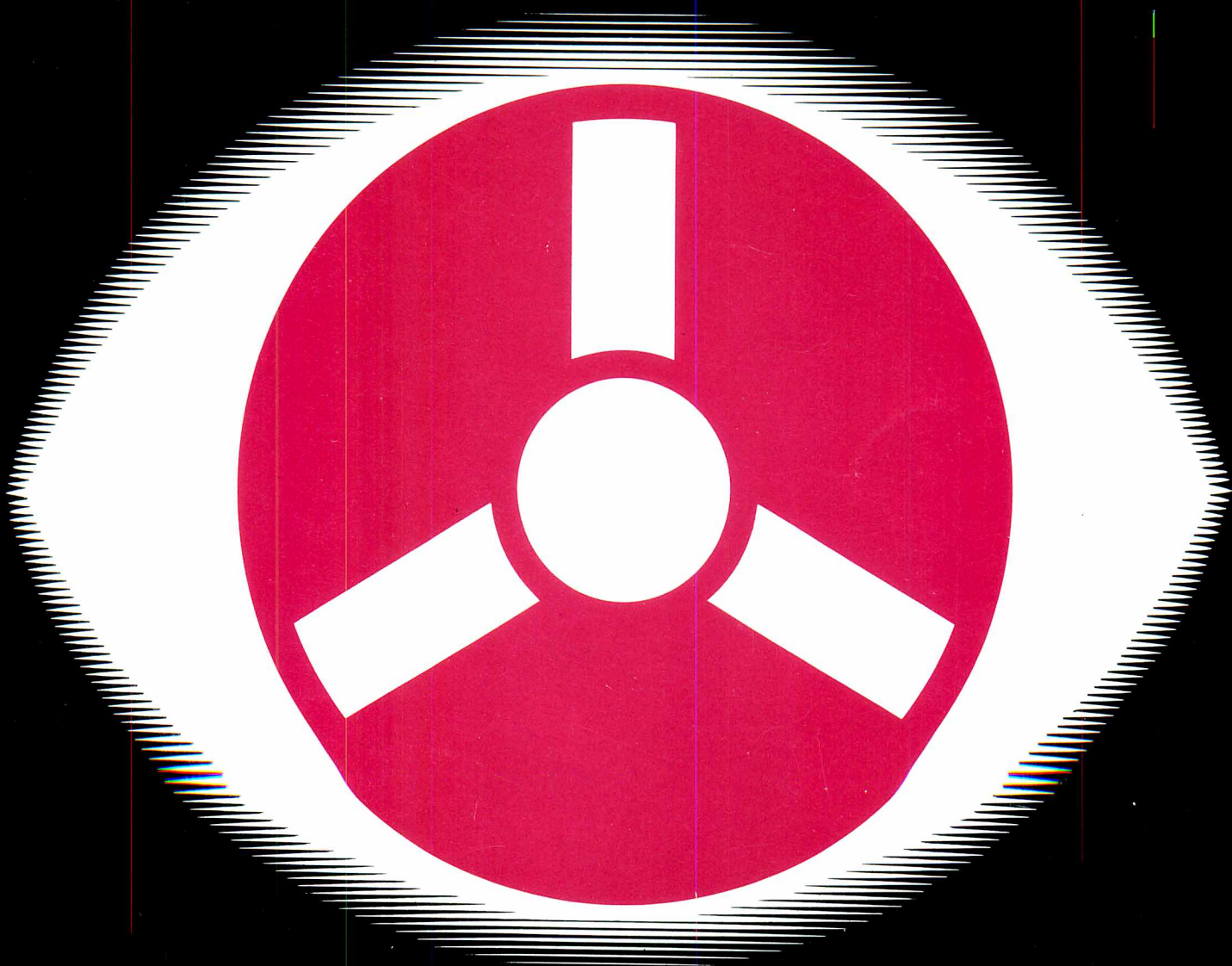
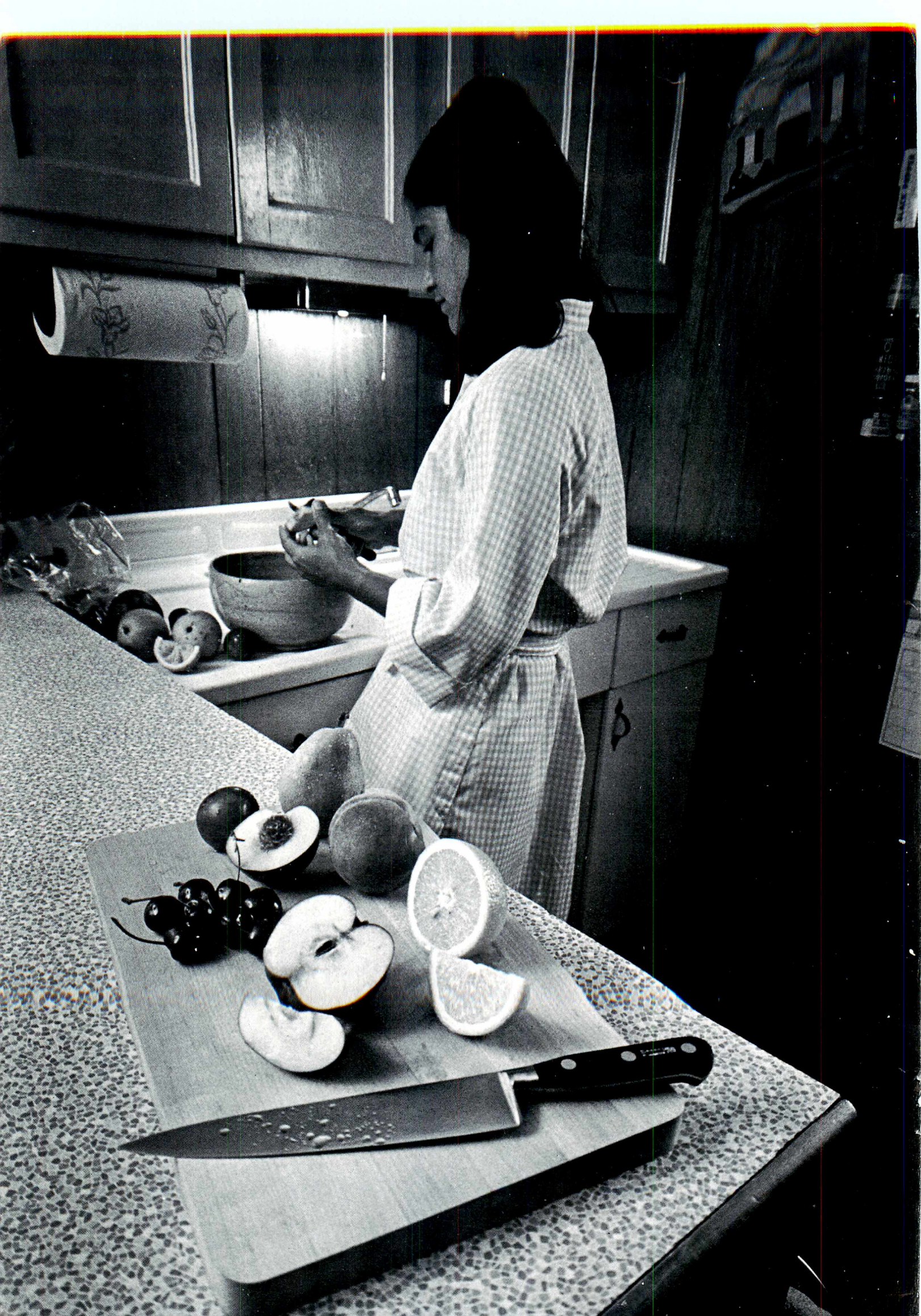


C^{FDA}**CONSUMER**

July-August 1976

X-ray Scans: Getting A Clearer Picture





This Month

Is it possible to get too much of a good thing?

When it comes to vitamins and minerals, FDA has long felt that dosages vastly in excess of what the body needs are—at the very least—wasteful. At one time the Agency proposed to restrict maximum dosages of vitamins and minerals to 150 percent of the U.S. Recommended Daily Allowance. Larger dosages, FDA reasoned, might be useful for therapeutic purposes but were unreasonable as dietary supplements, and, thus, should be regulated as drugs. A Federal court ruled that potency alone does not make vitamins and minerals drugs, and FDA should not regulate them as such on that basis. Now Congress has passed a law forbidding FDA from setting limits on maximum dosages of vitamins and minerals, unless they pose a health hazard. There are a number of other changes as a result of the legislation, and what it all adds up to is a whole new ball game. For a rundown on the new rules, see *Regulating Vitamins and Minerals*.

Any amount of radiation is too much—if there isn't a valid reason for being exposed to it. Medical diagnosis is a valid reason. Once it has been determined there is need for an x ray, however, it is important that the equipment and technique used produce a high quality picture with the least amount of radiation exposure to the patient. A new method of making radiographs combines the x ray's ability to penetrate tissue with the computer's capacity to store, interpret, and reproduce information. The result is a type of x ray that shows a cross section of the body and that holds great promise for diagnosing abnormalities which are hard to detect using traditional x-ray procedures. There's a report on this revolutionary way of looking into the human body under the title *X-ray Scans: Getting a Clearer Picture*.

One of the things there is too much of today—in the view of Commissioner of Food and Drugs Alexander M. Schmidt—is uninformed and unfounded criticism of FDA. Constructive criticism based on facts is in the public interest, Dr. Schmidt says, but when people criticize FDA as a means of promoting their personal biases, neither the Agency nor the public it serves benefits. *FDA and Its Critics* is the subject of an interview with Dr. Schmidt beginning on page 15.

Inside Front Cover Photo: *For most people, fruit can be an important part of a balanced and nutritious diet. But eating even a single piece of fruit can have serious consequences for people who have an unusual metabolic defect known as hereditary fructose intolerance. This condition is one of a number of inborn errors of metabolism discussed in an article beginning on page 20.*

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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 Design: Zeb Rogerson

Inside Front Cover Photo: Dan O'Toole

Consumer Forum

Canning Advice

Congratulations on your excellent article *Safety in Home Canning* in the May 1976 FDA CONSUMER. However, a vital step was not stressed—the importance of venting the canner. Air remaining within will result in lower effective temperatures than indicated by the pressure. Could one envision the upper left picture on page 14 replaced by one of a pressure canner with steam flowing from the petcock?

For this reason, following the directions supplied by the manufacturer of the canner is essential for adequate processing as well as the prevention of accidents.

Margy Woodburn
Professor and Head
Department of Foods and Nutrition
Oregon State University
Corvallis, Oregon

Vaccine Manufacturers

The May 1976 issue of the FDA CONSUMER contained a most informative article, *The New Flu: What It Is and What Is Being Done About It*. The article will undoubtedly be most helpful to many who may shortly be faced with the decision of whether or not to be inoculated. In this Herculean effort to produce vaccine, the FDA and private industry are working together in a cooperative and intimate manner in order that the health of the

American people be protected. I do not believe, however, that sufficient credit was afforded to the four participating pharmaceutical manufacturers. Without their resources, scientific acumen and productive capabilities there would be no vaccine. I believe we should be proud of the technical ability of our pharmaceutical industry, an industry which is all too often cast in the role of a giant predator whose motive is profit and profit only.

The very well written article might have given industry a more appropriate and balanced share of credit for its efforts in this potential threat to the health of the American people. This would seem to be only fair and I sincerely hope that this letter may be printed in a forthcoming issue of FDA CONSUMER in order for readers to more appropriately recognize the marvelous technical and productive abilities of our American pharmaceutical industry. Perhaps the editor would also like to identify those four pharmaceutical manufacturers who are working in a cooperative manner with the FDA and other governmental agencies.

H. I. Silverman
Professor of Pharmacy
Massachusetts College of Pharmacy
Boston, Massachusetts

The four firms manufacturing swine flu vaccine are Merck Sharp & Dohme, West Point, Pennsylvania; Merrell-National, Swiftwater, Pennsylvania; Parke-Davis, Detroit, Michigan; and Wyeth Laboratories, Marietta, Pennsylvania.

Quotes

“Despite the increasing importance of devices, the Food and Drug Administration has had inadequate authority to deal with them. FDA has had no reliable way of knowing how many devices there are, who is making them, who is selling them, what risks to health and life they may present, and when a manufacturer has found it necessary to remove them from the medical marketplace.

“In addition, no device was required to be proven safe and effective prior to marketing, no matter how crucial it might be to the person using it, even if that use involved implantation in his body. . . .

“The Medical Devices Amendments of 1976 elim-

inate the deficiencies that accorded FDA ‘horse and buggy’ authority to deal with ‘laser age’ problems. It is important not only in what it will do to protect the consumer, it is also important as a symbol for the kind of regulation that I feel is most appropriate to Government. It does not represent another expansion of Government into affairs we might better manage ourselves. Instead, this is an example of Government doing for the individual citizen what he or she cannot do unaided.”

President Ford in statement issued at the time he signed the Medical Devices Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act of 1938.

X-ray Scans: Getting A Clearer Picture

A new type of x-ray system uses a computer to produce a picture of a cross section of any part of the body as it would be seen looking down through the patient from head to foot. Called computed tomography, the new procedure is especially effective in helping to diagnose tumors, blood clots, and other abnormalities in soft tissue.

by Valorie A. Britain

A 21-year-old sailor complains of chronic headaches. A series of skull radiographs is negative.

A young boy is hit in the head while playing. X rays show only a small skull fracture.

A woman with severe pain in her hip is admitted to the hospital. X rays of her pelvis show nothing abnormal.

Fortunately for these people a new computer-aided x-ray machine has been added to the physician's diagnostic tools. The machine, using a technique called computed tomography (CT), makes it possible to obtain a clear x ray of a cross section or slice of any region of the body as it would be seen looking down through the patient from head to foot. These pictures, or scans as they are called, allow the doctor to pinpoint abnormalities that until now have been fuzzy or even undetectable on x-ray films or radioactive scans. The CT procedure can be done quickly, easily, and painlessly.

CT scans on the three patients cited revealed life-threatening situations. The sailor had a large brain tumor—almost impossible to detect without the lengthy, risky, and unpleasant procedure of injecting dye into the brain. The boy had a dangerous blood clot, requiring immediate surgery. The woman had an abnormality where the

pelvis connects with the spine, which was found to be cancerous. In all cases, the CT scan made possible quick, accurate diagnoses and appropriate treatment of the patients.

Physicians use a variety of diagnostic techniques to gain information about diseased tissue and bones within the body. Their sense of touch, x-ray pictures, radioactive tracers, and exploratory surgery are among their main methods. Although all are useful, each has its limitations.

Exploratory surgery involves the discomfort and risk that goes with any operation. Simple x-ray examinations are adequate for diagnosing most bone diseases and fractures, but often are not effective in diagnosing tumors or other problems involving soft tissue.

When ordinary x rays are inadequate, special radiographic procedures may be used. These may require injecting a dye or radioactive isotope into the bloodstream and tracing it through the system by means of an x ray or radioactivity counter. Another method requires removing some of the spinal fluid, replacing it with air or another gas, and tracing the gas through the brain. Such procedures may involve considerable discomfort and risk, and their reliability for distinguishing certain conditions is low. But until the development of computed tomography and diagnostic ultrasound, these procedures provided the best available diagnostic information on soft tissue. Ultrasound—extremely high frequency sound vibrations—is useful in diagnosing some types of disease, but its applicability is limited.

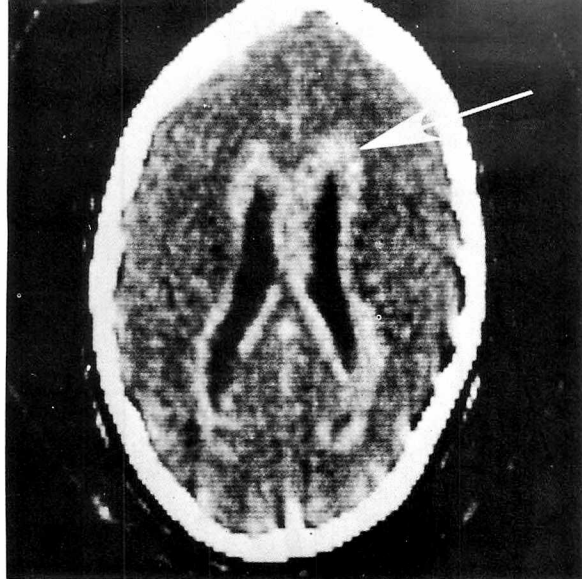
Computed tomography has been called, by its most enthusiastic proponents, "one of the world's major medical events" and the greatest break-

through in x-ray technology since the discovery of x rays by Wilhelm Conrad Roentgen in 1895. Others refer to it as a "revolutionary development" that will dramatically improve diagnostic capabilities. The reason for such praise is that CT scans usually provide as much diagnostic information as other radiation techniques and in many cases significantly more data on the extent and nature of a problem.

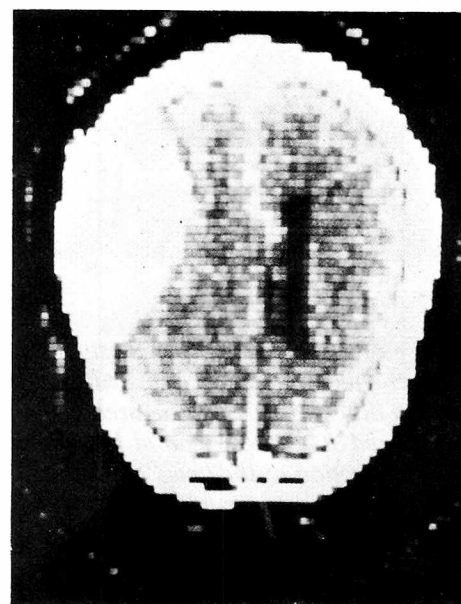
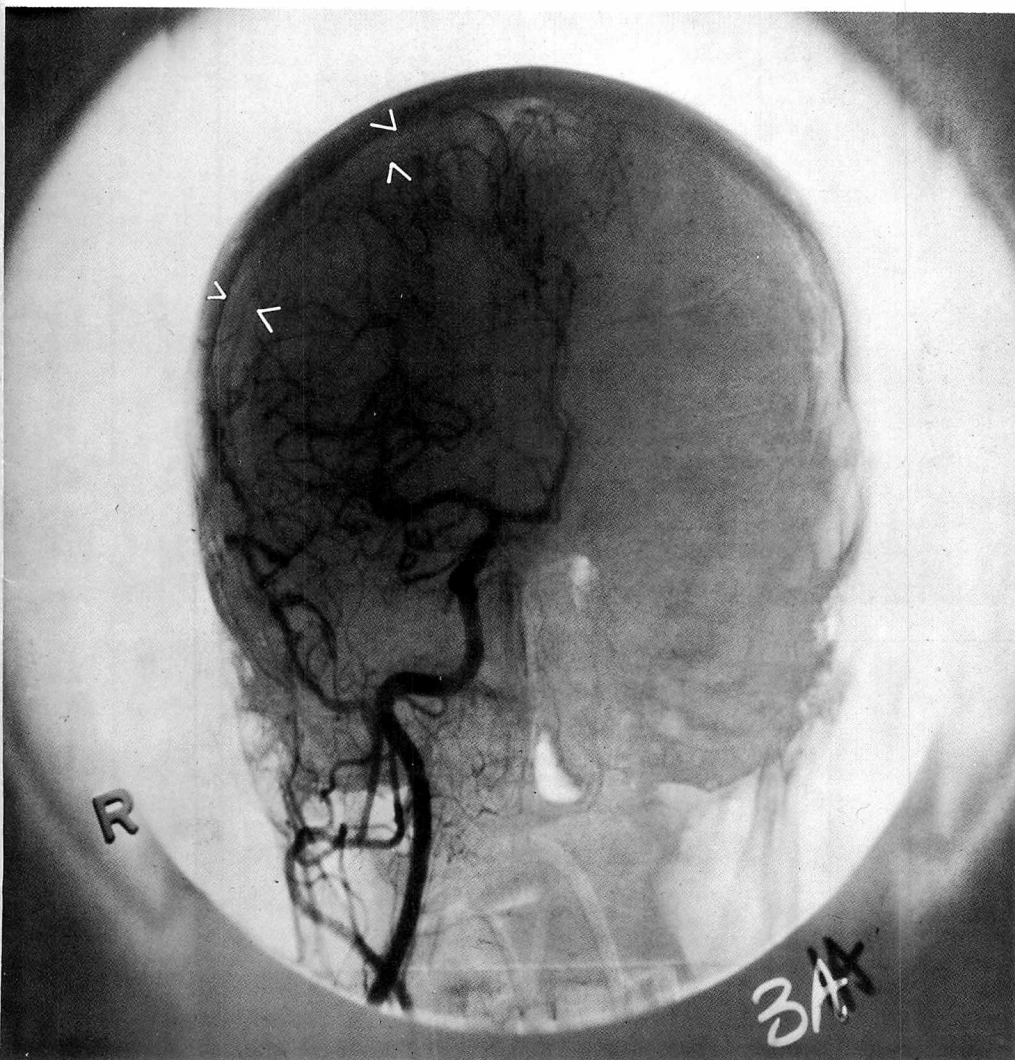
The primary difference between CT scanning and traditional x rays is the method of detecting the radiation that passes through the patient and the use of a computer system to process the data. The CT scanner replaces photographic film with a more sensitive sensing device or detector, such as sodium iodide crystals or semiconductors.

Conventional x-ray pictures are obtained by passing x rays through the body and onto the film to produce a projection or shadow of everything standing between the x-ray source and the film. While this method has been valuable, it has some significant shortcomings. Perhaps the most serious drawback is that images of objects at different depths in the body are shown one on top of the other on the x-ray film and are difficult or impossible to distinguish from one another. This is particularly true when the density of one structure in the body differs only slightly from the density of a neighboring one, as often is the case with a tumor and the tissue in which it is embedded. To overcome this problem, physicians may order many x rays from different angles, but this results in a large dose of radiation to the patient.

