitis virus in several of the plasma products, it survives in certain crucial ones, such as the antihemophilic factor. Consequently, hepatitis is a problem for the Nation's 10,000 to 20,000 hemophiliacs, many of whom contract hepatitis early in life.

In an effort to reduce the hepatitis hazard associated with blood transfusions, FDA has proposed (FEDERAL REGISTER, Feb. 25, 1977) a new labeling regulation that would require each container of whole blood— as well as platelet concentrates, antihemophilic factor, red blood cells, and plasma from single donors—to be marked as to whether it came from a paid or volunteer donor. Public comment on the proposal has been reviewed by FDA and a final regulation is being prepared. It will become effective 120 days after publication in the FEDERAL REGISTER, which is expected by the end of the year.

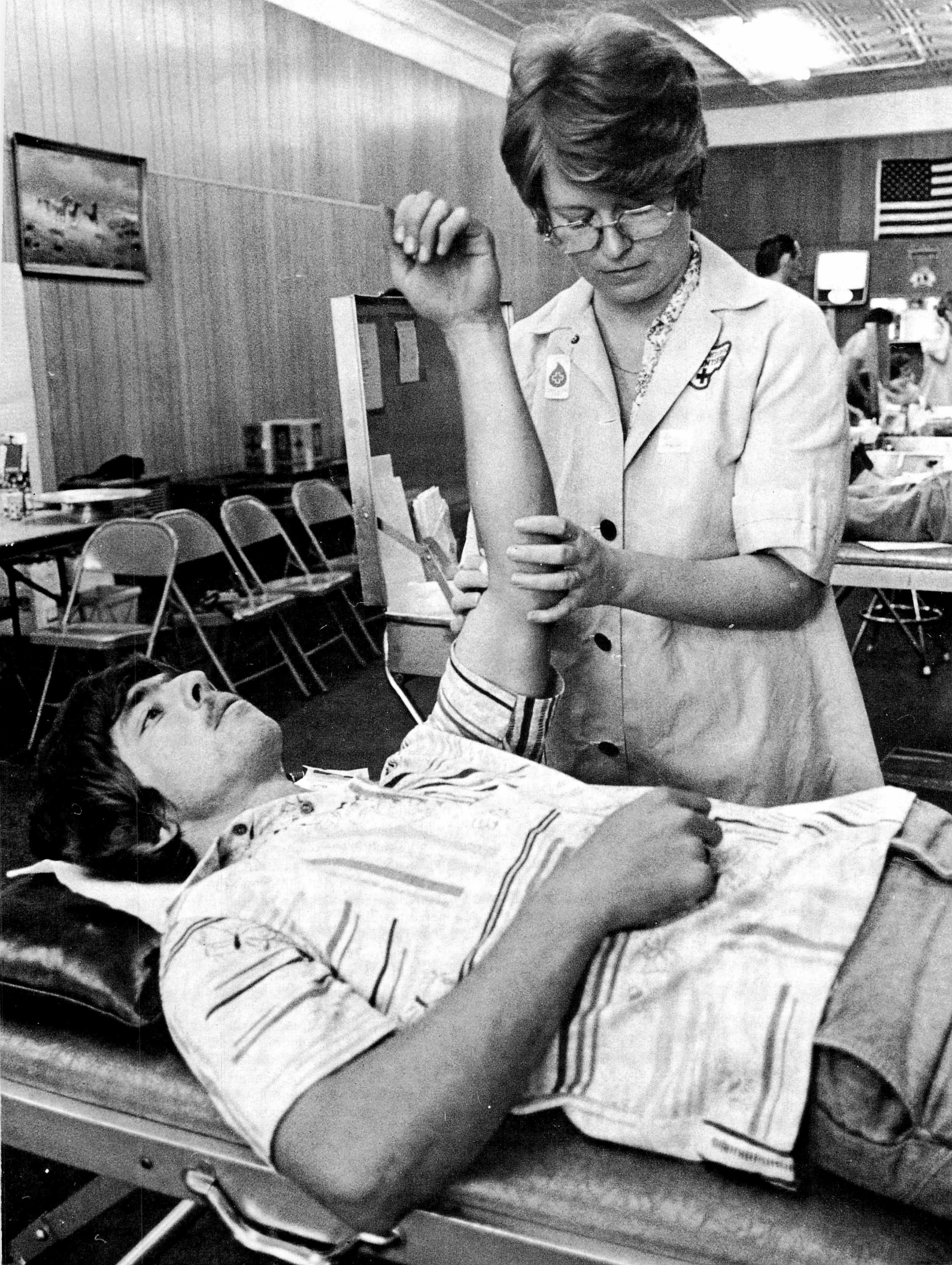
Under the Federal Food, Drug, and Cosmetic Act, FDA has authority to require that all drugs, including blood, be safe and properly labeled. Blood labeling, the Agency reasons, will inform physicians of the relative risk of hepatitis associated with the blood they prescribe.

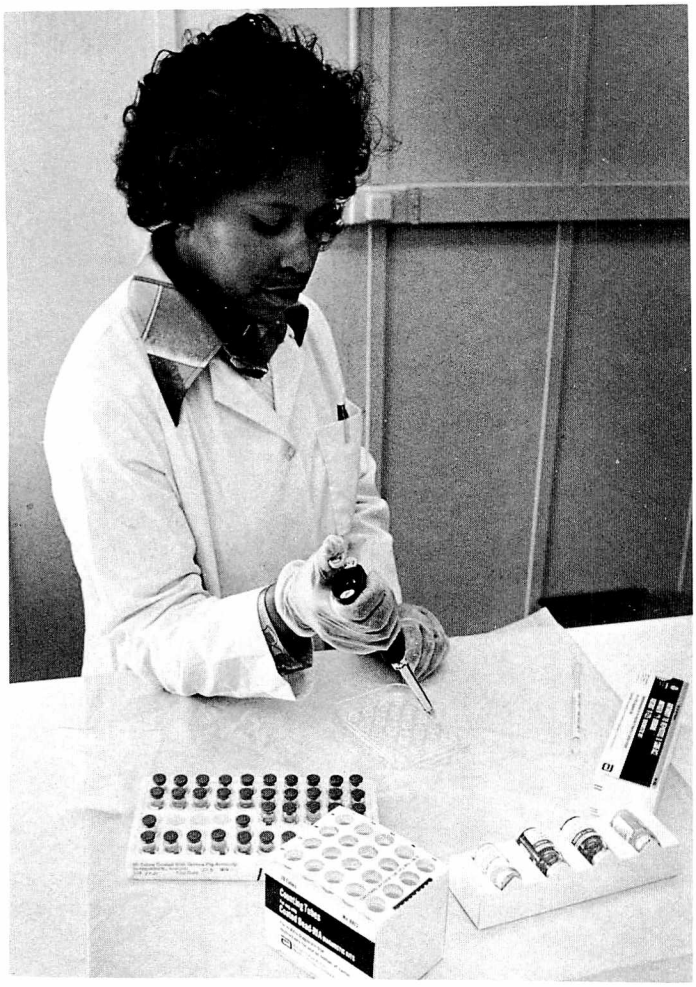
Human blood already has been the target of FDA regulation. Since July 1972, the Agency has required that all whole blood, blood plasma, and serum be tested for hepatitis B virus, until recently the most common and severe type of hepatitis transmitted by blood transfusions.

Testing has confirmed suspicions about the hazards of commercial blood. One study in New York City, for example, showed that hepatitis B was 12 times more prevalent in blood from paid donors than in blood from volunteers.

While testing has cut down the spread of hepatitis B, it certainly has not eliminated it. Low levels of the virus elude even the most sensitive tests, which are only about 40 to 60 percent effective in detecting units of blood contaminated by hepatitis B. And even with the required testing, the risk of

A Red Cross volunteer applies pressure to a donor's vein puncture.



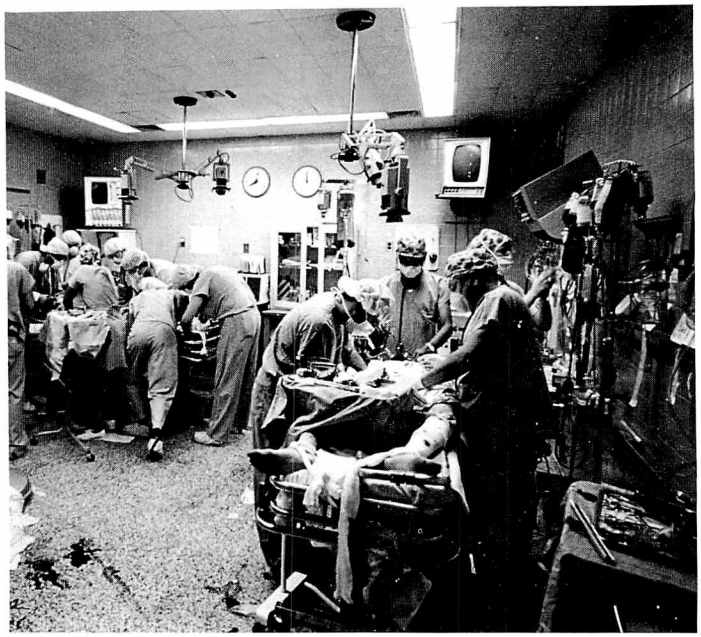


To reduce the risk that hepatitis will be transmitted to the recipient from the donor in blood transfusions, FDA requires that blood for transfusion be tested for the virus that causes hepatitis. Samples of the kits used by blood banks and hospitals to test blood for hepatitis are checked by FDA to make sure they will detect the disease. Here, Linda Smallwood of FDA's Bureau of Biologics carries out the first step in the procedure for checking the effectiveness of the test kits. No testing method now available, however, is 100 percent effective in detecting hepatitis virus in blood.

post-transfusion hepatitis still is much higher with blood from paid donors than from volunteer donors. The incidence of hepatitis decreases dramatically when paid donor blood is replaced with an all-volunteer supply. In a study at the Hines Veterans Administration Hospital in Chicago, nearly 21 percent of patients receiving blood transfusions developed hepatitis when 92 percent of the blood came from paid donors. But when 96 percent of the hospital's blood supply was obtained from volunteer donors, the incidence of hepatitis dropped by 62 percent.

Another, more important, reason why testing alone is not sufficient to prevent disease is that hepatitis B is no longer the major culprit in blood. Up to 90 percent of all post-transfusion hepatitis cases now are caused by some other type of agent for which there are no testing methods. Scientists have no idea how many different hepatitis viruses there might be.

The FDA has concluded, therefore, that the best way



Immediate availability of large amounts of whole blood is essential for emergency rooms, shock-trauma units, and operating rooms.

now available to reduce the risk of transmitting hepatitis caused either by the B virus or by the more exotic varieties is to discourage, and hopefully eliminate, use of blood from paid donors.

Indeed, there is a great deal of support for an all-volunteer blood supply system in the United States. Even those organizations that include commercial blood banks in their membership, such as the American Association of Blood Banks, support the principle of voluntary blood donation.

The idea of an all-volunteer system began gaining steam in 1972, when the President asked the Department of Health, Education, and Welfare (HEW) to recommend a plan for developing a safe, fast, and efficient nationwide system for collecting and distributing blood. A specially appointed HEW Task Force on Blood Banking came up with a National Blood Policy that calls for an end to paid donors and urges reliance on volunteers. Aside from reducing death and suffering from post-transfusion hepatitis, the task force reported, transition to an all-volunteer system would save the Nation some $18 to $29 million a year in hepatitis-related medical costs. To implement the National Blood Policy, HEW in 1975 convened the American Blood Commission, which has as its members virtually all the major blood banking organizations.

Despite this show of unity, there is considerable argument about whether Government regulation, such as the FDA labeling requirement, is necessary and whether it will hasten the transition to a voluntary blood collection system. Opponents of labeling have included, for example, the American Medical Association, American Society of Clinical Pathologists, American Association of Blood Banks, and American Blood Resources Association. Lined up on the other side are such groups as the American Red Cross, Council of Community Blood Centers, Blue Cross, American Association of Family Physicians, and the AFL-CIO.

The argument heated up in November 1975, when FDA proposed a regulation that would have required labels on

blood to include the statement that blood from paid donors carries a higher risk of hepatitis than that from volunteer donors.

Many comments on that proposal suggested that the terms "paid" and "volunteer" be defined precisely, because it is common practice to motivate people to donate blood by giving them time off work to do so; offering free tickets for food, the theatre, and taxi fares; or assuring free blood to the donor and the donor's family if they should need it. Even though no money changes hands in such arrangements, the donors might be considered "paid."

The idea of requiring a statement that paid blood is more dangerous than volunteer blood drew even more fire. Opponents pointed out that blood from paid donors is not always contaminated, and paid blood would, in fact, be mislabeled if it came from donors who are not among those groups considered most likely to carry hepatitis.

After convening a special conference on these issues and considering all comments received on the original proposal, FDA last February issued a revised proposal that takes into account many of the objections. For one thing, the new proposal clearly defines "paid" donors as those who receive money for giving blood and "volunteer" donors as those who do not. The Agency does not consider donors who receive such benefits as time off from work or membership in blood assurance programs as paid donors.

A major change in the new proposal is elimination of the required warning that paid blood is more likely to cause hepatitis. Since the hepatitis hazard and the issue of paid vs. volunteer blood have been well aired in both the medical literature and the general news media, FDA concluded that simply designating blood as "paid" or "volunteer" adequately notifies physicians and blood banks of the relative hepatitis risk.

Still, disagreement persists about whether *any* type of labeling is needed. Opponents of labeling argue that even marking blood "paid" or "volunteer" will attach a stigma to all paid blood, regardless of how safe it may be.

Opponents contend that labeling will put physicians in a bind if they have to prescribe "high risk" blood in order to save the life of a hemorrhaging patient, even though their action could well lead to a malpractice suit. And even though an all-volunteer blood system is a worthy goal, they say, it may always be necessary to collect blood from some paid donors in order to obtain rare types and certain blood components. Therefore, it would be unwise to stigmatize all paid blood by implying, through a label, that it is not as good as that from volunteer donors.

The real way to control hepatitis, say such organizations as the American Blood Resources Association, is to identify high risk donors, collection facilities, and perhaps even geographic areas and eliminate them as either paid or volunteer sources of blood.

Dr. Richard Walker, president of the American Association of Blood Banks, said the proposed labeling requirement would have the serious disadvantage of discouraging use of blood from very high quality paid donors "who presently provide the safest blood available to some of the most prestigious medical institutions in the United States." Walker further maintained that required labeling would cause critical shortages of blood in some inner-city hospitals which, unable to attract volunteer donors, must rely heavily on paid donors for their blood supply.

The FDA emphasizes that the labeling requirement would *not* prohibit payment for blood. The Agency recognizes that paying certain donors may be necessary to ensure an adequate supply of rare blood types.

Thanks to some State laws, there already is precedent for labeling blood by source. Three States—Illinois, California, and Georgia—specifically require blood to be marked as "paid" or "volunteer."

In Illinois, which enacted its labeling law in 1973, physicians using blood from paid donors must justify in writing why they are prescribing blood with a higher hepatitis risk. Despite this severe restriction on use of paid blood, feared shortages have not materialized. Fortified with a backup supply of frozen blood, the State made a quick and smooth transition to a volunteer blood donation system. In fact, the Illinois Department of Health has reported that since the labeling law went into effect, there have been enough volunteer donors to meet all of the State's transfusion needs. Heightened awareness of the public health risk associated with blood from paid donors apparently has motivated people to give blood voluntarily.

Hospital studies in Illinois showed that the number of cases of post-transfusion hepatitis dropped dramatically following the switch to volunteer blood. At the same time, according to the Illinois State Medical Society and the Chicago Medical Society, malpractice lawsuits resulting from post-transfusion hepatitis went down sharply. Obviously, with fewer cases of hepatitis, there was less reason—or opportunity—for patients to sue.

Other studies confirm that switching to a volunteer system weeds out those donors most interested in money, and who also happen to account for most of the hepatitis problem. Low-risk donors often can be motivated to continue giving blood without getting paid for it.

A volunteer system, supporters point out, can be just as effective as a paid system, but less expensive. Although administrative costs are the same, the volunteer system eliminates the extra expense of paying donors.

When all the evidence is considered, it clearly points to a continuing serious problem with post-transfusion hepatitis in this country, even with required testing for hepatitis B virus. The evidence further indicts blood from paid donors as significantly more hazardous than blood from volunteer donors. FDA has concluded that labeling is the best method now available for controlling the use of blood from paid donors and for giving doctors the information they need to evaluate the benefits and risks of using such blood.

There is no evidence that discouraging use of blood from paid donors will interfere with the overall supply of blood. At present, only about 6 million donors, both paid and volunteer, maintain the Nation's blood supply. Yet, there are at least 90 to 100 million people eligible to give blood. Experience on the local level indicates that many of these potential donors can be reached through effective recruitment campaigns.

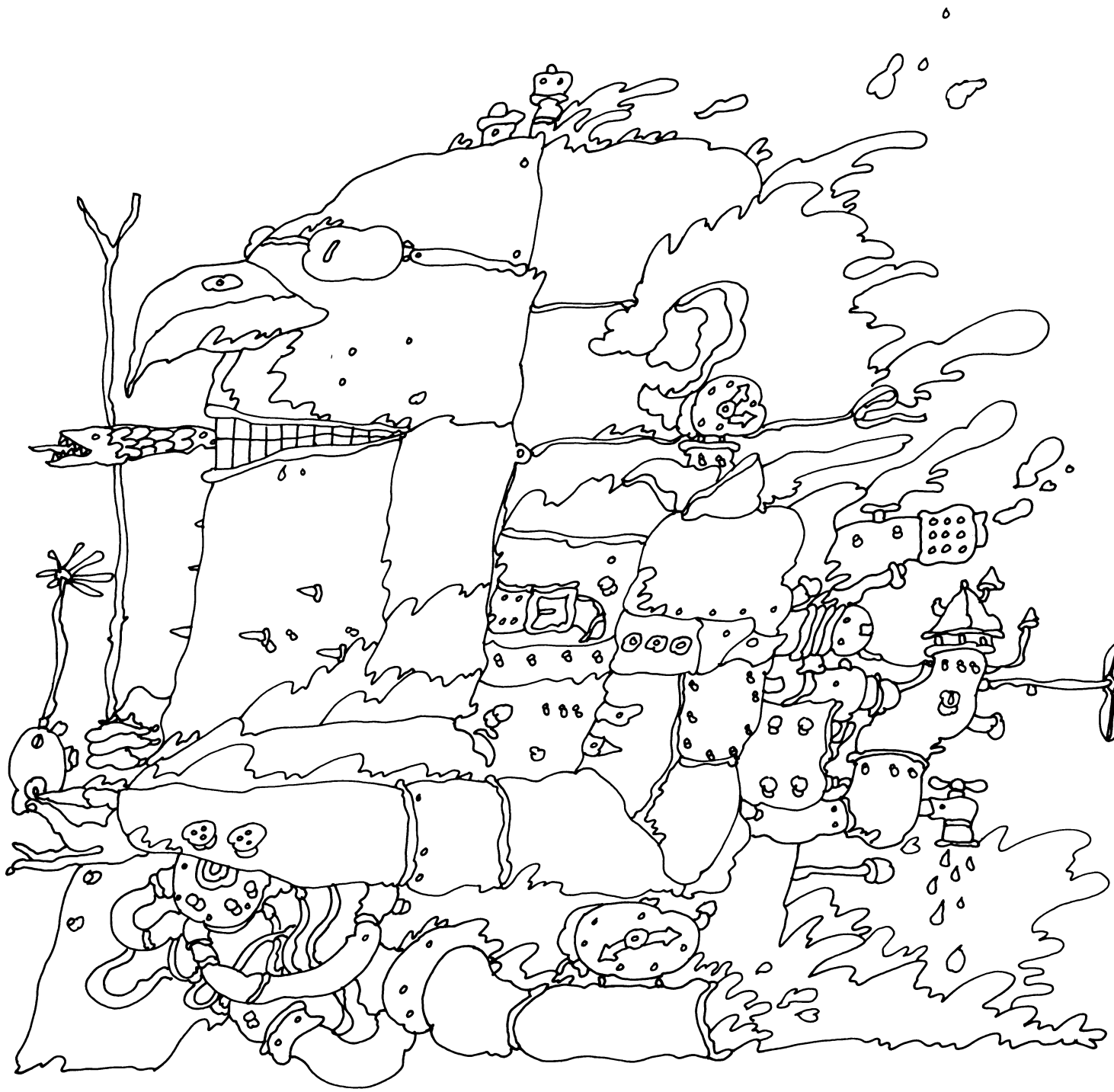
As Dr. Thomas Chalmers of New York's Mount Sinai School of Medicine, who has been studying viral hepatitis for some 30 years, has pointed out:

"It is my impression that if we just think in terms of the amount of money that is spent every year caring for patients with hepatitis and spend a segment of that money on public relations to attract volunteer donors, we can solve the [problem of] blood donor source."

