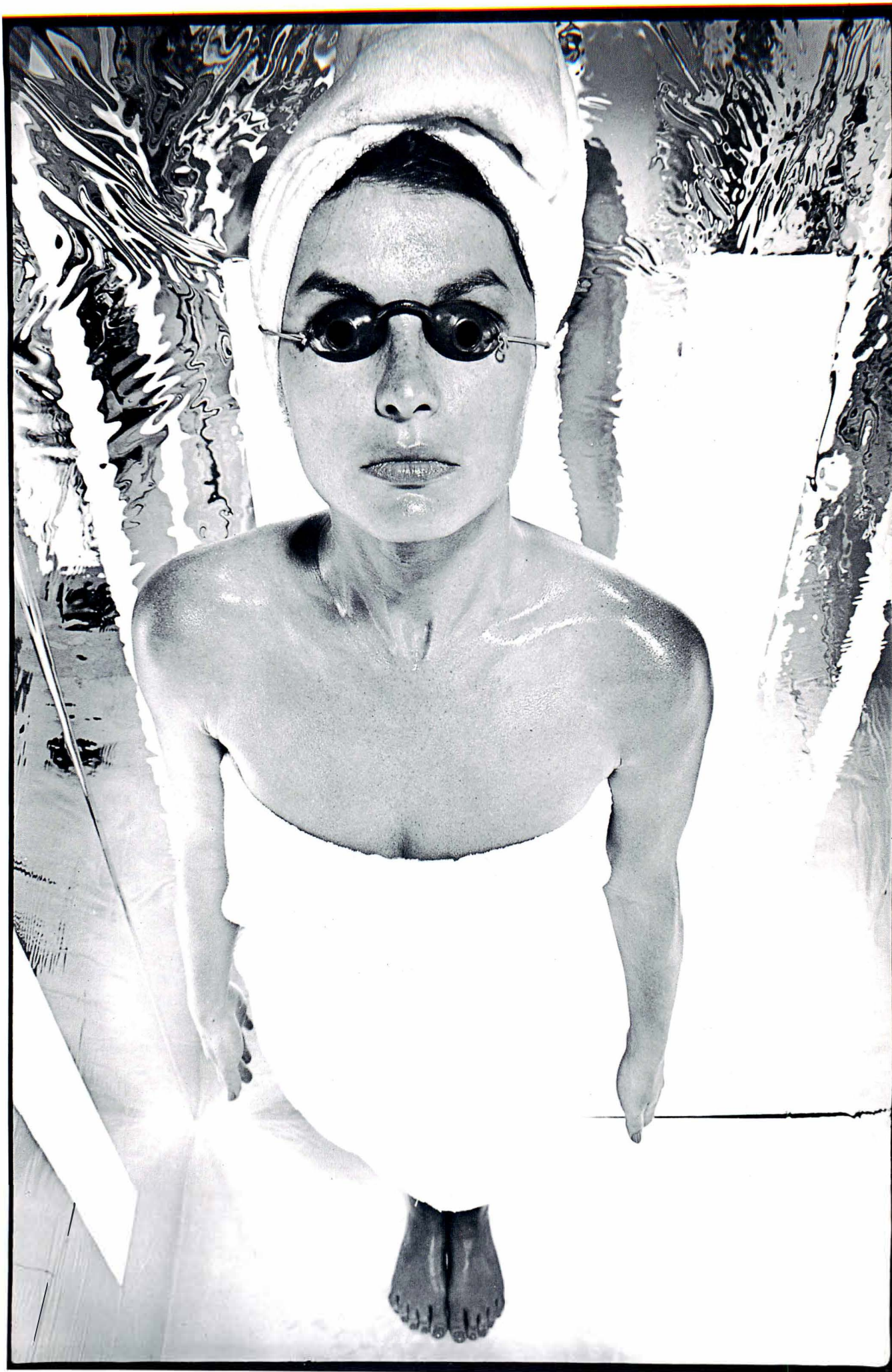


FDA
October 1980
CONSUMER

Caution Light
On Caffeine



CAFFEINE



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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.

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FDA CONSUMER

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Update

More on Overcoping

"... It is a matter of concern to see the . . . prescribing of these drugs for the ordinary situations of life . . .," said a top FDA'er. These comments were quoted in Overcoping With Valium, an article in the December 1979-January 1980 issue of FDA CONSUMER that traced the history of the drug and the consequences of its popularity. Here's an update.

The makers of widely prescribed tranquilizers have agreed to revise the information they provide to physicians to include the statement: "Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic (anti-anxiety) drug."

In announcing the revision in physician labeling, Dr. Jere E. Goyan, Commissioner of Food and Drugs, said, "I hope physicians adhere closely to these revised indications and become more discriminating in prescribing tranquilizers to relieve the symptoms of anxiety. I hope, too, that patients will not pressure their physicians for drugs that are not clearly needed."

Goyan said, "Tranquilizers can do great good in helping people get through crisis situations or in helping with problems of mental illness. Yet millions of Americans are taking them habitually just to deal with the anxiety of living."

Companies that have agreed to make the labeling change: Hoffmann-La Roche Inc., Nutley, N.J., makers of Librium and Valium; Warner/Chilcott Laboratories, Morris Plains, N.J., makers of Verstran; Abbott Laboratories, North Chicago, Ill., makers of Tranxene and Azene; Wyeth Laboratories, Philadelphia, Pa., makers of Serax and Ativan; and Parke-Davis, Morris Plains, N.J., makers of Centrax.

Physician labeling is provided by drug makers to inform physicians about the chemical composition of the drug, the recommended dosage, warnings, and indications (conditions the drug is useful in treating).

The newly revised labeling indication is expected to have an impact on advertisements in publications for physicians. Advertised claims made by drug manufacturers must reflect the labeling.

A statement from a drug manufacturer can be found in this issue's Consumer Forum.

Bath Not All Bubbles

Skin rash, redness, inflammation, itching, and burning are among the common problems consumers have with soaps, according to the article All

That Lathers Is Not Soap, in the February 1979 FDA CONSUMER. What FDA has done as a result of consumer complaints about one type of soap product is outlined in this update.

The Food and Drug Administration will require that bubble bath products carry a warning that prolonged use may cause irritation.

Medical reports and complaints from consumers have demonstrated that bubble bath products may be associated with skin irritation and urinary tract infections. The problem ingredients are the foaming agents themselves which, particularly with long and repeated exposure, can remove the skin's natural oil and cause drying, fissuring, irritation, and inflammation.

FDA will require that such products carry the following label warning:

"Caution—Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness, or itching occur. Consult your physician if irritation persists. Keep out of reach of children."

In the case of products intended for use by children, the phrase "except under adult supervision" may be added at the end of the last sentence.

The cautionary statement is required by August 19, 1981 [1 year after date of publication of the regulation in the FEDERAL REGISTER.] Any product shipped in interstate commerce after that date must carry the label warning.

The DMSO Story Continues

DMSO (dimethyl sulfoxide) is a drug approved by FDA only for treatment of a rare bladder condition (interstitial cystitis) in humans and for some veterinary use. It was the subject of an article, DMSO: No Proof of Miracles, in the September 1980 FDA CONSUMER and was looked at in a segment of the popular television program "Sixty Minutes," earlier this year. As a result of the TV program, many people have been using DMSO as a painkiller, particularly for arthritis. Here's an update.

Food and Drugs Commissioner Dr. Jere E. Goyan has expressed concern about the widespread use of DMSO for the treatment of arthritis and similar conditions.

Goyan said, "People are taking a risk whenever they use a substance of unknown quality and effect on the basis of a TV show."

"FDA is eager for researchers to test DMSO to see whether it is safe and effective for conditions besides interstitial cystitis. We are working with the company marketing DMSO as a human drug

to see that studies capable of yielding meaningful results are carried out.

"In the meantime, it's risky business to drink, inject, or apply to the skin any substance not intended for that purpose."

Clarifying its own position on DMSO, the Arthritis Foundation recently said it "did not and does not 'endorse' DMSO for arthritis. What we do endorse is the idea that it might have limited usefulness as a pain-reliever, and we are urging that the necessary testing of this possibility be carried out and an appropriate application be made to the FDA for approval for such limited use."

Since DMSO, a by-product of the paper-making industry, is available as an industrial solvent, and also is approved for use in horses and dogs, people can readily obtain it. Apparently both types of DMSO are being used for self-treatment. People are ingesting it as well as applying it to their skin; in some instances, it is being injected directly into the body.

Goyan said such use is risky for a number of reasons:

- The industrial grade DMSO is not of the quality used for drug treatment of humans and is made in plants that are not designed for the production of human drugs.

- The safety of DMSO in high concentrations and large amounts has not been established. Animal studies suggest that DMSO can affect the eyes and could cause loss of visual acuity or eye damage. Other side effects associated with its use include nausea, headache, and skin rash.

- Since DMSO is a "carrier" chemical, it could also deliver harmful substances into the bloodstream if they are present in impure DMSO or are on the skin.

Zeroing In on Net Weight

What goes on a food label and how it might be changed under proposals by FDA and the U.S. Department of Agriculture (USDA) was outlined in Telling More About the Stuff in Foodstuffs, in the February 1980 FDA CONSUMER. One item on the label is "net weight," a number that is not always precise. What FDA and USDA are going to do about that was revealed in this joint statement:

FDA and USDA are proposing to modify their respective net weight labeling regulations to precisely define just how much the weight of a packaged food may vary from the weight listed on the label.