Computed tomography is not all new. The principles of tomography



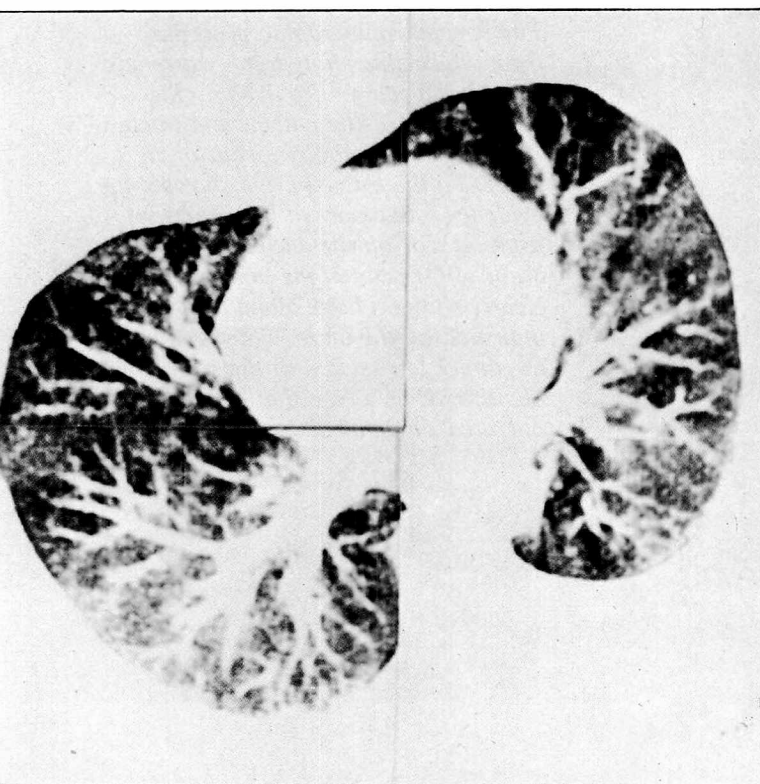
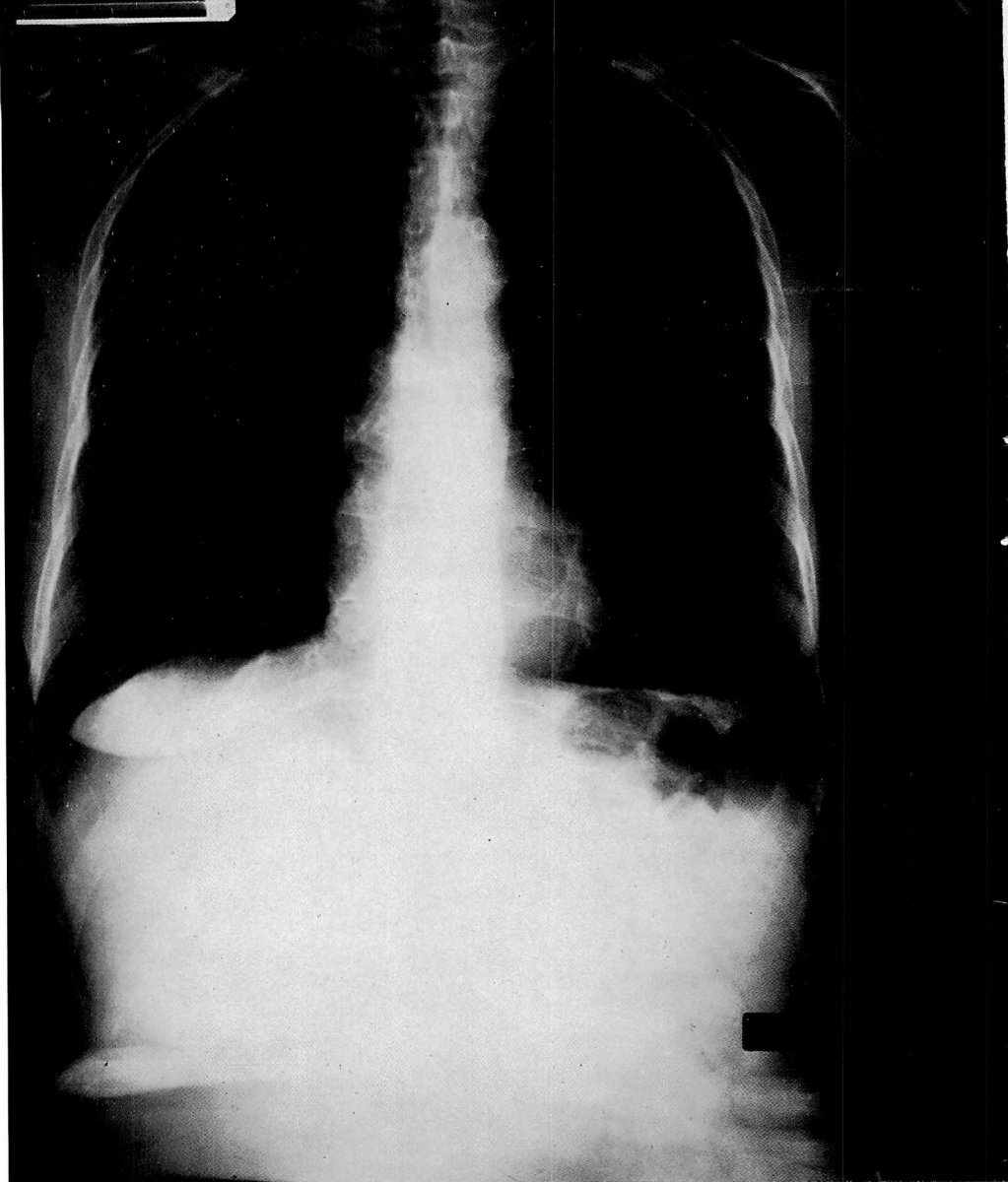
Scan shows tumor surrounding the cavity within the brain that contains cerebrospinal fluid. Without using a CT scan, diagnosis of this condition probably would require a procedure that involves placing a needle into the brain.



The special radiographic procedure from which this photograph was made required injection of a dye into the bloodstream of the patient and tracing it through the brain by means of an x ray. To the trained eye it shows some evidence (area marked by arrows) of a blood clot on the surface of the brain. A CT scan of the same individual clearly shows a large blood clot—indicated by the large white area in the upper left section of the scan—and identifies it as a type that should be operated on immediately.

A standard x ray of a normal chest.

These two CT scans of the chest show how the picture can be adjusted to depict different parts of the area being examined. The chest scan at left shows a cross section of the heart and lung fields with the image adjusted to show the pulmonary vessels. At right is a scan of the same section adjusted to show the heart.



have been used in medical radiography for over 50 years. It is the marriage of the tomographic process to the computer that is innovative. "Tomos" is the Greek word for cutting or slicing. Tomography is the special technique of making x rays from many different viewing angles in such a way that only one plane through the body is sharply focused on the film and the other planes are blurred. The addition of the computer has made it possible to look at a portion of the body from literally thousands of views and to reconstruct these views into a single image.

This is how it works: The patient lies on a stretcher-like table. A moveable frame that holds the x-ray tube and detectors is positioned so that it can rotate around the part of the body to be examined. The machine directs beams of x ray from one side of the frame through a narrow cross section of the body (about one-half inch thick) to be picked up by detectors on the other side of the frame. The detectors record the amount of radiation that passes through the body. The denser the tissue, the more radiation it absorbs, and the less reaches the detector.

The frame then rotates and the procedure is repeated until the body has been viewed from many different angles. During the procedure, thousands of x-ray intensity readings are taken and are fed continuously into a computer. From these data the computer calculates the relative densities of the tissues within the slice. These measurements of tissue densities are used to build a picture of the slice. Six to eight slices usually are taken as part of a routine scan.

The picture of each slice is displayed on a television monitor or oscilloscope and can be photographed for a

permanent record. It is then up to the physician to use his knowledge and experience to make diagnoses from the images of normal and abnormal tissues and organs.

The scanner is superior to ordinary x-ray techniques in many ways. It is far more sensitive to differences in tissues and therefore can distinguish between tissue structures of similar but not identical density.

Although the scanner, like conventional x-ray equipment, produces a two-dimensional picture, the picture is a cross section of the body instead of a projection. Thus, in effect, CT can produce three dimensional information in the form of a series of cross sections. This provides a more realistic representation of anatomy than conventional radiography.

The high diagnostic accuracy of the scanner was shown in a study involving 600 brain scans. The accuracy of CT was compared with the injection and tracing of dye, gas, or an isotope, in cases where both CT and one of these other techniques were used on the same patient. The results indicated that CT was equal to or superior to the other method in 95 percent of the cases.

Another important advantage is that all information is stored in a computer, making the computer itself a diagnostic tool—one that is far better equipped to record small irregularities than is the human eye.

From the patient's point of view, the major advantages of computed tomography are that the examination itself is painless and there are no significant side effects.

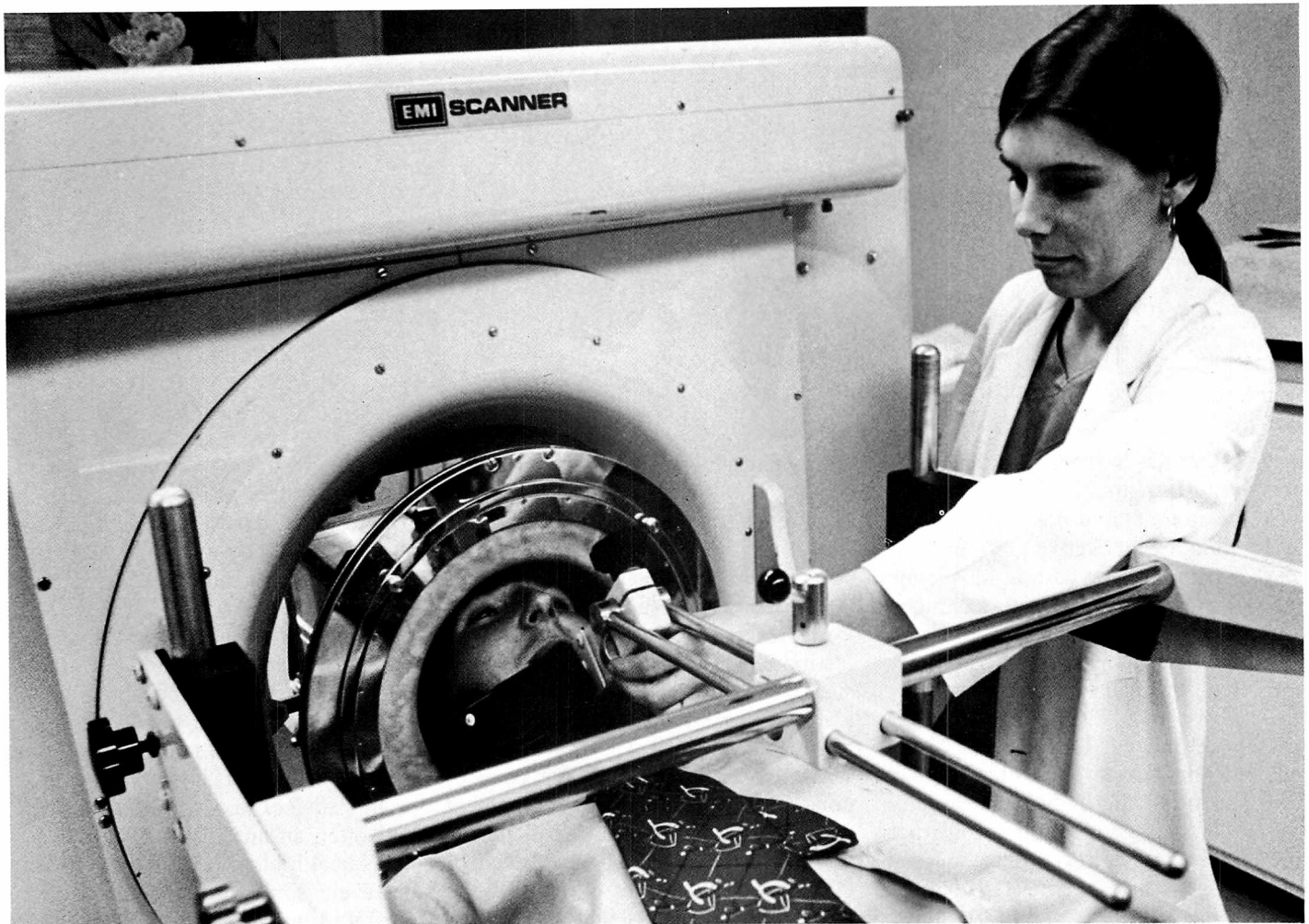
Finally, economics seems to be in favor of CT—at least for the present. Scanners are expensive to buy, ranging from \$250,000 to over \$600,000 for

the newest units. Nevertheless, most health planners and hospital administrators agree that this initial high cost is offset by the cost-effectiveness of the method. A CT brain scan, for example, can be done by a single technician in a half hour or less and costs about \$200. It does not require hospitalization of the patient. Procedures involving the injection and tracing of gas or dye, on the other hand, may require hospitalization for 3 to 5 days as well as the services of a specialist, a nurse, and often an anesthetist.

As health officials look to the future, however, some are concerned about the rapid proliferation of these expensive new machines. It seems that every hospital in the United States wants a CT scanner. If this comes to be, it could raise the cost of medical care.

There are also some technical disadvantages to the CT scanner. It is critical that the patient does not move because this can result in a blurred image or "artifacts"—artificial structures produced by motion—which may make it necessary to repeat the scan. In addition to voluntary patient movement, involuntary motion of organs is a problem when scanning the torso. This makes the scanner unsuitable for determining how certain organs are functioning, such as the gastrointestinal organs.

Motion problems can be alleviated by reducing scan time—the time required to accumulate all the data necessary to reconstruct the image of a single slice. Scan time now varies between 5 minutes and 5 seconds per slice, depending on whether the CT unit is an older or newer model. Manufacturers are working hard to overcome motion problems by faster scanning cycles and by synchronizing scanning with respiration and heartbeat.



Placement of the subject is checked by an x-ray technologist at George Washington University Hospital as part of the preparation for a head scan.

An x-ray technologist at George Washington University Hospital looks at a polaroid picture of a scan made by a camera mounted on the viewing unit of the scanner.



The first CT scanner, marketed in 1972 by a British firm, was designed to do only studies of the brain. It was not until 1974 that a whole-body scanner became commercially available.

Diagnosing brain disorders with conventional x-ray equipment is very difficult. Many brain abnormalities are virtually inaccessible to ordinary flat x rays because the bony skull absorbs most of the x rays and obscures the view of what lies within. But the brain seems especially well suited to the use of tomography because, unlike the heart and certain other organs, the brain does not have any movement of its own, and the relative uniformity in density of brain tissue does not pose the same problem for the scanner that it does for common x ray procedures.

CT scans of the brain have enabled doctors to differentiate between various types of strokes such as hemorrhage (bleeding) or infarction (a localized area of dead tissue); to determine whether bizarre behavioral changes are due to organic brain damage or non-organic causes such as emotional problems; to distinguish between white and gray matter in the brain; and to get x rays of lesions in the optic nerve.

Computed tomography is expected to reduce significantly the use of x rays and other radiographic procedures involving soft tissues in the head. For example, reports from clinical centers using head scanners show a decrease of 90 percent in the use of gas injection and tracing, a decrease of 60 percent in the use of isotopes, and a 10-15 percent drop in the use of dye in conventional procedures. It is unlikely that CT will completely replace these procedures, however, and CT is expected to have little effect on the number of skull x rays made to obtain information on bone damage.

While the usefulness of the head scanner is being heralded almost universally, much less is known about the potential of the newer whole-body scanners, which can examine any cross section of the body, including the head. According to one estimate, there are only 25 body units in clinical use in the United States and only a quarter of these are of an improved design that provides a high quality image. Approximately 250 head scanners are currently in use. An additional 400 scanners—about one-third of which are whole-body machines—are on order in the United States.

The most promising applications for the body scanner appear to be in areas where present diagnostic methods are inadequate. Projected uses include distinguishing among abscesses, cysts and tumors or between benign and malignant tumors; spotting cancer before it can be found by other means; monitoring the results of cancer therapy and identifying the area to be treated; and detecting post-surgery complications such as a hemorrhage.

The body scanner already has been used to demonstrate abnormal spinal cord cavities, masses in the kidneys and pancreas, lymph node irregularities, breast tumors, and aneurysms (a weakness in an artery). Some of this information otherwise would have been revealed only by surgery or autopsy.

Because of the limited experience with it, the extent to which the body scanner will replace traditional procedures has not yet been determined. Some established procedures provide unquestionably valid diagnostic information for some organs, but for other organs these techniques are inadequate. Fluoroscope examinations of the upper and lower gastrointestinal tract, for example, have been successful for years.

In contrast, certain liver diseases and cancer of the pancreas are most frequently diagnosed only as a result of their symptoms or exploratory surgery and tissue sampling. Just as in the case of skull scans, CT whole-body scanning is expected to have little or no effect on bone examinations because traditional procedures give adequate data.

As the agency with primary authority over radiation-producing electronic products, the Food and Drug Administration has evaluated the new CT scanners and found that radiation exposure from them is comparable to that from other radiation procedures used for the same purposes. Scanners must meet the applicable requirements of the Federal standard for diagnostic x-ray systems. The standard is aimed at keeping exposure to the patient and medical personnel as low as practicable, without sacrificing diagnostic information.

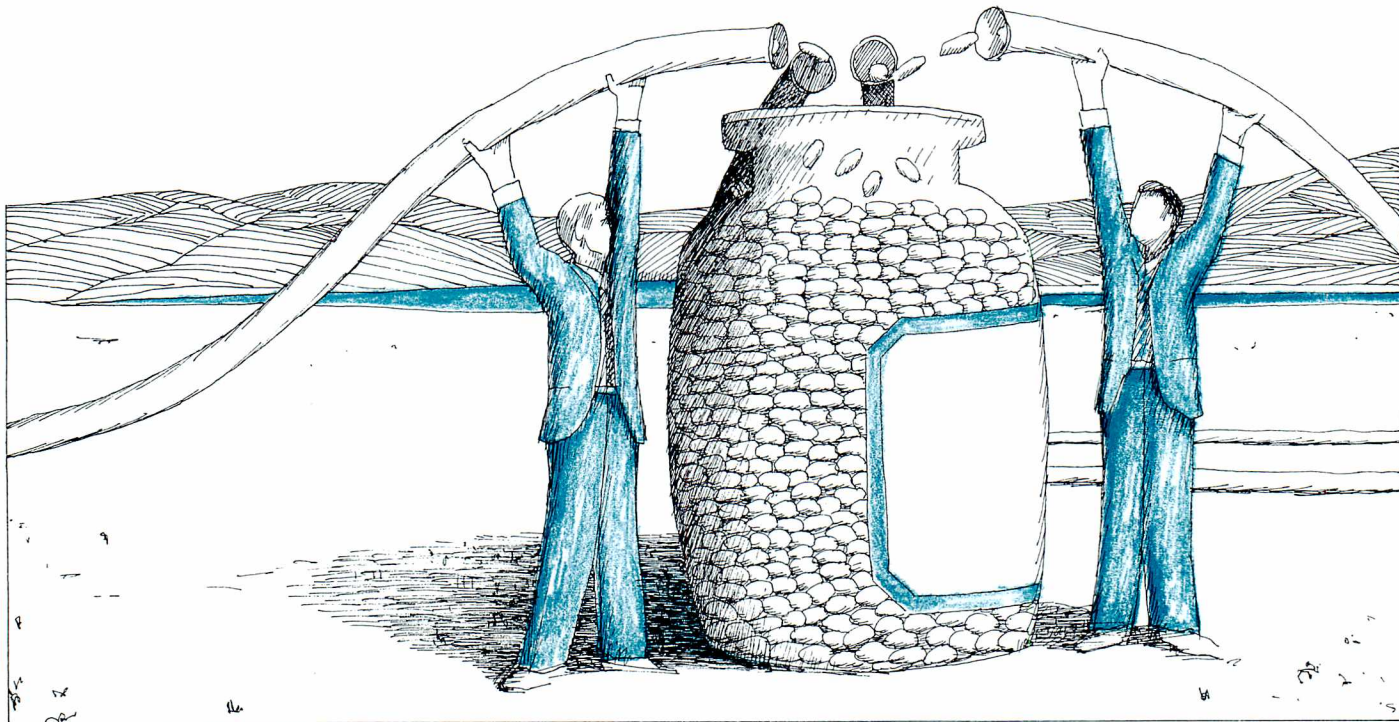
A brain scan gives a radiation dose of 2 to 4 rads (a unit to measure radiation), about the same as that from a routine x-ray series for skull fracture. Although the dose from a single conventional x-ray film is usually a fraction of a rad, x-ray procedures involving the injection and tracing of dye or gas require many films and can impart radiation doses as high as 25 to 50 rads. For examinations of the body other than the head, the dose from a scan is similar to that from the use of a fluoroscope—10-15 rads.

Since the design and performance of CT equipment are so radically different from existing x-ray machines it may be necessary for FDA to amend the x-ray standard to include a few special provisions for these "revolutionary" machines.

Valorie Britain is a freelance writer.

Regulating Vitamins And Minerals

by Harold Hopkins



A new law sharply restricts FDA's authority to regulate vitamins and minerals. It forbids the Agency to set maximum potencies on most vitamins and minerals and to limit the number of combinations of these products that may be sold. In passing the law Congress has made it clear that FDA should not attempt to provide economic protection for consumers by regulating vitamin and mineral supplements solely because they contain dosages the Agency believes are greater than the body needs or can use, or because they contain added substances that the Agency believes are nutritionally useless.

By an overwhelming vote, Congress has set limits on a program FDA instituted 14 years ago to improve the consumer's economic protection by heading off what the Agency felt to be extravagant and freewheeling promotion and marketing of vitamins and minerals. FDA was concerned about the ready availability of vitamins and minerals at dosages far greater than the body needs or can use. Also of concern was the presence on the market of a large number of vitamin and mineral combinations—often with other, non-nutrient substances added—that FDA thought confused and misled the consumer about his real needs, if any, for extra nutrients.

These concerns still exist, but a new law makes it clear that FDA should not try to deal with them by regulation. The right of the consumer to choose vitamins and minerals in high potencies and varying combinations, laced perhaps with such non-nutrient sub-

stances as rutin and para-aminobenzoic acid, now will be as wide open as his pocketbook, so long as they are not harmful.

The new Federal law limits FDA's authority to regulate vitamins, minerals, and certain other substances that are sold to supplement the nutrients people get from the food they eat. In effect, it says that:

- The proper role of FDA in regulating vitamins and minerals is to protect consumers from substances that might be harmful to their health and from false claims.

- FDA should not concern itself with protecting consumers' pocketbooks by seeking to restrict the maximum potencies or combinations of vitamins and minerals to those that the Agency believes have nutritional benefit.

The new law does not affect FDA's existing authority to act against any vitamin or mineral product whose labeling is false or misleading, nor does it

affect FDA's authority to classify and regulate vitamins and minerals as drugs if they are represented for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease.

The new limitations on FDA's authority to regulate vitamins and minerals are contained in an amendment to the Food, Drug, and Cosmetic Act. It was enacted after a wave of protests to Congress against FDA regulatory proposals by those who favor unrestrained marketing of vitamins and minerals.

In imposing the restrictions, Congress took the position that vitamins and minerals—except when potentially harmful to health—are foods that are safe to eat and thus are not subject to regulation as drugs or food additives. There shall be no more restriction on the maximum amounts and combinations of safe vitamins and minerals or other ingredients marketed than there are on other safe foods. It will be up to consumers to decide on their own the kinds and amounts of vitamins and minerals they need to supplement their diet, and whether massive doses of these substances are nutritionally useful or a waste of money.

The new law limits FDA's authority to regulate vitamins and minerals sold in the form of pills, capsules, or small units of liquid such as drops.

The new law's limitations do not apply, however, to vitamin and mineral products represented for use by children under 12, by pregnant women, or by women who are producing breast milk. To prevent inadvertent use by children or pregnant or lactating women of products not intended and not suitable for them, FDA is authorized to issue whatever regulations are necessary. Such regulations might require appropriate warnings on labels of those vitamin and mineral products for which FDA cannot control potencies and combinations. FDA is also authorized to prohibit the listing on labels of any vitamin or mineral unless its potency is high enough to be of nutritional significance.