Phyllis Lehmann is a freelance writer.

Health Frauds And Quackery

Stephen Barrett, M.D., a practicing psychiatrist in Allentown, Pennsylvania, has devoted considerable time to investigating and opposing quackery. Since 1970 he has been chairman of the board of directors of the Lehigh Valley Committee Against Health Fraud, Inc. He is also co-editor of the THE HEALTH ROBBERS—HOW TO PROTECT YOUR MONEY AND YOUR LIFE, *a book on quackery written by physicians, nutritionists, journalists, and health educators. In this interview with Wayne L. Pines, FDA's deputy assistant commissioner for public affairs, Dr. Barrett explains how he views health fraud and quackery today. This is part of a continuing series of interviews with people outside FDA in an effort to stimulate discussion on important matters of public interest and concern.*



Q. *Dr. Barrett, you've been investigating quackery in this country for seven years. How serious is the problem?*

A. Very serious. Few people realize how often or how skillfully they are being cheated in health matters. There aren't any exact figures, but my guess is that Americans are wasting between five and ten billion dollars a year on questionable "health" practices. And public confusion about many health matters is increasing.

Q. *To what do you attribute this increase?*

A. Publicity. Promoters of quackery have mastered the art of manipulating the media. Most people think that health claims must be true or somehow they "wouldn't be allowed." But the fact is that a false claim is against the law only if it appears in an advertisement or on a product label or is made in connection with a sale.

Nowadays very few health products carry false claims on their labels. They don't have to because the public is being flooded with false claims in news articles, in books, and on radio and TV talk shows. For example, take the claims that vitamin E will prevent heart disease and increase sexual performance. These claims would be illegal in an ad or on the label of a bottle of vitamin E pills. But if the bottle is simply labeled "vitamin E," and someone buys it because he heard somewhere that it might help him, no law has been broken. In effect, the media have become the label.

Q. *What are some of the more common health frauds?*

A. Cancer and arthritis fakes, fad diets, acupuncture, "organic" foods, phony gadgets, hair analysis, manhood fakes, bust developers, chiropractic adjustments, shots to "pep you up," nonprescription drugs which contain no effective ingredients. The list is endless.

Nutrition is a particularly fertile field for quackery. Perhaps half the people in this country are taking vitamins and other food supplements which they don't need. Some think that extra vitamins can give them extra energy or can prevent or cure many diseases. Some think that they will achieve some sort of "superhealth." But most are worried that they might not be getting enough vitamins or other nutrients in their food. The fact is that nutrients are very plentiful in our food, and extra nutrients don't do anything for people. Taking more than you need is a waste of money.

Q. *What about fad diets?*

A. In the area of weight reduction, it seems there's a new and revolutionary diet coming out every few months. They sell a lot of books but the simple fact is that the only really sensible way to lose weight is to eat a balanced diet that contains fewer calories than you burn off. I wish we could find a way to decrease the amount of inaccurate information about health that gets into the media.

Q. *You've been quoted as saying that the answer to quackery in general lies in increased public education, as well as in passing stronger laws.*

A. Yes, but that is more easily said than done. Anyone who tries to promote either one will run into stiff political opposition. For example, a few years ago the FDA tried to issue new standards for vitamin and mineral supplements so that people would get products that are formulated better, and so that certain misleading claims being made by sellers of food supplements would be stopped. The health food industry responded by generating more than two million letters to Congress and actually got a law passed to block some of the things the FDA wanted to do to protect people from being cheated. We see a similar effort being made today by proponents of Laetrile.

Q. *There is great concern today about the role of Government in protecting people. How far do you think Government should go to protect people from being cheated in health matters?*

A. My feeling is that Government action must be very vigorous. But in actual practice, that's not so simple. People don't know whom to trust anymore. Just because a Government agency says something is dangerous or doesn't work does not mean that people will believe it. To me, quackery is a form of stealing. But many of quackery's victims don't see themselves as victims. They don't believe they are being cheated and would like the Government to leave them alone. Laetrile promoters have been taking advantage of these anti-Government feelings.

Q. *Would you consider Laetrile to be the major health fraud in this country today?*

A. I'd say so. Many people are dying as a result of taking Laetrile instead of getting proper treatment for cancer in its early stages. But widespread publicity about people who think Laetrile has helped them has stirred up hopes among cancer victims and their families. Many people want to try it and State legislators are being pressured to "legalize" it.

Q. *What makes people so willing to try products like Laetrile which don't work?*

A. The modern quack has learned to reach people emotionally on the level that counts the most. What sells is not the quality of his product but his ability to influence his audience. It is not difficult to sell hope to people who feel desperate.

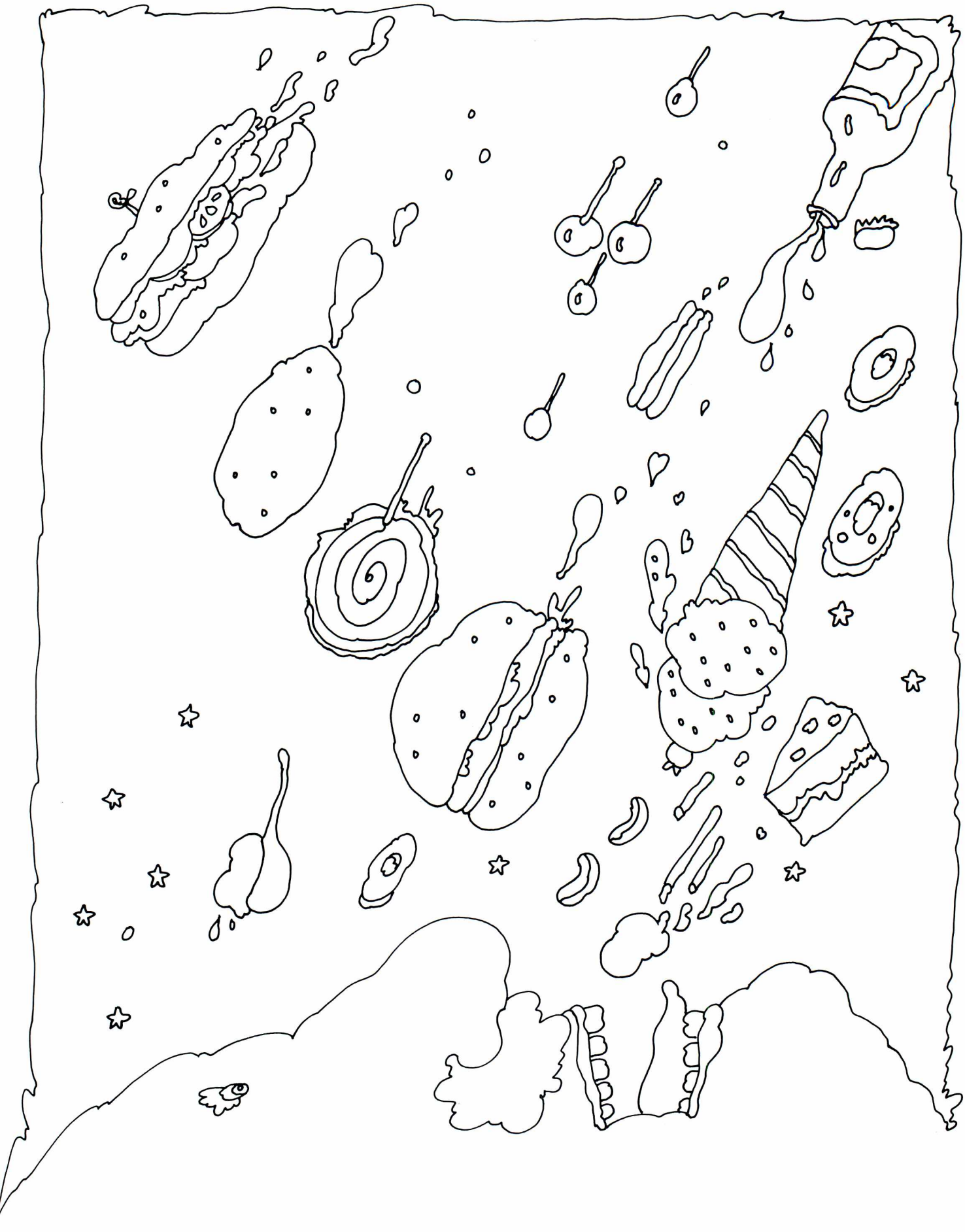
Q. *To what extent are doctors involved with quackery?*

A. A number of doctors have weird ideas about nutrition or make diagnoses of hypoglycemia, adrenal insufficiency, or subclinical hypothyroidism on all or most of their patients. Often they will diagnose these glandular disorders without laboratory tests to back them up. These doctors seem to have abandoned scientific thought, particularly in the area of body chemistry. There aren't very many of them—probably fewer than one in a hundred—but they present a special problem. Because they hold licenses to practice, people expect them to know what they are doing.

There is a larger group of licensed practitioners whose practice is unscientific—chiropractors. They base their practice on a false theory, that all diseases are the result of spinal difficulties. Chiropractors sometimes help people, but their training is poor and I generally recommend that people avoid them.

Q. *What makes people develop confidence in the types of doctors you would consider unscientific?*

A. That's a good question, but a very complicated one to answer. Most ailments are self-limiting, which means they will improve with



no treatment at all. Good doctors rarely take credit for what nature does, but unscientific practitioners usually do. We've all seen people who swear by a doctor or treatment method. I don't like to see that intense a feeling because it usually means the patient is far too dependent. Another factor that helps unscientific practitioners build their following is the placebo effect, that is, if a person thinks he has been helped by something, he may feel relief from his pain or other discomfort. A common example of the placebo effect is that most people feel better when the doctor walks into the room.

Q. *What about acupuncture?*

A. When acupuncture hit the headlines a few years ago, many people hoped that some kind of medical magic was about to be rediscovered. But most of them have had their hopes come crashing down.

Q. *Would you say that acupuncture never helps anyone?*

A. It's hard to make a generalization of that type. Cramped muscles sometimes relax when they are stuck with needles, so some people might get temporary relief in that way. No doubt some people who go to acupuncturists will experience a placebo effect. But there is no reason to believe that acupuncture can change the course of any organic disease—like arthritis, for example.

Q. *You mention the placebo effect again. Don't doctors use a lot of placebos in the form of sugar pills, dummy pills, and the like? Don't doctors also recommend vitamins to many people who eat properly and don't really need them?*

A. Yes, they do. Doctors are confronted by many people who complain of tiredness or a variety of vague symptoms which are reactions to nervous tension. Far too often, instead of finding out what is bothering them, doctors tell these people to take a tonic, a vitamin, or some other type of placebo.

Q. *If a placebo makes someone feel better, what's wrong with that?*

A. I am against people being misled. The quack who relies on a placebo effect is also pretending he knows what he is doing—that he can tell what is wrong with you and that he has effective treatment for just about everything. His customers are playing Russian roulette. The medical doctor who uses vitamins as placebos may not be as dangerous, but he is encouraging people to form lifelong habits of using things they don't need. In addition, patients who are not satisfied with this approach may reach toward alternate ways of getting attention—like going to chiropractors or treating themselves with food fads.

Q. *So on balance you feel rather negatively about placebos and the way they are used.*

A. Yes. Most people who use placebos do not get relief from them. So we're talking about practices that are not only misleading. They are also a financial rip-off. There are certain medical situations where use of a placebo is justified, but these situations are rare.

Q. *Do you find that most promoters of quackery have a financial motive?*

A. Some seem to be motivated by greed alone, some seem to have a sincere belief in what they are promoting, and some seem to have a mixture of both. For example, sellers of manhood devices, bust developers, and many other types of worthless mail-order gadgets know that they are peddling fakes. They are "hit-and-run" artists who open a post office box and hope to make enough money before the Postal Inspector shuts down their business. On the other hand, most people involved in nutrition quackery strike me as sincere believers. They may make money, but they also appear to be hopelessly confused.

The "true believers" are the ones who cause us the most grief because of their tendency to get involved in intense political activity—like the promotion of Laetrile.

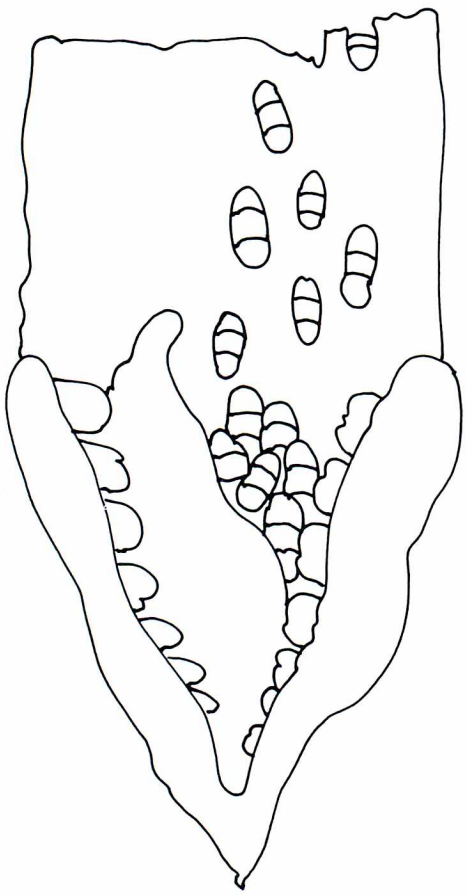
Q. *Laetrile has been around for more than 25 years. How do you account for its sudden burst into the political arena?*

A. The intensity of the political force is due to the fact that users rather than sellers appear to be the ones spearheading the drive to legalize its sale. The approach of turning victims into political foot soldiers is not new, but with Laetrile it has reached a new level of intensity.

Q. *So what looks to legislators like a grassroots movement is being orchestrated by people with vested financial interests?*

A. Yes. There are at least four national groups. The oldest, founded in 1955, is the National Health Federation. Since it began, NHF has been led mostly by people who have a financial interest in promoting questionable "health" products or ideas. Ten of them have been in legal difficulty for making false claims and four of them have even received prison sentences. The primary goal of NHF appears to be to weaken Government interference with quackery. Its major activities include lawsuits and letter-writing campaigns like the one that stopped the FDA vitamin regulations.

At least three other national groups are devoted to pushing the gamut of worthless cancer cures. One was founded in 1963 by a woman who thought she had been cured of breast



cancer by Laetrile but who died of the disease in 1969. Another is led by a woman who is a major distributor of food supplements. A third group, said to be the largest, is led by some of the major distributors of Laetrile who have been convicted of smuggling.

Q. *Your book goes into the politics of quackery in considerable detail. What role do you see for FDA in this fight?*

A. I am deeply concerned about the growing political power of those who are out to destroy Government protection of consumers against health frauds. Right now it is against the law to market drugs and devices that are dangerous or don't work. The FDA protects us against quackery mainly by forcing such products off the market. There are occasional criminal prosecutions and I hope frankly that there will be more. They are difficult and the courts have not usually sent people convicted of health frauds to prison. But the way I look at it is that misleading someone in a health matter may be a threat to his life—and that deserves a very stiff penalty.

Q. *What got you interested in fighting quackery?*

A. I've always hated to see people get hurt or cheated. In 1968 I happened to read two books about health frauds which made me angry enough to try and do something about them. It wasn't hard to find others in my community who shared this concern and were willing to join forces. We formed a nonprofit corporation in 1970 and later joined the Consumer Federation of America.

Q. *What does your committee actually do?*

A. Mostly we serve as an information clearinghouse—gathering and distributing information about health frauds. We look for deceptive ads about health products and report them. We involve ourselves in many legislative matters and testify at Government hearings. We invite people who have been cheated to complain to us. We also furnish speakers.

Q. *I understand you are also quite active in promoting water fluoridation.*

A. Yes. As you know, when a community adjusts the fluoride concentration of its water supply to about one part per million of water, its children will get fewer cavities in their teeth. Unfortunately, there is an organized effort under way to scare people into thinking that fluoridation is dangerous. The National Health Federation, one of the groups I just mentioned that promotes Laetrile, has also been very active in attacking fluoridation. For about two years NHF has been claiming that fluoride causes cancer. It doesn't, of course, but this type of publicity can succeed in frightening people. What makes this situation so sad is that the victims of antifluoridation quackery are innocent children who are unable to defend themselves.

Q. *It sounds like your definition of quackery is quite broad.*

A. Yes. Our committee is interested in any aspect of health in which deception may be involved. Incidentally, one thing we do that's particularly satisfying is to help victims who see the light and want to do something about it. This doesn't happen very often because even when people realize that they have been cheated, they are usually too embarrassed or afraid of "trouble" to do anything. We like to see victims fight back. Otherwise, whoever gypped them will go right on cheating others.

Unfortunately, the very word "quack" is very misleading because when most people think of a quack or quackery, they imagine some sort of outlandish person selling snake oil

from the back of a covered wagon. Most modern forms of quackery look more respectable and are harder to recognize.

Q. *Can you give some general guidelines for spotting quacks?*

A. The outright medical quack can usually be recognized by his talk of secret or miracle cures, of a single device or system which can diagnose or treat all ailments, of Government or AMA "persecution," and of the "dangers" of drugs or surgery in general. He is also apt to use testimonials from supposedly satisfied customers.