The USDA proposal defines net weight as the total weight of the package and contents minus the weight of the packaging materials. USDA has not determined whether to include liquid absorbed by the packaging in the net weight.

"Reasonable variations" from stated net weight have been permitted since Congress used the phrase in a 1913 amendment in recognizing the practical impossibility of packaging to exact weights. However, the current regulations do not define "reasonable variation."

The new proposal would replace the undefined standard with objective, quantifiable standards. Compliance would be based on the weight of a specified number of samples taken from each production lot.

Besides defining "reasonable variations" for the food under its jurisdiction, FDA is proposing to allow for weight losses as a result of lost moisture in selected food for which there are data. Frozen fruits and vegetables packed in cartons could lose up to 1.0 percent of their weight due to moisture loss, soft ripened cheese would be allowed up to 3 percent, and flour packaged in kraft paper would be permitted up to 4 percent.

Food processors or associations may submit data justifying moisture losses for other food products to FDA.

Hermetically sealed containers cannot always be used to reduce moisture loss. Some packaged commodities need to "breathe." Flour and rice, for example, deteriorate more quickly when stored in airtight containers. Certain cheese must be packaged to allow continued aerobic curing, and moisture must be allowed to escape from many baked goods to prevent foods from becoming soggy.

USDA's Food Safety and Quality Service is responsible for accurate labeling of federally inspected meat and poultry products under the Federal Meat Inspection Act and the Poultry Products Inspection Act. The Food and Drug Administration is responsible for the labeling of all other foods under the Food, Drug, and Cosmetic Act.

New Lease for Nitrites

Nitrites have been used for years as preservatives and for flavoring and coloring a number of food products, particularly fish and meat. When a study at the Massachusetts Institute of Technology (MIT) showed that nitrites might cause cancer, FDA and the U.S. Department of Agriculture (USDA) developed a plan to reduce the amount of nitrite in foods. What steps were planned was discussed in Bringing Home the (Nitrite-Less) Bacon, in the May 1979 FDA CONSUMER. The MIT study just completed calls for a new look at nitrites. Here's an update.

There is no basis for initiating action to remove nitrite from foods, FDA and USDA have concluded, after reviewing a study of the nitrite-cancer link.

The conclusion was announced jointly by Dr.

Jere E. Goyan, FDA Commissioner, and Carol Tucker Foreman, assistant secretary for food and consumer services of the Department of Agriculture. In a joint statement issued August 19, Goyan and Foreman said in part:

A group of independent pathologists has completed an extensive review of the study conducted at MIT that led FDA and USDA in 1978 to consider the need to phase out nitrite as a preservative in cured meats and poultry.

The pathologists evaluated 50,000 tissue slides from the 2,000 rats in the study and found a "much lower incidence of lymphoma" (cancers of the lymph system) than was originally reported.

A committee of scientists from several Government agencies has evaluated the pathologists' review and has concluded that insufficient evidence exists to support a conclusion that nitrite induced cancer in the rats, based on the MIT study.

As a result of the review and evaluation, FDA and USDA have concluded there is no basis for initiating any action to remove nitrite from foods at this time.

At the same time, efforts to eliminate pre-formed nitrosamines from foods will continue. Nitrosamines are chemicals formed when nitrite combines with naturally occurring substances known as amines. Nitrosamines are known carcinogens. Efforts to eliminate or reduce nitrosamines from such disparate products as bacon and beer have been highly successful.

The MIT study reported in 1978 was undertaken after an earlier study suggested that nitrite itself might be carcinogenic (cancer causing). FDA contracted with a leading expert in the study of nutrition-induced disease, Dr. Paul Newberne of MIT, to explore the possibility in a large and thorough study.

The MIT research, which involved 1,381 rats that were fed nitrite, plus 573 controls, was made public by FDA and USDA in August 1978. In it, Newberne reported that the nitrite-fed rats had an increased rate of cancer of the lymph system. Among the rats fed nitrite, 12.5 percent were reported to have been found with lymphomas, compared to 7.9 percent of the control rats. (Newberne later revised these figures to 10.5 and 5.75 percent respectively.)

The study had many possible ramifications. Nitrite is the preservative and color fixative used in bacon and all other cured meats, such as hot dogs, bologna, corned beef, and ham.

Nitrite serves a health purpose in that it inhibits the growth of *Clostridium botulinum* bacteria, thereby preventing the formation in meat of a toxin that can cause botulism, a deadly form of food poisoning. An estimated \$12.5 billion worth of food—7 percent of our food supply—has nitrite added to it. In many respects, the nationwide pro-

duction and distribution system for processed meats, poultry, fish, and other products depends on the use of nitrite. Consumers, too, are accustomed to the margin of safety that nitrite provides in such products as hot dogs and lunch meats, which are eaten cold or only after slight heating.

When the MIT study was received in 1978, FDA and USDA reached the tentative conclusion that nitrite might cause cancer. The two agencies suggested a phaseout of nitrite from the food supply, if justified by research. The phaseout would have been tied to development of an alternative preservation method.

The two agencies also decided that an outside review was needed of the Newberne study because of questions raised about it. That outside review led ultimately to the slide-by-slide review of Newberne's work.

Salt for Lens Cleaning

The ABC's of Contact Lenses, how they are made, and how to clean and care for them, was one of the articles in the February 1980 issue of FDA CONSUMER. Here's an update.

The Food and Drug Administration has approved a salt tablet kit for disinfecting soft contact lenses.

Soft contact lenses—worn by about 4 million Americans—are made of water-absorbing plastic. The water can act as a breeding ground for bacteria that could cause eye infections. To prevent this, the lenses must be disinfected daily, either by soaking them in special chemicals, or by heating them in a case filled with a solution of salt and distilled water.

Salt tablets for making the disinfecting solution had been available to consumers when soft lenses were first marketed in the United States in 1971. But FDA was concerned that the tablets might be misused. Leftover solution, for example, could become contaminated with bacteria. Eye injury also could occur if people applied the unsterile salt water directly into their eyes as a wetting agent or eyedrop. The manufacturer of the salt tablets, at FDA's request, withdrew the tablets from the market in 1978.

To replace the salt tablets, pre-mixed sterile solutions, with preservatives added to help prevent bacterial contamination, were introduced. Some soft lens wearers, however, are allergic to the mercury preservative in the pre-mixed solutions. In 1979, FDA approved several sterile, preservative-free solutions in single-use plastic bottles. However, these unit-dose, preservative-free solutions are more expensive.

In the new disinfecting kits, the tablets are 135 milligrams (mg), compared to the 250-mg tablets

previously available. Also, the kit contains a boilable plastic mixing bottle that is only large enough for 1-day's supply of solution and is marked to indicate how much distilled water should be added to get the proper strength solution.

The smaller tablets and bottle will permit the user to mix only enough solution for 1-day's use. With no leftover solution, the chances for bacterial contamination are reduced. Also, the marked bottle will help lens wearers avoid the problems of improperly diluted solutions, which can damage the soft lenses and irritate the eyes.

FDA also is requiring that the kits contain warnings about the hazards of not strictly following the instructions for use.

Address Corrected

In [*Overcoming With Valium*] the December 1979-January 1980 issue of FDA CONSUMER you listed my name as founder of Valium Anonymous and my address was wrong. I do not live in Altoona, Penn. I live at the following address: Box 155, Altoona, Iowa 50009.

Leland Ahern
Valium Anonymous
Altoona, Iowa

Consumer Forum

Manufacturer's Views on Valium

Both the December 1979-January 1980 and February 1980 issues of the FDA CONSUMER contained articles critical of minor tranquilizers, their use and safety. As the developer and manufacturer of two of the most widely used of these products, Valium and Librium, we have found that within the current environment, a rational review of the issues surrounding these medications becomes almost impossible. Many of the health care professionals who have witnessed the safe and responsible use of these products by the great majority of their patients over the past 16 years have spoken out publicly in an attempt to provide a balanced perspective and to call attention to the facts drawn from scientific data. Investigators of one carefully conducted government sponsored national survey, have repeatedly pointed to their findings which show that the great majority of physicians appropriately prescribe tranquilizers for patients with high levels of emotional distress and severe life crises.

Similarly, studies of patient attitudes by these and other investigators reveal that most patients have very realistic views regarding the limitations of tranquilizers and strong reservations about their use, as evidenced by a general tendency to decrease intake over time. Other investigators have made extensive and painstakingly thorough studies of toxicological data, and all have concluded that Valium and the benzodiazepines are the safest group of sedative/hypnotic drugs available in medicine today.

It should be remembered that no medication and no class of drugs will now (or perhaps ever)

meet every desired requirement. All medications—including tranquilizers—have some risks or drawbacks to some patients under some circumstances. Our investigations and those of independent clinicians have shown the problems associated with tranquilizers to be relatively infrequent when viewed within the context of total usage.

The benefits the average patient derives from tranquilizer therapy continue to far outweigh the risks involved. In general, when problems occur they are the result of noncompliance—use of the medication in a manner contrary to our recommendations and to the prescribing physician's directions—or of misuse by an individual who is prone to misuse other chemical substances, particularly alcohol.