The new legislation does not affect FDA's authority to regulate the kinds and amounts of vitamins, minerals, and other ingredients that are required in conventional foods such as milk, enriched bread, and enriched rice, as well as in products that simulate conventional foods, such as soy-based proteins for meats and poultry. Similar authority is retained by FDA for foods

used in the treatment of specific diseases and for foods that are sold or promoted as the sole item of a meal or of the diet, such as Metrecal. Congress said it is essential that consumers be confident that foods promoted as the only item of a meal or diet are nutritionally adequate to maintain the user's health during the period they are being used.

The legislation is the latest chapter in an FDA regulatory effort that had become embroiled in controversy and legal challenges. FDA had been required by a Federal appellate court's order to give up its earlier plans to classify high-potency doses of single vitamins and minerals as drugs. The court questioned the Agency's intentions to set maximum dosages for single vitamins and minerals, and advised FDA to consider increasing the maximum permissible potencies of ingredients in combinations and to consider petitions to allow a larger number of combinations on the market. The court upheld FDA's plans to keep non-nutrient ingredients out of vitamin and mineral combinations.

The court, which was acting on a group of combined appeals, had stayed the effect of the FDA regulations which were adopted in 1973 and had been scheduled to go into effect July 1, 1975.

Upon enactment of the legislation a good part of the court's orders became a dead issue. Under the new law, FDA:

- Cannot set maximum potencies for the vitamin and mineral products covered.

- Cannot classify such vitamin or mineral products as drugs solely because their potencies exceed those FDA deems to be nutritionally rational or useful.

- Cannot limit the kinds of and numbers of vitamin-mineral combinations offered.

- Cannot use the misbranding provisions of the Food, Drug, and Cosmetic (FDC) Act to prohibit the listing of nonvitamin or nonmineral substances as ingredients in such combination products.

The legislation authorizes FDA to retain controls under other provisions of the FDC Act where there is a concern for safety. FDA already has classified vitamins A and D as prescription drugs when in doses exceeding specified amounts because of their known potential for harm when taken

in high potency doses. FDA also retains the authority to impose appropriate restrictions on the use of vitamins and minerals as food additives when they are not generally recognized as safe under the conditions of use.

The new law permits non-nutrient substances such as rutin and para-aminobenzoic acid to be included in vitamin-mineral combination products and to be listed on the label as part of the ingredients statement. But the labeling and advertising for products that contain such ingredients must not give them emphasis or prominence and they may be carried only in a list of all ingredients. Although nutritional claims have been made for rutin, para-aminobenzoic acid, and certain other substances, they have never been scientifically shown to have any nutritional benefit.

New authority is granted FDA to institute seizure or injunction actions against vitamin and mineral products whose advertising is false or misleading "in a material respect." But seizure may not be made from a retailer unless he can be shown to be responsible for the advertising or is using it to promote the product at the point of sale. FDA may not institute seizure or injunction under this provision, however, unless the Federal Trade Commission first declines to take action under its authority to restrict false and misleading advertising. If the FTC does not act within 90 days after being notified by FDA of a suspected violation, FDA could then move against the product under its new authority.

In granting this new power over advertising, Congress said that FDA should issue a written notice or warning to a violator instead of taking judicial action when the Agency believes this will adequately protect the public interest. The new FDA authority to act against false advertising is intended as a partial substitute for the authority taken away from the FDA under the other provisions of the new legislation, Congress said.

FDA will now revise its regulations on vitamins and minerals to comply with the new amendments to the FDC Act as well as the directions of the appeals court. The target date for publication of the revised regulations is October 1, 1976.

Harold Hopkins is editorial director of FDA CONSUMER.

Strengthening Drug Manufacturing Practices

Devising a formula for a drug that will be safe and effective is only part of the battle. The drug also must be manufactured to exacting standards to make sure it is not too strong, or too weak, or impure. Good Manufacturing Practice Regulations for drugs are a little known but vital part of FDA's consumer protection efforts, and the Agency recently proposed to strengthen these rules in a number of important ways.

by Annabel Hecht

Millions of dollars and years of research and testing may go into the development of a new drug. The active ingredients are analyzed; their previous uses, if any, are thoroughly investigated; and the drug is extensively tested, first in animals and then, under carefully controlled conditions, in humans. If this process demonstrates that the drug's benefits outweigh any risks associated with its use, FDA will approve it for sale to the public.

But once mass production begins, what protection does the public have against manufacturing practices that might result in the drug being impure or too strong or too weak? This is where FDA's current Good Manufacturing Practice Regulations (GMP's) enter the picture. Though generally unfamiliar to the public, these requirements—which FDA recently proposed to strengthen—are a vital part of FDA's efforts to assure that consumers receive only drugs that are safe and effective.

The concept that all drugs must be manufactured in a plant established, equipped, administered, and operated in conformity with "good manufactur-

ing practices" was introduced in 1962 by the drug amendments to the Food, Drug, and Cosmetic Act. The purpose was to protect the public from faulty drugs coming from plants that had poor operational procedures, lacked quality controls, or were run by unqualified personnel. FDA inspectors had found wide discrepancies between the quality of operations from one drug manufacturer to another and even between different plants under the same management. The new regulations were intended to provide general requirements to assure that all drug products would meet the same standards of safety, strength, quality, and purity.

The first regulations, issued in June 1963, were general in nature. They covered such matters as personnel qualifications, design and maintenance of buildings and equipment, storage, handling and control of the various ingredients that go into the finished product, quality controls throughout production, controls to prevent mislabeling, and the kind of records that should be kept on the manufacturing process, distribution, and consumer complaints.

To explain the new regulations to industry and to foster a climate of cooperation, FDA personnel conducted conferences and demonstrations at various locations throughout the country, including visits to drug manufacturing plants. The primary targets of these educational programs were industry employees with responsibilities in the actual manufacturing process and those who were responsible for training other employees.

The first substantial revisions in the GMP's came in 1971. Under these new

regulations specifications for buildings and equipment and sanitary facilities were broadened. More safeguards were provided against mixups in ingredients, against traces of one drug getting into another during the manufacturing process (called cross-contamination), and against contamination of a drug from illness of employees. Stricter controls were required in a number of areas, including production, packaging and labeling, and laboratories.

The latest proposed revisions reflect changes in drug technology, FDA's experiences over the past 12 years with the GMP's, and the views of the drug industry and drug trade associations as expressed in meetings and discussions.

Two other considerations played a part in the decision to strengthen the regulations. First were studies by two Federal watchdog agencies, the Office of Management and Budget and the General Accounting Office, on the need for uniform standards for medical supplies purchased by Federal agencies. These studies led to FDA taking over responsibility for assuring the quality of all drugs purchased by Federal agencies. Previously the Public Health Service, the Veterans Administration, and the Department of Defense had handled quality assurance on the drugs they purchased.

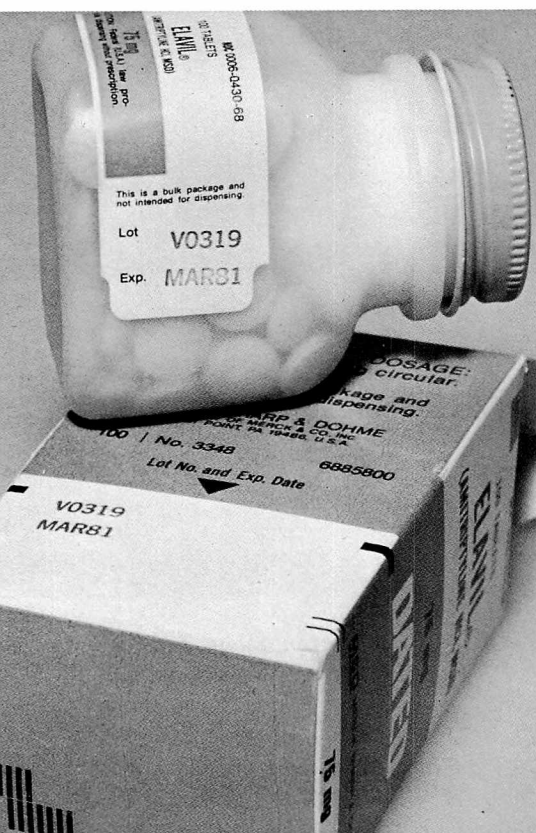
In addition, a drug study panel established by the Office of Technology Assessment of the U.S. Congress reported that the current GMP's were too general and were subject to wide differences in interpretation. The panel said that current regulations are not adequate to assure that different brands of the same generic drug will be absorbed by the body at the same rate



FDA's first Good Manufacturing Practice Regulations for drugs—issued in 1963—were rather general in nature. They included requirements that buildings and equipment must be adequately designed and maintained, that each lot of a drug must be tested for quality, and that key personnel must be qualified by education or experience.



Stricter controls on labeling were among the new requirements imposed in 1971, when the first substantial revisions were made in the drug GMP's.



Standards Proposed for Injectable Drugs

Strict manufacturing standards for large-volume parenterals—drugs that are injected into patients to supplement body fluids—have been proposed by FDA. The proposed regulations cover such areas as the quality of the water used to make the drugs, the quality of the air in the manufacturing plant, and minimum sterilization processes.

“Because these drugs are injected directly into the bloodstream of weakened or seriously ill patients, there is no margin for error in their manufacture or use,” said Alexander M. Schmidt, M.D., Commissioner of Food and Drugs. “The smallest problem of quality, strength, or purity can jeopardize a patient’s life.”

Four firms produce 95 percent of the large-volume parenteral drugs made in the United States. About 200 million units of the drugs are used each year, usually administered in hospitals and nursing homes. Since 1971 there have been six recalls of these drugs and in some cases plants had to be temporarily closed to correct deficiencies. As a result of these recalls, FDA undertook an intensive review leading to the proposed standards. Manufacturers already are changing their processing procedures to meet the proposed standards.

The proposed regulations were published in the *FEDERAL REGISTER*, June 1, 1976. Comments may be submitted within 120 days to the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20852.

Proposed new GMP's would require expiration dating on all drugs.

and thus will have the same therapeutic effect. (This is called bioequivalence.) The proposed revisions would not assure the bioequivalence of different brands of the same generic drug but they would help iron out some production deficiencies which may have contributed to bioequivalence problems.

The proposed revisions of the GMP's would impose specific mandatory requirements for drug manufacturing procedures and would apply to all drug products intended for humans or animals. For the most part, the revisions represent a strengthening of operational procedures, steps which many manufacturers have long since undertaken. Failure to follow them, FDA has warned, could lead to regulatory action.

Among the significant changes is the proposed requirement for expiration dating of all drug products. Earlier versions of the GMP's required dating only for those drug products “liable to deterioration.” Extending the requirement to all drugs would assure consumers that the products they purchase haven't lost their strength or purity while standing too long on a store

shelf, and would help them determine when to dispose of drugs stored in their own medicine cabinet. A stability testing program is called for to establish the accuracy of the expiration dates.

The new regulations also would require that specific production, control, and distribution records be maintained in such a way that written summaries covering every batch of each drug product can be prepared and evaluated on an annual basis.

All firms would be required to have a quality control unit with responsibility to approve or reject all drug components, finished drug products, containers, closures, and labels. These and other manufacturing and control procedures would have to be spelled out in writing. Specific procedures and responsibility for a sanitation program also would have to be put in writing.

To prevent cross-contamination and mixups of drugs, every step in the manufacturing process would have to be carried out in specifically defined areas, and penicillin production would have to take place in an entirely separate facility. The proposed new regulation would require that all non-penicillin drugs be free of detectable penicillin.

More teeth have been put into the

language of the proposed regulations. The word “prevent” has replaced “minimize” in several sections to eliminate confusion about what FDA wants to be accomplished. More specific procedures for handling complaints from consumers and health professionals would be required, including review of all written and oral complaints by the firm's quality control unit.

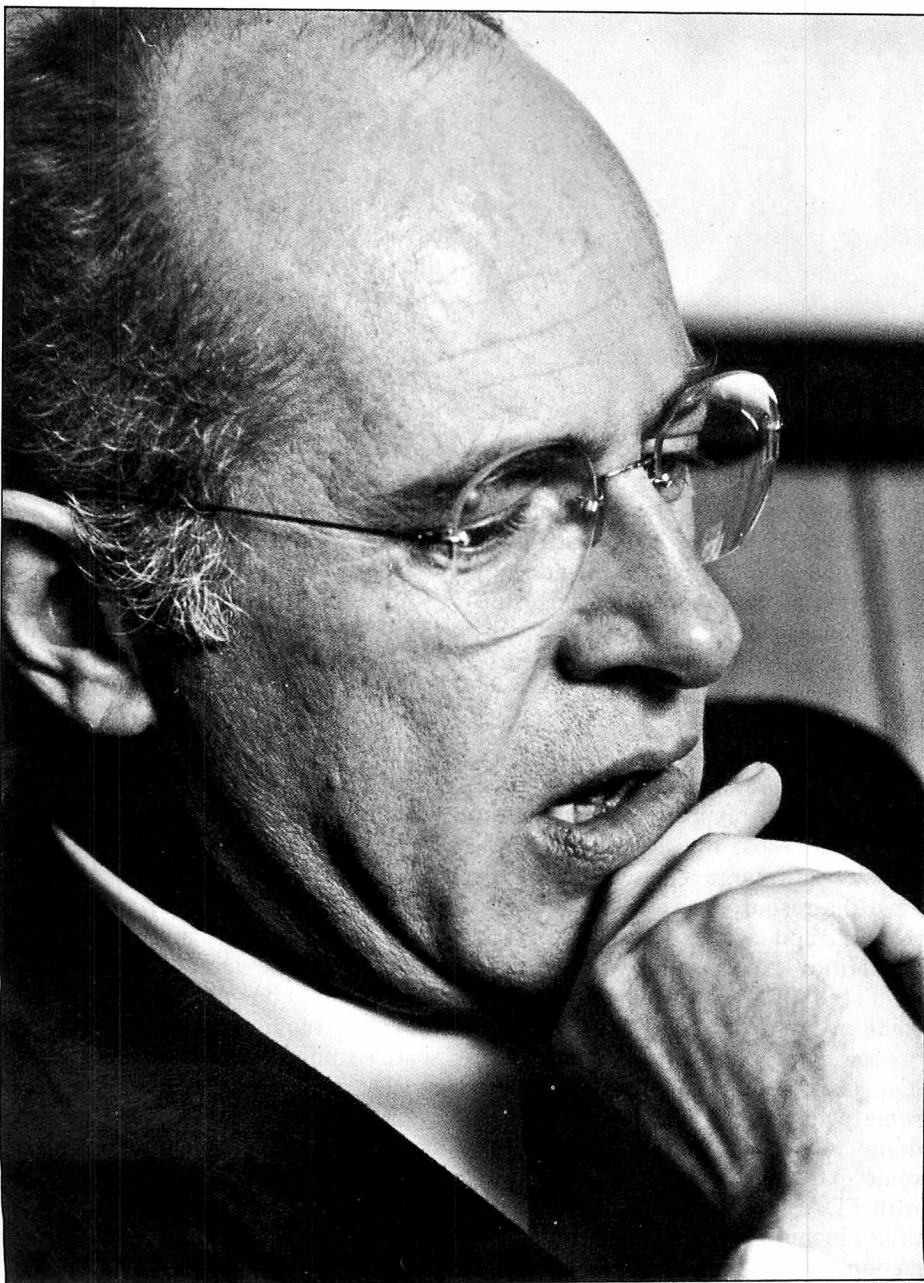
And to make certain that top management knows when something goes wrong, the proposed regulations would require that procedures be established for notifying responsible corporate officials of the firm in writing of any drugs recalled and of any investigations conducted by FDA.

Comments of consumers, drug manufacturers, and other concerned groups are being studied before final proposed regulations are issued. In the meantime, Good Manufacturing Practice Regulations are being developed for specific classes of drug products such as intravenous solutions, medical gases, and radiopharmaceuticals, and for certain production activities such as the manufacture of bulk drug components, repacking, and relabeling operations.

Annabel Hecht is a staff writer with FDA's Office of Public Affairs.

FDA And Its Critics

Alexander M. Schmidt, M.D., marks the start of his fourth year as Commissioner of Food and Drugs this July. During his tenure, the Agency has come under the most intense scrutiny and pressure in its history. In this interview with Wayne L. Pines, deputy assistant commissioner, Office of Public Affairs, Dr. Schmidt discusses a number of important issues: the amount of criticism FDA receives, Congress, regulatory reform, his goals for the Agency, and the need for a national debate on FDA's future role.



Q. Commissioner, earlier this year the Food and Drug Administration underwent an extended period of criticism by Congress and the General Accounting Office (GAO). In view of all this criticism, what is the state of FDA today?

A. I think FDA is doing a better job today than it ever has in its past, and I think most people agree. They know we have a staggering amount of responsibility and quite limited resources. I believe the people of this country are getting more than their money's worth from this Agency in terms of consumer protection.

As I've listened to the criticisms, they seem to stem from one basic fact — that people's expectations for FDA action have increased much more rapidly than our ability to act. For example, we were criticized for not having monitored 12,000 physicians who conduct clinical investigations. Well, we simply have never been given the resources to do that kind of a job.

Another reason there appears to be criticism of FDA is that we are now just beginning to debate, on a national level, some very important things that relate directly to what FDA does. I'm referring specifically to what I see as the start of a national debate on the meaning of "safety," and the considerations that go into the type of benefit-risk decisions FDA must make. We're beginning to debate things that have never really surfaced before.

Q. Is this debate necessary?

A. It's essential. Basically, the public must decide what it means by the word "safety," and what degree of risk they are willing to accept for the benefits they want. People fly in airplanes because they accept flying as "safe."

Let me give you just one example in the food area. Many people have differing opinions about food colors. The

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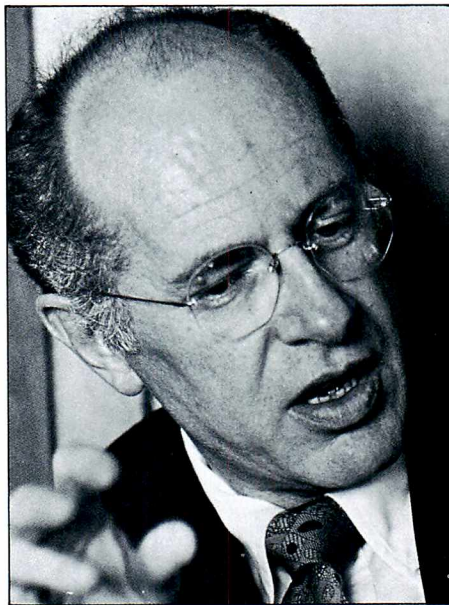
safety of both Red No. 2 and Red No. 40 has been questioned a lot lately. What is interesting to me is that for the first time in my memory the basic question is being asked of whether or not the American public wants food coloring at all. Now, debating questions like that, which I encourage, often sounds to some people like criticism of FDA, but it really isn't.

Q. *What effect does public opinion and a public debate like this have on FDA?*

A. Continuing with the color additive issue, I am assuming that if the majority of the people in this country felt that color additives used solely for cosmetic purposes should be removed from foods, then Congress would change the law. A lot of people forget that FDA does not decide whether there are to be color additives in foods. What we do we are instructed to do by the law. The law passed by Congress says that if a color additive is "safe," it is to be approved. Clearly our present public policy is that color additives can be used if safe. The American people, in many of the areas in which we deal, must speak through Congress to effect a change in the law or public policy. If the American people change their minds, then it will be up to Congress to reflect that change in law. The same principle applies in other areas, such as food additives. FDA did not decide that food additives should be allowed, or under what conditions. Congress did.

Q. *You said that people expect more now of FDA. Why is this so? And can FDA meet those expectations?*

A. People today expect more of all their institutions. This is one result of our communications systems; people are more knowledgeable today than ever before. More people know



about cyclamates than know the name of their Congressmen or Senators. As knowledge rises, so do expectations. People are becoming more and more concerned about what they put into their mouths, and more knowledgeable and concerned about their environment in general. They expect nearly perfect protection from their government.

If we look at recent criticism of FDA, and ask whether we can now meet the public expectation inherent in those criticisms, the answer is "No." We are not large enough, we don't have the resources, we don't have the scientific and legal expertise to do what our critics expect of us, and science hasn't all the knowledge required by some of the expectations.

Now, not all of our critics have high expectations of us. There are some people who believe that FDA is doing too much, and there are even some extremists who want to do away with FDA altogether, and leave everything, including safety and health protection, to the controls inherent in the

free enterprise system.

What we do need is a consensus about what FDA should be doing, about the measure of protection that the American people should get from their Government. Then we should be given the money to do the job. We must try to find the right balance between public expectations and Agency resources.

Q. *What does FDA need to do its job better?*

A. There are many things. Let me mention just a few, not necessarily in order of importance, but in the order I think of them.

First, we have become a court-oriented, legal-oriented, lawsuit-oriented society. This Agency is suffering in part just from a lack of enough lawyers. We also need more authority to handle directly some of the legal actions in which we get involved. We should not have to go through the Justice Department for certain limited kinds of cases or appeals.

We need to know who is making the products we regulate. Right now we don't have registration requirements in the food area, so we don't even know who makes what. We need some authority as basic as being able to go into a plant and look at certain kinds of production and quality control records. We could do much better if we had the authority—as do most other regulatory agencies—to subpoena records and people.

Some of the criticisms of Agency actions could be answered if the Agency could require certain kinds of research studies to be done, particularly in the drug area. I think we could approve some drugs earlier than we do now, if we could be assured that necessary studies on long-term effects of the drugs or studies refining the dose levels would be done as the drug was released. Right now we can't really re-

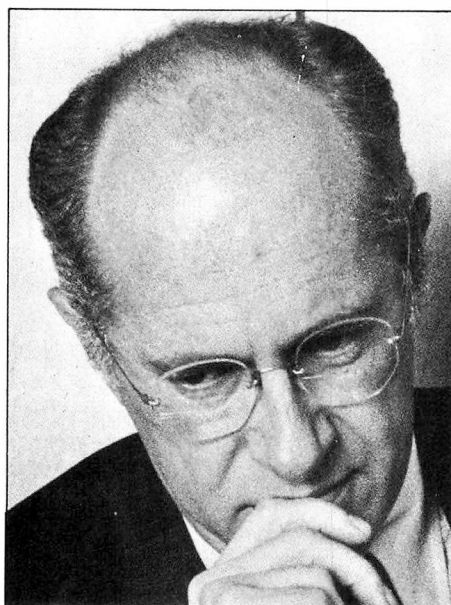
"I think people should know what it is they're putting in their mouths, and how much of it, whether it be sugar, or salt, or the principal ingredient of the food."

quire studies once a drug is approved so we tend to delay approval until we know everything. Senator Kennedy, Congressman Rogers, and FDA all have suggested improvements in this area, and I hope that in the next year or two there will be some desirable changes in FDA authority.

We also require a better scientific capability in the Agency. And we have to gather our scientific people, our legal people, all the people that make up this Agency, in one place. FDA, in the Washington area alone, is now spread out in about 23 different buildings. There is simply no way we can bring together frequently the people who need to work together. So getting the Agency in one location is becoming a higher and higher priority.