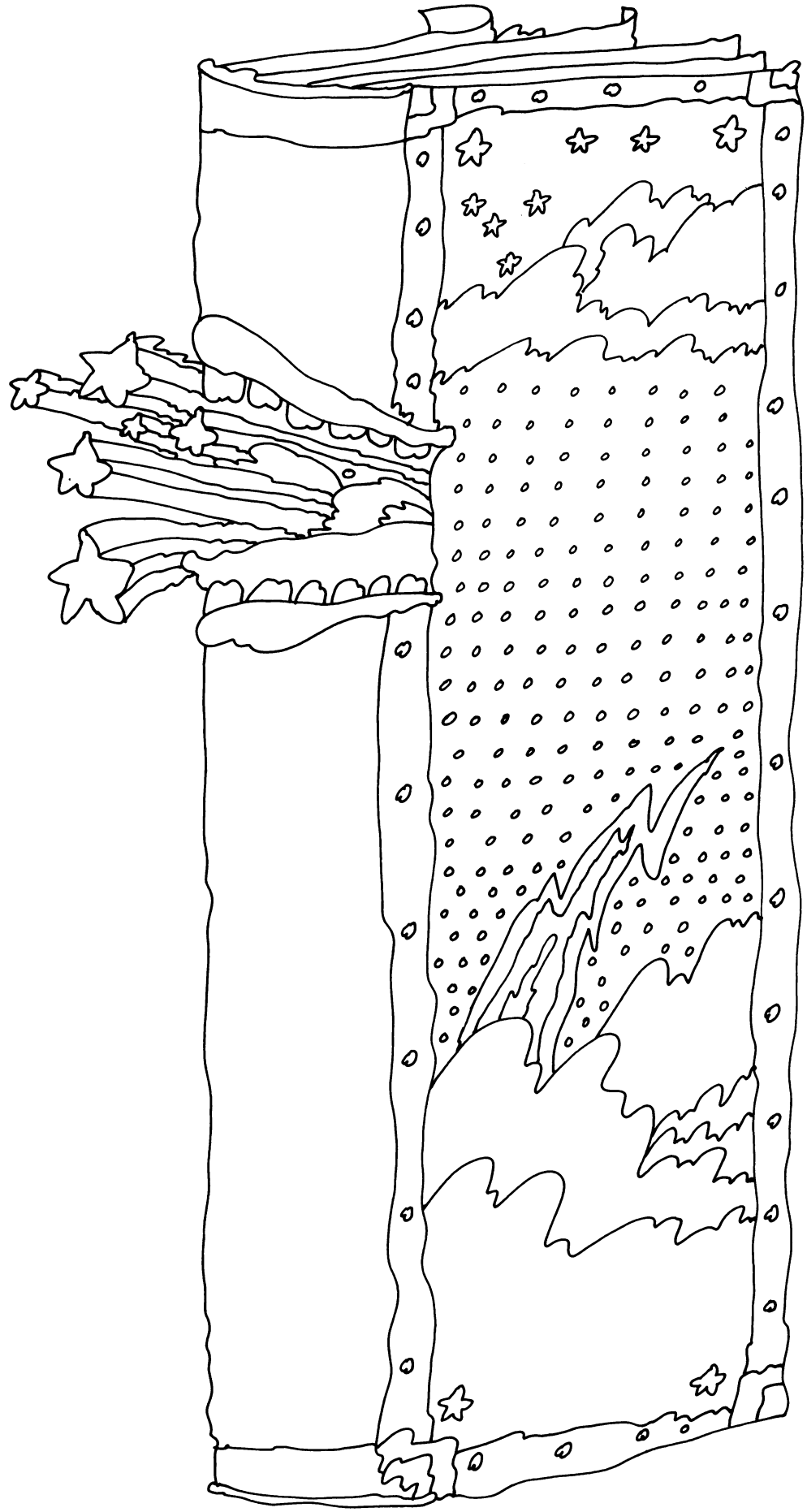
The food quack can usually be recognized by his claims that everybody should use food supplements or that many diseases can be cured or prevented by large doses of vitamins.

More subtle forms of quackery can often be avoided by an attitude of skepticism toward all forms of "health" products which are advertised to the public, particularly those sold by mail. Doctors who give shots to almost all of their patients should also be avoided.

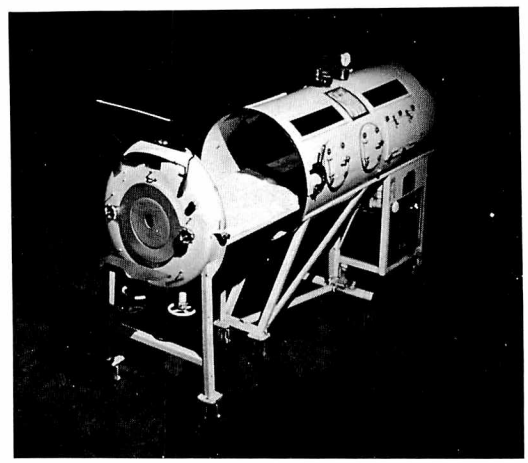
Q. *Where can people get reliable health information?*

A. Most medical doctors who regularly write columns for newspapers and general magazines are reliable. Some of them publish newsletters and books as well. For in-depth reporting, nothing can beat the health articles in CONSUMER REPORTS. FAMILY HEALTH magazine has good articles too, but occasionally will publish a misleading ad. Publications loaded with food supplement ads should be completely disregarded. About half of the books about health in the average bookstore and almost all of the ones in health food stores are filled with nonsense. News reports of all types tend to be overly sensational and therefore confusing. Regularly scheduled medical TV talk shows whose guests are mostly medical doctors are reliable. But some guests on the entertainment type talk shows are leading promoters of quackery.

For more individual attention, a good relationship with a doctor who can take the time to answer your questions can be a big help. Dietitians can be a good source of nutrition advice. Our book also lists more than 100 organizations which can give reliable information.



Closing The Immunization Gap



Of the 52 million American children under the age of 15, about 20 million have not been immunized against one or more of the preventable childhood diseases. Safe, effective vaccines are available and a nationwide campaign now is under way to obtain immunization of 90 percent of all children against measles, polio, rubella, diphtheria, whooping cough, and tetanus.

by Faye Peterson

Thursday, August 11: A man lay feverish in his summer home as his wife hurriedly summoned a physician. Despite pain, and apparent paralysis in the patient's legs, his illness was initially diagnosed by the doctor as no more than an ordinary cold. The victim, a successful politician at age 39, was normally full of vitality, but had felt strangely ill the day before. By the next day he couldn't stand and by evening had lost the power to move his legs. He complained of aching all over, was at least partly paralyzed from the chest down, and had so little control over his hands that he couldn't write.

The illness progressed to the point of complete paralysis of the legs, and on August 25, a specialist from Boston finally determined that the man was suffering from infantile paralysis—paralytic polio.

With dedicated and prolonged efforts, the patient eventually overcame some of the crippling effects of the disease. But he was never able to walk again or even stand without support.

The time was 1921. The place was Campobello, Canada. The man was Franklin D. Roosevelt. Similar stories were widespread during the years before the development and use in the 1950's of an effective vaccine against polio. Since the advent of polio vaccine, the disease has been virtually eradicated in this country.

But there are no guarantees that polio and other preventable childhood diseases won't reappear to cause needless suffering and even death. The number of children and young adults who have not been vaccinated against polio, measles, rubella (German measles), diphtheria, pertussis (whooping cough), and tetanus is alarmingly high. Some 20 million American children—almost 40 percent of the 52 million children under the age of 15—have not been fully immunized against one or more of the preventable childhood diseases. This includes:

- Polio—more than 19 million children are not fully immunized and the number of inadequately immunized children is going up.
- Measles—nearly 12 million children from ages one through 13 are not immunized.
- Rubella—more than 12½ million youngsters from ages one through 12 are not immunized.
- Diphtheria, pertussis, and tetanus (DPT)—more than 15½ million children under 14 years of age have not received a full course of DPT shots.

A major factor in the low levels of immunizations is an apparent lack of awareness by the public of the seriousness of preventable childhood diseases. In the past, very little Federal money has been allocated for public education on the importance of immunizations. In fact, for the last four years, such activities have been carried out mainly by volunteer organizations. As a result, many people—even school officials in some States—have lost sight of the importance of maintaining high levels of immunity in the community.

Forty-eight of the 50 States now require immunization of children entering school but these requirements have not been uniformly enforced throughout the country. In some localities the responsibility for ensuring that children are vaccinated has been left entirely up to parents. Many parents today don't seem to know or have forgotten about the serious and permanent health problems that can result from measles, polio, rubella, diphtheria, whooping cough, and tetanus. Complications range from paralysis, blindness, and deafness to brain damage and mental retardation. Almost all these diseases can cause death.

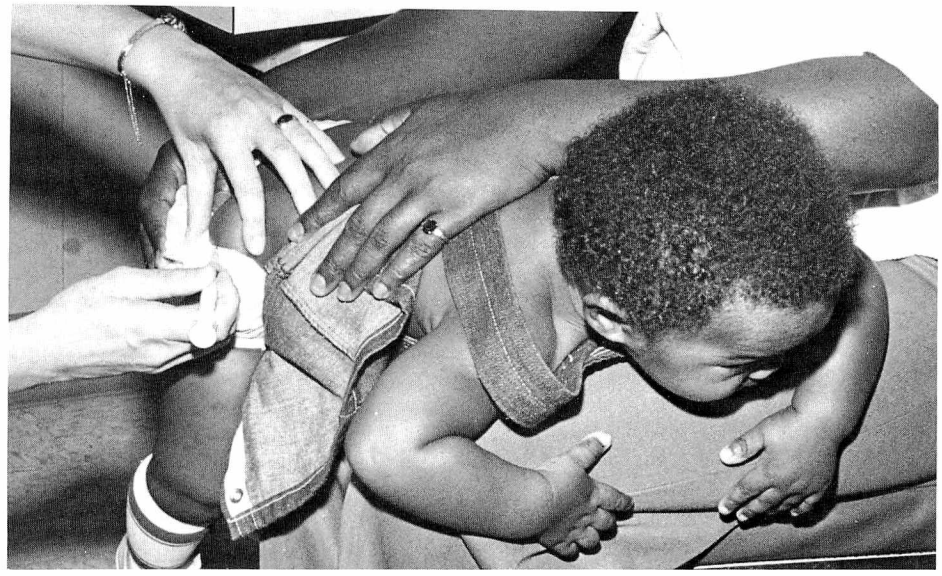
Measles, for example, is considered by many to be a mild childhood illness. But it can result in pneumonia, middle

ear infection, or encephalitis (inflammation of the brain). Encephalitis, associated with measles in approximately one of every 1,000 cases, often causes permanent brain damage and mental retardation, and it may be fatal. So far this year there has been more than a 50 percent increase over 1976 in the number of measles cases reported in the United States. The Public Health Service attributes this increase to unvaccinated or improperly vaccinated children.

Public trust and acceptance of mass immunization in the United States is also in a period of decline. This, according to some health experts is attributable to several factors. In general, the public no longer has the trust it once had in the Nation's medical authorities. The public also has become much more aware of the risks involved in all medical procedures, and some people have an unwarranted fear of adverse reactions to vaccines.

In addition, the difficulties that plagued the 1976 swine flu vaccine campaign have shaken public confidence in immunization programs. This is unfortunate because the swine flu vaccine was a new vaccine. It was developed because of the threat of a potential outbreak of an unusual strain of flu virus against which very few people had any natural immunity. When the new vaccine was tested in people no unexpected adverse reactions occurred. After mass inoculations began, however, some people receiving the shots, about one out of 110,000, developed a paralytic illness known as Guillain Barré syndrome. Discovery of this rare and unexpected reaction caused the inoculation program to be discontinued.

In contrast, measles, polio, rubella, and DPT shots have been in use for many years, and millions of people throughout the world have taken them with very few serious adverse reactions. For example, although mild and transient reactions to rubella vaccine have been reported in up to 15 percent of recipients, no serious or permanent injuries have been traced to use of the vaccine. More than 80 million doses of measles vaccine have been administered since 1963, with serious reactions possibly associated with the vaccine reportedly occurring, at most, only once for every million doses. These few reactions are unavoidable and

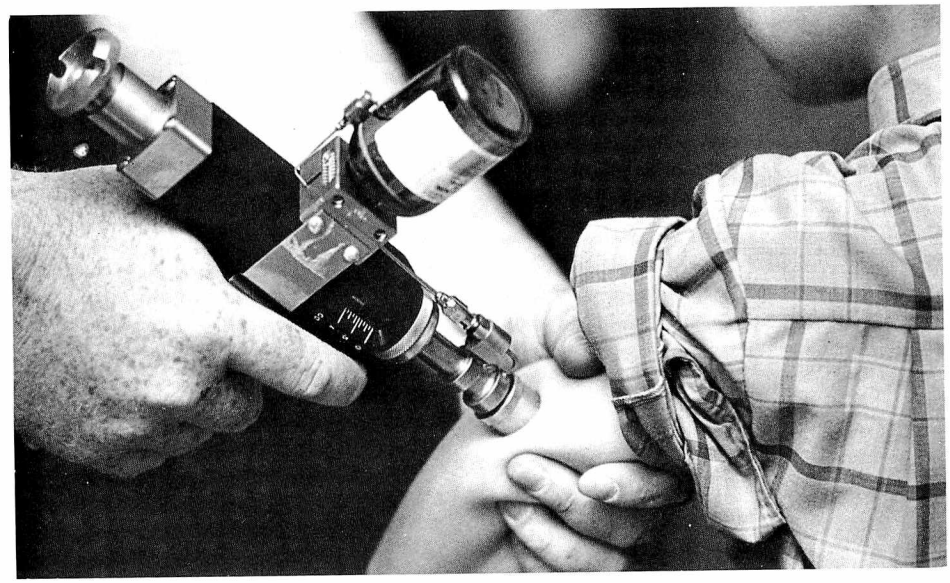


To obtain maximum immunity to the preventable childhood diseases, children must receive the full range of recommended shots at the proper ages.

health authorities believe they may be due to characteristics of the individual rather than to any characteristic of the vaccine.

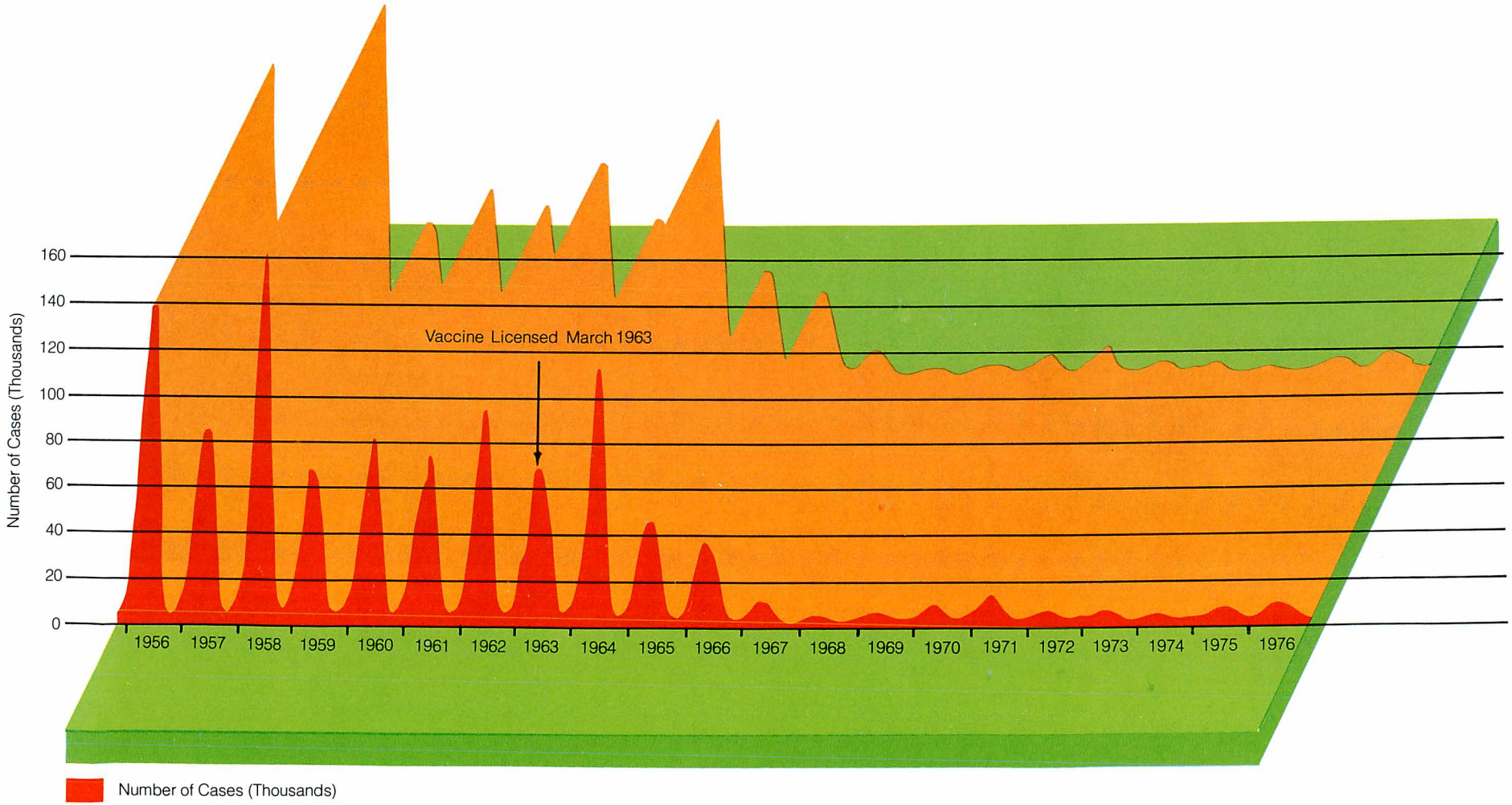
FDA's Bureau of Biologics routinely tests samples of every lot of these vaccines for safety and potency before they are released for general use. And these vaccines are 85 to 95 percent effective against diseases that have caused epidemics in the past.