Roche has always been deeply concerned about the misuse or abuse of any of its products, and is committed to the philosophy that effective and appropriate utilization of medicines can best be achieved when all parties involved in the health care delivery process have accurate, balanced, and meaningful information regarding them. We also believe that the manner used to communicate this important information to the lay public is an extremely serious matter which warrants careful thought and consideration in order to be both effective and responsible while at the same time avoiding the popular trend of negativism which can only result in the decline of public confidence in the science of medicine, its practitioners and prescription medication. We look forward to continuing to work together with government in a positive manner to address any problem areas that may exist.

Bruce H. Medd, M.D.
Assistant Vice President and
Director of Professional Services
Roche Laboratories
Nutley, N.J.

Caution Light On Caffeine

Caffeine's capability to cause birth defects in rats has prompted the Department of Health and Human Services to announce a series of actions. They include an information program aimed at pregnant women and a proposal to develop more studies on the health implications of the drug. Caffeine's history in the human diet, its widespread use in foods and drugs today, and an explanation of the actions proposed are outlined in the following article.

by Chris Lecos

For many people the consumption of caffeine starts at an early age—before birth even—and continues for much of a lifetime. Caffeine is taken up by the bloodstream of the mother and crosses the placenta to reach the fetus. It appears in the milk of mothers who breast feed their newborns while regularly consuming foods, drinks, and drugs that contain caffeine.

Most people probably know there is caffeine in a cup of coffee or tea. Perhaps not as many realize it is also in some soft drinks, and even fewer may know they are taking in caffeine when they sip a cup of cocoa, munch on a chocolate bar, or take some pills for a headache or cold. It is even used in some foods.

In short, caffeine is much a part of the human diet today. It is a natural ingredient in coffee, tea, cocoa, and some cola drinks; FDA requires it as an ingredient in cola and pepper-type beverages and permits it in other soft drinks; it is used in cold, headache, allergy, stay-awake, and other over-the-counter remedies and in some prescription drugs as well; and it is used in some baked goods, frozen dairy products, soft candies, gelatins, and puddings.

Its use in food and drink is hardly new. Tea's origins in China date back to around 4700 B.C. Around 500 A.D., in ancient Abyssinia, in what is now Ethiopia, a curious goatherder's munching on the fruit of an evergreen bush is, according to legend, what got the world started on coffee. America's young soft drink industry was given a real shot in the arm about 90 years ago when an Atlanta, Ga., druggist added a pinch of caffeine to his nonalcoholic mix to give the world Coca-Cola. Cola and pepper-type drinks account for 80 to 90 percent of the caffeine added to foods today.

Consumers are made aware of caffeine by some segments of the coffee industry itself. Actor Robert Young appears on television to extol the virtues of decaffeinated coffee. The technology for drawing most of the

caffeine out of a coffee bean results in a valuable product—almost pure caffeine—that is sold to soft drink and drug companies.

One of the newly announced goals of the U.S. Department of Health and Human Services (HHS) and its member agencies—the Public Health Service (PHS) and the Food and Drug Administration (FDA)—is to make Americans, particularly pregnant women, more aware of caffeine



and the products in which it occurs. The implications for health of caffeine consumption have been matters of concern and debate for years. This concern has now been heightened by new evidence from animal tests confirming earlier findings that caffeine causes irreversible birth defects and other abnormalities in the fetuses of pregnant rats—adverse effects that also have occurred in experiments with mice and rabbits. But the critical question—still unanswered—is whether this commonly ingested substance poses the same hazards and dangers to unborn children as it does to animals.

Caffeine is a drug, and it acts as a stimulant to the central nervous system, although it does not affect all people the same way. If consumed in large enough doses, it can cause insomnia, nervousness, irritability, anxiety, and disturbances in the heart rate and rhythm. It also seems to have an effect on coronary circulation, blood pressure, the diameter of the blood vessels and secretion of gastric acids. Around 10 grams of caffeine—as much as might be found in 70 to 100 cups of coffee—can be fatal. Its long term effects on people are not clearly known.

The latest evidence comes from a large teratology (birth abnormalities) experiment with pregnant rats completed recently in FDA laboratories. The experiment, which involved the forced feeding of caffeine in various, measured doses to the rats, was done under the direction of Dr. Thomas F. X. Collins, in FDA's Division of Toxicology and leader of its mammalian reproduction teratology team. The study, in part, revealed:

- Complete or partial absence of toes—an irreversible abnormality called ectrodactyly—in nearly one of five of the rat fetuses whose mothers were force fed caffeine at the two highest dosage levels. This was equivalent to the amount of caffeine a human might get from drinking 12 to 24 cups of strong coffee a day.
- Delayed bone development—particularly of the sternebrae or

breastbone—was evident in fetuses at all five caffeine dosage levels. This means that the bones of these rat fetuses did not develop or grow as fast as those whose mothers were fed distilled water that did not contain caffeine. Such abnormalities, which may be reversible, were found at caffeine dosage levels equal to what a human might consume from two cups of coffee a day.

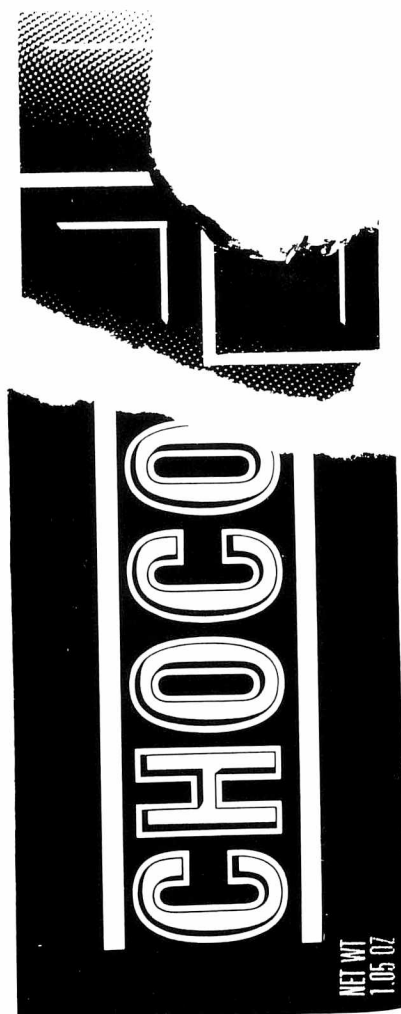
Although the Collins teratology study is regarded as an excellent, well-controlled study, one that confirms that caffeine can cause birth defects in rats, FDA officials said they still are uncertain about the relevance and applicability of the study to humans. It is stressed that there is no evidence “caffeine ever caused a

birth defect in a human being” and that there are “legitimate questions about whether rats metabolize caffeine the same way people do and whether the rat is the proper experimental subject for such tests.”

Although the study's implications for humans are not known, enough concern has been aroused for PHS scientists to advise pregnant women to avoid products containing caffeine or to use them sparingly. The educational program proposed by HHS would be aimed at pregnant women served by various PHS programs, including maternal and child health projects, community health centers, migrant health and Indian health programs, and PHS hospitals and clinics.

In addition, members of health professional organizations, such as the American Medical Association and the American College of Obstetricians and Gynecologists, have been urged by the Surgeon General's office to ask their members to caution pregnant women in use of caffeine. Various FDA publications, including the Agency's DRUG BULLETIN—which is mailed to 967,000 health professionals including 420,000 doctors, 200,000 nurses, and 120,000 pharmacists—would also be used to reach health professionals.

On the regulatory front, FDA proposed actions designed to change the present status of caffeine and to require new, comprehensive studies that may help resolve some of the unanswered issues. One proposed action is to remove caffeine from FDA's list of common substances classified as being “generally recognized as safe,” the so-called GRAS list. This status exempts caffeine from regulation as a food additive. Caffeine would instead be placed on an “interim list,” which would permit industry to continue using caffeine in its products but would require it to produce acceptable scientific evidence to resolve questions about its use. FDA also proposes changing its present regulation for cola and pepper-type soft drinks to permit indus-