Q. *In your view, is FDA particularly susceptible to criticism? Why is it that other regulatory agencies do not appear to be subject to as much criticism as FDA?*

A. There was a time when I didn't think FDA was being singled out for criticism, but I've changed my mind about that. Look at where our criticism comes from. It comes from the press, it comes from the "professional" consumer advocates, it comes from Congress. One reason for the volume of criticism is that FDA makes news. Whenever a Congressman holds a critical hearing on FDA, he makes headlines; when he holds a critical hearing on some other regulatory agency, he usually doesn't. The same



applies to consumer advocates. FDA is a very popular target, as we are so visible and newsworthy.

I have come to conclude that the underlying reason for this phenomenon is that the safety of foods, of drugs, of the birth control pill, of psychotropic drugs, of aerosolized antiperspirants, of cyclamate, of Red No. 2, of all these things, affect everyone in the country, individually and very personally. Everyone eats, everyone uses cosmetics, everyone takes medicine. These things are personal, close, easily understood. And unfortunately, some of our critics take advantage of this to seek notoriety and publicity. Some critics want to change the system, including FDA. Some criticism is quite valid.

Q. *All these questions, of course, lead to the issue of regulatory reform. What does regulatory reform mean to FDA? Is there a need to reform this Agency?*

A. If by reform you mean to improve, to make more efficient, to make more effective, to make better,

to open up more to public scrutiny, to use advisory committees better — if that's what you mean by reform, then yes, FDA should reform, and I think we are reforming.

If by reform you mean that the entire basic philosophy of food and drug regulation is faulty, that the 1962 Amendments requiring that a drug be proved effective are improper, that the system should be changed because it is crooked or because we have sold out to industry or are a captive of industry, then the basis for reform is improper, wrong, and unnecessary.

Q. *You have made the point in some of your speeches that FDA differs from other regulatory agencies. Could you expand on that?*

A. FDA is different from other regulatory agencies. We don't set rates. We don't allocate routes. We are not an agency which directly regulates the economy. What we do is basic: we assure that the foods and drugs and cosmetics and medical devices that are used by the American people are safe and effective. There can be legitimate debate over whether certain types of economic regulation are needed. But I know of few people saying that we don't need some assurance that the products we use every day are safe. And the Food and Drug Administration is the only Agency on a national level that works toward providing that assurance. So, I do think we're different, and I think that it's wrong for the American public to think of FDA in the same context that they think of other regulatory agencies.

Q. *What impact does the current regulatory reform atmosphere have on FDA?*

A. It has both a good and bad effect. It's good in the sense that we're being scrutinized by Con-

After this interview was prepared for publication, Commissioner Schmidt announced that he would leave FDA late this year to become vice chancellor for health services at the University of Illinois Medical Center.

*"... I know of few people saying that
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gress, by the press, and by public groups. While that would make anyone a little nervous, it also speeds up our efforts to improve ourselves. And we have been able, I might add, to withstand the critical scrutiny by these groups quite well.

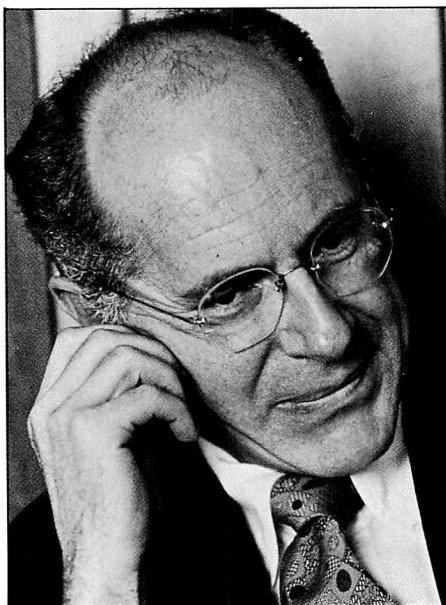
Now, what is bad is that some people are using the regulatory reform issue to try to discredit the Agency. These people are raising the flag of regulatory reform to try to rally others to personal objectives that they have not been able to accomplish in other ways. I think this is a misuse of the regulatory reform issue, and it is an attempt to fool the American people.

One example of this is the vitamin-mineral legislation just passed by Congress, which lessens our authority over vitamins and minerals. I don't think the American people understand what this legislation means. It means that they are less protected from fraud and from potentially unsafe and ineffective vitamin and mineral products. It is not regulatory reform; it is opening the door for fraud in the marketplace.

Q. *There are certain consumer advocates who are especially critical of FDA and who seem to have excellent access to the press. Is the criticism they offer helpful?*

A. Yes, it is, in the long view. I really am delighted that everyone pays a lot of attention to us. I think it's healthy that there is a wide and deep interest in FDA and what it does. My only objection is when people take unfair advantage of the Agency, when they say things they know aren't fair but which are reported in the press as being factual, and when they advocate an unsupported personal bias which is made to appear to be based in science.

Q. *How often does this type of unfair criticism occur?*



A. It occurs often.

Q. *One of the most common criticisms of FDA by consumer advocates is that it does not instantly order the recall of products when some new evidence comes along. This raises the larger issue of why it is that we are constantly finding out new and sometimes startling things about products and ingredients that have been around for such a long time.*

A. I think everyone in the country recognizes that science has grown and developed at an almost unbelievably rapid rate since World War II. Science is developing new detection techniques and information-gathering systems that will let us find out many new things about substances that have been around since time immemorial.

Finding out these new things doesn't mean that everyone should panic. The new hazards we are learning about represent generally infrequent events occurring after long-term exposure. When we discover an acute toxic hazard we ought to, and do, move quickly

to remove it from the marketplace. But I find that some of our critics scare the public by panicking over every new discovery, which just isn't reasonable or necessary.

FDA, like all other regulatory agencies, perhaps more so than the others, must be alert to new information, and we have to review on a periodic basis what has been learned about drugs and food additives and medical devices and the like. We are now working at establishing a routine periodic review of what has been learned about the substances we regulate.

Q. *Since there is much we do not know, would you advise an individual consumer to be cautious about the substances he or she uses?*

A. My grandmother once told me that a good rule to follow was, "Moderation in all things." (Then she added, "except hard work.") I think that people need to have enough information to make an intelligent and wise choice for themselves. FDA should provide sufficient information for people to make informed choices. As a general rule, moderation is wise. If one is immoderate about something, he should know what risks he's taking and make a conscious decision as to whether he wants to take that risk for the benefit he might receive.

Q. *Do you think that the state of the current food and drug supply is good? Do you have any reservations about it?*

A. Without question, our food supply is the safest of any in the world, and it is safer than it's ever been in this country. People forget that as recently as 1900, carbonic acid, sulfuric acid, and things like that were common in our food supply. Botulism was not infrequent; other food poisoning was much more frequent than it is today. Our drug supply

"FDA did not decide that food additives should be allowed, or under what conditions. Congress did."

is clearly the safest and most effective in the world. I am both content and comfortable with that knowledge.

At the same time, as I said earlier, science is going to continue to come up with some startling new revelations. The most important question is, "Can the Food and Drug Administration respond very quickly to that information to make our food and drug supply even better?" And I think the answer to that is, "Yes."

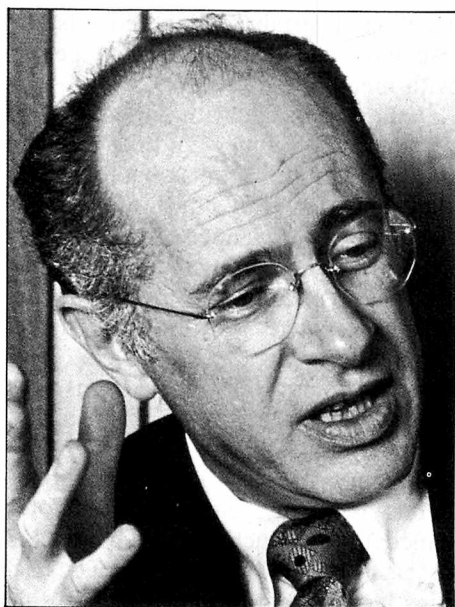
Q. *I guess every consumer would like to know whether there are any foods or drugs that you personally avoid.*

A. Well, I must confess to a desire to reduce risks for myself and my family. I avoid mood-altering and narcotic drugs totally. I avoid alcohol in excess. I avoid an imbalanced diet. I try to eat moderately and well. I refuse to allow my children to develop thoughtless habits. Junk foods, "empty calories," frequent ingestion of sugar—this is what I avoid. I eat bacon and sausage moderately.

Q. *If you are so concerned about junk foods and sugar, should FDA be doing something about them?*

A. Yes, I think we should. I think we should ensure that the labeling of all foods is as informative, quantitatively informative, as is economically feasible. I think people should know what it is they're putting into their mouths, and how much of it, whether it be sugar, or salt, or the principal ingredient of the food. And they should know what the nutritional value of it is. I think that what FDA should be doing is to make sure that people can make an informed choice. That's why I think our nutrition labeling program is so important.

Q. *You've been Commissioner for three years now. How has your*



perception of FDA changed since the first day you started?

A. Number one, I am more convinced than ever that the Food and Drug Administration is one of the most important of the Government agencies. Number two, the Agency is more competent, more professional, and does more and does it better than I or many people have realized. I have a tremendous admiration and respect for the people who work in FDA. Number three, I am more convinced than ever that the Agency must function in the open, use advisory committees more and more wisely, and be certain the public understands the basis for its actions. Number four, I realize more than before that there is a lot of scientific information that could and should be obtained, that is not now being obtained, that would impact directly on regulatory matters. In general, scientists do what they want to, and that sometimes doesn't match what needs to be done. One of the things I am pressing now is the need for a clear enunciation of our research

role and other agencies' research roles.

Q. *Has your perception of Washington changed since you've been Commissioner?*

A. It certainly has. I came here believing that Congress and the Administration were part of the same Government. What I have seen in practice is that often Congress acts solely as a critic and too seldom as a partner in doing things for the American people. That has been a surprise to me.

I knew before I came here that Washington was a relatively small city, perched on the edge of the country. And after three years here, the truth of the statement has become evident to me. I've learned again that the strengths of this country are spread well and are evenly divided across the country. They certainly aren't concentrated in Washington!

Q. *As you enter your fourth year as Commissioner, what are your goals?*

A. One goal is to build the resources of this Agency to match public expectations of it. We have taken major steps in that direction. The most important goal is to force the necessary public debate about what it is that we should be doing and how we ought to be doing it. I am looking forward to the next year because I hope we will have the opportunity to improve the Agency by writing some changes into our laws, and to gain the necessary consensus about what we should be doing. I enter my fourth year with the knowledge that FDA has been through some difficult times, and while we may be somewhat bloodied, we are unbowed. FDA is basically a sound agency, doing important and necessary work, and doing it well. My goal is to improve on that record.

Inborn Errors Of Metabolism

Deficiencies in the way their bodies break down certain essential substances mean that some people must avoid eating specific fruits, vegetables, or other foods that most of us eat without a second thought.

For most Americans it is relatively simple to select a diet that provides optimum nutrition for body growth and good health. Their diet can be planned by eating specified amounts of selected food or calculating intake from the amounts of nutrients stated on some labels. Normal persons rarely need to be concerned about metabolism of nutrients, which is the complex chemical process by which the body converts food into substances that promote growth and energy. But certain people—those who are affected by so-called inborn errors of metabolism—may have to watch their food consumption closely to avoid some foods or to make certain these foods are eaten only in limited amounts.

The term "inborn errors of metabolism" is applied to a group of inherited abnormal conditions which affect the metabolism of certain essential food constituents—amino acids (proteins are composed of amino acids), carbohydrates, vitamins, and essential trace minerals. These conditions generally are caused either by total absence of or insufficient amounts of specific enzymes (substances produced by the body that help it to break down and digest food) or by the absence of normal mechanisms within the body for transporting enzymes and other substances through the system. Another type of inborn error affects the way the body breaks down fat compounds. Although the fat compounds affected by these defects usually are produced within the body rather than being taken into it in foods, manipulation of the diet can be effective in controlling many of these fat metabolism errors. Fortunately, only a few of the various types of inborn errors of metabolism occur more than once in every 100,000 live births.

In the last 20 years, the number of diseases identified as being caused by inborn errors of metabolism has in-

creased more than tenfold. Typically, after each such error has been identified, cases are diagnosed in increasing numbers for several years thereafter. Because diet control is crucial to the treatment of these conditions, FDA has devoted increasing attention to the labeling of certain food ingredients that can have an adverse affect on people with metabolic defects.

Unless persons with inborn errors of metabolism understand the problem and are careful about what they eat, they may feel run down or at times become very ill. Under certain circumstances, such as intravenous administration of nutrients to which the patient is sensitive, severe and even life-threatening reactions may occur. It is, therefore, important that persons with inborn errors of metabolism advise their physicians of this fact.

Perhaps the best known metabolic defect is phenylketonuria, commonly called PKU, which occurs in about 8 of each 100,000 live births. The victims lack the enzyme hydroxylase that converts one amino acid (phenylalanine) into another amino acid (tyrosine). As a result, phenylalanine accumulates in the blood serum and appears in high levels in the urine. If not diagnosed and controlled early after birth, mental retardation and shortened life span results. Screening of infants for PKU, which is easily recognizable shortly after birth, is common practice in many hospitals today. If PKU is detected, the patient's diet can be adjusted to include appropriate semisynthetic foods such as protein hydrolysates from which phenylalanine has been removed. Patients who control their intake of phenylalanine can enjoy nearly normal growth and development.

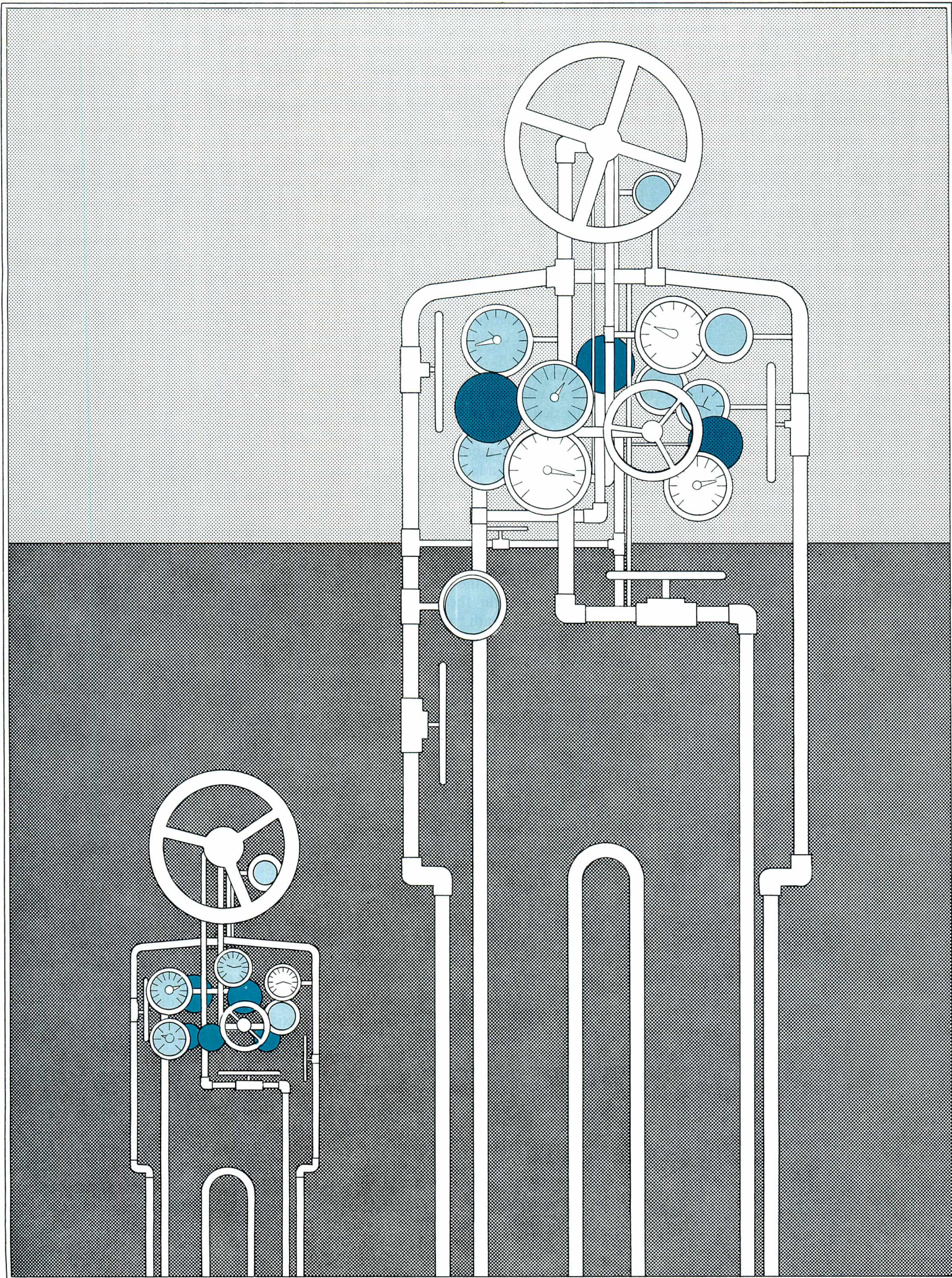
Examples of foods containing appreciable amounts of phenylalanine and which should be avoided by people with PKU are lima beans, broccoli, brussels sprouts, corn, cowpeas, green peas, kale, potatoes, and spinach. Many fruits and vegetables have low phenylalanine content and may be eaten safely. Tapioca and cornstarch are the only acceptable cereals. The diet can be adjusted to provide just

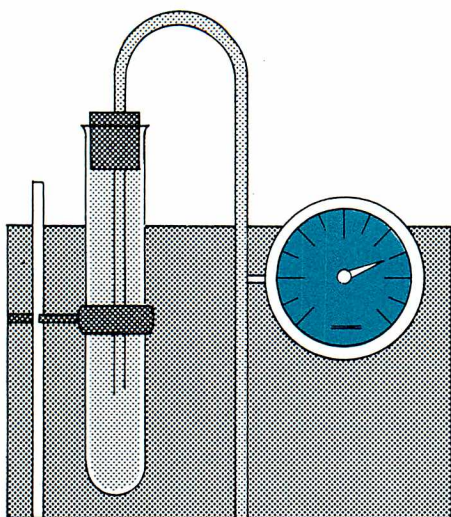
enough phenylalanine for the afflicted individual's minimum nutrition requirements.

Over 60 other inborn errors affecting amino acid metabolism have been identified and reported in medical literature. Many are dangerous to life. For example, the so-called maple syrup urine disease must be diagnosed at birth and treated immediately if the patient is to survive. Persons with some of these conditions do not respond even to intensive treatment and the quality of life remains poor. For some, no treatment is available. They must endure the symptoms common to many of these diseases—mental retardation, restricted growth, kidney failure, abnormal behavior, poor hair quality, and lack of hair color. The more severe types of disease occur with very low frequency—less than one in four million live births.

Some inborn errors of metabolism have no apparent medical consequences. For example, fructosuria occurs when the victim lacks an enzyme called fructokinase. Such persons have high levels of fructose (fruit sugar) in their urine, but have no apparent ill effects.

Another error involving fructose is hereditary fructose intolerance, which was not identified until 1956. The condition is caused by a deficiency of an enzyme called aldolase. This lack results in accumulation in the blood and liver of a fructose compound which causes the victim to react severely if he ingests even small amounts of fructose. Persons with hereditary fructose intolerance may also be harmed in the hospital by intravenous feeding with solutions containing fructose instead of glucose. In either case—ingestion or intravenous feeding—the rapid onset of severe hypoglycemia (low blood sugar), and occasionally death, can occur. The symptoms of hypoglycemia are sweating, trembling, nausea, vomiting, dizziness, and occasionally convulsions and unconsciousness. Persons known to have hereditary fructose intolerance should wear a bracelet (called a Med-Alert) to alert attending physicians to the presence of the condition.





Fructose is found mainly in fruits and honey. It is one of the two sugars formed when sucrose (cane or beet sugar) is digested. Sorbitol, a sweetener used in foods and drugs, is converted to fructose in the liver, and may, therefore, produce the same type of reaction as fructose. It is essential, therefore, that fruits, cane sugar, and sorbitol be avoided by affected persons.

Infants who have undiagnosed hereditary fructose intolerance often react to the fructose contained in fruit juices or fruit products. They may experience colic or abdominal pain, protracted vomiting, and retarded growth. Usually, repeated experience results in such children refusing to eat foods containing fructose even at a very young age. If their diets are free of fructose, persons with hereditary fructose intolerance may live normal lives and develop well both mentally and physically.

Inborn errors of metabolism and of transport that affect the way the body handles common carbohydrates also have been identified. Intolerances to ordinary cane sugar and to lactose (milk sugar) are caused by the body's lack of the enzymes called sucrase and lactase, respectively. Individuals with inadequate amounts of these enzymes cannot digest these carbohydrates. As a result, sucrose and lactose reach the lower digestive tract where bacteria ferment them and thereby cause severe gastrointestinal distress.

Another error which has a profound impact on the life of the individual is the absence or deficiency of the enzyme (glycogenase) required to convert glycogen (carbohydrate storage material in man) into glucose. Individuals having this condition are especially vulnerable to low blood sugar, and the

condition can become life-threatening if scheduled meals are delayed even a relatively short time.

Inherited errors associated with failure of the body to transport vitamins such as B and folic acid across tissue membranes are also well known. Persons with these problems experience vitamin deficiencies despite their intake of adequate quantities of the vitamins in the diet.

Metabolic errors also are associated with vitamin conversion. One example is the deficiency of the enzyme needed to handle Vitamin D. Persons who have this metabolic error develop rickets despite adequate vitamin D and calcium in the diet. Such persons do respond to massive doses of vitamin D. However, a special synthetic vitamin D, supplied in normal amounts, meets the individual's needs more safely. It avoids the formation of calcium deposits in the tissues and the possibility of death from kidney failure caused by the production of such deposits in the kidneys following prolonged massive doses of natural vitamin D.

Errors of metabolism also are responsible for diseases involving essential minerals. One example, Wilson's disease, characterized by uncontrollable staggering movements with rigidity, liver disease, personality changes, and anemia, is associated with defective copper metabolism and excretion. This results in very high levels of the metal in the liver, brain, and other tissues. Another example is a condition known as hemochromatosis which results in excess deposits of iron in the liver and other tissues. Affected persons have pigmented skin, liver disease, and decreased carbohydrate metabolism.

Detection of inherited errors of metabolism generally requires laboratory testing. Screening tests for some of these, such as PKU, are routinely conducted in some hospitals at the time of birth. With the development of automated equipment, such screening is becoming less costly. Detection of other inherited conditions, however, requires long, tedious analysis and the cost is so great that tests are made only when there are suspected cases. In any

event, behavior problems, abnormal physical appearance, unusual growth patterns, sensitivities to certain foods, digestive problems, and other abnormal conditions in a child always should be brought to the attention of a physician immediately.

Because errors in metabolism are hereditary, existence of a family history of metabolic diseases should be brought to the attention of the attending physician early in pregnancy. Most of these errors are very rare so that prenatal testing for them is generally not considered necessary.