Money is another factor influencing levels of immunity against childhood diseases. The most significant rates of decline in immunity levels are among the poor. For example, in one community surveyed, only 42 percent of children entering school from lower income families had been vaccinated against measles compared to more than 85 percent of children from middle and upper income families. Many poor families can't afford to go to private physicians, and routine immunizations are not generally given in hospital emergency rooms, a major source of health care for economically deprived children. Although every major city has at least one clinic where free immunizations can be obtained, many

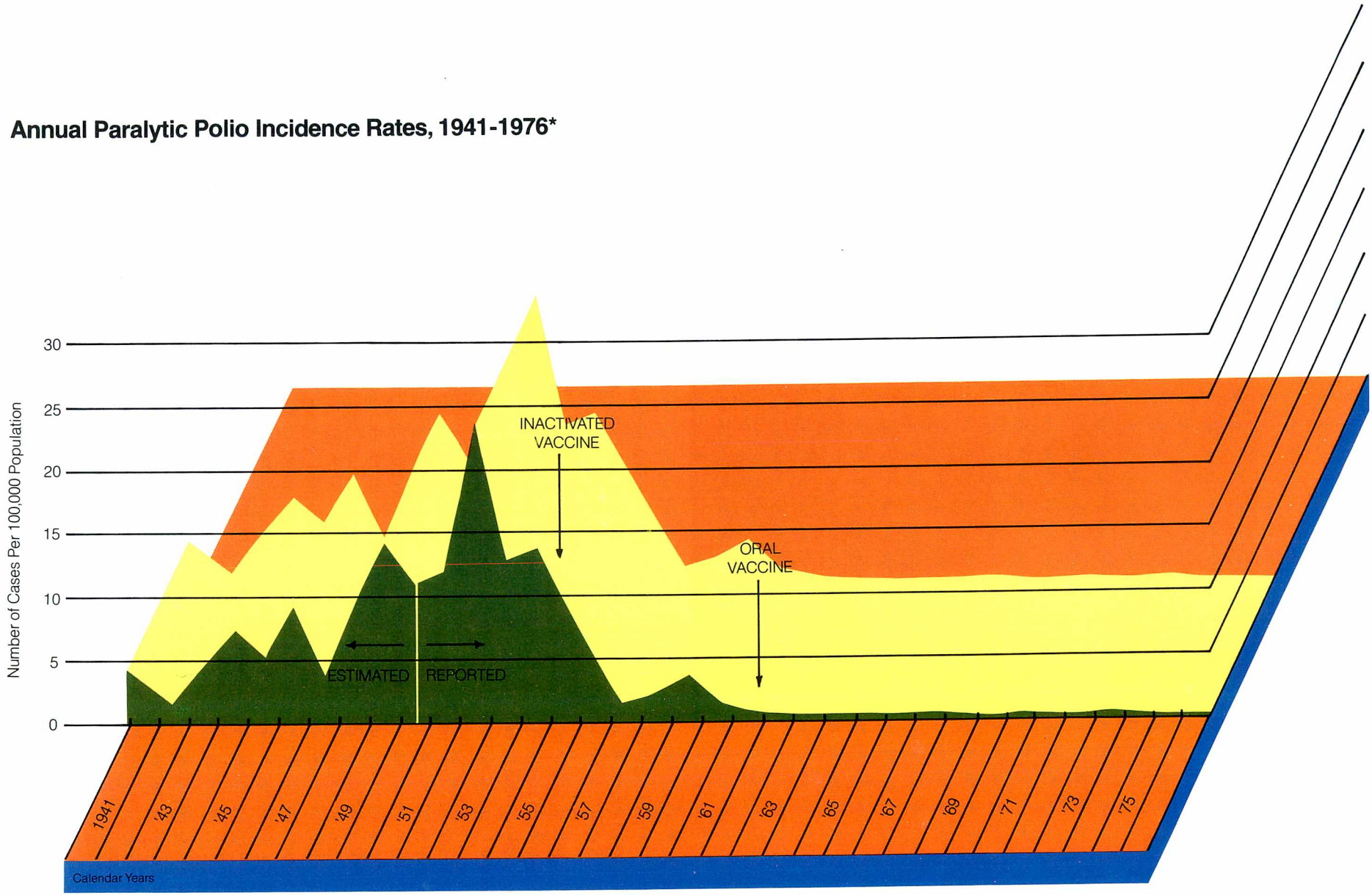


Inoculations cause little pain and can be given quickly when jet injection devices are used.

Cases of Measles by Four-Week Periods, 1956-1976



Annual Paralytic Polio Incidence Rates, 1941-1976*



Number of Cases Per 100,000 Population
*Provisional Data (1976)

For the years 1964 to 1976, the actual number of paralytic polio cases reported each year ranged from 7 to 106.

Technicians at a major biological firm prepare cell cultures used in the production of a vaccine that protects children against measles. Every lot of vaccine must be tested by FDA for safety and potency before it is released for general use.

people do not go to such clinics because of inconvenient location or clinic hours, or because they don't know about them.

State and local health agencies for the past several years have been greatly troubled by shifting levels of Federal financial support for immunization activities and therefore have had difficulty in making vaccinations easily available to low income families. Direct Federal support for immunizations has varied from $17 million in 1970 (when the entire amount was earmarked for rubella immunizations) to $4.9 million for all childhood immunizations in fiscal year 1976. As a result, health agencies have encountered problems in planning immunization programs and in giving them the emphasis they deserve.

The Department of Health, Education, and Welfare (HEW) is now engaged in a coordinated effort to remedy the problem of declining immunity against preventable childhood diseases. In April of this year, Secretary of Health, Education, and Welfare Joseph A. Califano, Jr., launched a national campaign to obtain immunization of 90 percent of all children against measles, polio, rubella, diphtheria, tetanus, and pertussis. The goal is to reach this level by October of 1979. HEW also plans to establish a permanent system to provide comprehensive immunization services for the three million children born each year.

To deal with some of the problems that have contributed to the decline in inoculations, HEW is planning a public information program directed at parents to make them aware of the risks of inadequate immunization against childhood diseases. A $106,000 contract has been established by HEW for the preparation and mass distribution of public information materials on the importance of maintaining immunizations. This material will be furnished for use by radio and TV stations, magazines, on billboards and buses. HEW also is preparing a booklet for consumers on vaccine-preventable diseases.

Secretary Califano has sent letters to the Nation's major corporations and unions asking them to initiate education campaigns among their employees and members. He has asked those organizations and citizens with special access to the urban and rural poor to assist in reaching and educating the parents of children who live in these areas. Public assistance programs also will be used to reach some 11 million mothers and children on welfare to urge them to participate in immunization activities.

The U.S. Office of Education has urged key State and local school officials to see that State laws requiring immunization of children entering school are enforced. In States where such laws do not exist, school officials are being asked to review the immunization status of school children and to provide immunizations through the schools to children lacking them.

Experience has shown that working through the schools can have a significant impact on reducing the number of unimmunized children. In April of this year, Los Angeles County officials announced that all school-age children would be required to present evidence of having had measles or having been immunized against it to remain in school. Within a little more than one month, all but 3.5 percent of the more

Childhood Immunization Schedule

Check your health records to make sure your children have received all of their immunizations. All children need protection against polio, diphtheria, tetanus, pertussis (whooping cough), measles, rubella (German measles), and mumps. You can help your child build up immunity to these diseases with immunizations during childhood.

For some diseases, only one shot is needed. Other diseases require a number of immunizations and booster shots. A child who has received less than the recommended number of shots in a series only needs to make up the ones that were missed, regardless of the length of time elapsed. The only exception is the 5-year-old child who did not receive his DTP (diphtheria, tetanus, pertussis) booster when he was 18 months old. He does not need to make it up, but does need to receive the preschool booster. If your child does need any immunizations, contact your doctor or local health department today.

At This Age	Your Child Should Receive
2 months old	DTP immunization Polio immunization
4 months old	DTP immunization Polio immunization
6 months old	DTP immunization Polio immunization[1]
15 months old	Measles immunization[2] Rubella immunization[2] Mumps immunization[2]
18 months old	DTP immunization Polio immunization (If your child has not already received measles, rubella, and mumps immunizations, they are needed.)
4 to 6 years, before starting school	DTP immunization Polio immunization (If your child has not already received measles, rubella, and mumps immunizations, they are needed.)
Thereafter	Tetanus-diphtheria (Td) booster should be given every 10 years or following a dirty wound if a booster has not been given in the preceding 5 years.

[1] Some doctors give one additional dose when the child is six months old.
[2] Only one shot is needed. Some doctors combine these vaccines in a single injection.

than one million school children in the county had met the requirement.

There has been a substantial expansion of Federal funding for immunization programs. The 1978 HEW budget includes $23 million for this effort. State health officials, through whom these funds are channeled to local clinics, are being required by HEW to present detailed plans on how they intend to review the present status of immunizations in their States and territories and how they intend to reach the 90 percent immunization goal.

HEW is contracting with the National League of Nurses to establish a program for recruiting and organizing volunteers throughout the country to participate in the immunization program. These volunteers will be involved in four major activities: reviewing records to determine the immunization status of children in the community; working with community groups, such as the PTA, Red Cross, Jaycees, and women's clubs to promote public education on vaccine-preventable diseases; canvassing homes to locate unimmunized children and directing them to appropriate sources for care; and assisting in administering vaccines in community clinics.

Secretary Califano is urging other Federal agencies to commit resources from their budgets to help support inoculation activites, and some of the funds allocated to States for general maternal and child health care are expected to be used for immunizations.

Community health centers, day care centers, and Head Start programs are being urged to assist in the effort to identify children who need inoculations and to help obtain shots for them.

The cost of protecting a child against the major preventable childhood diseases is relatively small. Vaccines that can safely and effectively immunize one child against polio, measles, rubella, diphtheria, whooping cough, and tetanus can be purchased for a few dollars. The vaccines are available. And now there is a nationwide effort to make sure that the children will be too.

Faye Peterson is a staff writer with FDA's Office of Public Affairs.

Canless Canning With Food Pouches

by Harold Hopkins

FDA has given the go-ahead for the use of pouches to market heat-treated food. The pouches, made of plastic and metal foil, can be filled with food, sealed, and then subjected to the same high temperatures used commercially to sterilize foods now processed in metal cans. The new containers are a revolutionary development in food processing and marketing, according to some industry observers.

Will the can opener, which generations of gagwriters have called the most vital article in many American kitchens, go the way of other utensils of yore that are now junk or antiques?

Probably not, but at least some of those foods that traditionally come in cans or jars or frozen food packages are likely to begin appearing on the market soon in a kind of package that's entirely new to American consumers.

Two companies which got the word from FDA recently that the Agency has no objections to their plans to market a new type of food container are now readying the so-called retortable pouch for marketing.

These pouches, made of plastic and metal foil, will be sold to food processing companies for commercial heat-treating and marketing of foods. The pouches can be filled with food, sealed, and then subjected to the same high temperatures used commercially to sterilize foods as is now done in metal cans. Some trade reports say the unusual containers will bring a revolution in food processing and marketing techniques, beginning perhaps before the end of this year.

Neither the idea for them nor the pouches themselves are brand new. Retortable pouches have been used to market heat-treated commercial foods in Japan, Canada, and Europe for some time. But in this country compa-

nies that have sought to develop pouches suitable for processing and marketing food have until now been unable to satisfy FDA as to the safety of the containers.

The safety question that delayed approval of the earlier pouches arose because chemical substances migrated into the food from the adhesive used to laminate these pouches. The regulation providing for use of the adhesive specified that there be a functional barrier between the adhesive and foods; there was no functional barrier in these pouches. The functional barrier requirement is intended to ensure that there is no migration of potentially harmful adhesives into food packaged in a pouch. Without a functional barrier, substances whose toxicity has not been adequately studied could migrate to food.

The two companies now preparing to market pouches got FDA permission to do so by using an adhesive made from material that already had been approved by FDA for use as a film coat on the interior wall of regular metal food cans. In effect, the FDA regulation permitting use of the can coating also will serve for the pouch material. FDA's go-ahead thus was given with the knowledge that the use of this material in pouches would be at least as safe as its use in cans. The Agency simply told the companies it would raise no objections to their pouches under the proposed conditions of use.

The two companies, Reynolds Metals and the Continental Group, were both careful not to identify publicly the exact formula they proposed to use, taking the position that this is a trade secret. FDA is prohibited by law from disclosing legitimate trade secrets to the public. This gives the two companies at least a temporary competitive advantage over other packaging companies seeking FDA approval of their own respective versions of retortable pouches.

There are a number of reported advantages in using pouches instead of cans to contain foods, some more obvious than others.

The main advantage is said to be better flavor because a pouch does not have to be heat treated by the manufacturer as long as a can to sterilize the food in it.

Pouches also may be more convenient. Consumers can heat an unopened pouch in a pan of water and if for some reason the food is not needed the unopened pouch can be returned to storage at room temperature. Food may be eaten directly from the pouch if desired. Pouches can be used for individual food portions and several pouches of different products can be included in a single pack. Single portions in bags can be served in restaurants, vending machines, hospitals, schools, and on airlines. The military services will be ordering rations in retortable pouches.

Other advantages mentioned, in comparison with cans and jars, concern reduced weight or volume or both. Retortable pouches weigh less than cans or jars and empty pouches require considerably less storage space at a food processing plant than do empty cans or jars. In addition, some types of food may require less space in a pouch and the packaged product may weigh less because of the reduction or elimination of water as a packing medium. Retortable pouches require less packing water than cans because the flexibility of the pouch lets it contour itself to fit the solid food within.

These advantages reportedly will make possible considerable savings in energy, transportation, and storage costs. In competition with frozen foods, the containers would also eliminate the need for refrigeration, resulting in energy savings, it's claimed.

Under the Food Additive Amendments to the Food, Drug, and Cosmetic Act, FDA is responsible for assuring the safety of foods containing additives, either direct additives put into food to accomplish certain functions, or indirect additives that may find their way into food during some stage of processing, storage, or transportation, or from packaging materials.

Indirect additives, such as those that may migrate from the food packaging into the food itself, are permitted by law if FDA is assured that their use accomplishes the manufacturer's intended purposes, that the migrating substances will have no functional effect on the food, and that they are safe in the amounts in which they may migrate into the food.

Therefore, manufacturers who propose to use retortable pouches containing a material that has not already been approved by FDA for use under similar conditions must petition FDA for a regulation specifying that the material can be used and the conditions of use.

FDA approval is still pending for proposed retortable pouches made with adhesive materials not previously approved by the Agency for use in situations where heat processing may cause traces of the adhesive to migrate to food. Manufacturers proposing to use such materials are conducting feeding studies of these adhesives in laboratory animals to provide FDA with the information it needs to determine whether the substances are safe for use.

Most of the retortable pouches now being tested by manufacturers consist of metal foil laminated between inner and outer plastic layers. The outer plastic layer protects the pouch from tearing, the foil provides a barrier to both light and gas penetration, and the inner plastic layer provides a heat sealable food contact surface.

The pouches can be opened by cutting with scissors or other sharp instruments. Most of them will have tear notches where they can be torn open to get at the contents.

Harold Hopkins is editorial director of FDA CONSUMER.

News Highlights

Poster Warns Public on Laetrile

The Food and Drug Administration has launched a poster campaign to warn the public about the dangers of Laetrile.

Laetrile, a substance made from ground up apricot or other fruit pits, is sold as a drug or as a "vitamin" and promoted nationally as a preventive or treatment for cancer. There is no evidence that Laetrile has any therapeutic or nutritional value.

The campaign involves the use of a warning message signed by the FDA Commissioner and posted in Federal and State buildings, in post offices, and in other public places.

In addition, FDA is mailing copies of the posters to nearly one million health professionals in the FDA DRUG BULLETIN. The BULLETIN will encourage health professionals to display the posters wherever cancer victims and their families are most likely to see them.

Donald Kennedy, Commissioner of Food and Drugs, said: "Our purpose is to bring to public attention as forcefully as we can the message that Laetrile is a true public health hazard.

"Our first concern is for patients with treatable cancer who delay or give up regular medical treatment and take Laetrile instead. Cancer is a progressive disease, and the time lost while patients experiment with Laetrile can mean the difference between life and death. We are increasingly learning from cancer specialists of patients who are coming to therapy too late or who have rejected established treatment altogether in favor of Laetrile.

"Further, I am concerned about the quality of the Laetrile now being imported and sold in this country. Laetrile is not routinely subject to FDA inspection, as are all approved drugs. The poster points out that we have found some Laetrile contaminated with toxic substances and some ampoules (for injection) with mold and other adulterants.

"The proponents of Laetrile say it is harmless; we want the public to know it is not. The public should know that Laetrile contains cyanide, a deadly poison. We know of 17 deaths caused by ingestion of Laetrile ingredients, including one infant who died after accidentally swallowing fewer than five Laetrile tablets.

"I feel strongly that FDA must make this further effort to discourage cancer victims from using this ineffective and dangerous drug, and to rely instead on proven therapies provided by reputable physicians," Dr. Kennedy concluded.

The poster (see inside back cover of this issue of FDA CONSUMER) encourages cancer victims to consult their physicians or to write to FDA for further information. The address is Food and Drug Administration, HFG-20, 5600 Fishers Lane, Rockville, Maryland 20857.

Hearing Set on Curbs on Amphetamine Use

The Food and Drug Administration will hold a public hearing December 2, 1977, on actions planned by the Agency to further curtail the abuse of amphetamine drugs.

Amphetamines are a class of prescription drugs primarily used for weight reduction and as "pep" pills. Less common uses are for the treatment of narcolepsy (a rare condition of uncontrollable sleepiness) and for minimal brain dysfunction (hyperactivity) in children.

There is increasing evidence that amphetamines remain subject to considerable abuse, even though stringent Federal controls have reduced the amount that can be legally manufactured by as much as 80 percent below that of the peak production year of 1965.

To deal with the continuing abuse problem, FDA is considering a three-pronged approach that would:

- Revoke approval of the drugs for use in weight control. About 88 percent of legal medical use of these drugs is for control of obesity, even though amphetamines are approved only for short term obesity control, have limited effectiveness for this purpose, and alternative drugs have less potential for abuse.
- Retain the use of amphetamines only for treatment of narcolepsy and minimal brain dysfunction.
- Require preparation of a special patient brochure for amphetamines to explain their limited usefulness and warn about their serious potential for abuse and for physical harm from overuse. The brochure would be distributed with every prescription.

If FDA revokes approval for obesity control the Drug Enforcement Administration (DEA) in the Department of Justice could lower still further the amount of the drugs that can be legally manufactured. Under the Controlled Substances Act DEA sets production limits for all drugs that, like amphetamines, are medically useful but have serious potential for abuse.

FDA announced last year it would consider taking action against amphetamines if studies documented a continuing and serious abuse problem. Since then, FDA has received considerable data from DEA and the National Institute on Drug Abuse on amphetamine abuse. The evidence indicates that amphetamines continue to be the most seriously abused of all appetite suppressant drugs.

FDA has for a number of years supported strong controls over amphetamines. In 1972 an expert advisory committee determined that amphetamines made only a "trivial contri-

bution" to weight reduction programs, and FDA immediately tightened physician labeling to reflect this judgment and to highlight the potential of the drugs for abuse.

The hearing will be held on December 2, 1977, beginning at 9 a.m., in Conference Room E, Third Floor, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

FDA Acts to Control Aflatoxin Problem

FDA is taking special precautions to protect consumers from potential hazard that could result from unusually severe aflatoxin contamination of the 1977 corn crop in the Southeastern United States.

Aflatoxin is a poisonous chemical produced by certain molds that grow on corn and other grains. In addition to being toxic, aflatoxin has caused cancer in experimental animals and there is evidence that consumption of aflatoxin-containing foods is associated with liver cancer. Corn (or corn products) that contains more than 20 parts of aflatoxin per one billion parts of corn (20 ppb) is considered contaminated by FDA and is not permitted to be shipped in interstate commerce.

Although the Southeast is expected to contribute only about 3 percent of the total U.S. corn crop this year, indications are that in several States in the region more than half the crop will be unmarketable due to aflatoxin in excess of FDA's 20 ppb action level.

FDA is first concerned that high aflatoxin corn not be milled into cornmeal or other human food. It has instituted a program to examine corn products intended for human consumption, such as cornmeal, moving in interstate commerce and to remove from the market any found to contain over 20 ppb aflatoxin.

FDA also has implemented a program to sample market milk and eggs from the Southeastern United States to determine the levels of aflatoxin in the milk and egg supply.

It appears that most of the corn grown in the Southern States does not move in interstate commerce and the problem is primarily one of control within each of the involved States. Some of this corn, however, is normally exported. FDA is monitoring this corn and if it contains over 20 ppb aflatoxin the Agency will advise the country to which it is being exported. If the receiving country wishes to accept the corn, FDA will not prevent shipment.

FDA's 20 ppb action level for aflatoxin in corn applies whether the corn is intended for direct human use (such as for cornmeal) or for animal feed use.