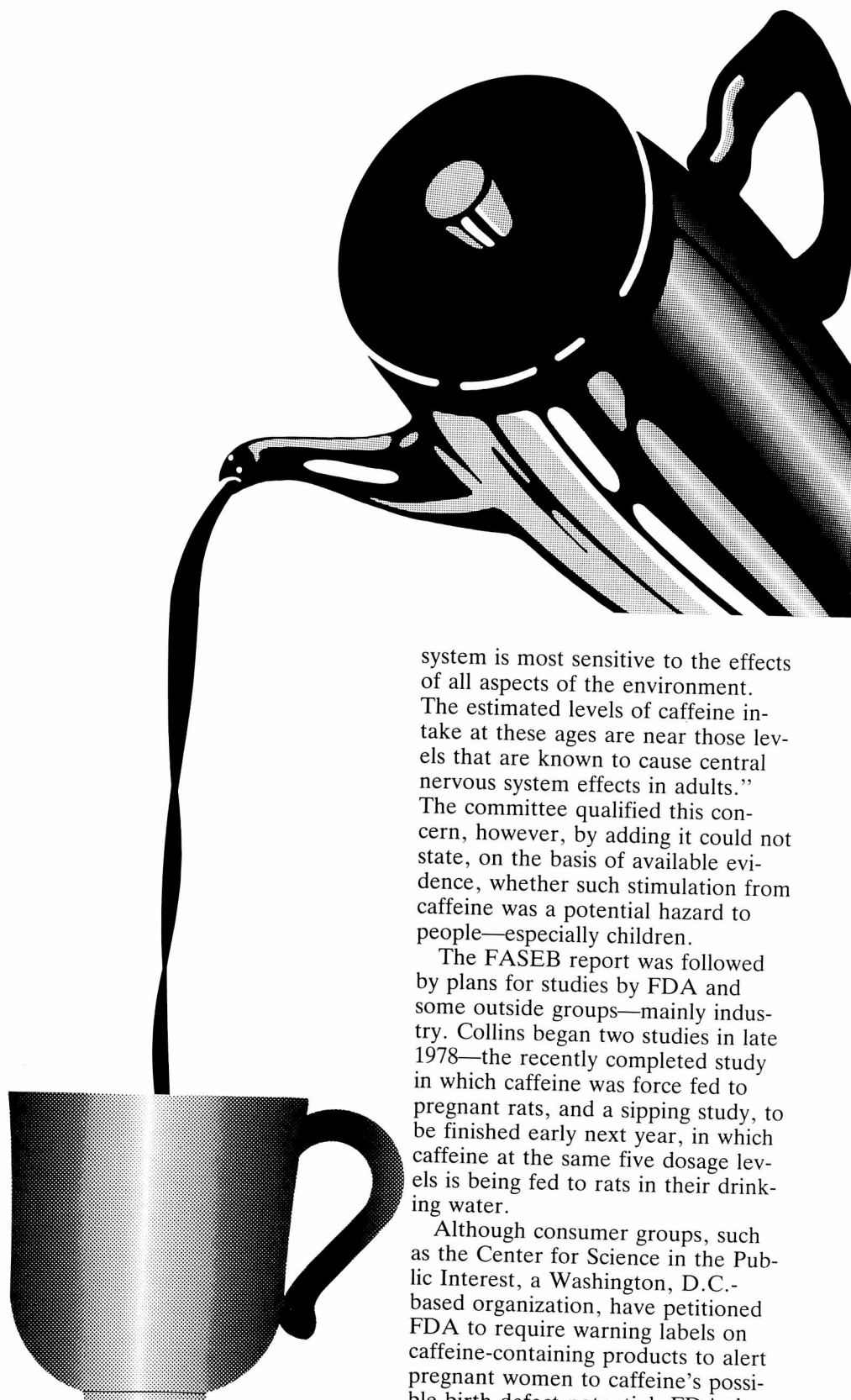
try to market new beverages with even less or no caffeine in them and still allow them to be called a cola. At present, a soft drink cannot be called a cola unless it contains caffeine.

The GRAS list has existed since 1961, 3 years after the adoption of the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act. The list includes more than 400 substances commonly used in foods—caffeine among them. In 1972, FDA contracted with the Life Sciences Research Office of the Federation of American Scientists for Experimental Biology (FASEB) to undertake a complete review of all substances on the GRAS list.

FASEB's review has led to the removal of some substances and affirmed the safe status of others. FDA uses FASEB's recommendations to decide whether it will propose removing a substance from the GRAS list or allow it to remain, whether the substance should remain with certain restrictions, or whether it should be on an interim basis, (a regulatory mechanism to allow FDA, to obtain appropriate studies from industry, to define the nature of the studies to be performed, and to prescribe reasonable schedules and deadlines for their performance; this is what is happening to caffeine).

FASEB's review of caffeine was published in a report released in June 1978, but was limited to caffeine's use as an ingredient in soft drinks. The FASEB scientific committee, with one dissenter, cited these conclusions: (1) that it did not find "clear cut evidence that demonstrated that caffeine was a hazard to the public" when used in beverages; (2) that "uncertainties," however, existed that warranted additional studies for determining the health implications of caffeine; (3) that it was "inappropriate" to permit caffeine to remain on the GRAS list—in effect, that it should be removed from the list.

The FASEB committee expressed concern about the behavioral effects of caffeine on children and on their brain growth and development and that heavy consumption of cola beverages starts at an early age, adding: "It is during this period of plasticity that the developing central nervous



system is most sensitive to the effects of all aspects of the environment. The estimated levels of caffeine intake at these ages are near those levels that are known to cause central nervous system effects in adults." The committee qualified this concern, however, by adding it could not state, on the basis of available evidence, whether such stimulation from caffeine was a potential hazard to people—especially children.

The FASEB report was followed by plans for studies by FDA and some outside groups—mainly industry. Collins began two studies in late 1978—the recently completed study in which caffeine was force fed to pregnant rats, and a sipping study, to be finished early next year, in which caffeine at the same five dosage levels is being fed to rats in their drinking water.

Although consumer groups, such as the Center for Science in the Public Interest, a Washington, D.C.-based organization, have petitioned FDA to require warning labels on caffeine-containing products to alert pregnant women to caffeine's possible birth defect potential, FDA de-

cided against the warning label approach because of the lack of documentation that caffeine poses the same risks to humans as it seems to for some animals.

Some of the main challenges to present animal studies have come from such industry groups as the International Life Sciences Institute (ILSI), an industrial consortium supported by the soft drink industry and the National Coffee Association.

ILSI has questioned the relevance of the rat as a testing subject, whether rats and other animal species metabolize caffeine in the same manner as humans, and whether Collins' method of feeding caffeine through the mouths of rats is comparable to human consumption of caffeine. One industry contention is that there is no animal that satisfactorily mimics caffeine metabolism in man.

Behavioral studies of children who

consume caffeine are now being conducted in laboratories of the National Institute of Mental Health. The coffee association is also involved in a collaborative study with ILSI and is designing a possible epidemiological study of pregnant women, one that would involve 5,500 women and take some 3 years to complete.

Chris Lecos is a member of FDA's public affairs staff.

About Your Caffeine Intake...

There is no easy way to tell how much caffeine a man, woman, or child consumes from coffee, tea, cocoa, soft drinks, and other products that have caffeine in them. Studies and tests often add to the confusion because the same standards are not always followed.

Some studies are based on a manufacturer's direction for brewing a cup of coffee or tea. In the home, some brew it strong, others brew it weak. Some brew it for a long time, others don't. It is also not easy to compare one study with another because the cup sizes are not always the same.

At the request of the National Coffee Association, Dr. Alan W. Burg, senior biochemist at Arthur D. Little, Inc., Cambridge, Mass., reviewed the scientific literature on coffee and caffeine content and, noting the discrepancies, suggested that the 150-milliliter cup (5 ounces) be considered the average size for technical work.

Basing his data on 29 coffee and 13 tea products, he suggested in a published article in 1975 that there was an average of 85 milligrams (mg) of caffeine in a 5-oz cup of percolated, roasted, ground coffee; 60 mg in instant coffee; 3 mg in decaffeinated coffee; and an average of 30 mg in instant tea.

But these were averages. He also showed a range of 64 to 124 mg of caffeine in percolated coffee; 40 to 108 mg in instant coffee; 2 to 5 mg in decaffeinated coffee; 42 mg

(based on one sample tested) in bagged tea; 30 to 48 mg in leaf tea; and 24 to 131 mg in instant tea.

Now, compare this with the findings of the Addiction Research Foundation of Ontario, Canada, which did a caffeine study based on 46 home-brewed coffee samples and 37 tea samples, some of which had cream and other dilutants in the samples. Cup sizes, obviously, also varied.

The foundation's findings were: Percolated coffee: 39 to 168 mg to a cup, with 74 as the median; drip or filtered coffee: 56 to 176 mg, with 112 as the median; instant regular coffee: 29 to 117 mg, with 66 as the median; decaffeinated coffee: 1 to 2 mg; tea: 8 to 91 mg, with 27 as the median.

For other products, other studies indicated cola and pepper-type soft drinks tested at 32 to 65 mg of caffeine in a 12-oz container; cocoa, from 5 to 40 mg; a half-ounce chocolate bar had 10 mg of caffeine; a headache tablet, 65 mg; and some stay-awake tablets, up to 100 mg of caffeine.

Soft drinks, including the cola and pepper-type drinks that have caffeine in them, are the number one beverage of Americans today, with coffee second. According to beverage industry sources, an American consumes on the average of 33.6 gallons of soft drink each year. The average consumption for coffee is 27.8 gallons per person each year, followed next by milk, at 24.8 gallons per person.

Advice On Caffeine

In making the public announcement in September of caffeine's possible dangers to unborn children, FDA Commissioner Dr. Jere E. Goyan urged prudence by pregnant women in the use of caffeine products. He also stressed that further studies, which may take 2 to 4 years, will tell more about the implications of caffeine's effects on people.