Once an error has been diagnosed, sticking to an appropriate diet frequently results in near normal life. In recent years, the food and drug industries have developed specific formulations for use as special diets in phenylketonuria, maple syrup urine disease, and other conditions. These carefully compounded diets appear to be particularly promising. The Food and Drug Administration regulates them and requires that their usefulness and safety be demonstrated before they are marketed.

FDA also recognizes that information concerning composition of foods is vital for diet planning by persons with certain metabolic diseases. As a result, manufacturers of foods are required to list on the label in descending order of quantity all ingredients included in amounts greater than 2 percent.

Research may eventually help persons with errors of metabolism for which treatment has not yet been found. There have been advancements in the use of specially prepared diets and work is continuing on the development of compounds which reduce the toxic effects of substances that accumulate in the body as a result of metabolic errors. Of particular importance is the need to develop screening techniques to identify people who have abnormal genes and whose children thus, may be subject to inborn metabolic errors. Genetic counseling can then be provided and prenatal testing recommended in those situations where advance knowledge of a potential metabolic defect could be beneficial.

Soft Contact Lenses

Many wearers of soft contact lenses find them more comfortable than the traditional hard contacts, but they require considerable special care and they correct only a limited range of visual problems.

by Margaret Morrison

“Soft, like Jello.”
“Colorless, like Saran wrap.”
“Contain variable amounts of water.”

These are some of the phrases used to describe the soft contact lenses that some people are now using instead of eyeglasses or “hard” contacts.

Soft contact lenses, like the traditional plastic lenses, usually are worn for cosmetic reasons—because the wearer feels more attractive when not wearing eyeglasses—and patients are choosing them because they are generally considered more comfortable than hard contact lenses.

First developed in Czechoslovakia, soft contact lenses were brought to the United States in 1964. Made of hydrophilic (water-absorbing) plastic,

they are brittle when dry, but soft and pliable when saturated with water.

Unlike hard plastic lenses, which are considered medical devices, the soft lenses are classified and regulated by FDA as drugs. When introduced into the United States the hydrophilic plastic was new and there had been few studies in this country of the material's safety and effectiveness for medical purposes. Also, an important factor in use of the new soft lenses was (and is) proper disinfection of the lenses to prevent the possibility of eye infections which could be serious. These are among the considerations that prompted FDA to classify soft contact lenses as drugs, thus making them subject to premarketing approval for safety and effectiveness.

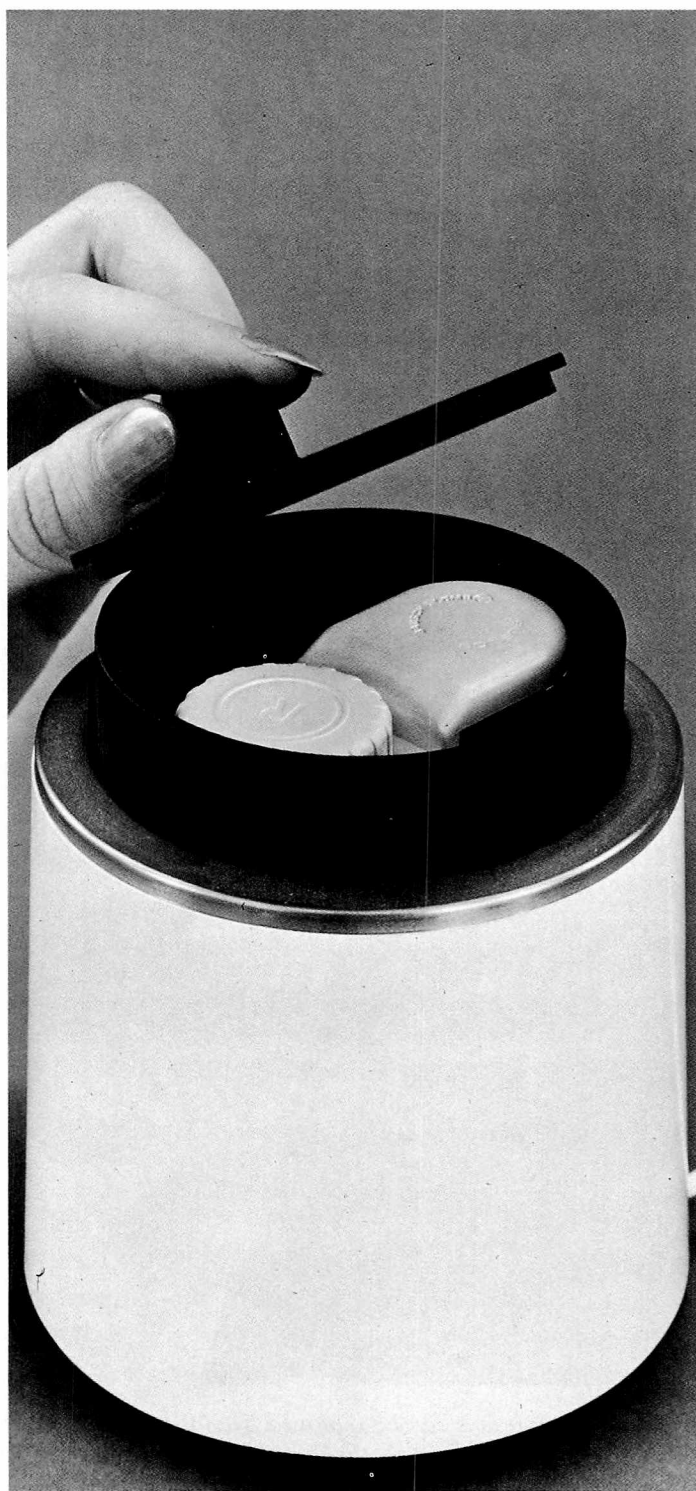


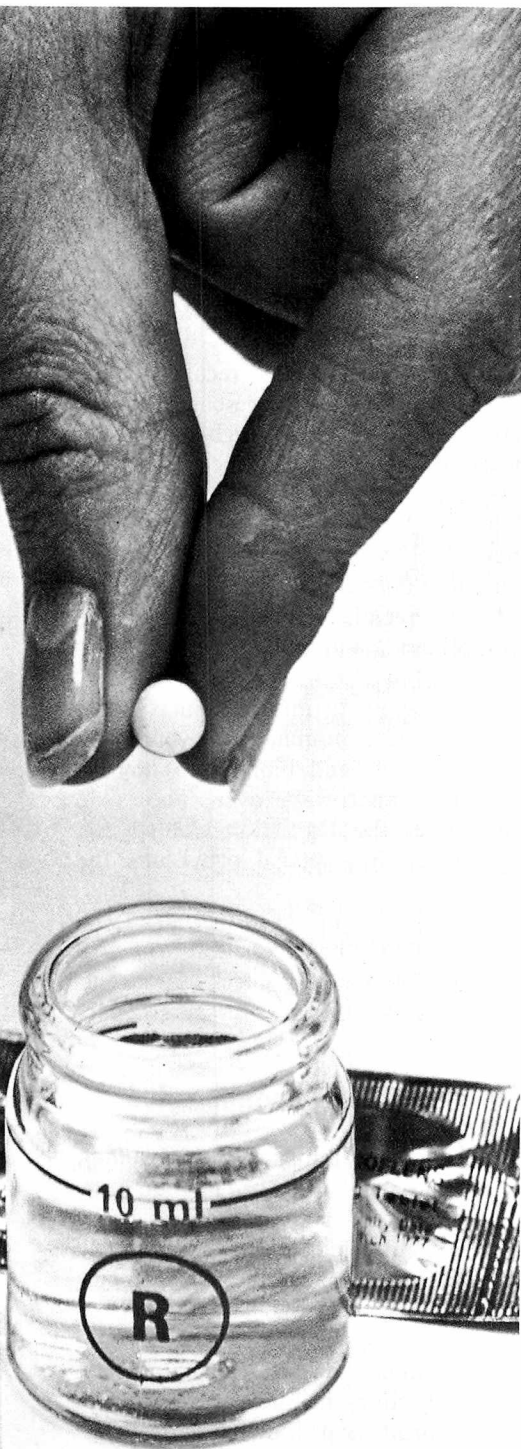
Because it is pliable, a soft lens can be removed from the eye by compressing it between the thumb and index finger. Rolling the thumb and finger together causes the lens to double-up, allowing air underneath.

A soft lens is placed in the eye in much the same way as a hard contact.

An electric disinfection unit must be used daily to boil the soft contact lenses in a solution of salt water. The lenses are placed in their carrying case for disinfection in this unit.

In addition to daily boiling, the lenses can be cleaned periodically with a special enzyme tablet which breaks up protein deposits that may build up on the lenses from the wearer's tears and reduce visual clarity.





Only two soft lens products for vision correction have been approved by FDA for sale in the United States. In addition, FDA has approved two other soft lenses for therapeutic use, mostly in the treatment of certain corneal diseases.

Soft contact lenses must be prescribed and fitted by a physician or optometrist. Usually they cost about twice as much as the hard contacts, and the average lifespan of the soft lenses is only one year. Despite the higher cost and shorter use-span, soft lenses are preferred by some people because they are more comfortable and more easily tolerated by the eye.

Most users of hard contact lenses must get accustomed to them, which means wearing the lenses for short periods of time at first, and then gradually lengthening the time until the wearer adjusts to the sensation of a foreign body in the eye. With soft contact lenses, the foreign body sensation subsides within four or five minutes and most wearers are quite comfortable thereafter.

Because of this quick adaptability, soft contact lenses are preferred for intermittent use. For example, if a person wears eyeglasses regularly but prefers not to use them for special occasions, he or she can easily insert soft contact lenses before going out and almost immediately feel comfortable with them.

But soft lenses are not without problems. They tear easily and become worn from handling. Moist and soft—with the gelatinous feel and flexibility of a thin wet noodle—they can absorb bacteria and other impurities. To prevent eye infections which might result from such impurities, soft lenses must be boiled daily in a solution of salt and distilled water, which must be mixed precisely according to directions. The metal container in which

lenses are put with the water-and-salt solution for boiling is subject to rusting and must be replaced periodically.

Although Canada has approved a cold-cleaning method for soft contacts, by which they are soaked in enzyme and germicidal solutions, FDA has not found sufficient proof that such solutions are safe and effective and has not approved any nonboilable solutions for daily disinfectant use with the lenses.

Besides being cleaned by boiling, soft contacts must be carefully stored in a liquid solution—usually a preserved saline solution—which is sold at pharmacies. If left exposed to air, the lenses will dehydrate, become brittle, and chip or break.

Even when a patient decides the comfort of wearing soft contacts is worth the price and the bother, the lenses may not be appropriate. Soft contact lenses correct only a limited range of visual problems, and can be prescribed for only four of every 10 contact-lens wearers. The physician determines whether the correction of vision which the patient requires is possible with soft contacts, and whether the patient is capable of following instructions for using the lenses correctly.

Because of the potential health hazard with soft contact lenses, FDA requires that physicians who prescribe them provide patients a "package insert" giving full information about the product and its use. In addition to a description of the lenses and instructions for handling, the package insert gives warnings and possible adverse reactions. Consumers for whom soft contact lenses are prescribed should make sure they receive and understand the patient package insert.

Margaret Morrison is a staff writer with FDA's Office of Public Affairs.

News Highlights

Magazine's Home-canning Advice Questioned

The U.S. Department of Agriculture (USDA) and the Food and Drug Administration have questioned the home-canning recommendations made in an article in the June issue of CONSUMER REPORTS magazine.

Consumers are advised in the article to increase pressure and reduce cooking time when canning foods at home.

Both agencies recommend that until the CONSUMER REPORTS' recommendations are "scientifically determined to be adequate to assure destruction of microorganisms" that consumers who can food at home should continue to rely on the standard pressure and cooking time recommendations established by competent processing authorities.

Time and cooking pressure are very important because bacteria which cause food poisoning, such as botulism, can develop in improperly processed foods, Government officials said.

Most cases of food poisoning in the United States, including botulism, are traced to improperly home-canned foods.

In a telegram to Consumers Union of the United States, Inc., Mt. Vernon, N.Y., the publisher of CONSUMER REPORTS magazine, USDA and FDA requested an opportunity to review "any data to support such a broad reduction in processing."

USDA has available publications on the home canning of fruits, vegetables, pickles, relishes, meat, and poultry. The times and temperatures recommended in these publications (HG-8, *Home Canning of Fruits and Vegetables*; HG-92, *Making Pickles and Relishes at Home*; and HG-106, *Home Canning of Meat and Poultry*) have been scientifically tested in laboratories and have proven to be safe and effective over the years.

Regulations Proposed on Product Recalls

The Food and Drug Administration has proposed regulations defining its policy and the procedures it follows for product recalls.

The regulations also describe, for the first time, the specific responsibilities of manufacturers and distributors in the conduct of recalls.

The policy makes clear that manufacturers and distributors are expected to assume the responsibility and expense for all product recalls, including followup checks on their success in removing defective products from the marketplace.

FDA's role is to monitor recalls and assess the adequacy of a firm's actions. FDA monitors an average of 900 recalls a year.

The new regulations proposed by FDA call on companies to develop detailed contingency plans for product recalls

which can be put into effect whenever needed.

The regulations state that companies should promptly notify FDA when removing a product, should initiate recalls when asked to do so by FDA, and should report to FDA regularly on a recall's progress.

The proposal calls on manufacturers to keep records which will enable them to trace a product's distribution, to use product coding so that a specific batch or item can be easily identified, and to follow up on recalls by finding out why the product was defective.

The proposed regulations explain how FDA evaluates the health hazard posed by a defective product, and how FDA develops, for each individual situation, a "recall strategy" describing how extensive the recall should be, whether a public warning is needed, and the extent to which the company must check the effectiveness of the recall.

The proposal also takes note of FDA's present policy of notifying the public about every recall through its weekly "Enforcement Report," published by the Office of Public Affairs.

The regulations define a "recall" as the removal or correction of a product which violates the law. Removal or correction of a product that does not represent a violation of the law is not considered a recall. Neither is the removal of a product that has not left a company's control—for example, a product that is still in a company's warehouse.

The proposed regulations apply to most products regulated by FDA, including foods, human and veterinary drugs, cosmetics, medical devices, and biologics. They do not apply to products such as microwave ovens and color television sets regulated under the Radiation Control for Health and Safety Act, which has special provisions for product recall.

The regulations were published in the June 30, 1976 FEDERAL REGISTER. Comments will be accepted for 60 days and should be addressed to the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20852.

Food Sanitation Training Plan Recommended

FDA has published recommendations for a Training Course for Food Service Managers to improve food protection practices in commercial and institutional feeding. A brochure containing these recommendations has been widely distributed to Federal, State, and local regulatory agencies and to industry associations.

FDA recommends fourteen hours of classroom training in sanitation plus one additional hour for a written test leading to certification. Instruction includes four hours on foodborne disease and food protection; four hours on facilities, equipment, utensils, and nonfood supplies; two hours on personal hygiene and operational procedures for food



handlers; and four hours on management techniques conducive to proper food protection. While recommending classroom instruction for all candidates for certification, FDA recognizes a home study option and the fact that many candidates will be able to pass an examination (and be certified) without classroom instruction.

FDA bases its recommendations on information gathered through contracts with three States and on assistance provided by the industry and State enforcement agencies.

A variety of programs to provide sanitation training to management personnel have already been initiated through government and industry cooperative programs. With the increased emphasis on training, FDA recommends that:

- Managers who demonstrate sufficient competence in the sanitary operation of a food service establishment should be so certified.
- Training and certification criteria should be uniform across the Nation.
- Uniform training and certification should result in reciprocity between governmental agencies and within industry.

Several State and local governments have made sanitation training mandatory for food service managers.

Copies of the FDA brochure may be obtained from FDA regional offices or the Division of Food Service, U.S. Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204.

Link Named to Head Medical Devices Unit

Commissioner of Food and Drugs Alexander M. Schmidt has announced the appointment of David M. Link, 46, as director of the Agency's Bureau of Medical Devices and Diagnostic Products. This Bureau has prime responsibility for enforcing the new Medical Devices Amendments of 1976 signed into law by President Gerald Ford on May 28.

Link has been with the Food and Drug Administration since 1970, and for the past two years has been Acting Director of the Bureau of Medical Devices. Before coming to FDA, Link worked as a senior consultant with the Sterling Institute in Boston and as an engineering manager for Hewlett Packard, Waltham, Massachusetts.

Plan Set to Monitor Hospital Drug Shortages

The Food and Drug Administration and The American Society of Hospital Pharmacists (ASHP) have launched a nationwide pilot program involving selected hospitals to monitor drug shortages.

The purpose of the program is to identify drug shortage problems as they are occurring so that appropriate actions can be taken.

One hundred hospitals have been asked to notify ASHP of any drug shortages they encounter which appear to be more than a very temporary "out of stock" situation. Whenever significant shortages appear to be developing a brief questionnaire will be sent to a second group of hospitals to help gauge the extent of the problem. If reports indicate a

serious or continuing shortage, the FDA may contact manufacturers of the drug products, alert hospitals to consider the use of alternate drugs, or take other action.

The need for this program has been demonstrated by the steady stream of reports of drug shortages in individual hospitals received by ASHP and FDA over the past few years. FDA and ASHP have been informally investigating these shortages and ASHP has been offering advice to help practitioners via its newsletter. Through this pilot project of ASHP and FDA, a systematic approach now exists for monitoring and reporting drug shortages.

Ultrasound Equipment Standards Proposed

FDA has proposed a mandatory safety performance standard to protect people from improper exposure to radiation emitted by ultrasonic therapy and surgery equipment.

Ultrasound, a form of energy similar to but higher in frequency than ordinary sound waves, can penetrate body tissues. It is widely used by physicians and physical therapists to produce "deep heating" effects for relief of pain and to promote healing in muscles and joints.

About 37.5 million ultrasound treatments are administered each year in the United States. About 15,000 ultrasonic therapy units are in use in hospitals, and about 35,000 additional units are located in other facilities such as physicians' offices and nursing homes. There are nine manufacturers of ultrasonic equipment producing a market in excess of \$8.5 million annually.

Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, explained why the mandatory Federal standard is needed: "A voluntary industry standard for ultrasonic equipment has been in effect since 1956, but equipment now being produced does not meet this standard. An FDA survey showed wide discrepancies between claims made for equipment and their actual performance.

"We found that most of the units now in use cannot deliver enough energy for adequate treatment. Some equipment, however, produced too much radiation, which can result in burns, swelling, and damage to nerve and other sensitive tissues.

"The standard we are proposing would assure that ultrasonic equipment will perform as it is supposed to. The standard also would require that information be provided to machine operators so that they can make the best use of the equipment."

The regulation would be the first mandatory Federal safety performance standard for ultrasonic equipment. It would not apply to ultrasonic equipment used in dentistry or for removal of eye cataracts, or to diagnostic ultrasonic equipment. FDA is investigating the need for separate radiation safety regulations for diagnostic ultrasonic equipment.

The proposed standard was published in the June 14, 1976, *FEDERAL REGISTER*. Comments will be accepted for 60 days and may be submitted to the FDA Hearing Clerk, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20852.

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, and Vermont

The Federal Government seized approximately \$90,000 worth of flour, sugar, salt, raisins, and sesame seeds at B. Rothstein & Co., Inc., a Boston bakery supply house, after an inspection by FDA's **Boston District** revealed extensive rodent and bird infestations in the warehouse. Several lots of the stored foodstuffs were rodent gnawed and were contaminated with bird and rodent excreta and urine. The inspection at the Boston firm resulted from an earlier routine FDA inspection at a bakery in Cambridge, Massachusetts, where investigators observed a lot of flour which apparently was contaminated before its arrival at the Cambridge firm. Investigators traced the shipment to the Boston firm where the seizure took place.

REGION II

New Jersey, New York, and Puerto Rico

"Discover the secret of foot massage and observe how it activates the complicated functioning of your body,"

read the labels for 200 pairs of imported "health" sandals offered for import from Hong Kong and refused entry into the United States by FDA's **New York District**. The literature included a diagram of the human foot which suggested a direct correlation between areas of the foot and various parts of the body. The company claimed, for example, that if the large toe is massaged by the rubber tips that cover the inner sole of the sandal a beneficial effect would result in the liver, lungs, and large intestine. Other claims cited benefits from wearing the sandals for people with flat feet, cold or hot feet, or people with weak foot muscles. FDA considers such medical claims to be false and misleading, and has ruled that the labeling of the sandals, which are valued at about \$525, must be brought into compliance with U.S. regulations, or the product must be returned to Hong Kong.

FDA headquarters in Rockville, Maryland, issued a General Import Alert to all FDA District offices advising them of possible bread imports which contain linseed oil, a substance promoted in some countries for its laxative properties but not approved for use as a food additive in this country because it is considered toxic by FDA. The alert was suggested by FDA's **Buffalo District** after its investigators discovered—during a routine inspection at the Buffalo port—a shipment of specialty bread with labels listing linseed as an ingredient. The shipment, 40 one-pound loaves, offered for import from Rudolph Speciality Limited, Toronto, was refused entry by FDA. Following that action, Buffalo investigators refused entry into the United States of another shipment of specialty bread and a shipment of whole grain cereal,

both from different Toronto-based firms, because they contained linseed. These recent shipments prompted FDA to issue the General Import Alert to protect consumers from a possible new wave of foreign-made food products containing linseed.

The Great Atlantic and Pacific Tea Co., Horseheads, New York, has completed changes in its manufacturing facilities enabling it to comply fully with FDA's Current Good Manufacturing Practice Regulations. The firm spent about \$20,000 to upgrade equipment used to process various foods, including chocolate and spaghetti sauce, after a routine inspection by Buffalo District investigators found inadequate heating of some canned foods and inadequate acidity testing equipment.

E. R. Squibb & Sons, Princeton, New Jersey, voluntarily recalled over a million single-dose bottles of Noctec brand chloral hydrate syrup because of improper fill following an inspection by FDA's **Newark District** which confirmed a complaint by a pharmacist who had discovered that some of the bottles were underfilled, and others overfilled. Noctec, used in hospitals and institutions for preoperative and nighttime sedation, is packed in five-milliliter doses. The firm checked warehouse stocks and discovered fills ranging from zero to 15 milliliters and sent recall letters to more than 900 customers including 742 hospitals.

A U.S. marshal seized about \$20,000 worth of groceries at the Cash & Carry Supermarket warehouse, San Sebastian, Puerto Rico, after a routine inspection by FDA's **San Juan District** revealed the building and much of its contents were infested by rodents and insects. The firm destroyed



about 10 percent of its stock under FDA supervision at a local dump. Most of the contaminated foodstuffs were dry products such as pastas, cereals, and cornmeal. The remaining food was transferred to another warehouse and released for distribution.

REGION IV

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

The Federal Government seized approximately 300 pounds of shelled pecans, valued at \$500, from a wholesaler after samples taken by FDA's **Atlanta District** confirmed the presence of *E. coli* bacteria. The seizure resulted from an earlier routine inspection by FDA investigators at the Dasher Pecan Co., Valdosta, Georgia, the processor and distributor, which revealed the presence of *E. coli* at various stages of the processing, as well as other insanitary conditions including rodent contamination. A second FDA inspection at the Valdosta firm revealed the company had taken proper action to eliminate the insanitary conditions.