Human exposure to the aflatoxin present in the 1977 corn crop can occur in two ways. The first is through direct consumption of products made from corn. Only dry-milled corn products such as cornmeal and corn grits are of concern, since refined corn oil, fresh (sweet) corn, and the human products prepared from wet-milling of corn (e.g., corn starch) do not contain aflatoxin even if they are prepared from contaminated raw material. In these cases aflatoxin is removed or destroyed during processing.

A second possible route of exposure is through consumption of meat, milk, and eggs from animals that may have eaten aflatoxin-contaminated corn. Because most ingested aflatoxin is excreted by such animals, the levels of aflatoxin expected in meat, milk, and eggs are generally well below the level present in ingested feed. However, because of the importance of meat, milk, and eggs in the human diet and because infants and young children may be more susceptible to the effects of aflatoxin, there is a need to control this route of exposure by limiting the level of aflatoxin in corn used for animal feed. About 80 percent of corn is used for animal feed.

It has been known for more than a decade that under some conditions aflatoxin can contaminate certain foods and feeds produced and consumed in the United States. Because of the possible human health effects of this substance, FDA considers aflatoxin contamination of food a significant public health problem, and has established regulatory controls to limit exposure to the extent possible.

Complete elimination of aflatoxin from susceptible commodities such as corn, peanuts, and tree nuts is not now possible. Aflatoxins may contaminate foods whenever environmental conditions are such as to favor growth of the producing molds. Favorable growth conditions can sometimes exist in the field while susceptible crops are growing. Such conditions can also be created when crops are improperly stored. In the latter situation, human intervention can correct the problem. In the case of field contamination, human action is largely ineffective in that insect damage, drought stress, the weather, and other as yet unknown factors can create conditions under which mold growth and aflatoxin production can occur.

Diabetes Drug Removed From Market

The diabetes drug phenformin has been removed from the market. The ban was effective October 23, 1977.

This action is the final step in carrying out an order issued July 25, 1977, by Secretary Joseph A. Califano, Jr., of the Department of Health, Education, and Welfare.

All physicians and pharmacists were directly notified by the Food and Drug Administration about the phenformin action shortly after the July 25 order was issued. Doctors were advised to begin switching patients to other therapies. A reminder notice has been mailed to health professionals.

Secretary Califano's order was based on evidence that phenformin is associated with lactic acidosis, an uncommon but serious side effect that occurs in perhaps as many as 4 per 1,000 users of the drug each year. About half of the patients who get lactic acidosis die from it and this degree of risk is higher than was judged acceptable.

The Secretary's order was issued under the "imminent hazard" provision in the Food, Drug, and Cosmetic Act, the first time that this provision has been used.

The manufacturers of the drug, Ciba-Geigy (which sells it under the brand names DBI and DBI-TD) and USV Pharmaceuticals (which uses the brand name Meltrol), have been asked by FDA to recall stocks from pharmacies.

FDA advises diabetics who have questions about the discontinuance of this prescription drug to contact their physicians. Alternative therapies are available. Diabetics who still have a supply of the drug should not stop taking it before contacting their physicians.

FDA has tried repeatedly to work out with the two companies and the medical profession a restricted distribution system under which the drug could continue to be marketed for those few patients for whom insulin poses

special hardships and for whom the benefits of phenformin might continue to justify the risk involved.

No arrangement could be found that was acceptable to FDA, the manufacturers, and the American Medical Association. Phenformin, therefore, is no longer being marketed and outstanding stocks have been recalled.

Ciba-Geigy and USV have not agreed to sponsor Investigational New Drug Applications(IND's) under which phenformin might be supplied directly to individual physicians for those few patients who may meet the previously announced criteria for phenformin use. The FDA is considering an alternative approach under which individual physicians may obtain their own IND's for this purpose, and Ciba-Geigy has agreed to ship the drug to physicians who have submitted an acceptable IND to FDA. Physicians with patients meeting the criteria may obtain additional information from FDA's Bureau of Drugs by calling (301) 443-3490.

FDA Proposes Trichloroethylene Ban

The Food and Drug Administration has proposed to ban the chemical trichloroethylene (TCE) from foods, drugs, and cosmetics.

The substance has been shown to cause liver cancer in mice, according to tests by the National Cancer Institute (NCI).

TCE once was widely used to remove caffeine from coffee. When a preliminary alert on the NCI study became public in 1975, the manufacturers of decaffeinated coffee voluntarily stopped using it.

TCE also has been used to extract flavorings from hops to enhance the taste of beer, in the production of spices, and in the manufacture of food-packaging products. To FDA's knowledge, TCE is no longer used in the beer manufacturing process, and only trace amounts have been found in spices and food packages. For all these uses, there are alternative chemicals that can be substituted.

In drugs TCE once was used as a painkiller and anesthetic, for use by inhalation. FDA knows of no currently marketed drug products containing TCE.

TCE is currently being used as a solvent in a small number of cosmetic products. Suitable substitutes are also available.

FDA allowed 60 days for comment on the proposals, and intends to issue final regulations no later than 60 days after the comment period ends.

The proposals appeared in the FEDERAL REGISTER September 27, 1977.

Hearings Set on Net Weight Labeling Rules

Commissioner of Food and Drugs Donald Kennedy will hold two public hearings about the possible need for FDA to modify certain net weight labeling regulations.

The hearings will be at the San Francisco State Building, 455 Golden Gate Avenue, on December 8, and at the Sheraton-Biltmore Hotel, 817 W. Peachtree Street, N.E., Atlanta, on December 15, starting at 10 a.m.

At issue is an FDA regulation that makes it acceptable for a package of food to weigh slightly less than the amount stated on the label, if the reason for the lower weight is that the product has lost moisture after it was shipped. A product such as flour, which ordinarily contains 13 to 14 percent moisture at the time of packaging, may lose moisture if shipped to a dry climate, and may gain moisture if shipped to a humid climate.

California had regulations which made no allowance for gain or loss of moisture during distribution. The State therefore required that the weight of the package at retail must be no less than that declared on the label. The U.S. Supreme Court earlier this year ruled that the Federal regulation pre-empted California's.

Since then, many State and local agencies and a consumer group have written to FDA asking it to amend the Federal regulations to require accuracy at the time of retail sale, without provision for moisture loss.

Court Refuses to Block Hearing Aid Rules

The U.S. Court of Appeals of the District of Columbia has upheld a decision of a lower court to deny a request for a preliminary injunction to stay FDA's hearing aid regulations. This means that the hearing aid regulations continue to be in effect.

A suit seeking a permanent injunction, which was brought by the American Speech and Hearing Association, still is active, however, in the lower U.S. District Court. FDA has asked the U.S. Attorney's Office to seek dismissal of the suit on the grounds that it is without merit.

The new regulation forbids the sale of a hearing aid to any patient who does not have a statement from a physician saying that an aid may help. The examination on which the physician's statement is based must have taken place within six months before the purchase of an aid. Buyers 18 years of age and older may waive the requirement for the medical evaluation but the regulation forbids hearing aid dispensers from encouraging them to do so.

The regulation also established labeling requirements for hearing aids.

The Speech and Hearing Association has sought the injunction against the hearing aid regulations so it could present further arguments to FDA in an effort to modify the rules.

Comment Time Extended on Penicillin in Feed

FDA has extended the comment period on its proposal to prohibit the routine addition of penicillin to animal feeds until November 28. The period was to have ended September 29.

Senator John Tower asked for the extension because the Council on Agricultural Science and Technology, which is conducting research on antibiotics in animal production, will not complete the studies until late October and the Senator felt this information should be evaluated by FDA along with other comments.

Small amounts of penicillin are added to animal feed to help food-producing animals gain weight faster and to protect them from disease. FDA wants to end this routine use of penicillin because it presents the risk that bacteria in the animals which eat the feed gradually will develop resistance to the antibiotic. This resistance can be transferred to bacteria in people, and if that happens penicillin and other antibiotics used as medical treatments in people will become less effective.

Regional Reports

"Regional Reports" consists of important information on inspections, product seizures, court proceedings, and other regulatory and administrative actions initiated by FDA's regional and district field offices across the country to provide protection to consumers under Federal laws. "State Actions," the section immediately following "Regional Reports," consists of similar information about the consumer protection activities of State and local governments.

REGION I

Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

A U.S. marshal seized over $3,500 worth of almonds at a Boston candy manufacturer because of aflatoxin contamination and labeling violations. Aflatoxin is a toxic substance produced by certain molds. The seizure was part of a surveillance program by FDA's **Boston District** in which samples were collected at the Boston firm and found to be contaminated and mislabeled. The almonds were shipped by Kane International Corp, New Jersey.

A deputy U.S. marshal supervised the destruction of 23 cases of Cramore lemon flavor crystals, manufactured by A-W Brands, Inc., Carteret, New Jersey, because they contained the food additive saccharin. Saccharin is prohibited when used in an alcoholic beverage base mix since that does not constitute a valid dietary use. The seizure and subsequent destruction resulted after samples collected at a wholesaler in New Haven, Conn.,by the Boston District revealed the product contained saccharin.

The Boston District detained over $124,000 worth of frozen shrimp, offered for import from Hong Kong, because of *Salmonella* contamination. The detention resulted from a routine dock inspection at the port of Boston by the Boston District.

REGION II

New Jersey, New York, Puerto Rico, Virgin Islands

U.S. marshals seized 24 drums of zinc undecylenate, valued at over $5,000 at the Lucidol Division of Pennwalt Corp., Buffalo, New York, after investigators from FDA's **Buffalo District** found the drug ingredient was produced under grossly insanitary conditions. The investigation further revealed that the zinc compound was being made from an agricultural grade raw material instead of the required pharmaceutical grade. Laboratory analysis confirmed that the drug was contaminated. The seized material had been intended for use in a topical ointment that would have been sold to the U.S. military services.

Four drums of potassium penicillin V, valued at almost $20,000, were seized by U.S. marshals in Syracuse, New York, bringing to a close a journey by the product that took two years and covered half the globe. The story began in 1975, when Bristol Laboratories, a division of Bristol-Myers, Syracuse, New York, sold a lot of penicillin to the Agency for International Development. Because the drug was destined for Vietnam, the Syracuse-based firm did not submit samples to FDA for certification, a procedure required for all antibiotics intended for domestic consumption, but not specifically demanded for exported drugs. While the drug was en route, Saigon fell to the North Vietnamese. The shipment was diverted and next turned up at an auction in Singapore, where it was purchased by White Laboratories and then sold to John D. Copanos and Co., Baltimore. Copanos used five drums of the original nine-drum lot to manufacture a penicillin oral suspension for Parke-Davis Laboratories, Detroit. At about this time Bristol Labs, the original manufacturer, submitted to FDA for certification a nine-unit sample taken from Bristol's single reserve container which had not been sold to AID. FDA refused to certify the drug Copanos had bought because the conditions of its storage and handling during its two-year odyssey were completely unknown, and moved to seize the four drums Copanos had shipped back to Bristol. FDA also informed Parke-Davis of the situation and that company then destroyed the oral suspension made by Copanos.

A trade complaint to FDA's Buffalo District about a magnetic bracelet which supposedly relieved leg cramps, arthritis, and headaches resulted in the detention of more than 20 bracelets by the Buffalo District at various post offices in the Buffalo area. The bracelets, manufactured by Magnetics, Inc., Toronto, Ontario, Canada, were detained because of false and misleading directions which claimed that they were effective for pain relief. Each shipment contained a bracelet and a booster magnet and was valued at $32. Customers were supposed to tape the magnet to the body or place it under the bed sheets for the desired results.

A lot of approximately 400 pounds of frozen fish was seized by the Federal Government at a cold storage warehouse in Englewood, New Jersey, because of mislabeling. Laboratory analysis of samples collected at the firm by FDA's **Newark District** during a routine inspection revealed the fish, labeled Carnation brand breaded flounder fillets, was actually Greenland turbot, a cheaper fish. The product had

been packed and labeled by Massachusetts Coastal Seafoods, Inc., Magnolia, Massachusetts, and was distributed by Seabrooks Foods, Inc., Seafood Division, Great Neck, New York.

REGION III

Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia

Schindler's Peanut Products, Inc., Baltimore, Maryland, has agreed to correct misbranding violations found at the firm by FDA's **Baltimore District** during a routine inspection. Investigators found that salted blanched peanuts and other products packaged in cellophane bags failed to conform to labeling regulations in that they did not contain ingredient statements. The firm agreed to correct the violations after it received a regulatory letter from the Baltimore District which pointed out the violations and requested prompt action be taken to correct them.

REGION IV

Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee

The Independent Wholesale Grocery Co., Kannapolis, North Carolina, and its responsible officials were fined $2,000 by the U.S. District Court for the Middle District of North Carolina for storing food under insanitary conditions. The fines resulted from separate inspections of the wholesaler by the North Carolina Department of Agriculture and FDA's **Charlotte Resident Post**. State inspectors reported to the FDA resident post that the firm had a history of insanitary conditions. Additional inspections and sample collections by FDA confirmed rodent and insect adulteration of nonfat dry milk, cake, pancake and hot cocoa mixes, flour, cereal, and egg noodles. The corporation was fined $1,000 and the president and general manager $500 each. In addition, each was placed on probation for one year.

An FDA investigator from the **Nashville District** witnessed the voluntary destruction of more than 400 dozen recalled or quarantined sutures by Lukens Sutures, Division of Ainsworth Corp., Nashville, Tennessee, because of FDA findings that the sutures were not sterile, as their labeling indicated. The destruction resulted from a followup of an inspection of the firm's manufacturing plant in St. Louis, Missouri, by investigators from FDA's St. Louis District. The Nashville District was asked by the St. Louis District to collect samples of the product from the firm's Nashville distribution facility. Subsequent analysis revealed the nonsterility problem and the recall and voluntary destruction followed.

A trade complaint to FDA's **Orlando District** from a firm in Princeton, Florida, about a drum of honey that did not look or taste like pure honey resulted in a seizure by the Federal Government at National Papaya Co., Tampa, Florida, of over 40,000 pounds of honey. Analysis of the honey at FDA's laboratory in Atlanta revealed that syrup had been substituted for part of the honey, which was valued at over $14,000 and subsequently was re-exported to Greece.

Lighthouse Wholesale Distributors, Inc., Miami, was fined $5,000 by the U.S. District Court for the Southern District of Florida for allowing rice, flour, grits, macaroni, and cake mix to become contaminated with rodent filth while being held for sale at the food warehouse. David Feinsilver, president, and Charles Markusfeld, vice president of the firm, were fined $500 each and placed on two years' probation. The legal action resulted from two inspections at the firm by FDA's Orlando District which revealed a continuing problem of rodent infestation.

REGION V

Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin

Cooperation between FDA's Cincinnati and Philadelphia Districts led to the recall of four lots of No Rinse brand shampoo, totaling 3,200 gallons, by its manufacturer, No Rinse Laboratories, Centerville, Ohio, because of bacterial contamination. A Philadelphia hospital complained to FDA's Philadelphia District that its supply of the shampoo was contaminated with *Pseudomonas* bacteria, pathogenic bacteria which can invade the body through a scratch or sore and result in infection. The Philadelphia District then notified the **Cincinnati District** which conducted laboratory analysis of samples obtained at the manufacturer and confirmed the shampoo was contaminated with the bacteria *Pseudomonas aeruginosa*. The shampoo is designed for hospital patients and invalids and for uses where wet shampooing is not possible or not desirable. It is applied directly to the hair and towel-dried without the use of water. The product was distributed nationwide and was marketed in 4-, 8-, and 16-ounce and one-gallon containers. All lots coded 7207 or lower were recalled.

REGION VII

Iowa, Kansas, Missouri, Nebraska

The Federal Government seized the entire stock of medicated feeds, drug premixes, and in-process feeds at Paul Skaggs and Sons, Fredericktown, Missouri, because of the firm's failure to comply with FDA's Good Manufacturing Practice Regulations. The mass seizure of the stock, which was valued at over $5,000, resulted from a series of inspections by FDA's **Kansas City District** at the firm. Among other violations, the inspection revealed failure to maintain clean equipment and to run laboratory controls; failure to keep grounds and facility in a suitable condition; and failure to maintain adequate production records and the inadequate handling of labels. Despite written warning by the Kansas City District, the firm failed to take corrective actions, thus prompting the seizure.

REGION IX

Arizona, California, Guam, Hawaii, Nevada

A deputy U.S. marshal, accompanied by an investigator from FDA's **Phoenix Resident Post,** seized 54 cases of Glow Goop, a novelty product, from the manufacturer, Imagineering, Inc., Phoenix, Arizona, because it contained zinc sulfide, a color additive not approved by FDA for use in cosmetics. The seizure resulted from an FDA investigation which was based on a consumer's complaint to the resident post that the ingredient in the product which caused it to glow when applied to the body might be harmful. The 54 cases were valued at over $1,700.

REGION X

Alaska, Idaho, Oregon, Washington

Middle East Bakeries, Inc., Portland, Oregon, has agreed in court to shut down its bakery until it can comply fully with FDA regulations. Inspection by FDA's **Seattle District** disclosed the firm was holding and preparing food under insanitary conditions. The firm's bread products, distributed in Oregon and Washington, are specialty items typical of those traditionally made in the Middle East. In entering into a consent decree of permanent injunction in the U.S. District Court for the District of Oregon, the firm and responsible officials agreed to establish an effective sanitation control program, clean and renovate its facilities and equipment, and select a qualified individual to be responsible for maintaining the facilities and equipment in a sanitary condition. The decree also requires that all foods stored within the facility be examined for filth. Contaminated food found must be either destroyed or otherwise brought into compliance with the Federal Food, Drug, and Cosmetic Act. The firm is permanently enjoined from distributing foods which are adulterated, which means, in effect, that if there are any further violations, the firm could be held in contempt of court.

A U.S. marshal in Seattle, Washington, seized over 5,000 pounds of decomposed salmon in the possession of City Ice and Cold Storage in Seattle. The seizure resulted from a report from the State Department of Agriculture to FDA's Seattle District which indicated the salmon might be decomposed. Trans Asiatic, Inc., Seattle, shipped the lot of salmon from Anchorage, Alaska, to Seattle where it was sampled by the Seattle District. Laboratory examination confirmed the product was decomposed. The lot is valued at $8,000.

A U.S. marshal in Boise, Idaho, seized approximately 6,400 pounds of rice in the possession of Norton Fruit Co., Idaho Falls, following an inspection by FDA's Seattle District which disclosed the rice was held under insanitary conditions. Subsequent laboratory analysis of samples collected during the inspection confirmed the rice was adulterated with rodent urine.

A lot of approximately 92,000 pounds of dehydrated potatoes was seized by the Federal Government at a distributor in Clearfield, Utah, because of bacterial contamination. The seizure resulted from an inspection of the manufacturer, R. T. French Co., Shelley, Idaho, by FDA's Seattle District which revealed through laboratory analysis that the potatoes contained *Escherichia coli,* excessive coliform bacteria, and excessive total bacteria. In addition, investigators found the potatoes were prepared, packaged, and held under insanitary conditions.

Approximately 80,000 pounds of potato flakes were seized by U.S. marshals at Magic Valley Foods Inc., Rupert, Idaho, following an inspection at the firm by FDA's Seattle District. FDA investigators found that the potato flakes were prepared, packed, and held under insanitary conditions. Subsequent laboratory analysis of samples collected also revealed that the potato flakes contained *Escherichia coli,* excessive coliform bacteria, and excessive total bacteria.