Goyan's words to mothers-to-be:

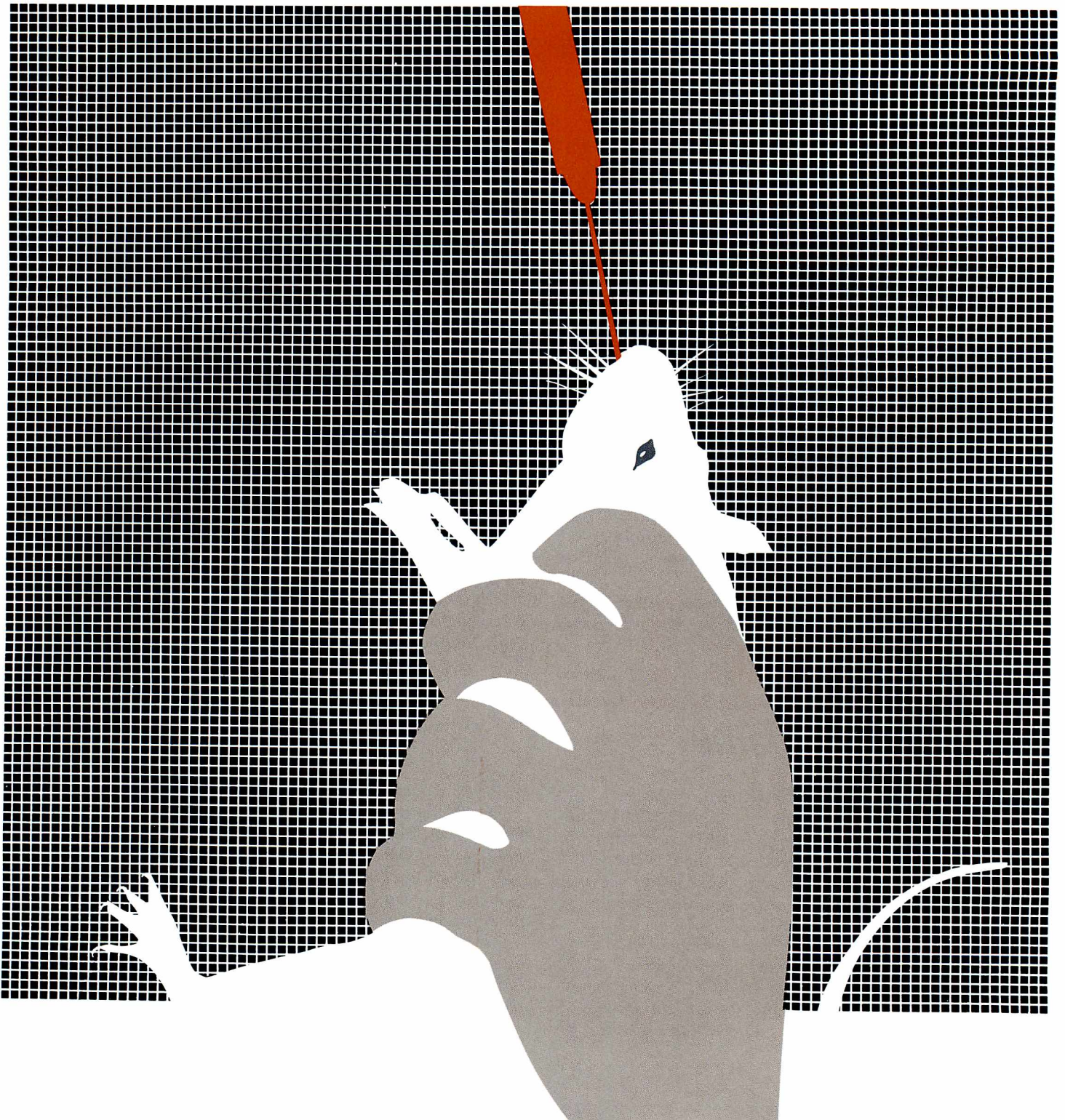
"So while further evidence is being gathered on the possible relationship between caffeine and birth defects, a prudent and protective mother-to-be will want to put caffeine on her list of unnecessary substances which she should avoid. The old saying that a pregnant woman is 'eating for

two' has a special meaning in regard to caffeine."

The Commissioner also noted that studies to date support the wisdom passed down from generation to generation that caffeine is not for pregnant women or children. "We hope some day to have better scientific assessments," Goyan said, "but for now adhering to the guidance of our parents seems to be the most prudent course."

Noting that caffeine is also a stimulant and has a definite drug effect, Goyan said, that, as a general rule, pregnant women should avoid all substances that have drug-like effects.

Anatomy Of A Scientific Study: Rodents, Pregnancy, And Distilled Water



What constitutes a scientific study? And what makes one study better than another? The recent FDA study of caffeine's effect on rats is a good case in point. Just how that study was constructed and carried out and just why the conclusions are especially meaningful—but yet possibly limited—are described below.

A major experiment of force feeding caffeine to a large population of pregnant rats has accomplished several major objectives for the Food and Drug Administration:

(1) The FDA study clearly demonstrates that caffeine can cause irreversible birth defects in rats at doses not much greater than what many people consume from a fairly heavy intake of coffee, tea, cola, and other products containing the drug. This confirmed earlier studies.

(2) It shows that even low levels of caffeine—the equivalent of what a person might consume in two cups of coffee a day—may have adverse effects on bone and skeletal development of the fetuses of pregnant rats. These are abnormalities that may be reversible—in other words, adverse effects that, in time, may correct themselves.

(3) The study employed a large enough population of animals—2½ to 3 times more than previous teratology (birth defect) studies—to help establish what FDA scientists describe as a “no-effect” level for caffeine—that is, the highest dosage level at which no birth defects were found.

The study, which took 18 months to complete, was done under the supervision of Dr. Thomas F. X. Collins, head of the mammalian reproduction and teratology team at FDA's Bureau of Foods in Washington. The team also included biologists John J. Welsh, Ph.D., and Thomas N. Black, and two biological laboratory technicians, George Gray and James Rorie. All are with the Bureau of Foods' Division of Toxicology.

Earlier studies in the area had been viewed with skepticism because of the limited number of rats used.

However, Collins and his staff decided to tackle that issue at the start by using at least 300 rats of the Osborne-Mendel strain, a breed FDA has used in experiments for more than 40 years. Collins actually began the experiment with 366 rats that were believed to be pregnant (based on smear tests). There were 61 rats assigned to each of five dosage level groups and the same number assigned to a control group.

The rats subjected to caffeine were fed it at the rate of 6, 12, 40, 80, or 125 milligrams (mg) a day for each equivalent kilogram of body weight. (A kilogram equals 2.2 pounds.) A syringe with the measured dose of caffeine in distilled water was used to force feed the rats. The control group was given only distilled water, unspiked with caffeine, along with the ground chow that all the rats received as food.

The study ended up with 332 rats, 7 having died during the study and 27 others, when later dissected, found not to be pregnant.

The 332 rats were more than enough to satisfy the study's objectives. The females produced a total of 4,093 living and dead fetuses (a rat litter ranges from 1 to 26 in size, with an 11-fetus average); 3,419 of the fetuses survived the 19-day gestation period during which the mother received either caffeine or, in the case of the control group, unspiked distilled water; 674 fetuses had died before the 20th day. When each pregnant rat reached its 20th day of gestation, it was sacrificed by carbon dioxide asphyxiation and examined by the team.

Around half of the 3,419 fetuses that survived to the 20th day were examined to determine the effects caffeine may have had on such vital

organs as the heart, brain, eyes, kidneys, liver, pelvic region, thoracic region, and circulatory system. The other half were examined to determine caffeine's effects on skeletal or bone development. All the surviving fetuses were examined for ectrodactyly, a birth defect characterized by the total or partial absence of digits on the paws. Findings from the experiment were checked, recorded, and checked again, before the data was stored in computers for later tabulation.

The study showed that ectrodactyly occurred among nearly 19 percent (175 of 940) of those fetuses whose mothers had been fed caffeine at the 80 and 125 milligram dose levels. This congenital deformity occurred among 62 out of 544 fetuses produced at the 80-mg level and in 113 out of 396 fetuses at the 125-mg level. In other words, 11 percent of the fetuses suffered birth defects at the 80-mg dosage but the number jumped to more than 28 percent at the highest dosage.

At the two highest dosage levels, irreversible birth defects were more evident among the female fetuses than among the male, with 13.6 percent of the females, and 9.2 percent of the males showing defects at the 80-mg level and 31.4 percent of the female and 25.7 percent of the male fetuses at the 125-mg level. The defects occurred mostly in the hind paws of the fetuses; their front paws were minimally affected.

Also evident at the two highest dosage levels was an assortment of skeletal ossification (calcification or hardening) problems including misshapen or poorly developed vertebrae, reduced dorsal arches and pubic bones, missing hind phalanges,

and reduced metacarpals and metatarsals (bony portions of the foot).

At all the dosage levels—from 6 to 125 mg of caffeine—a total of 1,146 of the fetuses (nearly 67 percent) displayed at least one or more abnormalities of the sternebrae (or breastbone). In other words, the bones of

the offspring did not develop or grow as fast as those whose mothers were not exposed to caffeine.

The number of litters with at least one sternebral problem grew significantly with increases in dosage. At the two highest dosage levels, virtually all the fetuses were affected.



At the 6-mg dose level, nearly 51 percent were affected; at the 12-mg level, 52 percent; at the 40-mg level, 77 percent; at the 80-mg level, 98.9 percent; at the 125-mg level, all of the fetuses displayed at least one problem in breastbone development. By comparison, only 39 percent of the fetuses in the control group had one or more such variations.