Two firms, Purity Ice Cream Co.,

Charleston, South Carolina, and Aristocrat Ice Cream Co., Atlanta, Georgia, voluntarily recalled over 3,250 gallons of ice cream after two routine inspections by the Atlanta District revealed the companies were using Red No. 2 food coloring, which FDA has banned, in their ice cream. Purity Ice Cream Co. voluntarily destroyed all its strawberry ice cream in stock and instructed its sales representatives to recover the outstanding stock, estimated to be 250 gallons. Shipments were limited to South Carolina and included stock under military contract. Aristocrat Ice Cream also voluntarily initiated a recall of over 6,500 half gallons of two of its brands: Old Favorite and Shurfresh strawberry and neopolitan. Distribution was limited primarily to Georgia.

Deputy U.S. marshals seized the entire stock of ophthalmic ointment, including raw materials, manufactured by Manhattan Eye Salve Co., Inc., Louisville, Kentucky, after a series of inspections by FDA's **Nashville District** revealed the firm's quality control procedures did not insure sterility of the product. Value of the products seized was estimated between \$50,000 and \$60,000.

A consumer inquiry to FDA's **Orlando District** led to the voluntary recall of a drug called Formula K distributed by Pharmex, Inc., Hollywood, Florida. The subsequent investigation by Orlando District investigators found that Pharmex was promoting the combination of Formula K and procaine hydrochloride as the drug KH3, which is hailed in Europe as an arthritis cure, but which is not approved for sale in the United States. Formula K is an illegal drug in the United States because it has not been approved by FDA as safe and effective for the treatment of arthritis or any other disease. Pharmex was distributing a magazine article to physicians about the beneficial effects of KH3, and instructions on how to mix Formula K and procaine hydrochloride to resemble KH3. Procaine hydrochloride is a commonly used drug, but it is classified as an unapproved new drug if it is promoted for uses not sanctioned by FDA, such as the treatment of arthritis.

Some 175,000 Rusch Silkolatex endotracheal tubes manufactured during the past 2-3 years by Willy Rusch, Stuttgart, West Germany, have been voluntarily recalled by that firm after the Orlando District confirmed a report by Palmetto General Hospital, Hialeah, Florida, that the tubes were defective and possibly nonsterile. An FDA investigation confirmed the hospital's report that the inflatable collar attached to the tube would not inflate symmetrically, and further discovered that some of the tubes had defective polyethylene package seals which could cause nonsterility of the tubes. The tubes are inserted into the trachea to facilitate respiration during surgery.

REGION V

Indiana, Illinois, Michigan, Minnesota, Ohio, and Wisconsin

Medwick Laboratories, Inc., Melrose Park, Illinois, has entered into a consent decree of permanent injunction in the U.S. District Court of the Northern District of Illinois to stop the manufacture and shipment of all sterile injectables and ophthalmic drugs until it has complied with FDA's Current Good Manufacturing Practice (GMP) Regulations regarding these products. The injunction, signed

by the firm's president, Robert S. Tutag, and vice president, James J. Boyce, was the result of a 20-month investigation by FDA's **Chicago District** which revealed the firm's failure to comply with numerous GMP regulations. Deficiencies at the firm included preparing subpotency drugs and manufacturing drugs under insanitary conditions. All lots of sterile injectables and ophthalmic drugs currently held at the firm must be examined by an expert consultant and approved by the FDA before they can be sold. Any portion of a batch already distributed and found after examination not to be in compliance will be recalled.

REGION VII

Iowa, Kansas, Missouri, and Nebraska

The Federal Government seized over 3,000 cases of K-Mart Medicated Cream, at Lander Co., St. Louis, a manufacturer of medicated creams, mouthwashes, and cosmetics, following a series of inspections by FDA's **Kansas City District** which revealed violations of FDA's Current Good Manufacturing Practice Regulations. The investigation revealed inadequate testing of raw materials and products, failure to keep adequate records, and inadequate label accountability, along with ten other violations. The seized cream was in 18-ounce jars, 12 to a case, and was valued at over \$18,200.

Kem-Vet, Inc., Fremont, Nebraska, and its officers, Rodney F. Wartig,

Marilyn Ann Wartig, and Thomas B. Thompson, have been ordered by Chief Judge Warren K. Urbom of the U.S. District Court of Nebraska to stop distributing prescription veterinary drugs to lay persons without a written prescription or other order from a licensed veterinarian. The preliminary injunction signed by Judge Urbom also ordered the firm to submit a list of offices, warehouses, storage facilities, and distributors used by the defendants, and to allow FDA investigators free access to these establishments. The legal action resulted from activities by investigators of the Kansas City District who posed as routine customers and made 24 undercover purchases of prescription veterinary drugs at the firm without a prescription or order from a veterinarian. The investigation was promoted by a trade complaint that the firm was improperly dispensing prescription drugs. A trial is set for August 16 in Lincoln to determine if the preliminary injunction should be made permanent.

Approximately \$2,500 worth of granulated sugar, nonfat dry milk, and chocolate-flavored powder used in manufacturing chocolate-flavored beverages was seized by a U.S. marshal at the Pepsi Cola Bottling Co., New Haven, Missouri, after a routine inspection by the Kansas City District revealed that raw materials were stored under insanitary conditions in the firm's storage area and were adulterated by rodents.

REGION IX

Arizona, California, and Hawaii

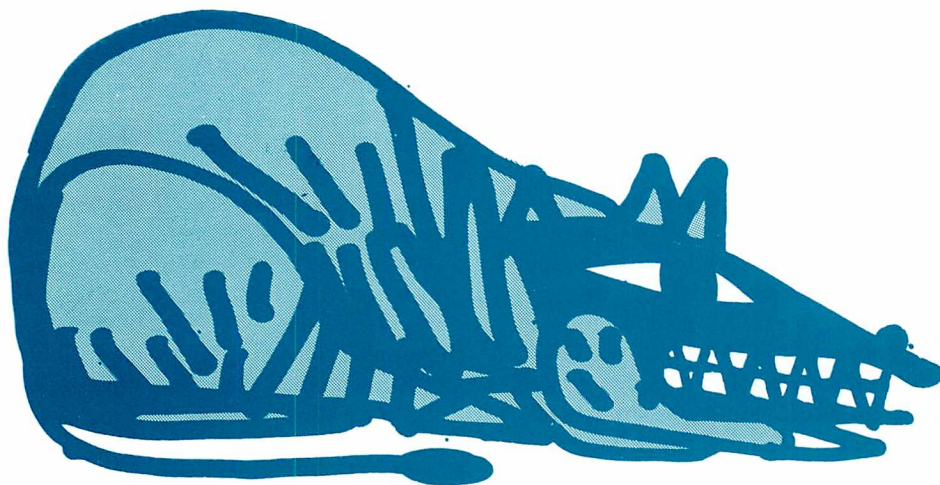
A consumer complaint to FDA's **Los Angeles District** resulted in the destruction of 43,000 cans of Foul Mudammas brand small fava beans because of insect contamination. Following up on the consumer complaint, FDA investigators discovered that two Los Angeles warehouses where the beans were stored—Indo-European Cash and Carry and C&K Importing Company—had received similar complaints. The warehouses voluntarily destroyed the beans, valued at \$15,000. The beans, which had been contaminated with a bean weevil, were processed by H. C. Hemingway, Clyde, New York, and had been shipped by Sahadi Importing Co., Brooklyn, New York.

A complaint from dog's best friend resulted in the Sound-Off Co., Northridge, California, agreeing to an FDA-initiated recall of all its Bark Restrainer and Training Collars, which were designed to prevent a dog from barking. A Los Angeles veterinarian who treated a dog that had worn the device told investigators from the Los Angeles District that the device caused lesions resembling burns around the dog's neck. Tests performed by FDA's Bureau of Veterinary Medicine confirmed that the product, which shocked the dog when it barked, was dangerous and caused injuries to the animal on which it was tested. When notified of the test results, the company ceased production of the collars and began an immediate recall of all those that had been distributed.

REGION X

Alaska, Idaho, and Washington

A U.S. marshal in Seattle, Washington, seized 286 cases of canned salmon valued at about \$15,000 and in possession of Whitney-Fidalgo Seafoods, Inc., Seattle, at the Port of Anacortes, Washington, after an examination by FDA's **Seattle District** mobile laboratory revealed the presence of decomposed salmon. The shipment, of approximately 13,300 pounds, was shipped to Washington by the Whitney-Fidalgo cannery, in Alaska.



State Actions

\$20,000 Penalty Paid

National Drinks Bottling Co., Gardena, California, charged with selling soft drinks containing glass, rubber hose fragments, and dead insects, has agreed to pay \$20,000 in civil penalties and to keep its operation sanitary. The stipulated judgment, which was agreed to by the company without a trial or admission of wrongdoing, was signed by Commissioner Lee Ragins of the Superior Court of Los Angeles. In agreeing to the judgment, the company stopped a pending civil suit filed by the City of Los Angeles and the State of California. The suit resulted from unsanitary conditions discovered during an inspection of the plant conducted by State inspectors under a contract with FDA. The monetary penalties were split four ways: \$2,000 to the State Department of Health for investigative costs, \$6,000 to the city of Los Angeles, \$6,000 to Los Angeles County, and \$6,000 to the State. Under terms of the judgment, the company must sell only products free of foreign material and must label the products accurately, stating the quantity of contents and all ingredients. The company sells Dr. Pepper, Orange Crush, Squirt, Dad's Root Beer, Vernor's Ginger Ale, Mother's Pride Cola, Strawberry Crush, and low-calorie or diet versions of some of these soft drinks.

Salvaged Food Seized

The New York State Department of Agriculture and Markets seized the total contents of a warehouse belonging to J & R Trading Corp., Brooklyn, New York, after a routine inspection by FDA's New York District disclosed

that the firm was functioning as an unlicensed salvage food dealer. The firm was buying damaged shipments of coffee and spices from import brokers and reselling the goods—unreconditioned—to other warehouses, in violation of State law. FDA immediately advised New York State, which conducted its own investigation, and seized the contents of the warehouse, valued at about \$100,000.

Bakery Closes

Jay Goodman, owner and manager of the Goody-Goody Bakery and Ice

Cream Parlor, Hot Springs, Arkansas, voluntarily went out of business after he received an order to appear before Judge J. W. Chestnut of the Garland County Chancery Court to show reason why a permanent injunction should not be issued prohibiting him from violating the State Food and Drug Act. The case marks the first time that the Arkansas Department of Health has initiated legal action against a firm as a result of inspections performed by State personnel under a contract with FDA. The inspection at the bakery-ice cream parlor had revealed rodent and insect infestation.



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 27 actions to remove from the consumer market products charged to be violative was reported in May. These included 19 seizures of foods: 1 involved charges concerning poisonous and deleterious substances, 16 involved charges concerning contamination, and 2 involved charges concerning economic and labeling violations. Other seizures included 3 of food additives, 3 of drugs (including 1 for veterinary use), 1 of a medical device, and 1 of cosmetic.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD/Poisonous and Deleterious Substances		
Apricot kernels/St. Augustine, Fla. 3/23/76	Shipped from Maywood, Calif.	Contain the poisonous or deleterious substance hydrocyanic acid, and is unfit for food.
Contamination, Spoilage, Insanitary Handling		
Beans, green, canned/Canton, Miss. 3/9/76	Shipped from Junction City, Oreg.	Unfit for food—swollen cans.
Chili peppers, canned/San Francisco, Calif. 3/31/76	Imported from Mexico.	Unfit for food—leaking and swollen cans.
Coffee beans/New Orleans, La. 3/19/76	Hansen & Tidemann, Inc./New Orleans, La. (D)	Held under insanitary conditions; bird contaminated.
Cornmeal mix, ground coffee, rice, flour/Hattiesburg, Miss. 3/11/76	Hudson Mercantile Co., Inc./Hattiesburg, Miss. (D)	Held under insanitary conditions; rodent contaminated.
Fennel seed/Denver, Colo. 4/21/76	Imported from India.	Contaminated with animal excreta.
Flour/Bloomington, Ind. 4/16/76	Wetterau Foods, Inc./Bloomington, Ind. (D)	Held under insanitary conditions; rodent contaminated.
Cambridge, Mass. 4/23/76	Central Bakery/Cambridge, Mass. (D)	Held under insanitary conditions.
Lawrenceburg, Tenn. 1/23/76	MGH Wholesale Grocery, Inc./Lawrenceburg, Tenn. (D)	Held under insanitary conditions; rodent contaminated.
Grits, cornmeal, and flour/Eunice, La. 2/18/76	Kelly Weber & Co., Inc./Eunice, La. (D)	"
Noodles, Chinese/San Francisco, Calif. 4/1/76	Orientex Imports/San Francisco, Calif. (D)	Held under insanitary conditions; insect contaminated.
Rice, rolled oats, beans/Salt Lake City, Utah 3/23/76	Buie International/Salt Lake City, Utah (D)	Held under insanitary conditions.
Salmon, canned/Anacortes, Wash. 4/22/76	Whitney-Fidalgo Seafoods, Inc./Anchorage, Alaska (S)	Decomposed.
Shrimp, frozen/Warren, Mich. 4/9/76	Imported from Taiwan; Ben Kozloff, Inc./Chicago, Ill. (S)	"
Shrimp rolls, frozen/Mechanicsville, Va. 4/20/76	Flavo-Rite Foods, Inc./Bronx, N.Y. (M, S)	Contain <i>E. coli</i> ; prepared and packed under insanitary conditions.
Sugar, nonfat dry milk, chocolate-flavored powder/New Haven, Mo. 4/1/76	Pepsi Cola Bottling Co./New Haven, Mo. (D)	Held under insanitary conditions; rodent contaminated.
Tomatoes, canned/Austin, Tex. 3/23/76	Shipped from Antioch, Calif.	Unfit for food—swollen cans.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Economic and Labeling Violations		
Cereals, presweetened/East Bridge- water, Mass. 4/26/76	Sovex, Inc./Collegedale, Tenn. (M, S); Topco-Sovex, Inc./Bridgeview, Ill. (S)	Label lacks common or usual name of foods, since "100% Natural Cereal" and "100% Natural Cereal with Raisins & Dates" are not common or usual names for these cereals.
Relish, sweet/Nashville, Tenn. 1/15/76	Paramount Foods, Inc./Louisville, Ky. (S)	Quantity of contents statement inaccurate—short in volume.
FOOD ADDITIVES		
Dye-gen soluble concentrate/Cullman, Ala. 2/21/76	Dan-Mar Enterprises/Commerce, Ga. (M, S)	Contains the unsafe food additive gentian violet.
Grease, yellow/Pearl, Miss. 3/18/76	Shipped from Memphis, Tenn., and Moultrie, Ga.	Contains the unsafe food additive endrin.
Vanilla extract/Fort Worth, Tex. 4/20/76	Productos La Pureza/Tampico, Mex- ico (M); Charles E. Moore III/Fort Worth, Tex. (S)	Contains the nonconforming food additive cou- marin; and required information did not appear in English.
DRUGS/Human Use		
Medicated skin cream/St. Louis, Mo. 4/15/76	Lander Co., Inc./St. Louis, Mo. (M, D)	Not manufactured in conformity with current good manufacturing practice.
Phenobarbital, meprobamate, chlor- promazine HCl, and tuloidin tablets and other tablets/Broomfield, Colo. 3/25/76 & 3/26/76	Cord Laboratories, Inc./Broomfield, Colo. (M, S)	Not manufactured in conformity with current good manufacturing practice.
Veterinary/Medicated Feed		
Formula 707 for Horses feed supple- ment/Dallas, Tex. 5/1/76	John Ewing Co./La Salle, Colo. M, S)	Strength differs from and quality falls below that represented, since deficient in chlortetracycline hydrochloride.
MEDICAL DEVICE		
Neuro-structural Scanner device/ Decatur, Ala. 5/3/76	Dr. L. L. Hardy/Decatur, Ala. (D)	Lacks adequate directions for use, since such could not be written for laymen, nor could adequate information for licensed practitioners be fur- nished.
COSMETIC		
Lipstick, eye shadow/Santurce, P.R. 3/15/76	Fernando Rogue/Barcelona, Spain (S)	No quantity of contents statement on label; con- tain a nonconforming color additive; and no statement of place of business of distributor on label of lipstick.

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

- January 22, 1976: **Jay Norris Corp.**, 25 W. Merrick Rd., Freeport, New York 11520. Advertising and sale through the mail of the product "Beauty Bands," representing the ability to cause youthful appearance, lift and smooth the skin, facial muscles, and condition the face.
- January 23, 1976: **Universal Gospel Church**, P.O. Box 2267, Alameda, California 94501. Advertising and sale through the mail of a plan for "natural therapy," representing the ability to cure arthritis.
- January 28, 1976: **Limithe Enterprises**, 809 S.W. Coconut Drive, Fort Lauderdale, Florida 33312. Advertising and sale through the mail of a treatment representing the ability to reduce and/or eliminate acne pimples, and improve the complexion.
- January 28, 1976: **Mears and Myers Distributors**, 235 Scottsdale Square, Winter Park, Florida 32789. Advertising and sale through the mail of the product "Liv'n'On Diet," representing the ability to improve the skin appearance and the skin texture.
- February 3, 1976: **Hotline**, 4523½ Van Nuys Blvd., Sherman Oaks, California 91403, and 7106 Alabama Avenue, Canoga Park, California 91306. Advertising and sale through the mail of the product "Turn On," representing the ability of a sexual stimulant for women, and "Peter Power," representing the ability to prevent premature ejaculation.
- February 4, 1976: **Beauty Bust**, 2410 Sylvester Dr., Dayton, Ohio 45409, and P.O. Box 16037, Cincinnati, Ohio 45217, and 232 W. Front St., P.O. Box 544, Napoleon, Ohio 43545. Advertising and sale through the mail of a product representing the ability to develop and increase the bustline.
- February 4, 1976: **Beauty**, P.O. Box 7481, Oakland, California 94601. Advertising and sale through the mail of a cassette tape recording representing the ability to cause weight loss from repeated listening of the recording.
- February 10, 1976: **Malcolm Butler**, P.O. Box 108, Alexandria, Louisiana 71301. Advertising and sale through the mail of a plan representing the ability to cause a weight loss of forty pounds in thirty days.
- February 10, 1976: **Holt's Sauna Slimmers**, 7471 Melrose Ave., Los Angeles, California 90046. Advertising and sale through the mail of a product representing the ability to cause a loss of inches in days by wearing this device.
- February 11, 1976: **R & N Distributors**, P.O. Box 35445, Los Angeles, California 90035. Advertising and sale through the mail of "Penis Enlargement Techniques," representing the ability to increase the size of the penis.
- February 13, 1976: **Successful Living Center**, 1235 Cowles Street, Long Beach, California 90813, and 9622 Vons, Garden Grove, California 92642. Advertising and sale through the mail of a tape recording representing the ability to cause self-hypnosis to command your body to burn up fat, and lose weight without dieting or willpower.
- February 24, 1976: **Rancho Distributors**, 1242 So. La Cienega, Los Angeles, California 90035. Advertising and sale through the mail of the product "Linga Pendulum," representing the ability to increase the size of the penis and the muscles of concern.
- February 24, 1976: **New Skin**, P.O. Box 214, New Hampton, New York 10958. Advertising and sale through the mail of the product "ginroy capsules," representing the ability to restore and increase vitality in persons of all ages.

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

- January 27, 1976: Against **Royal**, Box 1548, Pompano Beach, Florida 33061. Advertising and sale through the mail of the product "Instant Erecto Cream," representing the ability to restore lost and increase present ability to attain and retain an erection of the penis with no discomfort.
- January 29, 1976: Against **B.B.M. Associates**, P.O. Box 333, Broadview, Illinois 60153. Advertising and sale through the mail of the product "Breast Beautifier and Massager," representing the ability to beautify and increase the size of the bustline.
- February 5, 1976: Against **Kelpers**, 155 Oraton Street, Newark, New Jersey 07104. Advertising and sale through the mail of a remedy representing the ability to reduce obesity, without requiring calorie restriction or dieting.
- February 6, 1976: Against **Poston Distributing**, P.O. Box 390, Van Nuys, California 91408. Advertising and sale through the mail of the product "Linga Pendulum," representing the ability to increase the size of the penis and develop the muscles of concern.
- February 10, 1976: Against **Buchanan Medical Supplies**, 324 So. First St., Dept. BM, Alhambra, California 91802. Advertising and sale through the mail of a product representing the ability to cause "sexcitement," an uncontrollable state of sexual excitement.
- February 25, 1976: Against **Universal Gospel Church**, P.O. Box 2267, Alameda, California 94501. Advertising and sale through the mail of a plan for "natural therapy," representing the ability to cure arthritis.
- February 25, 1976: Against **MW**, Box 5626, Van Nuys, California 91413. Advertising and sale through the mail of the product "Vim," representing the ability to enlarge the user's penis, and restore lost or increase present sexual desires and abilities.
- February 25, 1976: Against **Eastern Imports**, 130 W. 42nd Street, Suite 1305, New York, New York 10036. Advertising and sale through the mail of the product "Hypnotic Dust and Spray," representing the ability to cause instant sexual desire in a person.
- February 27, 1976: Against **National Distributors**, P.O. Box 1692, Hollywood, California 90028. Advertising and sale through the mail of a product representing the ability to enlarge the penis by two inches.
- March 10, 1976: Against **Vicki's Contacts**, 256 S. Robertson Street, Beverly Hills, California 90211. Advertising and sale through the mail of the product "Spheroids," alleged sexual pep pills representing the ability to cause "youthful desire in aging bodies."
- March 16, 1976: Against **Beauty**, P.O. Box 7481, Oakland, California 94601. Advertising and sale through the mail of a cassette tape recording representing the ability to cause weight loss from repeated listening of the recording.

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Salmon, canned, Sea Lark, at South San Francisco, N. Dist. Calif. Charged 5-29-75: when shipped by F. A. Gosse Co., Seattle, Wash., the article contained the added poisonous and deleterious substance polychlorinated biphenyls (PCB's) in excess of the tolerance of 5 ppm prescribed by regulations; 402(a)(2)(A). No one claimed the article and the default of all parties was entered by the court. However, the article was subsequently claimed by Harrison Pierce & Co., Inc., New York, N.Y., who denied the charges. The claimant stated that it was aware of a seizure of another portion of such goods at Hammond, Oreg., that the claimant had made inquiries concerning this article at South San Francisco, and that the claimant assumed this article was under State embargo only, since neither legal nor actual notice of the Federal seizure had been received. The claimant asserted that it was involved in complex litigation concerning this salmon, and would suffer great hardship if the salmon was destroyed.

Accordingly, Harrison Pierce & Co., Inc., was permitted to intervene and the article was saved from destruction at that time. Subsequently, however, the claimant entered into a consent decree of condemnation which ordered the destruction of the article. Ultimately, the article was destroyed. (F.D.C. No. 60375; S. No. 28-326 H; N.J. No. 1)

FOOD/Contamination, Spoilage, Insanitary Handling

Almonds, shelled, Haig's HB, at Boise, Dist. Idaho.

Charged 12-17-74: when shipped by Haig Berberian, Inc., Modesto, Calif., the article contained insect filth; and had been prepared, packed, and held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for salvaging. (F.D.C. No. 60106; S. No. 20-534 H; N.J. No. 2)

Annatto seed, at Puerto Nuevo, Dist. P.R.