State Actions

Drug Firm Fined

The New York State Board of Pharmacy imposed a fine of $2,500 on Contract Pharmacal, a small drug manufacturer in Hauppauge, New York, for failure to follow good manufacturing practices in the production of prescription and nonprescription drugs. Violations discovered during a routine inspection by FDA's New York District included lack of a stability testing program, lack of standard procedures, and lack of documentation that the plant performed the required double-checks on added ingredients. FDA referred the findings to the State agency, which performed followup investigations, reviewed the firm's history of repeated violations, and imposed the fine. FDA also referred reports on two other small drug firms to New York State. Lewfer Drug Products Co., Long Island City, and Plastodent Inc., Bronx, both of which make cosmetics and prescription drugs, were each fined $250 for failure to maintain adequate drug manufacturing records.

Candy Bars Embargoed

The North Carolina Department of Agriculture embargoed an estimated 10,000 candy bars at the Stokes Distributing Co., Roanoke Rapids, North Carolina, because of insect contamination. The embargo ensued following a joint inspection of the firm by the State Department of Agriculture and FDA's Atlanta District which revealed extensive live insect infestation of over 30 brands of candy. The State is supervising the reconditioning of the stock.

Contaminated Food Seized

Cooperation between FDA's Denver District and the Colorado Department of Health resulted in a mass seizure by the Federal Government of various foods at Shetakis Wholesalers of Colorado, Inc., a Denver firm supplying food principally to institutions. Investigators found during a joint inspection that the food which included rice, pancake mix, and dehydrated potatoes, was contaminated with insects and held under insanitary conditions.

Seizures and Postal Service Cases

SEIZURE ACTIONS charging violation of the Federal Food, Drug, and Cosmetic Act are published when they are reported by the FDA District Office.

A total of 33 actions to remove from the consumer market products charged to be violative was reported in September. These included 21 seizures of foods: 1 involved charges concerning poisonous and deleterious substances, 13 involved charges concerning contamination, and 7 involved charges concerning economic and labeling violations. Others included 6 of food additives and 6 of drugs (including 2 of veterinary).

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
	FOOD/Poisonous and Deleterious Substances	
Apricot kernels, ground apricot kernels, and in-process amygdalin materials (white powder & gelatin capsules)/ Manitowoc, Wis. 5/16/77	Mosinee Research Corp., U.S. Pharmaceuticals, Inc./Manitowoc, Wis. (D)	Contain the poisonous or deleterious substance hydrocyanic acid (hydrogen cyanide); articles unfit for food; and lack adequate directions for use and are not exempt, since they are new drugs without effective approved New Drug Applications, and since they lack adequate information for use by licensed practitioners.
	Contamination, Spoilage, Insanitary Handling	
Coffee beans/New Orleans, La. 7/25/77	Hansen & Tidemann, Inc./New Orleans, La. (D)	Held under insanitary conditions.
Conch meat/Newark, N.J. 6/22/77	Shore Shell Fish, Inc./New York, N.Y. (S)	Contains decomposed conch meat.
Flour and cornmeal/Meridian, Miss. 5/ 10/77	Hasson Grocery Co., Inc./Meridian, Miss. (D)	Held under insanitary conditions; rodent contaminated.
Laver, dried, seasoned, and dried nori seaweed/Honolulu, Hawaii 6/28/77	Shira Kiku Hawaii, Inc./Honolulu, Hawaii (D)	Packed under insanitary conditions whereby they might become injurious to health; labeling is false and misleading since it fails to state that containers also hold a package of desiccant which is not appropriate as food and should not be eaten.
Marjoram and basil/Brooklyn, N.Y. 5/ 12/77	Gel Spice Co., Inc./Brooklyn, N.Y. (D)	Held under insanitary conditions; marjoram contains insects.
Pepper strips, sweet red and green, canned/Oneida, N.Y. 5/5/77	Suzy Bel Canning Co., Inc./Port Elizabeth, N.J. (M,S)	Prepared, packed, and held under insanitary conditions.
Potato flakes/Rupert, Idaho 6/24/77	Magic Valley Foods, Inc./Rupert, Idaho (M,S)	Prepared, packed, and held under insanitary conditions; contains *E. coli* and bacterial filth.
Skim milk powder/Christiansted, St. Croix, V.I. 7/29/77	Island Dairies, Inc./Christiansted, St. Croix, V.I. (D)	Held under insanitary conditions; rodent gnawed.
Sugar; textured vegetable protein; canned pitted cherries/Richmond, Va. 6/10/77	Finer Foods Sales Co., Inc./Richmond, Va. (D)	Sugar and textured vegetable protein held under insanitary conditions; textured vegetable protein rodent contaminated; cherries unfit for food.
Vegetables, mixed, canned, Dainty Pak/ Oakland, Calif. 6/14/77	Rossville Packing Co./Rossville, Ill. (S)	Unfit for food, since contained in corroded, swollen, and leaky cans.
Vegetarian "meat" (Mock Chicken)/ Sausalito, Calif. 7/8/77	Sohensha Co., Ltd./Yokohama, Japan (S)	Contain insects, mites, and feather barbules.
Vegetarian "meats" (Mock Abalone and Mock Chicken)/Sausalito, Calif. 5/12/77	"	"
Whey solids/Atlantic City, N.J. 6/9/77	Superior Bakers, Inc., t/a Ginsburg's Bakery/Atlantic City, N.J. (D)	Held under insanitary conditions; rodent contaminated.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
	Economic and Labeling Violations	
Dairy powder, chocolate-flavored/Norfolk, Nebr. 6/8/77	Consolidated Flavor Corp./Bridgeton, Mo. (M,S)	Chocolate-flavored dairy powder made with cocoa and carob was substituted for chocolate-flavored dairy powder made with cocoa.
Charleston, S.C. 6/15/77	"	"
Flounder fillets, breaded, Carnation/ Brooklyn N.Y. 7/6/77	Coastal Seafoods, Inc./Magnolia, Mass. (P)	Turbot fillets have been substituted for flounder fillets.
New York, N.Y. 7/15/77	"	"
Magnolia, Mass. 6/9/77	"	Turbot substituted for flounder fillets; turbot offered for sale under name of flounder; false and misleading labeling due to representation that the fish in the article is flounder; and lack common or usual name, since "flounder" is not the common or usual name for turbot.
Nuts, mixed/Grand Rapids, Mich. 6/23/ 77	Thrift Products Co./Grand Rapids, Mich. (D)	Fails to conform to standard of identity for mixed nuts.
Sorghum syrup, Racoon Mountain/ Chattanooga, Tenn. 6/6/77	Racoon Mountain Syrup Co./Pisgah, Ala. (M,S)	Fails to conform to standard of identity for sorghum syrup, since it contains corn syrup.
	FOOD ADDITIVES	
Ginseng capsules/Largo, Fla. 5/16/77	R. P. Scherer Corp./Detroit, Mich. (M,S)	Contains the nonconforming food additive ginseng.
Lemon flavor mix with egg white, Cramores Crystals/Carteret, N.J. 6/9/77	A-W Brands, Inc. (Cramore Products, Inc.)/Carteret, N.J. (M)	Contains the nonconforming food additive saccharin and the saccharin is not for a valid special dietary purpose, since the product is intended as a mixer for alcoholic beverages.
Newburgh, N.Y. 6/24/77	A-W Brands, Inc. (Cramore Products, Inc.)/Carteret, N.J. (M,S)	"
New Haven, Conn. 6/30/77	"	"
Ribonucleic acid tablets/Los Angeles, Calif. 5/18/77	Continental Vitamin Co., Inc./Los Angeles, Calif. (D)	Contains the nonconforming food additive ribonucleic acid; false and misleading claim "One tablet daily as a food supplement" represents that the article is a significant and nutritionally valuable adjunct to the daily diet; label lacks complete address of distributor; required label information lacks conspicuousness; and label lacks common or usual name for ingredient "meat flour."
Vitamin B_{12} and ribonucleic acid combination tablets/Compton, Calif. 6/10/ 77	I. D. Co./Compton, Calif. (D)	Contains the nonconforming food additives ribonucleic acid (RNA) and deoxyribonucleic acid (DNA).
	DRUGS/Human Use	
Cyanocobalamin injection and Ferroway liver injection/Dearborn, Mich. 7/29/77	D-M Pharmaceuticals, Inc./Rockville, Md. (M,S)	Circumstances of products' manufacture, processing, packing, and holding not in conformity with current good manufacturing practice.
Dioctyl sodium sulfosuccinate capsules/ Blairsville, Ga. 6/11/77	Pharmacaps, Inc./Elizabeth, N.J. (M,S)	Strength differs from standards set forth in an official compendium, since it is subpotent.
Progesterone vaginal insert tablets/Kirkwood, Mo. 7/25/77	Kirkwood Drug Co./Kirkwood, Mo. (D); Private Formulae, Inc./St. Louis, Mo. (M)	Labeling fails to bear adequate directions for use, and it is not exempted, since there is no effective approved New Drug Application.
Quinidine sulfate tablets/St. Louis, Mo. 4/25/77	Alpha Pharmacal, Inc./St. Louis, Mo. (M); California Retired Persons Pharmacy/Long Beach, Calif. (S)	New drug without an effective approved New Drug Application.
	DRUGS/Veterinary	
Comfrey Leg-Gel salve/Canby, Oreg. 6/ 23/77	Western Comfrey, Inc./Canby, Oreg. (D)	New animal drug and no New Animal Drug Application is in effect with respect to its use and intended use.
Furazolidone medicated premixes/Modesto, Calif. 6/27 & 7/20/77	Rhodia, Inc. (Hess & Clark Div.)/Ashland, Ohio (M,S)	New animal drugs and no New Animal Drug Applications are in effect with respect to the use and intended use of such drugs.

U.S. POSTAL SERVICE

actions taken in medical cases as authorized in the Mail Fraud Statute (18 U.S.C. 1341) and/or the False Representation Statute (39 U.S.C. 3005) as reported by the Chief Postal Inspector.

Complaints Filed by Law Department Under 39 U.S.C. 3005 (False Representation)

August 31, 1977: **Nutranail,** 521 Fifth Avenue, Suite 803, New York, New York. Advertising and sale through the mail of the product "Nutranail," representing the ability of vitamins to increase nail growth.

August 31, 1977: **Don Landers,** P.O. Box 24625, Seattle, Washington. Advertising and sale through the mail of the product "Bust Plus," representing the ability to enlarge the bustline.

September 1, 1977: **Dermatone Laboratories,** 5100 Pearl Road, Cleveland, Ohio. Advertising and sale through the mail of the product "Rejuvene Stretch Mark Lotion," representing the ability to remove stretch marks.

September 23, 1977: **Cosvetic Laboratories,** P.O. Box 18596, Atlanta, Georgia. Advertising and sale through the mail of the product "Right Places Protein Powder," representing the ability to increase the size of the breasts.

October 6, 1977: **Basic Health Aids,** P.O. Box 517, Canal Street Station, New York, New York. Advertising and sale through the mail of various sexual products representing the ability of aphrodisiacs in nature.

October 6, 1977: **Skandia Distributors,** Box 430, Canal Street Station, New York, New York. Advertising and sale through the mail of various sexual products representing the ability of aphrodisiacs in nature.

False Representation Orders Issued by Judicial Officer Under 39 U.S.C. 3005

August 16, 1977: Against **P. A. Distributors,** 6311 Yucca, Hollywood, California. Advertising and sale through the mail of the product "Peter Pump," representing the ability to enlarge the size of the penis.

August 16, 1977: Against **Doctor's Formula,** 829 Catamaran, Foster City, California. Advertising and sale through the mail of the product "Doctor's Natural Formula," representing the ability to reduce high blood pressure and fatigue.

August 16, 1977: Against **Vital Nutrients,** P.O. Box 1082, Southgate, Michigan. Advertising and sale through the mail of the product "Vanish Plus Stretch Mark Lotion," representing the ability to remove stretch marks.

August 18, 1977: Against **Vital Nutrients,** P.O. Box 1059, Wyandotte, Michigan. Advertising and sale through the mail of the product "Vitality Pep Pills," representing the ability to boost a person's energy level.

August 30, 1977: Against **American Research Labs,** P.O. Box 369, Taylor, Michigan. Advertising and sale through the mail of the product "Phenatrol Reducing Plan," representing the ability to cause weight loss.

August 30, 1977: Against **American Research Labs,** P.O. Box 369, Taylor, Michigan. Advertising and sale through the mail of the product "Alive Energy Booster," representing the ability to stimulate, energize, and increase alertness and awareness.

August 30, 1977: Against **Emil-John Research,** P.O. Box 369, Taylor, Michigan. Advertising and sale through the mail of a diet kit representing the ability to cause weight loss.

August 30, 1977: Against **Med-Cal,** Box 48950, Los Angeles, California. Advertising and sale through the mail of the product "Caladine Time Pill," representing the ability to cause weight loss.

September 19, 1977: Against **Thomas Johnstone,** P.O. Box 16-B, San Ysidro, California. Advertising and sale through the mail of the product "Algamar," representing the ability to cure cancer and other body ailments.

September 27, 1977: Against **Derma Diet,** P.O. Box 906-A, San Mateo, California. Advertising and sale through the mail of the product "Derma Diet Skin Conditioner," representing the ability to erase wrinkles, acne, and stretch marks.

September 29, 1977: Against **Geneva Importers,** 516 Fifth Avenue, New York, New York. Advertising and sale through the mail of the product "Super Vibrator Belt," representing the ability to cause weight loss.

September 30, 1977: Against **Carter-Ross Labs,** P.O. Box 1082, Southgate, Michigan. Advertising and sale through the mail of the product "Bio Trim Diet Plan," representing the ability to cause weight loss.

September 30, 1977: Against **Advanced Nutrient Products,** P.O. Box 1059, Southgate, Michigan. Advertising and sale through the mail of the product "Diet Plan," representing the ability to cause weight loss.

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Frog legs, frozen, at Brownsville, S. Dist. Tex.

Charged 5–7–74 and amended 12–5–75: when shipped by various East Coast importers, the article was adulterated and/or misbranded under the Federal Food, Drug, & Cosmetic Act; and, while held by Manuel Sanchez, Jr., (Progressive Sea Food Products, Inc.), Brownsville, Tex., the article had been entered and/or introduced or attempted to be entered into U.S. commerce by means of various false and/or fraudulent entries, declarations, or statements, in violation of 19 U.S.C. 1592 and the U.S. Customs regulations.

The article was claimed by the dealer who denied the charges and asserted: that the claimant was in the business of purchasing shrimp and frog legs, which had been denied entry into the United States by reason, in part, of the presence of *Salmonella,* which food was transshipped from the East Coast importers to Brownsville, for export to Mexico where the product was reprocessed, and which largely was reimported to the United States after U.S. Government inspection; that the product was held in bonded cold storage warehouses in Brownsville, Tex., pending final exportation; that the claimant had relied upon the East Coast sellers to ship the product for export via Brownsville, Tex.; that, though the product was normally shipped in bond, the seized 76,552 pounds of frog legs (comprising four separate shipments) had not been transshipped in bond; that, until seizure, the claimant had no knowledge that the frog legs had not been properly shipped; and that claimant did not hold the product for sale or for introduction into interstate commerce, but rather for export.

The claimant moved for release for export of the article, prior to condemnation. Subsequently, at a hearing on such motion, the claimant moved in the alternative for release of the article for reconditioning. The claimant also moved for a more definite statement concerning the charges. The Mercantile Trust Co. National Association, St. Louis, Mo., also moved to intervene as a claimant. The Government and Progressive Sea Food Products, Inc., moved for summary judgment in their own favor. The court granted a partial summary judgment of condemnation, forfeiture, and release for reconditioning, saying:

"Agent Gene Nicko, of the United States Customs Service, received information from a confidential informer that certain frog leg shippers were engaged in illegal activity. He was told that frog leg importers are forced to sell, at depressed prices, all contaminated frog legs that had been refused importation entry into the United States. Salvage buyers, who bought this food product at reduced prices, would subsequently illegally reintroduce this food into the United States at regular prices. His information was that Manuel Sanchez, Jr., owner of Progressive Sea Products, Inc., was buying large quantities of rejected frog legs, and consigning them to Jose Mendoza, a buyer in Mexico, for export. Once out of the country, the contaminated frog legs would be packed under other sea products and brought back into the United States and sold as a wholesale food product. Pursuant to this information Agent Nicko began his investigation.

"He inspected records kept at the Brownsville Port of Entry which indicated that large quantities of frozen frog legs, consigned to Jose Mendoza, were being kept at the Tex-Mex Cold Storage facility in Brownsville, Texas. Agent Nicko enlisted the aid of Customs Agents at the Port of Entry to keep him informed when frog legs were either exported or imported. Nothing happened for six weeks so Nicko decided to check out the local cold storage facilities in Brownsville. When he interviewed the Manager, Walter Brimmer, he was told that some of Progressive's employees were in the back of the facility repackaging frog legs at that very moment. The agent investigated and discovered that Penninsular Brand Frog Legs, Products of India, were being repackaged into boxes marked 'Products of Mexico, packed by Industrias G.M.E., Mexico, D.F.', but this was not being done under the supervision of a Customs Officer. He was told the boxes from India were in such poor condition they necessitated repackaging.

"During his investigation he noticed the boxes had been manufactured by the International Paper Company in Edinburg, Texas. The manager of the paper box company was contacted and he told Nicko that the boxes had been sold to a distributor named D. K. Young. Mr. Young was contacted and it was determined that Progressive, of Brownsville, Texas, ordered 15,000 ten-pound boxes and 4,000 forty-pound boxes. All these boxes were labeled: 'Products of Mexico, Frozen Frog Legs, Packed by Industrias G.M.E., Mexico, D.F.' These boxes had been shipped to Winter Garden Cold Storage facility in Brownsville, Texas.

"In investigating the records of Winter Garden Cold Storage, Nicko determined that 20,000 pounds of frog legs stored there had been shipped north. He determined that some of the frog legs came from Marine Protein, Inc., some from Pez-Mex, Inc., in Matamoros, Mexico, and some had been trasferred from Tex-Mex Cold Storage, where he had witnessed the repacking. Most were repackaged in the Product of Mexico box. Nicko was skeptical of what he had been told about the repacking because only five to ten percent of the boxes needed repackaging. He also discovered Progressive had ordered enough boxes to pack the contents of the entire warehouse and these boxes were being stored in Brownsville, Texas, instead of being sent to Mexico. It was probably thought unusual that an American company would order boxes labeled 'Products of Mexico' and bearing another company's name. This could be explained by credit necessities and the close connection claimant Sanchez alleges he had with the Mexican company. Some doubt is cast on this explanation, however, since it was disputed during the hearing whether claimant Sanchez was authorized to use the name of the Mexican company.

"Further investigation revealed that a great number of frog legs were in violation of the 90-day export limitation and extensions had not been requested. The Customs Agent felt this indicated the frog legs were not intended for export and that the repacking had been done to conceal the true nature of the frog legs. When it was discovered that Progressive had in fact sold contaminated frog legs in domestic commerce when they should have been under bond but were not, both the Secretary of the Treasury and the Secretary of Health, Education and Welfare, decided to seek forfeiture of the food for various violations of the Customs statutes and the Food and Drug Act.