The number of fetuses with at least two sternebral variations was significant at the three highest dosage levels. Only 7 percent of the fetuses in the control group had two or more sternebral variations compared to more than 50 percent at the 80- and 125-mg dosage levels. The study report also noted that less than 1 percent of the control group had three or more such variations, but at the two highest dose levels, there was a "ten-fold increase" in fetuses with at least that many breastbone abnormalities.

In their examination of the fetuses for other skeletal development problems, the scientists also found significant increases at the three highest dose levels. At the highest dose level, all the fetuses had at least one skeletal variation, 90 percent had four or more, and 32 percent had 10 or more skeletal problems.

The "no-effect" level for the irreversible congenital defects—the level at which none of these defects turned up—was at the rate of 40 milligrams of caffeine a day for each kilogram of body weight. "Our no-effect level compares very favorably with what other investigators determined," Collins said. "The question that we had to ask, as food and drug people, is not whether caffeine is a teratogen (causes birth defects), which we confirmed, but at what level does caf-

feine stop being teratogenic." Because of the size of the study, it was possible to establish a clear-cut no-effect level as far as ectrodactyly was concerned.

A scientific review on caffeine by the Federation of American Scientists for Experimental Biology (FASEB), released in 1978 stated that many animal tests showed that teratogenic effects were generally absent at caffeine doses of up to 50 mg of caffeine. At doses up to 75 mg, the FASEB report said, the effects were "neither striking nor consistently demonstrated." At doses greater than 75 mg, teratogenic effects were readily apparent.

Other effects of caffeine on the pregnant rats were noted by Collins and his crew. Although the paucity of weight gain was much more apparent at the higher dose levels, the weight gain of the pregnant rats was not as great at any of the dosage levels as the maternal weight gain of the pregnant rats that received only water. Collins said that the caffeine-fed rats also developed anorexia—loss of appetite—during the first week of gestation, but that feeding returned to normal after that.

The study further revealed significant decreases in the fetal weights and size, from the tip of the head to the rump, of both female and male fetuses at the two highest dosage levels. To a lesser extent, both sexes showed similar effects at the 40-mg level although, Collins added, it was more evident among the females.

Caffeine's toxic effects apparently took a toll of some entire litters, Collins said. When the animals were dissected, two entire litters were found dead in the mothers of those fed at the 80-mg level and four litters had

died at the 125-mg level.

The examinations made by Collins and his staff of the vital organs and tissues of the fetuses revealed no variations that could be related to caffeine intake.

Collins' study is described as a gavage study because the caffeine dosages were force fed, in controlled amounts. The caffeine was dissolved in distilled water and the solution fed to each pregnant rat daily in carefully calculated amounts. Weights of the pregnant rats were recorded on the first day (called day zero), then on the 7th, 14th, and 20th days.

The results of this study will be compared with another Collins and his staff are doing in which similar caffeine dosages are being given to rats in the distilled water they drink each day. It is commonly referred to as a sipping study and is expected to be finished early next year. "The advantage of the gavage study," he explained, "is that you know how much caffeine you are giving the animals each day and that you will be able to sustain that amount throughout pregnancy."

When the basic findings of the gavage study were announced this summer, FDA officials emphasized that the study—though excellent in its size and methodology—could only be viewed as one that revealed adverse effects to rats, not to humans. Still unanswered is whether rats metabolize caffeine the same as humans, and whether feeding caffeine directly into the stomach of a rat is relevant to the way humans consume caffeine.

Seizing Food And What To Do With It

What happens when FDA finds food unfit for human consumption? It may be destroyed, it may be diverted to nonhuman use, it may be returned to the country of origin in the case of imported food, or it may—under certain circumstances—be reconditioned for use. This article looks at what happens to such foods.

by Chris Lecos

One day not long ago Gerald E. Scholze left his home in the village of Ashwaubenon, Wis., and drove the 8 miles it takes to reach the one-room office he shares with Douglas Nelson in the football-obsessed city of Green Bay. Together, the two started to map out their plans for enforcing the Federal Food, Drug, and Cosmetic Act in an 11-county area of northeast Wisconsin. Scholze and Nelson are consumer safety officers—investigators, to be more precise—for the U.S. Food and Drug Administration.

Their schedule had been worked out a month ahead by FDA's district office in Minneapolis. But in the development of events this day, and several that followed, their carefully planned schedule started to come apart. The plan had called for a number of inspections to be made over the entire month, but a manufacturer's emergency recall of canned mushrooms contaminated by botulin toxin—a dangerous food poison—took over top priority. It remained at the head of their priority list for most of the month. The mushroom recall covered 19 States.

Scholze and Nelson ascertained that four distributors in their 11-county area had obtained mushrooms from the Pennsylvania manufacturer; from the files and computers of each

distributor they developed a list of some 300 food establishments, mainly restaurants, that bought the mushrooms. They alerted each food operator about the recall by phone or by direct visit, personally going to one-fourth of the places to verify that the mushrooms had been removed. In one restaurant, says Scholze, the manager pulled the mushrooms from the storage area but had "missed one that an employee had under the shelf."

The two FDA men, like their colleagues in field offices and resident posts throughout the country, have performed a routine task to help protect consumers from a contaminated food product. It is not unusual for investigators to concentrate their time and effort on what Agency officials describe as "high-risk work"—food, drug, and other problems with a high degree of risk or hazard to the public. It often means other inspections must be delayed or deferred.

The Food, Drug, and Cosmetic Act is intended to assure that the public gets food that is wholesome and safe to eat and that is stored and produced under sanitary conditions. FDA uses its regulatory and investigative powers to move against foods that the law defines as adulterated or misbranded. This includes food produced in the United States or shipped from foreign countries. Periodic inspections, voluntary recalls, and corrective actions by industry, educational programs, and legal proceedings, when deemed necessary, are employed by FDA to obtain compliance. But, say FDA officials, it is a function not always understood by the public.

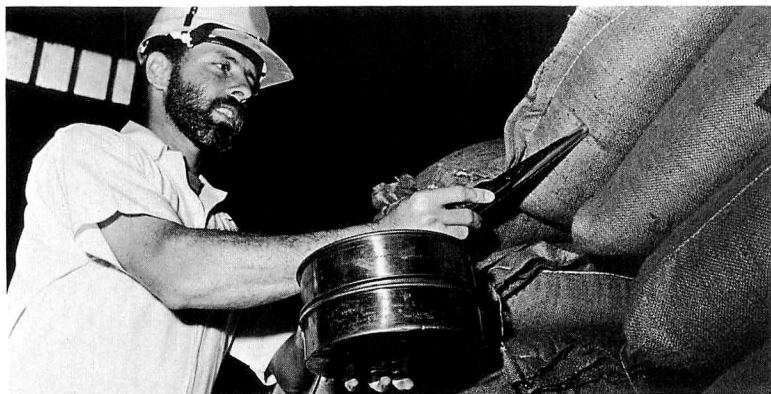
Many people, says Scholze, believe FDA guarantees that foods on the market are safe and good to eat.

Thus, when something goes wrong, they think FDA did something wrong. "They fail to realize that we can't get into a [food] plant that often, that we are only a regulatory agency that acts when it finds a violation. They also don't understand the enormous responsibilities we have in so many different areas." He is alluding to the fact that there are 150,000 food, drug, cosmetic, medical device, radiological, and other firms whose operations are within FDA's jurisdiction. The size of the food industry alone illustrates the difficulty of FDA's inspection responsibilities.

FDA currently is concerned with the operations of an estimated 79,000 food establishments. Most of these manufacture, process, ship, pack, label, and store a substantial portion of the food Americans eat each day. When one considers the sheer volume of food involved, one begins to understand why many FDA officials feel they face an almost impossible task in trying to monitor the safety of all foods, and why, in the view of many investigators, they can only scratch the surface of the total amount of food involved.

Donald C. Heaton, executive director of regional operations (EDRO), which oversees FDA's field offices and activities from FDA headquarters in Rockville, Md., said recently that inspections of food establishments are being conducted on the average of once every 6 years. In 1976, it was once every 4½ years. During the 12-month period ending September 30, 1979, FDA conducted 12,855 inspections of food operations.

When a food contamination situation is considered serious or widespread, FDA has the option of filing a complaint and obtaining the ap-



Samples of grain or other dried foodstuffs stored or shipped in bags are obtained for analysis by forcing an opening in the bag with a tryer, a tubular spout sharpened on one end. At a warehouse on a New Orleans wharf, Imports Inspector Tom Mascari spills chips of chicory, used as an ingredient in some coffee blends, into a sieve that has a pan attached beneath into which any insects or small pieces of foreign matter are shaken for visual examination.



Random samples of bananas from Panama are removed by Import Inspector Mascari from boxes being unloaded via conveyor belt from a freighter docked in a slip off the Mississippi River. The samples will go back to the laboratory to be tested for pesticide residues.

proval of a U.S. district court for a mass seizure of food. In this fashion food, good and bad in a single location, can be brought under Federal control to prevent contaminated foods from being sent into the marketplace.