Charged 9-2-75: while held for sale, the article contained insect filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60467; S. No. 76-50-772; N.J. No. 3)

Artichoke hearts, canned, at Denver, Dist. Colo.

Charged 10-30-75: while held for sale, the article had been contained in swollen cans; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 60534; S. Nos. 76-17-145/6; N.J. No. 4)

Biscuit mix, at Crowley, W. Dist. La.

Charged on or about 12-23-75: while held by Calcasieu Mercantile Co., Crowley, La., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60599; S. No. 76-38-422; N.J. No. 5)

Butter, at Los Angeles, C. Dist. Calif.

Charged 6-18-75: while held for sale, the article contained decomposed butter; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60402; S. No. 70-454 H; N.J. No. 6)

Cashew nuts, shelled, at Portland, Dist. Oreg.

Charged 12-11-74: when shipped by the National Cashew Co., Ltd., Dar es Salaam, Tanzania, the article contained insects; 402(a)(3). Consent decree authorized release to Roger Russell, Portland, Oreg., for salvaging. (F.D.C. No. 60085; S. No. 18-236 H; N.J. No. 7)

Coating mix for seafood, at San Bruno, N. Dist. Calif.

Charged 7-7-75: while held for sale, the article contained insect filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60390; S. No. 28-371 H; N.J. No. 8)

Cookies, at San Jose, N. Dist. Calif.

Charged 12-5-75: while held for sale, the article contained animal hairs; 402(a)(3). The article was claimed by Puentes Brothers, Inc., San Jose, Calif., who initially sought the release of the articles for salvaging. Subsequently, the claimant withdrew the claim, and a default decree ordered the destruction of the article. (F.D.C. No. 60408; S. No. 28-674 H; N.J. No. 9)

Crabmeat, canned, La Reine, at Seattle, W. Dist. Wash.

Charged 8-15-75 and amended on or about 9-23-75: when

shipped by Taisin International, Inc., Taipei, Taiwan, the article contained decomposed crabmeat, and insect and rodent filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60429; S. Nos. 76-52-642/3, 76-52-939; N.J. No. 10)

Figs, dried, Mr. Fig Organic Farmer, at Portland, Dist. Oreg.

Charged 1-19-76: when shipped by Simone Fruit Co., Inc., Fresno, Calif., the article contained moldy figs, dirt, and insect and rodent filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60604; S. No. 76-53-530; N.J. No. 11)

Fish steaks, breaded, at Louisville, W. Dist. Ky.

Charged 12-19-75: while held by Fish Processors, Inc., Louisville, Ky., who was preparing the article, the article, labeled in part "Breaded . . . COD Whitefish Steaks . . . Packed for Fulton Fish Market, Inc., Louisville, Ky.," contained added *E. coli*, bacterial filth, and insect filth, and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60590; S. No. 76-34-263; N.J. No. 12)

Flour mixes, at Anchorage, Dist. Alaska.

Charged on or about 5-23-75: while held by North Star Bonded Warehouse (North Star Terminal & Stevedore Co.), Anchorage, Alaska, the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60384; S. No. 22-462 H et al.; N.J. No. 13)

Ice cream cone mix, at Chattanooga, E. Dist. Tenn.

Charged 12-15-75: when shipped by Specialty Mix Co. (a subsidiary of Turnbull Cone Baking Co., Inc.), New Orleans, La., the article had been prepared, packed, and held under insanitary conditions; 402(a)(4). Consent decree authorized release to Turnbull Cone Baking Co., Inc., Chattanooga, Tenn., for salvaging. (F.D.C. No. 60572; S. No. 76-32-113; N.J. No. 14)

Mozzarella cheese, at Brooklyn, E. Dist. N.Y.

Charged 3-25-75: while held for sale, the article contained mold; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 60227; S. No. 42-919 H; N.J. No. 15)

Mushrooms, stems and pieces, canned, at Black River Falls, W. Dist. Wis.

Charged 1-26-76: while held for sale, the article was contained in swollen and leaking cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60610; S. No. 76-30-214; N.J. No. 16)

Pecans, unshelled, at Tulsa, N. Dist. Okla.

Charged 1-15-76: while held by Safeway Stores, Inc., Tulsa, Okla., the article contained rodent filth, and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60620; S. No. 76-16-121; N.J. No. 17)

Popcorn, pinto beans, scratch grain, and poultry feed, at Paintsville, E. Dist. Ky.

Charged 2-11-75: while held by Williams Wholesale Grocery Co., Paintsville, Ky., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 60203; S. No. 60-156 H; N.J. No. 18)

Potatoes, dried, at Honolulu, Dist. Hawaii.

Charged 10-24-75: while held by Honolulu Transport & Warehouse Corp., Honolulu, Hawaii, the article contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60522; S. No. 76-48-829; N.J. No. 19)

Potatoes, french-fried, frozen, at Myrtle Beach, Dist. S.C.

Charged 1-5-76: when shipped by the Potato Processing Co., Atlanta, Ga., the article contained *E. coli* and bacterial filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60586; S. No. 76-00-305; N.J. No. 20)

Pumpkin seed, shelled, at City of Industry, C. Dist. Calif.

Charged 8-26-75: while held by El Molino Mills, City of Industry, Calif., the article contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree



authorized release to ACG Co., City of Industry, Calif., for salvaging. (F.D.C. No. 60463; S. No. 76-26-865; N.J. No. 21)

Rice, at Mayaguez, Dist. P.R.

Charged 10-1-75: while held for sale, the article contained insect filth; 402(a)(3). Consent decree authorized release to Almacen De Linea Completa, Inc., San Juan, P.R., for salvaging. (F.D.C. No. 60492; S. No. 76-51-007; N.J. No. 22)

Rice flour, sweet, at Buffalo, W. Dist. N.Y.

Charged 10-31-75: while held for sale, the article contained insect filth; 402(a)(3). Consent decree authorized release to Federal Bakers Supply Corp., Buffalo, N.Y., for salvaging. (F.D.C. No. 60541; S. No. 76-07-204; N.J. No. 23)

Salmon, dressed, frozen, at Seattle, W. Dist. Wash.

Charged 11-7-75: when shipped by Osmar's Ocean Specialties, Inc., Clam Gulch, Alaska, the article contained decomposed salmon; 402(a)(3). Consent decree authorized release to Traco, Inc., Seattle, Wash., for salvaging. (F.D.C. No. 60538; S. Nos. 76-52-718/19; N.J. No. 24)

Salmon, frozen, at Seattle, W. Dist. Wash.

Charged 6-30-75: when shipped by the Sitka Sound Seafoods, Inc., Sitka, Alaska, the article contained decomposed salmon; 402(a)(3). Consent decree authorized release to Denton Sherry, Seattle, Wash., for salvaging. (F.D.C. No. 60400; S. No. 22-474 H; N.J. No. 25)

Salmon, frozen, at Seattle, W. Dist. Wash.

Charged 11-3-75: when shipped by Traco, Inc., Anchorage, Alaska, the article contained decomposed salmon; 402(a)(3). Consent decree authorized release to shipper for salvaging. (F.D.C. No. 60526; S. No. 76-52-717; N.J. No. 26)

Sugar, at Salt Lake City, Dist. Utah.

Charged 7-16-74: while held by Duffins Candy (Robert B. Beall), Salt Lake City, Utah, the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59849; S. No. 80-796 H; N.J. No. 27)

Sunflower seeds, hulled, at Pittsburgh, W. Dist. Pa.

Charged 7-26-73: while held by North Pole Cold Storage, Inc., Pittsburgh, Pa., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59379; S. Nos. 83-367/70 G et al.; N.J. No. 28)

Tomatoes, canned, at Cincinnati, S. Dist. Ohio.

Charged 12-30-75: when shipped by The Home Canning Co., Blissfield, Mich., the article, labeled in part "Premier Tomatoes . . . Francis H. Leggett Co., Inc. Distributors, Cincinnati, Ohio," contained decomposed tomato material; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60603; S. Nos. 76-13-817/18; N.J. No. 29)

Walnut pieces, at Salt Lake City, Dist. Utah.

Charged 1-14-75: when shipped by Haig Berberian, Inc., Modesto, Calif., the article contained insect filth and had been prepared, packed, and held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for salvaging. (F.D.C. No. 60160; S. No. 79-741 H; N.J. No. 30)

FOOD/Economic and Labeling Violations

Butter, at New York, S. Dist. N.Y.

Charged 9-11-75: when shipped by Madison Coop Creamery, Madison, Nebr., the article, which was labeled in part "Zenith Godley Co. New York Salt Butter 68 LBS Net Churn," and which contained less than 80 percent of milk fat, had been substituted for and labeled as butter (which is required to contain not less than 80 percent milk fat); 402(b)(2). The article was claimed by the shipper. A consent decree authorized release to the claimant for reconditioning. (F.D.C. No. 60470; S. No. 76-40-482 et al.; N.J. No. 31)

Corn oil, Enrico Caruso, at Elizabeth, Dist. N.J.

Charged 8-21-75: when shipped by Caruso Products Dist. Corp., Pelham, N.Y., the article's label vignette of a slender female body and the label statement "Slenderizing" were false and misleading in representing and suggesting that the article was of unusual value in controlling body weight—403(a); and the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not separated from other printed label information appearing above and below the declaration, and since the quantity of contents

declaration, appearing on the principal display panel area of more than 25 square inches, was in a type size less than 3/16 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Default decree authorized donation to charitable institution. (F.D.C. No. 60447; S. No. 76-34-441; N.J. No. 32)

Crabmeat, canned, at Richmond, N. Dist. Calif..

Charged 6-7-74: when shipped from Kaohsiung, Taiwan, the article, labeled in part "Green Island Natural Snow Crab Meat . . . Distributed by HSU Enterprises, Corte Madera, Calif. . . . Product of Taiwan," contained insect filth; 402(a)(3). The article was claimed by Safeway Stores, Inc., Richmond, Calif. The claimant and the Government agreed to a consent decree of condemnation which permitted the return of the article to the original foreign supplier. Since the court expressed concern about exporting, from the United States, food which might be unsafe for human consumption, FDA provided an affidavit summarizing the extent and nature of FDA's analytical findings and stating that, as far as FDA knew, the filth in the article did not pose a hazard to health. The court entered the decree which had been consented to by the claimant and the Government, but added a last sentence reading: "There shall be no sale, export or other disposition, except destruction, unless the Secretary or the F.D.A. shall unequivocally certify that the articles are safe for human consumption." The claimant filed a motion to amend the judgment by the deletion of the above quoted condition which had been added by the court. The Government filed a statement of nonopposition to claimant's motion and joined in the claimant's motion. The court denied the claimant's motion. The claimant asserted that, if an appeal were filed, the court would not have an opportunity to respond to the issues because the Government had joined in the claimant's motion. Accordingly, the claimant petitioned the Court of Appeals for a writ of mandamus, arguing that 21 U.S.C. 334(d)(1) specifically provided for the return of a food adulterated under 21 U.S.C. 342 to the original foreign supplier, and that such food (which was imported into the United States but which had not been released from customs custody was merely refused admission to the United States) might be re-exported to the original supplier, without any certification from FDA that such food was safe for human consumption. Upon due consideration, the Court of Appeals ordered that the last sentence of the consent decree be stricken from the consent decree "as not in conformity with the legislative intent behind 21 U.S.C. § 334." Thereafter, pursuant to the terms of the consent decree as modified by the Court of Appeals, the article was released under bond for export to the original supplier in Taiwan. (F.D.C. No. 59797; S. No. 27-132 H; N.J. No. 33)

Shrimp, breaded, frozen, at San Antonio, W. Dist. Tex.

Charged 9-19-75: when shipped by Singleton Packing Corp., Tampa, Fla., the article, labeled in part "High Tide . . . Fresh Frozen . . . Butterfly . . . Breaded Shrimp . . . Distributed by High Tide Co., Tampa, Florida," failed to conform to the definition and standard for frozen raw breaded shrimp, since it contained less than 50 percent (i.e., approximately 36 percent) of shrimp material; 403(g)(1). The article was claimed by the shipper. Subsequently, a consent decree authorized the donation of the article to a charitable institution for use of its charges only. (F.D.C. No. 60482; S. Nos. 76-21-987/8; N.J. No. 34)

FOOD ADDITIVES

Chubs, dressed, at Monmouth, Dist. N.J.

Charged 6-4-75: when shipped by Big Bay De Noc Fisheries, Garden, Mich., the article contained the nonconforming food additive dieldrin; 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 60370; S. No. 10-127 H; N.J. No. 35)

Stock solution concentrate for poultry, Dye Gen, at Cullman, N. Dist. Ala.

Charged 2-20-76: when shipped by Dan-Mar Enterprises, Inc., Commerce, Ga., the article contained the nonconforming food additive gentian violet; 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 60656; S. No. 76-60-992; N.J. No. 36)

DRUGS/Human Use

Cholipan choline bitartrate combination tablets, at Denver, Dist. Colo.

Charged 4-25-73, and amended 6-12-73 and 8-24-73: while held by Western Research Laboratories, Inc., Denver, Colo., who manufactured the article using choline bitartrate, methionine,



and desiccated ox bile shipped in interstate commerce, the listing in the article's labeling of choline bitartrate, dl-methionine desiccated ox bile and dried pancreas substance, as ingredients, was false and misleading in representing and suggesting that each such ingredient was effective for, or contributed to the article's use "as an aid for indefinite biliary insufficiency and an aid in improving digestion and bowel function—502(a); and the article's labeling lacked adequate directions for use, and was not exempted therefrom since the article was a new drug without an effective approved New Drug Application—502(f)(1). The article was claimed by the manufacturer who denied the charges. The complaint was amended to delete an erroneous charge. The Government moved for and obtained post-seizure samples of the article. Based on the post-seizure samples which revealed different labeling than that originally charged, the complaint was again amended. The parties served written interrogatories on each other. The claimant moved to strike the language concerning the lack of a New Drug Application in the charge involving allegations that the article's labeling lacked adequate directions for use. The claimant asserted that language concerning the exemption from adequate directions for new drugs was immaterial since it was one of at least five possible exemptions and that the only thing material was that the article was not exempt. The Government asserted that such language was relevant and informative and was not immaterial to the case. Thereafter, with the consent of the claimant, the motion to strike was denied. Ultimately, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 59101; S. No. 43-741 G; N.J. No. 37)

Ipecac, powdered, at South Hackensack, Dist. N.J.

Charged 4-22-70: when returned from Rensselaer, N.Y., to South Hackensack, N.J., the strength of the article, labeled in part "A. C. Curran Corporation Subsidiary of Dr. Madis Laboratories, Inc., . . . South Hackensack, N.J. . . . Powdered Ipecac Root U.S.P. XVII . . . Caution for Manufacturing, Processing, or Repacking," differed from, and its quality and purity fell below U.S.P. standards, since the article's potency of ether-soluble alkaloids of ipecac was less than that required by the standard and since the article contained 0.2 percent ephedrine—501(b); ephedrine had been mixed and packed with the powdered ipecac so as to reduce its quality and strength—501(d)(1); ephedrine had been substituted in part for powdered ipecac—501(a)(2); and the article's label statement "Powdered Ipecac Root U.S.P. XVII" was false and misleading since the article failed to conform to the U.S.P. standard in that its potency was less than 1.9 percent of the ether-soluble alkaloids of ipecac and it contained 0.2 percent ephedrine—502(a). The article was claimed by A. C. Curran Corp., South Hackensack, N.J., who denied the charges. The claimant sought and was granted representative samples of the article and copies of the analyses upon which the proceeding was based. The Government served written interrogatories on the claimants. Subsequently, the claimant withdrew its claim and its answer, and consented that a default decree of condemnation ordered the article destroyed. (F.D.C. No. 56370; S. No. 18-922 D; N.J. No. 38)

Lipo-K pancreas extract and chondroitin sulfate combination injectable, at Torrance, C. Dist. Calif.

Charged 12-17-75: when shipped by Marcen Laboratories, Inc., New Rochelle, N.Y., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 60578; S. No. 76-27-715; N.J. No. 39)

Prednisone tablets, U.S.P., at Valley Stream, E. Dist. N.Y.

Charged 6-30-72: when shipped by Marshall Pharmacal Corp., South Hackensack, N.J., the strength of the article, labeled in part "Prednisone . . . U.S.P. . . . tablets . . . Manufactured for Spencer-Mead Inc. Valley Stream, N.Y.," differed from the U.S.P. standard, since the article contained approximately 84 percent of the declared prednisone; 501(b). Consent decree authorized release to the shipper for salvaging. (F.D.C. No. 58012; S. No. 56-381 F; N.J. No. 40)

Viro-Zyme sodium nucleate injectable, at Kirkwood, E. Dist. Mo.

Charged on or about 12-23-75: when shipped by Marcen Laboratories, Inc., New Rochelle, N.Y., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 60575; S. No. 76-23-535; N.J. No. 41)

MEDICAL DEVICES

Electro-sedation electronic therapy unit, at Sidney, E. Dist. Ill.

Charged 10-9-75: when shipped by Tri-Tronics Laboratory, Inc., Eules, Tex., the labeling of the article contained false and misleading claims for the article as a new approach to treatment for patients for whom hypnotics, barbiturates, sedatives and addictive tranquilizers are now being prescribed, as a harmless, nontoxic, nonaddictive, and quite safe procedure, and as a treatment for: insomnia, random aches and pains, the relief of pain in arthritis, bursitis, tendonitis and sprains, neuroses, headache, stimulating circulation, and speeding the healing of a fracture, and contained further false and misleading claims that the article was intended to be used only for investigation and experimentation in the field of relaxation and sleep—502(a); the labeling lacked adequate directions for use for the article's intended purposes, since such could not be furnished; and the labeling lacked adequate warnings against unsafe uses—502(f)(1), 502(f)(2). Default decree ordered destruction. (F.D.C. No. 60458; S. No. 96-216 H; N.J. No. 42)

NOTICES OF JUDGMENT on Criminal Actions FOOD

Adams & Thompson Milling Co., Inc., and Zane G. Thompson, president, and Doyle S. Adams, vice president, Midland City, M. Dist. Ala.

Charged on or about 4-25-75 by grand jury: when shipped, Adams enriched white cornmeal contained insect filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty pleas; fines. (F.D.C. No. 60261; S. No. 115-718 H; N.J. No. 43)

C & S Wholesale Grocers, Inc., and Joseph S. Szalucka, president, Claremont, Dist. N.H.

Charged 9-26-74: shortening, breakfast cereal flakes, and cocoa mix were held in a building accessible to rodents and insects and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (F.D.C. No. 59846; S. No. 100-267 G; N.J. No. 44)

Everett Fisheries, Inc., and Eric E. Johnson, vice president and general manager, Port Wing, W. Dist. Wis.

Charged 12-19-72: when shipped, smoked ciscoes, smoked herring, and smoked whitefish were prepared, packed, and held under insanitary conditions whereby they might have been rendered injurious to health, contrary to the Current Good Manufacturing Practice Regulations for smoked fish; 402(a)(4).

The defendants pleaded not guilty. The defendants moved to dismiss the information on the grounds that the statute, as supplemented by the regulations was unconstitutionally vague. The defendants also filed additional motions including a motion for a bill of particulars and a motion for disclosure of all evidence favorable to the defendants. After a hearing, the court denied the defendants' motion to dismiss based on the ground that the statute was unconstitutionally vague. The court also ruled that the regulations involved were not arbitrary or unreasonable, and that such regulations were interpretive and not substantive. Upon the consent of the Government, the defendants waived a jury trial and consented to trial by the court. After trial by the court, the court found the defendants **not guilty** and dismissed the information, saying:

Facts * * *

"The fish described in the information were removed from Lake Superior at times when about one to two percent of the fish in that lake harbored [*Clostridium botulinum*] spores capable of producing [*Clostridium botulinum*] toxin, type E, which can be deadly to humans who ingest it. Brining at certain temperatures for certain periods can inhibit the outgrowth of this toxin; smoking at certain temperatures for certain periods can destroy toxin and spores; refrigeration thereafter can inhibit the outgrowth of toxin from any surviving spores. The higher the salt content resulting from the brining, the more effective in destroying spores and in inhibiting outgrowth of surviving spores is the application of heat during the smoking process. Toxin is destroyed by the application of heat at lower temperatures than those necessary to the destruction of spores. * * * "No [*Clostridium botulinum*] type E spores were observed in any of the fish processed at defendants' plant on February 14, 1972 and February 15, 1972.

"The government agent who checked defendants' plant on February 14, 1972 and February 15, 1972 observed a large



rat outside the plant on its threshold. On those days, smoke racks, both wooden and steel, were stored by being placed directly on the floor. The smoke sticks in use were wooden; the use of wooden sticks was common in the industry at the time. Of the eight ovens, three were not equipped to monitor temperatures within the bodies of the fish, but were equipped with thermometers by which the heat of the ambient air within the ovens could be observed.

Opinion

"Each count of the information herein charges that on the day in question the defendants violated 21 U.S.C. § 331(a) by shipping interstate food which was adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that it was prepared, packed, and held under insanitary conditions, 'contrary to the provisions of 21 CFR § 128a, Subpart A, current good manufacturing practice in manufacturing, processing, packing, or holding of smoked and smoke-flavored fish.' § 331(a) prohibits such interstate shipments of 'food . . . that is adulterated. . . .' 21 U.S.C. § 332 provides for injunctive relief against such acts and 21 U.S.C. § 333 makes them punishable by imprisonment or fine, or both. § 342(a)(4) provides that food is deemed adulterated if it has been 'prepared, packed, or held under insanitary conditions whereby . . . it may have been rendered injurious to health. . . .'

"The word 'may' is troublesome.

"Early in the course of this case, I rejected the government's contention that if food has been prepared, packed or held in a manner which does not meet the requirements of 21 C.F.R. § 128a, it follows necessarily that it has been prepared, packed or held 'under insanitary conditions whereby . . . it may have been rendered injurious to health. . . .' This was a contention that Congress had made it a crime to violate any FDA regulation duly promulgated pursuant to the Act. But Congress clearly has not chosen this course. I concluded, and I continue in the view, that in each criminal prosecution under 21 U.S.C. §§ 331(a) and 333, the government must prove beyond a reasonable doubt, not that the FDA regulations have been violated, but that the food was adulterated within the meaning of 21 U.S.C. § 342.

"Also early in the course of this case, I denied defendants' motion to dismiss the information for vagueness, stating that I would adopt a statutory construction which would save it from vagueness. I stated my intention to require the government to prove beyond a reasonable doubt that the fish had been prepared, packed or held under insanitary conditions whereby it became reasonably probable that the food would be rendered injurious to health. I repeated this statement of intention several times before and during the trial. However, following the trial I became aware that I had misread or misunderstood certain decided cases, and that apparently the proper test is one of 'reasonable possibility' rather than 'reasonable probability.' Any doubts on this score have since been resolved in this circuit by *United States v. H. B. Gregory Co.*, 502 F.2d 700, 705 (7th Cir. 1974), in which the reasonable possibility standard was embraced in a criminal prosecution under the Act. Defendants contend that it is fundamentally unfair to them for the court to announce its intention to apply one standard and then, subsequent to trial, to apply another. I agree that this shift has been unfortunate, but I do not agree that defendants have been prejudiced by it. It is quite clear that the defendants' presentation of their case would not have been affected in any significant way had the court declared in advance of trial its intention to apply the reasonable possibility standard.