"At the hearing the claimants argued that some of the frog legs were mistakenly sold in domestic commerce when they were mistakenly commingled with wholesome frog legs. The Government argues this position is untenable because: the documentary evidence in claimant's possession should have put claimant on notice these frog legs were contaminated and under bond; the testimony reflects, as does claimant's failure to produce proof to the contrary, that at the time of the alleged mistake claimant only had contaminated frog legs in storage and there were no sound ones with which they could have become confused, and the claimants admitted that Mr. Sanchez, a successful businessman, knew these shipments of frog legs were contaminated when he bought them.

"On May 10, 1976, after pleading guilty to Count One of a seven-count indictment, charging him with selling adulterated frog legs in domestic commerce, the claimant Manuel Sanchez thereafter received a $7,500 fine and a one-year sentence, suspended, and one year probation without supervision after the fine is paid. The claimant, Progressive, pleaded guilty to two counts of the indictment, charging it with selling a portion of this shipment of adulterated frog legs in domestic commerce and with introducing misbranded frog legs in interstate commerce, and it received a total fine of $15,000. Both counts of the indictment to which the claimants pleaded guilty charged them with violations of the Food and Drug Act and not with violation of the Customs laws.

"Turning from a review of the facts this Court will dispose of two cumbersome preliminary issues. Before delving into the crux of the matter, this Court will first consider Mercantile Trust Company's Motion to Intervene and the original claimants' Motion for More Definite Statement.

"Subsequent to the extensive hearing which forms the basis for this Summary Judgment, Mercantile Trust Company filed a Motion to Intervene as a claimant alleging that it has a security interest in co-claimants' inventory and after-acquired property. The Government opposes such intervention because the security interest was not perfected prior to seizure and the Motion to Intervene was untimely.

"Unless the claimant had perfected a security interest in the frog legs prior to seizure it would not be entitled to priority even

though it has an interest in Progressive's inventory. Any interest Mercantile might have is being virtually represented by the original claimants. Even though Mercantile might have an interest in the frog legs its Motion to Intervene in the Summary Judgment proceeding has been filed too late and is denied in part. The claimant Mercantile will be allowed to intervene in the trial of the customs violations to try to establish its claim, if any.

"In support of their Motion for More Definite Statement the original claimants assert that the frog legs under seizure include four separate shipments. Claimants contend that the Government's customs violation charges do not apprise them of whether they introduced or attempted to introduce frog legs into commerce by means of false or fraudulent entries or declarations, or false statements, or fraudulent practices. They further contend that the Government's F.D.A. charges do not apprise them how the frog legs were misbranded or what they were adulterated with or whether they were all adulterated or misbranded.

"At the hearing it was clearly developed, stipulated to and admitted that all of the frog legs were adulterated and part were misbranded. This portion of claimants' motion relating to the F.D.A. violations was satisfied.

"The Government attempted to prove a customs violation by trying to show the claimants made certain false statements and engaged in certain fraudulent practices. The hearing demonstrated there was a genuine issue of fact regarding the falsity of certain statements and practices and the shipments to which those statements relate. The following statements or practices were disputed: that Jose Mendoza of Mexico was not a bona fide consignee; that Progressive did not have authority to use Industrias G.M.E.'s name on the boxes; that the repackaged boxes were intended for domestic sale and not export; that the fraudulent practice of selling contaminated frog legs related to all the frog legs under seizure. Since this listing may not be exhaustive the Government will be allowed 90 days to supplement it unless this claim is settled or trial is set. If trial is set the list of disputed statements and practices will be set forth in the pre-trial order. The claimants' Motion for More Definite Statement is well taken and is hereby granted in part.

"The principal violation of the Federal Food and Drug Act involved transporting adulterated food in interstate commerce and holding adulterated food for sale after it has traveled in interstate commerce. . . .

"After disposing of the preliminary issues this Court will next consider the crucial F.D.A. violations. There are several statutory procedures that allow a claimant to obtain repossession, for various purposes, of adulterated food he has imported or attempted to import when the United States has seized such food. . . . Section 334 (d)(1) makes reference to several statutory provisions but only sections 381 (d) and 342 (a)(1) apply to the facts of this case.

"Both sections of the Act contain import-export provisions. The Fifth Circuit has harmonized the apparent incongruity but has not extensively interpreted the statute. The pervasive feature of the statutes of allowing repossession by the owner-claimant under certain circumstances indicates a congressional intent to prevent waste of food whenever it can be safely done. . . .

"Because there are few cases interpreting these statutory provisions this Court must provide its own gloss. The jurisdiction conferred by the Federal Food, Drug and Cosmetic Act encompasses the seizure and condemnation of any article of food physically in interstate commerce or which is sold or held for sale after traveling in interstate commerce even though it has been denied admission into this country by the Bureau of Customs of the Treasury Department. cf. *United States* v. *231 Boxes of 'Frozen Tullibees'*, (No. 14597, S.D. Cal., March 12, 1949). The Act in Title 21 U.S.C.A. §381 provides that prior to condemnation the Secretary of the Treasury has authority, for certain purposes, to release adulterated food that has been denied entry into the United States. When the Secretary seeks condemnation, under the circumstances presented in the factual setting of this case, he has exercised his d[i]scretionary authority to disallow any of the alternatives favorable to the claimant. After condemnation if appropriate, the Courts have discretionary authority to release adulterated food for certain purposes. In either case the guidelines set forth in the statutes must be followed in exercising this discretion. Subject to the conditions and within the guidelines provided in the Act, the Secretary or the Courts have authority to allow exportation, reconditioning, salvage or destruction of adulterated food. The burden of pleading and proving the applicability of one of the statutory alternatives to destruction is on the one who seeks the benefit of such exemption. *United States* v. *6,796 Bags labeled 'River Enriched Rice'*, Civ. No. 75-H-618 (S.D. Tex., May 19, 1975).

"The statutory import-export exemption in 21 U.S.C.A. §381 does not apply to claimant's, Progressive Sea Products, Inc., frog legs. The clear wording of the statute provides that articles intended for export under the provisions of the statute are not exempt if such article is sold or offered for sale in domestic commerce. The record establishes that some of the frog legs in the shipments under seizure were sold and offered for sale in domestic commerce. The statute further provides that the Secretary shall seek condemnation if the article is not exported within 90 days and an extension is not granted under the appropriate regulations. The record establishes that the frog legs, if ever intended for export, were not exported within 90 days and an extension was not granted.

"After being given an opportunity to establish his entitlement to the statutory exemption the claimant failed to meet his burden. Claimant failed to establish that the food was not in conflict with the laws of Mexico. The evidence establishes that the claimant does not have a permit to export adulterated frog legs into Mexico and that the laws of Mexico would be violated if he did try to export the contaminated frog legs.

"This Court holds that the claimant is not entitled to the benefits of the statutory exemption, 21 U.S.C.A. §381, allowing the exportation of adulterated frog legs which have been refused entry. This Court further holds the Secretary of Health, Education and Welfare, through the F.D.A., did not abuse its discretionary power to revoke claimant's import-export privilege under §381 and seek condemnation. cf. *Carl Borchsenius Co., Inc.* v. *Gardner, U.S. Secretary of Health, Education and Welfare,* 282 F. Supp. 396 (E.D. La., 1968). After considering the threshold question of the applicability of a statutory exemption this Court must next consider the further question, whether the United States has proven that the food should be condemned and if condemned what disposition should be made.

"This Court finds from the terms of the Federal Food, Drug and Cosmetic Act that it has jurisdiction to proceed with the condemnation of an article of food physically in interstate commerce even though that article has been refused importation and is in transit through the United States for exportation under bond where the owner of the food destined for export fraudulently sells part of it in domestic commerce and the food is physically present in the United States in excess of the ninety-day export limitation. The holding that a claimant can lose his export exemption is based on statutory interpretation, a reading of analogous case law and the need to protect citizens of the United States from unknowingly consuming contaminated food products. There is no genuine issue of fact regarding the issue of condemnation and Summary Judgment is appropriate.

"The frog legs are a food within the meaning of 21 U.S.C.A. §321 (f)(1). It is undisputed they are adulterated within the meaning of 21 U.S.C.A. §342 (a)(1) with pathogenic *Salmonella*. They were introduced into interstate commerce and were held for sale, after shipment in interstate commerce, within the meaning of 21 U.S.C.A. §334 (a), when they were shipped by truck, without bond, from New York, New York, to Brownsville, Texas, and not exported before expiration of the ninety-day grace period. Once part of the shipment was sold in interstate commerce the entire shipment can be deemed to have entered interstate commerce. This Court holds the frog legs are subject to condemnation pursuant to 21 U.S.C.A. §334 (a) and (d) and the United States is entitled to a judgment of condemnation. A Summary Judgment of condemnation is this day being entered.

"Having determined that the frog legs should be condemned, this Court must next determine whether to order the frog legs destroyed or to allow the claimant conditional repossession. This Court has discretionary power to permit the claimant's attempt to salvage a potentially valuable food regardless of the claimant's mala fides. Federal Courts must, however, protect the public

interest in keeping from the channels of commerce food products so adulterated as to injure or endanger health, and to ensure that food products are properly branded so the consumer can know there is no misrepresentation as to substance, and that the food purchased is what it purports to be.

"This Court holds the claimant is not entitled to the benefit of the import-export provisions found in 21 U.S.C.A. §334 (d) (1). As previously discussed the claimant cannot comply with all the requirements found in 21 U.S.C.A. §381 and this is a condition precedent to invocation of the import-export provisions found in 21 U.S.C.A. §334 (d)(1). Since the claimant offered part of the frog legs for sale in domestic commerce he is not entitled to the benefits of its import-export provisions. Additionally, Section 334 (d)(1) is not available where food is condemned because it is injurious to health. This is necessary to prevent adulterated food from being commingled with good lots of the same food and again offered for import under conditions that would make the adulteration difficult to detect. The evidence presented at the trial and the guilty plea entered in Criminal No. 76-B-112, prove that the claimant had cause for believing and knew that the frog legs were adulterated and were sold in domestic commerce. Claimant's Motion to be allowed to export the frog legs is denied.

"The Government contends the claimant is not entitled to conditional repossession because: the evidence proves a fraudulent scheme to sell contaminated frog legs to an unsuspecting public and the claimant has pleaded guilty to this charge in a criminal proceeding, and the evidence proves that the claimant did not make a mistake as alleged at the hearing. The claimant contends that he has been adequately punished for his wrongdoing in the criminal proceedings and should be allowed to salvage a potentially valuable food under conditions that adequately protect the public.

"This Court holds that the frog legs should be turned over to the claimant to be brought into compliance with the Act provided they have not deteriorated to such an extent they cannot be reconditioned. If they cannot be reconditioned, they will be destroyed. The reconditioning process will be under strict supervision by agents of the Federal Food and Drug Administration and the reprocessing will be completed in the United States. . . .

"Prior to release of the bulk of the frog legs, the claimant, in the presence of an F.D.A. agent, will be allowed to inspect the frog legs and to withdraw samples to determine if reprocessing is feasible. If the claimant determines reprocessing is not feasible, the frog legs will be destroyed. The claimant shall bear the costs of this proceeding of reprocessing, and of Government supervision. An order granting Partial Summary Judgment carrying out these provisions is this day being entered.

"The resolution of claimant's motions has been complicated by the customs violations which arose from the same factual setting as the food and drug violations. There is a genuine issue of material fact regarding the exact nature of each false statement and fraudulent practice and the exact frog legs to which such statements or practices relate. . . . The record of the hearing indicates the frog legs subject to the customs violations may have already been destroyed. Summary Judgment of Forfeiture based on customs violations is denied.

"The claimant also contends Customs has no authority to seek condemnation since the frog legs had been refused entry into the United States and would have been under a transportation and export (hereinafter T&E) bond but for the negligence of the customs agents. . . .

"Claimant's argument overlooks the fact that this is a privilege that may be revoked and that the merchandise may be deemed imported, even where there is no actual entry. There is such a deemed entry provision in 19 U.S.C.A. §1592 but the factual predicate for the invocation of the deemed entry provision must be proved.

"Since a Summary Judgment determining possible violations of the customs laws is not appropriate at this time, the claimant will be allowed, as the Government agreed at the hearing, to post an additional bond for the value of the frog legs at the time of seizure. The value will be the average price paid by the claimant for contaminated frog legs or $50,000, whichever is greater. cf. 19 U.S.C.A. §1592. The Government can proceed at trial to prove the falsity of any alleged statements and the shipments of frog legs to which they relate. Subsequent to trial the claimant must seek remission from the Secretary of the Treasury for the value of any frog legs that might be forfeited for customs violations."

Subsequently, a consent decree was entered which: authorized release of the article to Progressive Sea Products, Inc., and its president Manuel Sanchez, for salvaging; ordered recovery of $15,000 from them as an agreed upon civil penalty (resolving amicably the Customs laws violations); ordered the denial of the Mercantile Trust Co. National Association's motion to intervene; and ordered payment to the Government of all taxable costs of the action. (F.D.C. No. 60009A; S. No. 84-941 H et al.; N.J. No. 1)

Halibut chunks, frozen, at Chicago, N. Dist. Ill.
Charged 4-4-77: when shipped by Pelican Sales Co., Bellingham, Wash., the article contained the added poisonous and deleterious substance mercury (approximately 0.56 parts per million); 402 (a) (1). Default decree ordered destruction. (F.D.C. No. 61141; S. No. 77-03-884; N.J. No. 2)

Swordfish, gutted, at New York, S. Dist. N.Y.
Charged 5-5-77: when shipped by Melrose Fish Co., Salerno, Fla., the article contained the added poisonous and deleterious substance mercury (approximately 0.55 parts per million); 402 (a) (1). Default decree ordered destruction. (F.D.C. No. 61195; S. No. 77-89-506; N.J. No. 3)

FOOD/Contamination, Spoilage, Insanitary Handling

Chick peas, at Houston, S. Dist. Tex.
Charged 3-3-77: while held by Dalton Steamship Corp., City Dock 24, Houston, Tex., the article contained bird excreta, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Blaine Richards & Co., Inc., Lake Success, N.Y., for salvaging. (F.D.C. No. 61045; S. No. 77-22-750; N.J. No. 4)

Corn, shelled, at New Orleans, E. Dist. La.
Charged 4-11-77: while held by El Sol, Inc., New Orleans, La., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60994; S. No. 77-78-733; N.J. No. 5)

Cornmeal, rice, flour, oat cereal, and **other warehouse food stocks,** at Springfield, S. Dist. Ill.
Charged 8-4-77 and amended 8-9-77 while held by Springfield Produce, Inc., Springfield, Ill., a number of the articles contained rodent and/or insect filth, and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 61373; S. No. 77-04-502 et al.; N.J. No.6)

Flour, at Worcester, Dist. Mass.
Charged 2-25-77: while held by Yankee Products Co., Inc., Worcester, Mass., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 62064; S. No. 77-91-225; N.J. No. 7)

Rice, at San German, Dist. P.R.
Charged 5-11-77: while held by A. Sanchez Sucrs., Inc., San German, P.R., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 61185; S. No. 77-83-623; N.J. No. 8)

Sesame seeds, at Elk Grove Village, Chicago, N. Dist. Ill.
Charged 12-3-76: while held by Flavor Tree Foods, Inc., Elk Grove Village, Chicago, Ill., the article contained insect filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Hoye, Inc., Villisca, Iowa, for salvaging. (F.D.C. No. 61024; S. No. 77-09-309; N.J. No. 9)

Soybeans and **mung beans,** at Irving, N. Dist. Tex.
Charged 3-29-77: while held by Yong Ho Co., Irving, Tex., the mung beans contained rodent urine, and both articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 62017; S. Nos. 77-21-489/90; N.J. No. 10)

Sunflower seeds, hulled, Spanish peanuts, roasted mixed nuts, and

roasted peanuts in the shell, at Everett, Dist. Mass.
Charged 11–1–74: while held by Leavitt Corp., Everett, Mass., the hulled sunflower seeds contained clumps of mold, the other articles contained insect and/or rodent filth, and all of the articles had been prepared, packed, and held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction of the Spanish peanuts and authorized release to the dealer for salvaging of the other articles. (F.D.C. No. 60039; S. No. 108–097 H et al.; N.J. No. 11)

Sugar, brown, at Brooklyn, E. Dist. N.Y.
Charged 4–12–77: while held for sale, the article contained rodent filth, and had been held under insanitary conditions at Duso Food Distributors, Inc., Ellenville, N.Y.; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61140; S. No. 77–58–115; N.J. No. 12)

FOOD/Economic and Labeling Violations

Shrimp, breaded, frozen, Deal's, at Omaha, Dist. Nebr.
Charged 7–15–77: when shipped by Deal's Seafood Co., Miami, Fla., the article failed to conform to the definition and standard of identity for frozen raw breaded shrimp, since the article tested less than 50 percent of shrimp material; 403(g)(1). Consent decree authorized donation to charitable institution. (F.D.C. No. 62010; S. No. 77–54–440; N.J. No.13)

Shrimp, breaded, frozen, Kitchen Ready, at Elberton, M. Dist. Ga.
Charged 5–11–77: when shipped by Seabrook Foods, Inc., Tampa, Fla., the article failed to conform to the definition and standard of identity for frozen raw breaded shrimp, since the article tested less than 50 percent of shrimp material; 403(g)(1). Default decree authorized donation to governmental institution. (F.D.C. No. 61196; S. No. 77–62–639; N.J. No. 14)

Sugar, raw, at New Orleans, E. Dist. La.
Charged 2–4–77: while held by Atlantic & Gulf Stevedores, Inc., New Orleans, La., the article (which was contained in six railcars) had had urea substituted in part for sugar, due to the sugar being emptied into a hopper containing agricultural-grade urea during debarkation; 402(b)(2). The article was claimed by the importer, Southdown Sugars, Inc., New Orleans, La., who denied the charges. Meanwhile, upon motion of the government, the dealer was appointed as consent keeper of the article, without remuneration, in order to minimize expenses. Subsequently, a consent decree ordered destruction. (F.D.C. No. 62044; S. No. 77–78–626; N.J. No. 15)

FOOD ADDITIVES

Ginseng combination capsules, at Chatsworth, C. Dist. Calif.
Charged 5-27-77: while held by Banner Gelatin Products Corp., Los Angeles, Calif., who manufactured the article using ginseng shipped in interstate commerce, the article bore and contained the nonconforming food additive ginseng—402(a)(2)(C); the article lacked the common or usual name of the article's ingredients—403(i)(2). Consent decree authorized release to the manufacturer for salvaging. (F.D.C. No. 61249; S. Nos. 77-10-084/5; N.J. No. 16)

Lemon flavor mix with egg white, Cramores Crystals, at New Haven, Dist. Conn.
Charged 6-27-77: when shipped by Cramore Products, Inc., Carteret, N.J., the article contained the nonconforming food additive saccharin, and the saccharin was not for a valid special dietary use (the article was intended as a mixer for alcoholic beverages); 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 61287; S. No. 77-80-276; N.J. No. 17)

Orotic acid, anhydrous, for manufacturing, at St. Louis, E. Dist. Mo.
Charged 1-30-75 and amended 9-23-75: while held by Private Formulae, Inc., St. Louis, Mo., the article was a nonconforming food additive; 402(a)(2)(C). The article was claimed by Robert Moravek, West Chicago, Ill., who denied the charge. The Government served written interrogatories on the claimant. The claimant served written interrogatories and a request for documents on the Government. The case came on for trial by the district court. In finding for the Government and in condemning the article, the court said:

Findings of Fact

"1. This action was filed by the United States of America pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et seq., to have seized and condemned, pursuant to 21 U.S.C. 334, an article of food labeled in part: 'Orotic Acid Anhydros' and 'Orotic Acid Anhydros "Kyowa" ' (hereafter called Orotic Acid).