Because the food standards and laws of other countries are not always as strict as those here, imported foods are a major concern to FDA. Again, the Agency's problem is one of dealing with volume. Some products from certain foreign outlets and countries are detained automatically because of past violation histories and poor standards. Fresh fish and seafoods of various types are spot checked carefully. During the 1979 fiscal year, ending September 30, there were nearly 5,977 detentions of imported food, resulting in more than \$205 million worth of food that was either reconditioned under FDA supervision or was refused entry into the country, according to Richard R. Klug, assistant for import operations. For the 8-month period October 1979 through May 1980, Klug said, FDA district officers had detained 4,306 shipments of food valued at \$185 million.

Under the Food, Drug, and Cosmetic Act, foods shipped to the United States are subject to inspection at the point of entry through U.S. Customs and can be detained by FDA and denied entry if they fail to comply with requirements of the law. Products that fail FDA's inspections sometimes can be brought into compliance through reconditioning if the methods to be used are first approved by FDA. If the detained shipments are not reconditioned satisfactorily, they must be exported or destroyed. The approval of a Federal



court is not needed in an import detention because the product is technically not yet in the United States.

In the case of foods produced in the United States, a court-approved seizure is an involved, cumbersome process that begins with a detailed inspection of a food establishment, the preparation of a large volume of reports that spell out the violations, the gathering of evidence to back up FDA findings of adulteration of food, a series of administrative approvals at district and headquarters levels, and finally, the preparation of legal documents by a U.S. attorney who will file FDA's complaint in a U.S. district court. If a food seizure is approved by a Federal judge, U.S. marshals carry out the court's edict. The owner of the goods can contest the charges and demand a trial or, if he does not want to fight it, can enter into a consent decree that would permit condemnation. The owner then has the option of agreeing to the destruction of the seized goods or requesting an opportunity to recondition at least some of the foods under

FDA's supervision so they can be used for human and/or animal consumption.

Unlike drug firms, which are required to register with FDA and which are subject to inspection once every 2 years, there are no registration requirements for most food operations in the United States. FDA's surveillance of domestic food operators is concentrated on manufacturing and processing plants, packing and labeling plants, grain elevators, and warehouses. Warehouses that store and distribute foods alone comprise about 24,600 of the 79,000 food establishments FDA has on its inventory of places deemed within its jurisdiction. The only exceptions to the nonregistration requirement are commercial producers of low-acid foods that are heated and packed in hermetically sealed metal, glass, or plastic containers, and acidified foods—those to which acid or acid food is added (beans, cucumbers, cabbage, peppers, etc.) who must register with FDA. This applies to U.S.-based companies and those in other coun-

tries which export their goods to the United States. The registration requirements were adopted by FDA in 1973 after Agency investigations revealed lax practices in canned food processing and inadequate safeguards against botulism, an often fatal form of food poisoning.

A comprehensive June 1976 study provides an insight into the Agency's surveillance and compliance activities. The study was prepared at a time when FDA was asked to re-examine its policy on "blending"—the mixing of adulterated with unadulterated foods—a practice which FDA currently prohibits. The 1976 study was based on a review of more than 1,000 court-approved food seizures, 195 industry recalls of foods, 1,985 "corrective action" reports by industry that resulted in the destruction and/or diversion of foods to nonhuman food channels, and 604 import detentions, selected to represent a statistical sample of 12,000 detentions. The data covered the fiscal years 1973 through 1975.

During the 3-year study period the report revealed that:

- Nearly 47 million pounds of food produced in the United States was either destroyed or diverted to nonhuman food uses as a result of FDA enforcement activities—seizures, recalls, and voluntary destruction—and another 115 million pounds of food offered for import was refused entry and exported or destroyed.

- Sanitation violations—those caused by rats, mice, insects, and birds along with nontoxic molds, and other filth and foreign materials—were responsible for the largest quantities of destructions and diversions from human food channels. More than 32.3 million pounds (69 percent of the total) of the domestically produced foods and more than 50.3 million pounds (nearly 44 percent) of detained imports resulted from such violations.

- Botulism, salmonellosis, and other microbiological contaminants were responsible for the destruction or diversion of 8.6 million pounds of U.S.-produced foods and 36.2 million pounds of imported foods.

- The rest, as illustrated by the table, were foods destroyed or diverted because of contamination by chemi-

cals, metals, natural poisons, and such miscellaneous adulterants as glass particles in food.

The report noted that court-approved seizure actions had a big impact on domestically produced foods. During the 3-year period, the report said, 20.1 million pounds of seized foods had to be destroyed or diverted to nonhuman use. Other seized foods were reconditioned and some foods may have been distributed before the necessary legal action could be taken. FDA investigators point out that some food gets past them into normal food channels between the times a plant or warehouse is inspected and a court order is obtained to seize the food. The report also indicated that there is a direct relationship between the amount of food destroyed or diverted each year and the frequency with which the Agency is able to inspect food operations.

In an evaluation of 50 general categories of food commodities, the impact of enforcement actions was greatest on cereal and grain products produced in this country. Of the 47 million pounds destroyed or diverted, 18.6 million pounds—or more than 40 percent—were in this cereal/grain category.

Out of some 40 food categories of imported products, fresh fish and shellfish accounted for 26 percent of the foods refused entry. Most operators whose foods are denied entry generally choose to re-export to other countries. The report estimated that "probably less than five percent" of the detained imports actually were destroyed.

The 1976 report was prepared at a time when there was widespread concern over a projected food shortage in the world and FDA officials were asked to determine whether more food could be made available if FDA eased its prohibitions against blending. At that time, most FDA officials were generally opposed to any lowering of the standards, a policy that is unchanged today.

Said Healton recently: "We don't think people should take garbage and mix it with good food and make lots more garbage—which is really what you are talking about, because that would be deliberately hiding a contaminated product through the blend-

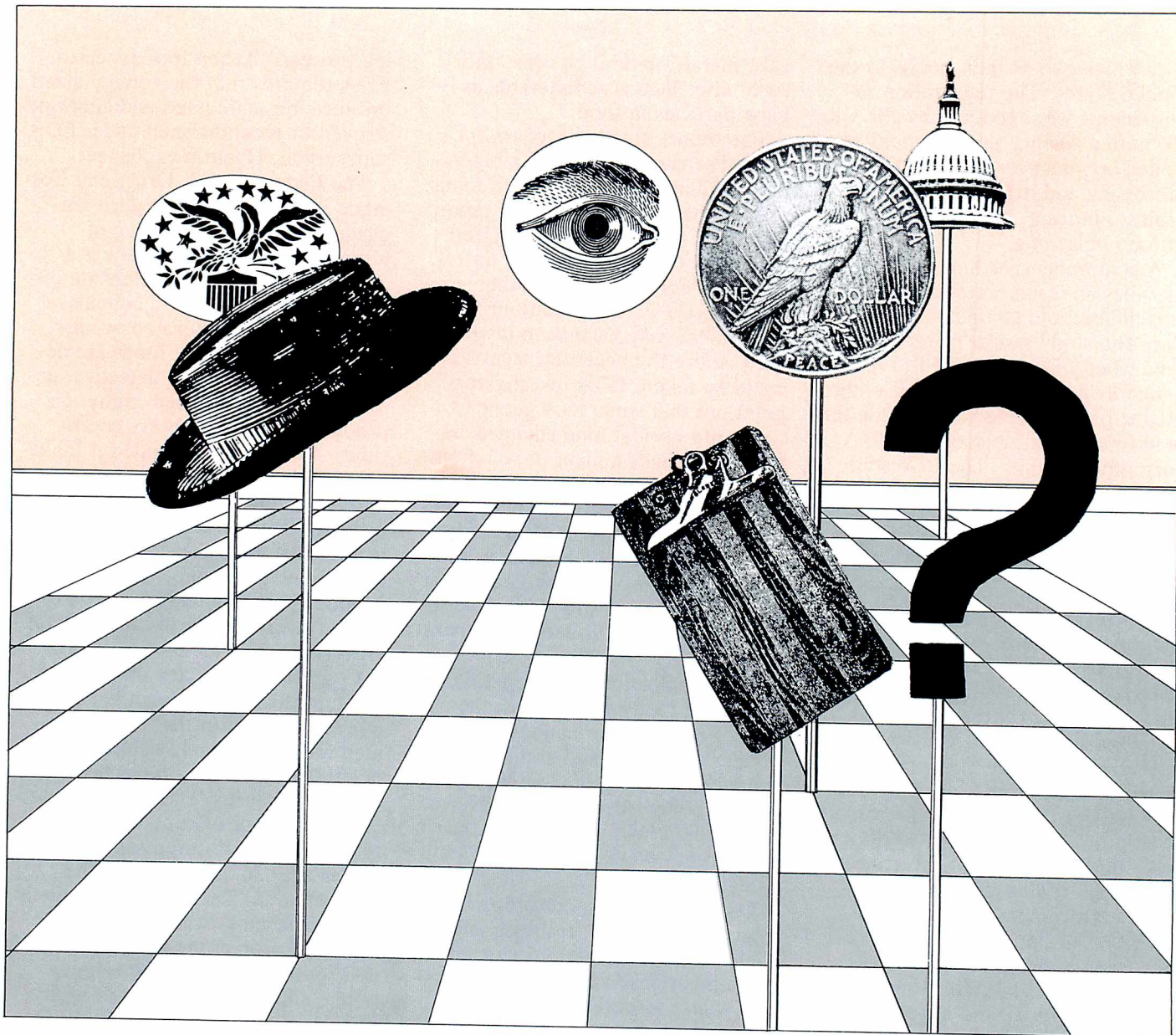
ing process." When food is seized, FDA requires that the contaminated products be segregated and either destroyed or reconditioned under FDA supervision, Healton explained.