"The question, then, is whether the government has proven beyond a reasonable doubt that the defendants prepared, packed or held the fish under insanitary conditions whereby it became reasonably possible that the food would be rendered injurious to health. Of course it became possible, but I conclude that it did not become reasonably possible. It seems clear that if fish are salted heavily enough and smoked in ovens hot enough, both E-9 toxin and spores capable of producing E-9 toxin can be destroyed. But it is also clear that in terms of taste and appearance, the fish can be rendered inedible and unappetizing if the salt content is too high or the fires too hot. Considerable study and effort was devoted to the development of the standards embodied in 21 C.F.R. § 128a.7 before it was promulgated in 1970. The government has provided sufficient evidence to establish that the fish would not be rendered inedible or unappetizing in appearance if the brining and

smoking standards embodied in § 128a.7 were observed. But the evidence is that observance of those FDA standards does not eliminate the possibility that spores capable of producing E-9 toxin, if such spores are present, will survive the brining and smoking.

"Of course, the government contends that if § 128a.7 standards are observed, the possibility that the food has been rendered injurious to health would not be reasonable. But the government contends, as it must, that the degree of deviation of defendants' practices from § 128a.7 practices was sufficient to transform an unreasonable possibility into a reasonable possibility. I conclude that this proposition, which lies at the core of this case, has not been proven beyond a reasonable doubt." (F.D.C. No. 58377; S. No. 50-9-05 F et al.; N.J. No. 45)

NOTICE OF JUDGMENT on Criminal Action DRUGS

Wallace Rubin, M.D., Metairie, E. Dist. La.

Charged 5-3-73 by grand jury: that schemes to defraud E. I. duPont deNemours & Co., Wilmington, Del., (count 1), and Charles Pfizer & Co., Inc., Groton, Conn., (count 2), were devised, in that fraudulent representations were made purporting to show that experimental drug studies of the drug EXP-999 (metopimazine) (count 1), and the drug P-2647(benzquinamide) (count 2), had been performed; and that, in furtherance of such schemes, the defendant mailed a letter to duPont's Clinical Evaluation Section and a letter to Pfizer's Department of Clinical Pharmacology—18 U.S.C. 1341; that the defendant knowingly caused the filing with FDA by Pfizer (count 3), and by duPont (count 4), of false patient case studies and clinical summaries of the results, on benzquinamide, and metopimazine, as part of the Investigational New Drug Applications on such drugs—18 U.S.C. 1001; and that, subsequently, the defendant knowingly filed (count 5) with FDA false patient case studies on metopimazine, as part of the Investigational New Drug Application on such drug—18 U.S.C. 1001. The defendant filed a motion to dismiss the indictment, for failure to afford a speedy trial and for denial of due process of law. After an evidentiary hearing on such motion, the court denied the motion. Subsequently, the defendant pleaded nolo contendere; a sentence of 5 years' imprisonment was suspended; and three years' probation was imposed with special conditions, including three months of *pro bono* service outside New Orleans, La. (Misc. No. 196; N.J. No. 46)

NOTICES OF JUDGMENT on Injunction Actions

Belford Co., and Richard A. Belford, Jr., president, Savannah, S. Dist. Ga.

Charged 5-20-75: that the defendants, at their food warehouse in Savannah, Georgia, held food for sale after its interstate shipment, which food was held under insanitary conditions and some of which food contained rodent filth; that FDA inspections disclosed a number of specified insanitary conditions at the warehouse; and that the defendants had been warned of such insanitary conditions on a number of specified occasions; 402(a)(3). 402(a)(4). A consent decree of permanent injunction enjoined the placing (after a specified date,) in the warehouse involved in the original complaint, of any interstate food, and from selling and distributing after such date any interstate food held at the warehouse until such food was brought into compliance (such compliance including any food held at the warehouse being examined for filth, necessary analyses being made, and all contaminated food being destroyed or otherwise being brought into compliance). The decree also enjoined the sale and distribution of interstate food from the defendants' building that had been subsequently acquired for warehousing, unless and until: (a) such building had been examined and reported upon by a qualified person selected by the defendants to assure that the storage circumstances of the building would not contaminate food with filth, (b) the responsibility for the operation of warehouse sanitation was assigned to a person competent to maintain sanitary conditions, (c) a warehouse sanitation control program was established to assure sanitary warehouse conditions, (d) such building was in compliance with the consent decree and with the requirements of the Federal Food, Drug, and Cosmetic Act, and (e) such FDA inspections as deemed necessary, were permitted in order to determine



that the requirements of the decree and the Act had been met. After compliance with the above requirements, the defendants were enjoined from the complained of violations with respect to the subsequently acquired building. (Inj. No. 699; S. No. 117-359 H, et al.; N.J. No. 47)

New Colonial Bakery, Inc., and Nicholas Maisto, president, **Hamlet Maisto**, vice president, **Peter Casarico**, secretary-treasurer, and **Nicholas J. Maisto**, general manager, Trenton, Dist. N.J.

Charged 12-11-74 in complaint for injunction: that the defendants were engaged at their bakery at Trenton, N.J., in holding interstate flour for use and sale in bakery products, in manufacturing, packing, and holding various bakery products, in distributing in interstate commerce bakery products (including bread and rolls), and in holding for sale such bakery products after interstate shipment of their components; that such foods were prepared, packed, and held under insanitary conditions; that the flour contained insect and rodent filth; that FDA inspections disclosed a number of specified insanitary conditions and practices; and that the defendants had been warned of insanitary conditions existing in the bakery on a number of specified occasions; 402(a)(3), 402(a)(4). The court granted a temporary restraining order enjoining the defendants. Subsequently, the defendants consented to a consent decree of preliminary injunction which extended the terms of the temporary restraining order, enjoining the complained of violations and enjoining the defendants from placing in their bakery any interstate food, from shipping any bakery products prepared, packed, or held in the bakery, and from preparing, packing, and holding in the bakery and distributing therefrom any bakery products of interstate components, unless and until: the bakery methods, facilities, and controls were in conformity with practices which would assure that food was not contaminated with insect, rodent, or other filth; the defendants' bakery, raw materials, bakery products, and equipment were examined and certified (by a qualified person selected by the defendants) to determine that the bakery practices would not contaminate the food with filth; all food on hand was examined for filth, necessary analyses made, and all food shown to be contaminated with filth was destroyed or brought into compliance. (Inj. No. 687; S. No. 58-816 H et al.; N.J. No. 48)

NOTICES OF JUDGMENT on Miscellaneous Actions

Anorectic combination drugs with barbiturates and tranquilizers, and their status in the possession of physician, Lancaster, E. Dist. Pa.

Petitioned on or about 10-1-73 by Henry J. Glah, Jr., M.D., Lancaster, Pa., against the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) in petition for declaratory judgment and injunction: that plaintiff was a licensed and practicing physician; that, prior to FDA's regulation to the effect that most combination anorectic drugs were unmarketable, the plaintiff had purchased quantities of such drugs for the treatment of his patients and had some drugs remaining; that FDA and DEA had attempted to apply such regulation retroactively and to make the possession of such drugs subject to criminal penalties and seizure, and had threatened the plaintiff with criminal and civil prosecution for his possession of such medications; that, if plaintiff was subjected to criminal prosecution, his reputation and his ability to practice his profession would be diminished and impaired and he would suffer irreparable damage; that, if the drugs were seized, plaintiff would be prevented from professionally and adequately treating his patients and practicing his profession; that plaintiff prayed the court to declare that such lawfully obtained drugs in his possession were not subject to criminal and civil sanctions of FDA and that the court grant an injunction. The Government moved to dismiss on the grounds that the action was an unconscionable suit against the Government which was barred by sovereign immunity, that the plaintiff had failed to identify any statute giving the court jurisdiction, and that plaintiff had failed to state a claim for which relief could be granted in declaratory relief. Ultimately, by agreement of counsel, the action was dismissed with prejudice and without costs. (Misc. No. 258; N.J. No. 49)

Listerine Antiseptic, and suit to enjoin FTC and FDA from proceeding simultaneously against claims for product, Washington, Dist. Columbia.

Charged on or about 4-4-73 in complaint for injunction by Warner-Lambert Co., Morris Plains, N.J., against the Federal

Trade Commission, and its chairman and members, and H.E.W. Secretary Caspar W. Weinberger, and Acting FDA Commissioner Sherwin Gardner: that the FTC had complained of Warner-Lambert's labeling, packaging, and advertising claims for Listerine Antiseptic for colds, cold symptoms, and resultant sore throat; that subsequently FDA had commenced administrative rulemaking proceedings involving all nonprescription cough-cold remedies, which, in effect, would determine whether the labeling claims of such remedies, including Listerine Antiseptic, for colds, cold symptoms, and resultant sore throats, were in violation of the Food, Drug, and Cosmetic Act; that a basic issue in both the FTC and the FDA proceedings was the effectiveness of Listerine Antiseptic for such recommended conditions of use; that both proceedings involved the identical factual issue, i.e., the effectiveness of Listerine Antiseptic for the recommended conditions; that the simultaneous initiation and conduct of the FTC and FDA proceedings was in violation of 36 Fed. Reg. 18539 which recognized the unfairness and undesirability of duplicate proceedings relating to the same products and which precluded the "initiation of proceedings involving the same parties by both agencies" except in "those highly unusual situations where it is clear that the public interest requires two separate proceedings"; that simultaneous proceedings before the FTC and FDA would cause substantial harm to Warner-Lambert by unreasonably prejudicing Warner-Lambert precluding a fair hearing, and denying due process of law, as follows: Warner-Lambert was required to defend its product simultaneously before two separate Federal agencies contrary to a rule precluding such simultaneous proceedings, Warner-Lambert might be subject to and be liable for inconsistent determinations of fact and law, Warner-Lambert (as a practical matter) was deprived of independently conducted agency proceedings because the actions and determinations of one agency would have a substantial effect on the other agency, a determination by either FDA or the FTC might be *res judicata* and the first concluded proceeding would appear to be binding, and such a "race" for priority of decision would be inconsistent with fair hearing and due deliberation; that Warner-Lambert had exhausted all available administrative remedies, and had no other adequate remedy than this action; that plaintiff requested the court to find that the simultaneous proceedings of the FTC and FDA were unlawful, and to enjoin those agencies until they took action to prevent the conduct of two simultaneous proceedings with regard to the cold and sore throat claims of Listerine Antiseptic and to restrain the FTC from further proceeding with respect to the plaintiff's labeling claims.

The Government moved to dismiss or, in the alternative, moved for summary judgment. Meanwhile, the plaintiff's motion for a preliminary injunction was heard by the court. In denying the preliminary injunction the court said:

"The plaintiff, Warner-Lambert, in its motion for a preliminary injunction has asked this Court to restrain the Federal Trade Commission from undertaking further proceedings in Docket No. 8891; and restrain the Secretary, Commissioner of Food and Drugs, from further proceedings with respect to their rule-making proceeding regarding plaintiff's product in their review of over-the-counter cold remedies unless and until the two agencies take appropriate action to prevent the conduct of simultaneous proceedings with respect to the subject matter of those two proceedings; and, secondly, to restrain the Federal Trade Commission from undertaking further proceedings with regard to the labeling claims of plaintiff's product.

"With respect to the second point, it is our opinion that this contention can be raised before the Commission not only at the hearing stage before a trial examiner but on review before the full Commission, and finally on review to a Circuit Court of Appeals should the decision of the Commission be adverse.

"Under these circumstances, we hold that we have no jurisdiction to grant this particular relief.

"With respect to point one, namely, the restraint on the two agencies until they take appropriate action to prevent the conduct of two simultaneous proceedings, the plaintiff relies on a so-called rule between the two agencies under which only one agency will proceed with respect to the same respondent on the same subject matter except in unusual circumstances.

"This so-called rule was published in the *Federal Register*.

"In our judgment this so-called rule is an agreement between the two agencies promulgated primarily for the convenience of the agencies in carrying out their functions under two different



statutes.

"It is not similar to the consent order in the Elmo case, which we just read, under which order the Federal Trade Commission consented to proceed by way of reopening a prior case rather than by initiating a new one. And in that case, of course, the Court of Appeals reversed this court which dismissed the case for want of jurisdiction.

"In the Elmo case there was a consent between the parties involved, the respondent and the Commission, that is, a consent order. In this case the only parties to the so-called agreement were the two agencies involved. . . .

"As far as the proceedings themselves are concerned, it is our opinion that they are quite different. As has been pointed out in argument, the one before the Federal Trade Commission is an adversary proceeding. It is an adjudicatory proceeding. It only involves the Warner-Lambert Company.

"The one before the Food and Drug Administration is a rule-making proceeding. It involves manufacturers of thousands of products, including cold remedies; and it is one in which individual companies can participate or decline to, as was pointed out, to their possible disadvantage.

"If we were to require the Food and Drug Administration to exempt the plaintiff from its proceeding, it seems to us that we would give them a discriminatory preference over the manufacturers of thousands of products of a similar kind, namely, over-the-counter cold remedy products.

"Finally, our jurisdiction to grant preliminary relief in this court, as is well known, is subject to definite limitations. . . .

"For the reasons previously expressed, we feel that the plaintiff has failed to meet at least two of the [four] criteria [for preliminary relief]. It has not shown that there is substantial likelihood that it will succeed on the merits in this case. And, secondly, reviewing the matter in its entire perspective, we feel that the public interest lies on the side of the defendants."

Subsequently, the court also ruled in favor of the Government and dismissed the action saying:

"This action seeks to restrain the Federal Trade Commission from undertaking further proceedings in FTC Docket No. 8891, and to restrain the Secretary of Health, Education, and Welfare and the Commissioner of Food and Drugs from further proceeding with its review of over-the-counter cold remedies, unless and until the two federal agencies take appropriate action to prevent the conduct of two simultaneous proceedings with regard to the cold and sore throat claims of Listerine Antiseptic. The action further seeks to restrain the Federal Trade Commission from undertaking further proceedings in FTC Docket No. 8891 with regard to the cold and sore throat labeling claims of Listerine Antiseptic. * * *

"Plaintiff argues the two proceedings complained of are unlawful in that they violate a 'rule' of both agencies. The 'rule' which plaintiff asserts is binding upon defendants is a 'Memorandum of Understanding' issued jointly by FTC and FDA and published at 36 F.R. 18539. Plaintiff's contention is erroneous. Even assuming, arguendo, the 'rule' is binding on defendants, it is clear it does not apply to the proceedings in issue.

"The Memorandum is an agreement between the two agencies promulgated primarily for the convenience of the agencies in carrying out their functions under two different statutes. The only parties to the agreement were the two agencies involved, and an individual private party, such as plaintiff, may not invoke the agreement in challenging these agency actions. Furthermore, in the Court's opinion, the agreement has not been breached. It is apparent from the affidavits of Messrs. Freer and Fine filed with the Court on May 1, 1973 that there was considerable liaison resulting in an express agreement between the two agencies sufficient to satisfy the requirements of the Memorandum of Understanding.

"As far as the proceedings themselves are concerned, it is the Court's opinion they are quite different. As has been pointed previously, the proceeding before the Federal Trade Commission is an adversary proceeding. It is an adjudicatory proceeding. It involves only Warner-Lambert.

"The proceeding before the Food and Drug Administration is a rule-making proceeding. It involves thousands of manufacturers of over-the-counter products, including cold remedies. It is a proceeding which individual companies can participate in or decline to participate in, at their option, recognizing it may also be to their possible disadvantage.

"If this Court were to require the Food and Drug Adminis-

tration to exempt plaintiff from its proceeding, it seems such action would give plaintiff a discriminatory preference over the manufacturers of many products of a similar kind, namely, over-the-counter cold remedy products.

"The joint proceedings which FDA and FTC agreed to limit were intended to be proceedings where the FTC would file a complaint seeking a cease-and-desist order on the basis of false and misleading claims, and where the FDA would institute a seizure proceeding seeking to condemn the product on the same grounds. It is certain that the present proceedings, i.e., the FDA review of all OTC drugs, and the FTC complaint against one OTC drug, are not within the provisions of the Memorandum of Understanding. For if this were the case, then the FTC would now be foreclosed from proceeding against any of the 100,000 to 500,000 OTC drugs currently on the market, no matter how false or how misleading the claims for such a product. * * *

"In the present case, even if the disparate actions of the FTC and FDA could be construed as simultaneous duplicative proceedings against Listerine Antiseptic, it is clear that the action is neither unlawful nor arbitrary and capricious and therefore plaintiff has no basis upon which to maintain this action. . . .

"Plaintiff has available administrative remedies before each agency which have not been exhausted. Still to be completed before FTC is the administrative proceeding in which Warner-Lambert will have full opportunity to present evidence and argument in its behalf. If the adjudicative proceedings to terminate in an order against Warner-Lambert to cease and desist, Warner-Lambert has the right to appeal directly to a United States Court of Appeals. Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. The Act further provides that the jurisdiction of the courts of appeals 'to affirm, enforce, modify or set aside orders of the Commission shall be exclusive.' 15 U.S.C. § 45(d). The Act nowhere provides for a review in district courts of interlocutory rulings by the Commission, and 5 U.S.C. § 704 expressly provides: 'A preliminary, procedural or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action.' Similarly, if FDA issues a monograph at the conclusion of its proceedings, review of that action may be sought in the courts.

Conclusion

"Having considered the foregoing, the Court concludes: there is a rational basis for the actions of each of the agencies in initiating and pursuing their individual proceedings; plaintiff does not have standing to challenge, in this action, the Memorandum of Understanding between the agencies; the two agencies complied with the provisions of the Memorandum of Understanding; the proceedings before the two agencies are not duplicative; plaintiff has not exhausted its administrative remedies; there is no evidence of record that plaintiff is required to respond to the proceeding before FDA, although its failure to respond may be at its peril; and there is no indication that it is in the public interest to enjoin the disparate agency proceedings at this stage.

"In summary, plaintiff has not met the criteria for the granting of a preliminary injunction and its motion for a preliminary injunction is denied. Count II of the complaint seeking a permanent injunction against FTC maintaining the labeling charges against plaintiff is dismissed and defendants' motion for summary judgment is granted." (Misc. No. 225; N.J. No. 50)

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.

Alexander M. Schmidt, M.D., *Commissioner of Food and Drugs*
Washington, D.C., July 1, 1976

Don't Let The Silent Killer Silence You.

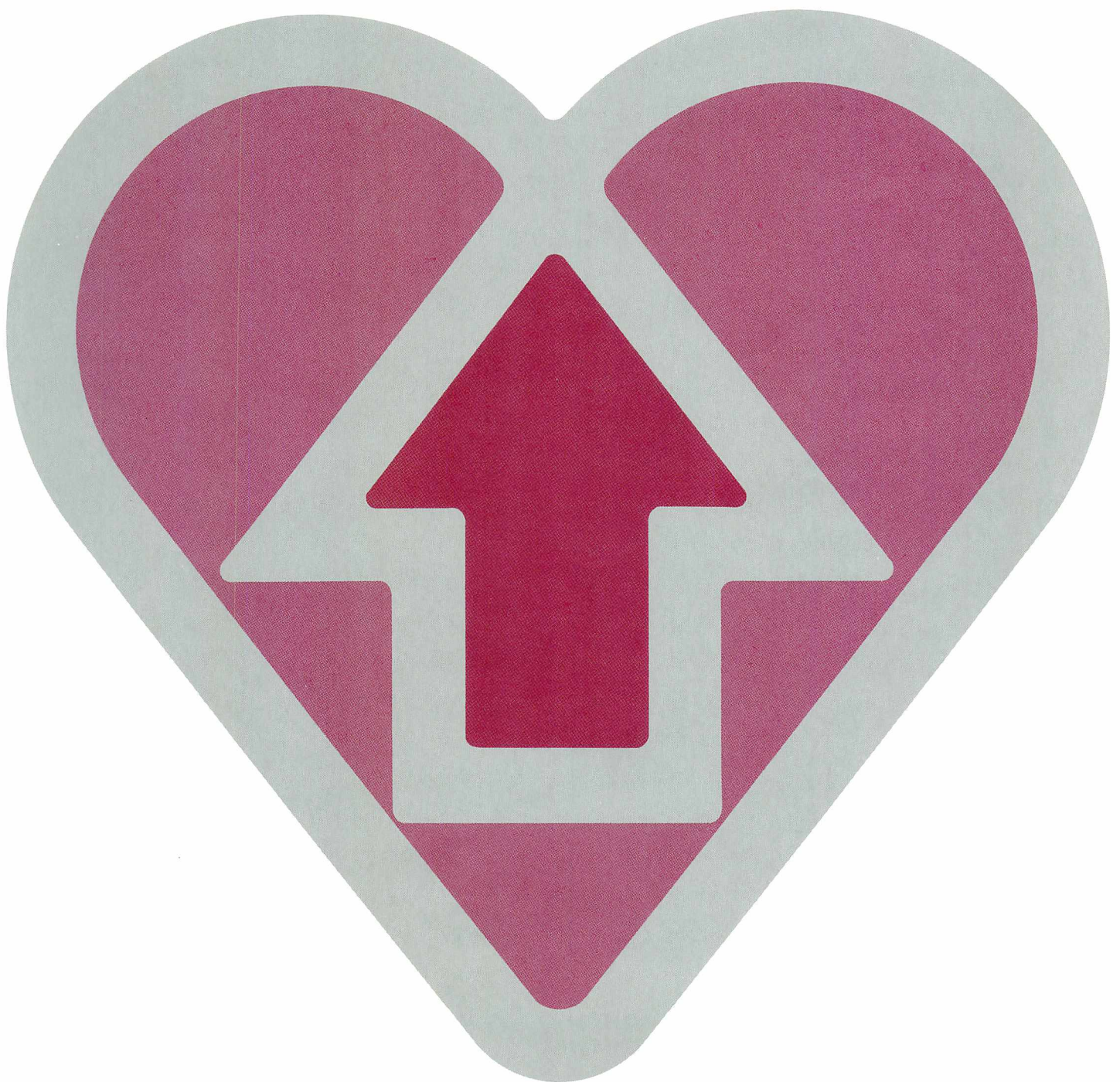
It's called the silent killer because it usually has no symptoms. You might not even know you have it. But high blood pressure can lead to stroke, heart failure, and kidney disease.

There isn't any cure for high blood pressure. Not yet,

anyway. But it can nearly always be controlled, and if you have it, you can live a normal, healthy life.

Get a blood pressure check for yourself and every member of your family. Even the kids. If your blood pressure is high, see a doctor—and follow his advice.

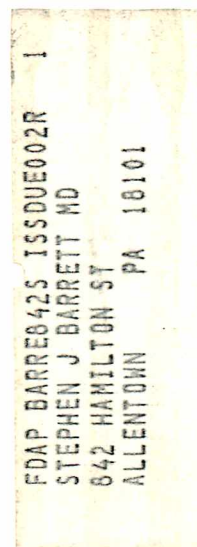
Don't let the silent killer silence you.



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