"2. The complaint for forfeiture was filed on January 30, 1975. The Orotic Acid was seized by the United States Marshal on that date. Thereafter, Robert Moravek intervened in this action and filed a claim and answer. A first amended complaint for forfeiture was filed on September 23, 1975, to substitute a different lot, but otherwise identical, Orotic Acid.

"3. The Orotic Acid was shipped in interstate commerce to Private Formulae, Inc., in St. Louis, Missouri, where it was seized. At the time it was seized, it was being held for the purpose of further processing and sale. It was being held to manufacture 'Magora' and/or 'Calora' for the Miller Pharmacal Co., of West Chicago, Illinois. The Magora and Calora products as marketed were intended to be sold as dietary supplements and were intended to be sold as a food for humans.

"4. Orotic Acid is found naturally in cow's milk. The Orotic Acid seized in this action was manufactured by a fermentation process, it was not obtained from cow's milk.

"5. Based on the testimony and exhibits before this Court, the Court finds that Orotic Acid is not accepted among knowledgeable nutritionists and physicians as having either nutritional or therapeutic properties. There is no evidence that Orotic Acid is needed in the diet of humans to supplement the body's synthesis of Orotic Acid.

"6. Orotic Acid was not in common use as a separate food ingredient in dietary supplements or in any other food prior to January 1, 1958.

"7. Orotic Acid is not generally recognized among experts qualified by scientific training and experience to evaluate its safety as having been adequately shown through scientific procedures or experience based on common use in food to be safe under the conditions of its intended use.

"8. No sanction or approval was ever granted prior to September 6, 1958, under any federal law permitting the use of Orotic Acid in foods as a food additive.

Conclusions of Law

"1. This Court has jurisdiction of this action under 21 U.S.C. 301, et seq.

"2. The Court finds there is no regulation in effect permitting the use of Orotic Acid in foods as a food additive or exempting Orotic Acid from the food additives requirements of the Federal Food, Drug, and Cosmetic Act.

"3. The Court finds that Orotic Acid is a food, a food additive, an unsafe food additive, and adulterated within the meaning of 21 U.S.C. 312(f), 321(s), 342(a), 342(a)(2)(c). The Orotic Acid will be condemned and cross-charged against the claimant."

The claimant appealed. The case having been submitted to a panel of judges of the court of appeals, the judgment of the district court was affirmed on the basis of the opinion of the district court. (F.D.C. No. 60183; S. No. 79-113 H; N.J. No. 18)

DRUGS/Human Use

Antiperspirant, at Hato Rey, Dist. P.R.
Charged 12-6-76: when shipped by Dorchester Products, Inc., New York, N.Y., the article, labeled in part "Sutton Very Dry anti-perspirant deodorant Roll-On . . . Contains Aluminum Chlorhydroxide Sutton Cosmetics (P.R.) Inc., Hato Rey, P.R.," had been manufactured, prepared, compounded, and processed in an unregistered drug establishment in the State of New York; 502(o). Default decree ordered destruction. (F.D.C. No. 60980; S. No. 77-50-953; N.J. No. 19)

Aspirin tablets, at Landover, Dist. Md.
Charged 12-28-76: when shipped by Davis Manufacturing Co., Inc., (United Pharmaceuticals, Inc.), Knoxville, Tenn., the article, labeled in part "Tablets Dart Drug Aspirin . . . Distributed By Dart Drug Corp., Landover, Md.," had been manufactured, processed, packed, and held under circumstances that failed to conform with current good manufacturing practice; 501(a)(2)(B). The shipper claimed the article and entered into a consent decree, condemning

the article and providing an opportunity to recondition the article. The claimant subsequently advised that it had decided not to recondition the article. The Government moved for a decree of condemnation and destruction. Such decree was entered and the article was destroyed. (F.D.C. No. 61038; S. Nos. 77-90-541/3; N.J. No. 20)

Chlorothiazide 500 mg tablets, and **chlorothiazide 250 mg tablets,** at Cumberland, Dist. Md.
Charged 8-4-76: when shipped by Bolar Pharmaceutical Co., Inc., Copiague, N.Y., the articles were new drugs without effective approved New Drug Applications; 505(a). Default decree ordered destruction. (F.D.C. No. 60838; S. Nos. 77-04-159/60; N.J. No. 21)

Mephenesin preparation tablets, at Denver, Dist. Colo.
Charged 4-22-77: while held for sale, after manufacture by Western Research Laboratories, Denver, Colo., using mephenesin purified powder shipped in interstate commerce, the labeling of the article, labeled in part "Calmtabs Each Tablet Contains Mephenesin . . . 320 mg . . . . Manufactured for C & A Laboratories, Inc. . . . Manufactured by Western Research Laboratories, Inc., Denver, Colorado," lacked adequate directions for use and was not exempted, since the article was a new drug without an effective approved New Drug Application; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 61192; S. No. 77-25-125; N.J. No. 22)

Mersalyl & theophylline injectable, prednisolone acetate suspension, testosterone propionate injectable, rubivite cyanocobalamine injectable, hydrocortisone acetate suspension, and **liver injection,** at Los Alamitos, C. Dist. Calif.
Charged 5-11-77: when shipped by Bel-Mar Laboratories, Inc., Inwood, N.Y., the circumstances used for the articles' manufacture, packing, and holding failed to conform with current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 61216; S. Nos. 77-10-276/80, 77-10-721/7; N.J. No. 23)

Phendimetrazine tartrate T.D. capsules, at Melville, E. Dist. N.Y.
Charged 10-5-76: when shipped by Cord Laboratories, Inc., Broomfield, Colo., the article, labeled in part "Wolins C-III Phendorex T.D. Caps (Phendimetrazine Tartrate) 105 mg. T.D. Capsules . . . Manufactured For Wolins Pharmacal Corp. Melville, New York . . . by Cord Laboratories, Inc., Broomfield, Colo.," was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 60900; S. No. 77-42-580; N.J. No. 24)

Prescription ophthalmic ointments, solutions, and **component drugs,** at Quincy, Dist. Mass.
Charged 9-18-75: while held by Muro Pharmacal Labs., Inc., Quincy, Mass., the circumstances used for the articles' manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; 501(a)(2)(B). Consent decree authorized release to the dealer for salvaging; however, because salvaging did not prove to be feasible, the articles were destroyed. (F.D.C. No. 60474; S. No. 76-04-844 et al.; N.J. No. 25)

DRUGS/Veterinary

Dexamethazone injection, prednisone injection, adrenal cortex injection, and **other veterinary prescription drugs,** at National Stockyard, E. Dist. Ill.
Charged 6-21-73: while held for sale after shipment from outside the State of Illinois, the articles lacked adequate directions for use, and were not exempted therefrom as veterinary prescription drugs, since the possessor regularly engaged in the retail distribution of the articles, but did not limit the sale only to or on the prescription or order of a licensed veterinarian, but held the articles for sale to any purchaser and delivered the articles at retail, without such prescription or order, and without labels bearing the name and address of a licensed veterinarian who issued such prescription or order; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 59314; S. No. 23-895 G et al.; N.J. No. 26)

Dexamethasone sodium phosphate injection, U.S.P., at Elwood, Dist. Kans.
Charged 1-12-77: when shipped by Lypho-Med, Inc., Chicago, Ill., the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to its use or intended use; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 61066; S. Nos. 77-15-501/2; N.J. No. 27)

Nitrofurazone soluble veterinary powder, at Moultrie, M. Dist. Ga.
Charged 4-18-77: when shipped by Performance Products, Inc., St. Louis, Mo., the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to its use and intended use; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 61182; S. No. 77-63-189; N.J. No. 28)

MEDICAL DEVICE

Neuro-Structural Scanner device, at Point Marion, W. Dist. Pa.
Charged 1-10-77: the article, which had been shipped by Sea Communications, Inc., Seattle, Wash., lacked adequate directions for use, since such could not be written for the article's intended purpose for treating psychosomatic illnesses, and the article was not exempted therefrom since adequate information for use by licensed practitioners could not be furnished; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 61028; S. No. 77-45-200; N.J. No. 29)

PROPHYLACTICS

Prophylactics, rubber, Rx 707, at Newark, Dist. N.J.
Charged 2-28-77: the article which had been shipped by Circle Rubber Corp., St. Louis, Mo., fell below its purported quality, and the label statement "Sold for the Prevention of Disease Only" was false and misleading as applied to a product containing holes; 501(c), 502(a). Default decree ordered destruction. (F.D.C. No. 62045; S. No. 77-87-948; N.J. No. 30)

NOTICES OF JUDGMENT on Criminal Actions

FOOD

Lloyd W. Gordon, t/a Yuma Wholesale Produce & Grocery Co., Yuma, Dist. Ariz.
Charged 10-13-76: salt was held under insanitary conditions in a building accessible to rodents and was contaminated with rodent filth; 402(a)(3), 402(a)(4). Nolo contendere plea; imprisonment suspended, and probation. (F.D.C. No. 60435; S. No. 76-28-509; N.J. No. 31)

J. H. Haar & Sons, Inc., North Bergen, Dist. N.J.
Charged 7-31-74: converted rice (two lots), crumb cake mix, lima beans, rice, Great Northern beans, salt, and granulated sugar were held in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (F.D.C. No. 59350; S. No. 55-022 F et al.; N.J. No. 32)

Progressive Sea Products, Inc., and **Manuel A. Sanchez, Jr.,** president, Brownsville, S. Dist. Tex.
Charged 2-27-76 by grand jury: frozen frog legs, which had been received in interstate commerce and which contained added poisonous and deleterious viable *Salmonella* organisms, were, with intent to defraud and mislead, delivered for pay—402(a)(1); and, when shipped with intent to defraud and mislead, the label of frozen frog legs, labeled in part "Product of Mexico . . . Frozen Frog Legs . . . Packed by Industrias GME Mexico, D.F.," was false and misleading, since the article had been repacked in Brownsville, Tex., by order of the defendants—403(a). Guilty plea by corporation to both charges; fine. Guilty plea by individual to delivery for pay charge; fine, imprisonment suspended, and probation. (F.D.C. No. 60009; S. No. 84-941 H et al.; N.J. No. 33)

NOTICE OF JUDGMENT on Injunction Action

Aunt Martha's Foods, Inc., and **Elmer L. Reichert,** president, Denver, Dist. Colo.
Charged 1-15-76: that the defendants were engaged at their Denver, Colo., bakery in preparing, packing, holding, and distributing in interstate commerce, pizza crusts; that such pizza crusts contained metal fragments, paint particles, and sponge rubber particles and/or were otherwise unfit for food, and such pizza crusts had been prepared, packed, and held under insanitary conditions; that three FDA inspections of the defendants' bakery disclosed continuing insanitary conditions and practices; and that the defendants had

been repeatedly warned of insanitary conditions and practices in their bakery; 402(a)(3), 402(a)(4).

A consent decree of permanent injunction perpetually enjoined the defendants from shipping in interstate commerce any food from their bakery and from preparing, packing, holding, and distributing at their bakery any food of which it or its component had been shipped in interstate commerce, unless and until: a number of specified conditions were effected to assure that food was not contaminated with nuts, screws, string, metal and paint fragments, sponge rubber, or other filth, and/or were not otherwise unfit for food. After compliance with the above conditions, the defendants were similarly enjoined from making or shipping any food which was adulterated as alleged above. (Inj. No. 721; S. No. 76-17-383 et al.; N.J. No. 34)

NOTICE OF JUDGMENT on Miscellaneous Action

Drug research involving human volunteers, Jessup, Dist. Md.

Charged 10-11-74 by Shirley Bailey, George T. Davis, Robert Jones, Stanley Losiewski, Robert McGee, Robert Morgan, Samuel Payne, Gary Sabatini, and John Shiflett, prisoners of Maryland House of Correction, Jessup, Md., on behalf of themselves and others similarly situated, against Maryland Governor Marvin Mandel, Correction Services Secretary Robert J. Lally, Commissioner of Correction James Jordan, Parole Division Director John N. Pettibone, Warden Ralph Williams, Assistant Warden Marcellus Moore, Assistant Warden John Byrnes, Maryland Board of Regents Chairperson Lewis L. Caplan, University of Maryland President Wilson H. Elkins, University Chancellor Alvin O. Kuhn, School of Medicine Dean John Dennis, Department of Medicine Chairperson Theodore Woodward, Maryland House of Correction Medical Research Unit Director Richard B. Hornick, Medical Research Unit Physician William Woodward, Medical Research Unit Physician Robert Gilman, School of Medicine Human Volunteers Committee Chairperson Felix Heald, Maryland Health & Mental Hygiene Department Secretary Neil Solomon, Maryland Medical Chirurgical Faculty Chairperson Manning W. Alden, Maryland Medical Chirurgical Faculty Executive Director John Sargeant, H.E.W. Secretary Caspar Weinberger, and Department of Defense Secretary James Schlesinger, in a suit for declaratory judgment, injunction, and compensatory and punitive damages: that plaintiffs Bailey, Davis, Jones, Losiewski, McGee, Payne, Sabatini, and Shiflett had participated in tests involving being exposed to various diseases such as viral diarrhea, shigella infection, malaria, typhoid, and cholera, had become ill with either more severe symptoms than they expected or more severe symptoms than they remembered being told about, or had had relapses, or had other subsequent illnesses; that plaintiff Morgan (because of the presence of the Medical Research Unit which paid money and because of insufficient necessities at the Maryland House of Corrections to maintain health and personal hygiene without money) was under constant pressure to subject himself to such medical research experiments, and was subjected to the fear of being infected by the participants in the "walk-in" type tests who were in no way segregated from the other prisoners; that plaintiff Payne (when his cellmate was a participant but Payne was not a participant in a shigella experiment) had developed symptoms similar to those of a shigella infection; that the Jessup House of Correction was an overcrowded medium security institution built in 1859 and housing almost 700 prisoners beyond its approximately 1,000-prisoner capacity; that the Medical Research Unit (having 33 beds divided into three wards and having air conditioning, color TV, sandwich kitchen, and private hot showers) was far superior to the usual prison accommodations and the prison hospital; that the two kinds of studies ("ward tests"—where the subject was exposed to a disease, became ill, and was given the treatment under study; and "walk-in" tests—where the subject was given an experimental vaccine, then exposed to the disease, and only the prisoners who became ill were hospitalized at the Medical Research Unit) were controlled and supervised by the University of Maryland and its Department of Medicine; that the Federal Departments of Defense, and of Health, Education, and Welfare had funded contracts involving human medical research at the Medical Research Unit; that the defendants' tests were a denial of the plaintiffs' rights to privacy and dignity guaranteed by the First, Fourth, and Ninth Amendments, were an invasion of the protection of one's bodily integrity secured by the Fourth and Fourteenth Amendments, and, when performed on the prisoners with the cooperation of prison officials, were a form of cruel and unusual punishment forbidden by the Eighth Amendment; that plaintiffs' participation in the tests was coerced by the conditions of incarceration; was (despite signed consent forms) not informed participation, since over 60 percent of the plaintiff class was functionally illiterate and the oral explanation was inadequate; that a system of incarceration which forced prisoners to choose between remaining on idle status and going without necessities, or participating in such potentially fatal tests, was a form of cruel and unusual punishment forbidden by the Eighth Amendment; that those plaintiffs who came into contact with previously infected prisoners were similarly subjected to cruel and unusual punishment in that they must endure the risk of and fear of being infected and the cellmates of such previously infected prisoners were denied equal protection of the laws as guaranteed by the Fourteenth Amendment since the cellmates' conditions of incarceration are significantly worse with no rational basis for discrimination; that the prisoners were further denied equal protection of the laws, since participation in the tests was regardless of prison classification or custody status and non-participants were forced to endure harsher conditions of confinement, since prisoner participants were paid two dollars per day (plus $8 into special prison hospital fund) when defendants had recently contracted to pay nonprisoner participants (such as college students) twenty dollars per day; that, for the above reasons, petitioners prayed for a declaratory judgment declaring defendants' practices to be unconstitutional, for an injunction against the continuation of the Medical Research Unit, for an alternative order making such changes in the operation of the Medical Research Unit as were necessary, for an order accompanying the injunction or the alternative order providing a number of specified improvements in prison condition, and for minimum compensatory damages and punative damages.

The plaintiffs served written interrogatories on the defendants, and made requests for the production of documents concerning the Medical Research Unit and concerning current regulations and rules involving prisoner participation in tests. H.E.W. Secretary Weinberger moved to dismiss the action and moved for judgment on the pleadings; he also moved for a protective order to stay of all discovery pending a ruling on the motions for dismissal and judgment on the pleadings. The damage claims against the H.E.W. Secretary were dismissed at the instance of the plaintiffs. The equitable claims remaining against the H.E.W. Secretary were subsequently dismissed, based in part upon representation that the test program had been terminated, that no future testing was contemplated, and that, accordingly, the case was moot. (Misc. No. 287; N.J. No. 35)

Notices of Judgment are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act. Notices of Judgment report cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizure proceedings are civil actions taken against *goods* alleged to be in violation, and criminal and injunction proceedings are against *firms* or *individuals* charged to be responsible for violations. The cases generally involve foods, drugs, devices, or cosmetics which were alleged to be adulterated or misbranded or otherwise violative of the law when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce.

Notices of Judgment are prepared by Food and Drug Division, Office of the General Counsel, DHEW.

Published by direction of the Secretary of Health, Education, and Welfare.

Donald Kennedy, *Commissioner of Food and Drugs*
Washington, D.C., November 1, 1977

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LAETRILE WARNING

Cancer patients and their families are warned that:

LAETRILE IS WORTHLESS

Whether sold as a drug (amygdalin) or as a "vitamin" (B-17), Laetrile is worthless in the prevention, treatment or cure of cancer. The substance has no therapeutic or nutritional value.

LAETRILE IS DANGEROUS

Laetrile can be fatal for cancer patients who delay or give up regular medical treatment and take Laetrile instead.

Laetrile contains cyanide and can cause poisoning and death when taken by mouth. One infant is known dead of cyanide poisoning after swallowing fewer than five Laetrile tablets. At least 16 other deaths have been documented from ingestion of Laetrile ingredients (apricot and similar fruit pits).

Laetrile is especially hazardous if the injection form is taken by mouth. This can cause sudden death.

LAETRILE MAY BE CONTAMINATED

Laetrile is not routinely subject to FDA inspection for quality and purity as are all other drugs.
Analysis has shown some Laetrile to contain toxic contaminants. Ampules of Laetrile for injection have been found with mold and other adulterants which can be dangerous when injected.

Those who persist in the use of Laetrile or its ingredients should:

- Be prepared to deal promptly with *acute* cyanide poisoning if the oral product is used. Vigorous medical treatment must be started immediately or death can result.
- Watch for early symptoms of *chronic* cyanide poisoning, including weakness in the arms and legs and disorders of the nervous system.
- Keep the drug out of reach of children.

GET THE FACTS

For full details about the hazards of Laetrile, see your family physician or a cancer specialist, or write the Food and Drug Administration, HFG-20, 5600 Fishers Lane, Rockville, Maryland 20857.

Donald Kennedy
Commissioner of Food and Drugs

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