The Federal Food, Drug, and Cosmetic Act contains no explicit language dealing with the issue of blending. In general, the law is a prohibition against the interstate distribution to humans and animals of foods that are adulterated or misbranded. Adulterated foods are defined as those that are defective, unsafe, unfit, decomposed, filthy, or produced under insanitary conditions. A food is misbranded if the label contains false, misleading, or incorrect statements. The law also concerns itself with prohibitions against the addition of "poisonous or deleterious" substances; it requires action if pesticide residues in foods exceed tolerances set by the Federal Government.

Court decisions back up the basic position that Government is not required to establish that an adulterated food is unfit and dangerous to health before it can take action. As one court put it: "There is no room for controversy over percentages of filth under the statute itself, for it excludes all." In another case, the court stated: "There can be no doubt that this section of the act was designed to protect the esthetic tastes and sensibilities of the consuming public and that the visible presence of such material in food would offend both." In this particular case, the defendant had argued that the statute was directed only to filth that was perceptible to the consumer, but the court rejected that argument, adding:

"To so interpret this section of the statute would largely deprive the people of the protection it seeks to give. The consumer ordinarily requires no governmental aid to protect him from the use of food products, the filthy adulteration of which he can see, taste or smell. What he really needs is governmental protection from food products, the filthy contamination of which is concealed within the product."

Chris Lecos is a member of FDA's public affairs staff.



Public Willing To Take Some Cancer Risks

Regulators are constantly making judgments based on risks. And businessmen are constantly complaining about those judgments. The regulators say their judgments help the public by protecting health. The businessmen say the regulators overprotect the public. What does the public think? A leading national polling firm went to them to find out.

Linking a food substance with cancer doesn't necessarily warrant banning it from the food supply.

So the public told pollster Lou Harris recently. In fact, most of those who responded to a question in a nationwide survey said they would prefer to make the decision themselves about whether to use a substance that has been linked with cancer. And a large number of respond-

ents would have each case decided separately.

The survey, done for an insurance firm, also uncovered a very positive image of the Food and Drug Administration among four leadership groups. The survey "Risk in a Complex Society" covered 1,488 adult members of the public, plus 400 top corporate executives, 102 investors/lenders, 47 members of Congress or their aides, and 47 Federal regulators.

The question asked about preferred policies toward food substances linked with cancer was as follows:

Q. Now, I'd like to ask you some questions about individual responsibility and risk in our society. Some food substances, such as saccharin and nitrites, have been linked with cancer. In general, which do you think is the better principle to follow? (a) ban all food substances linked with cancer, (b) publicize the dangers, but let people decide for themselves whether to use them, or (c) decide each case separately, banning some substances and allowing individuals to decide for themselves on other substances.

The results were:

	Corporate Executives (400)	Investors/ Lenders (102)	Congress (47)	Federal Regulators (47)	Public (1,488)
	%	%	%	%	%
Generally ban all food substances linked with cancer	2	1	11	11	10
Let people decide for themselves	32	39	11	6	46
Decide each case separately	65	60	79	83	43
None	—	—	—	—	*
It depends	1	—	—	—	1
Not sure	—	—	—	—	1

*Less than .5%

In its executive summary of the survey, the Harris firm noted that there are “very substantial areas of disagreement between public and corporate leadership opinion.” Said the report:

“In particular, the public has a much greater sensitivity to risk in the areas of household products, medical care and our food and water supply. While more than three in four Americans believe that we are now taking realistic, and not unreasonable, precautions against known risks, a majority of corporate executives feel that the American public has now become overly sensitive to risk and wishes to be protected from all dangers.”

The pollster said that the corporate leaders do not subscribe to a “tip of the iceberg” theory about today’s knowledge of risk—i.e., that the risks we know about represent only a fraction of those that technology produces. They “. . . feel that the risks associated with tech-

nology have been blown out of proportion by recent events such as Love Canal and Three Mile Island.”

In the survey the Federal regulatory agencies were also rated by the four leadership groups—corporate executives, investors/lenders, Congress, and Federal regulators themselves. The Food and Drug Administration was rated very good or excellent by 56 percent of the corporate officials and investors/lenders, 61 percent of the congressional group, and 66 percent of the regulators. Among the eight agencies evaluated, only the Civil Aeronautics Board received a similarly high rating. The Department of Energy, by contrast, got 2 to 8 percent “very good” and “excellent” ratings from the four groups. Other agencies evaluated were the Environmental Protection Agency, the Occupational Safety and Health Administration, the Consumer Product Safety Commission, the Nuclear Regulatory Commission, and the Congressional Office of Technology Assessment.

Here’s how the FDA ratings looked:

	Corporate Executives	Investors/ Lenders	Congress	Federal Regulators
	%	%	%	%
Excellent	7	7	4	4
Very good	49	49	57	62
Only fair	34	29	37	26
Poor	8	15	2	6
Not sure	2	—	—	2

In their summary, the pollsters noted that there is a broad consensus that future benefits to society from continued technological advancement in the next 20 years will outweigh the risks. “Thus despite a heightened sense

of the dangers and risks associated with contemporary living, the public’s longer view of history emphasizes the future benefits of advanced technology,” the pollsters commented.



A Careful Look Into Tanning Booths

"A woman can never be too rich or too thin," the saying goes. "Or too tan," might be added. For that copper-colored skin is chic in many circles, whether on a man or a woman. Thus, the popularity of tanning booths. But tanning—and tanning booths—pose some health problems, as this article notes.

It might be said that tanning booths are the suspenders of the Sun Belt.

For, if a line were drawn horizontally across the United States, it would appear that most of the Nation's several thousand tanning huts are below the line.

It might also be said that the healthy look obtained in a tanning booth could make one awfully sick.

For the lights in a tanning hut bombard the body with ultraviolet radiation of two types. One type increases the risk of skin cancer. The other may cause skin aging. And both can cause eye damage.

Just why more tanning huts are found in the Sun Belt States and why more are found in southern California than northern California is a question for armchair sociologists. It may be that suntans are more prevalent in the sunny States and, therefore, more a social necessity. Thus, if a person in Phoenix can't work a session in the sun into a busy schedule, he or she can always grab some time at a tan hut and still remain "in."

Copper-colored skin wasn't always a status symbol. In fact, back 75 years or more a maiden hid herself in the summertime under a sun umbrella so that she would not look like she had been out working in the fields. However, it might have been the development of the outdoor swimming pool (not to mention briefer swim attire) that led to a suntan being associated with recreation and the wealthy. That association holds true today, particularly among the young who want to remain trendy and are so many years away from cancerous and/or sagging skin.

Just why that bronzed look is equated with a healthy appearance is another puzzler for armchair sociologists. Before the days of tanning booths, it did indicate that a person had been outside, which may have been associated with breathing good air. Of course, sunshine has long been touted as a source of vitamin D, although the average American's diet today probably provides all the vitamin D needed. The benefit, then, is largely cosmetic. Along with this "beauty" being skin deep, so are the bad effects.

The trouble is ultraviolet radiation. The type that causes skin cancer (ultraviolet-B, or UV-B) comes mostly from the sun. The prevalence of that cancer is a matter of statistics, with some 500,000 cases a year in this country making it the No. 1 cancer. The location of the cases—there is more cancer in the Sun Belt than in the Northern States and likewise more in Florida than in Minnesota—points the finger clearly at Old Sol as the culprit.

Skin cancer is largely a curable cancer. Although mortality rates may be low, morbidity rates can be high in terms of disfigurement, scars, etc. The high cure rate is because the cancer is usually a nonspreading type and is easily detected on the skin surface. Malignant melanoma is a form of skin cancer that is increasing in incidence in this country and is the exception that proves the rule. Melanoma often spreads throughout the body and is difficult to treat.

Aging starts in layers of the skin that are deeper than those where skin cancer occurs. Skin aging may be the result of ultraviolet-A (UV-A) radiation because those rays go deeper into the skin and attack the fiber that normally keeps skin resilient. The result is sag.

FDA's Dr. F. Alan Andersen, chief of the Standards Support Staff in the Division of Biological Effects, Bureau of Radiological Health, points out that early-type tanning

Some Potential Photosensitizing Agents

The following table lists agents that may increase sensitivity to ultraviolet light resulting in a phototoxic or photoallergic response:

Product Class	Generic or Chemical Name	Product Class	Generic or Chemical Name
Acne Treatment	Retinoic acid (tretinoin), Retin-A	Antipsoriatics (also in cosmetics)	coal tars and coal-tar derivatives, wood tars, and petroleum products
Antibacterials	sulfonamides (sulfamethoxazole, sulfisoxazole, trisulfapyrimidines), nalidixic acid, trimethoprim and sulfamethoxazole, halogenated salicylanilides, halogenated carbani- lides, halogenated phenols (antibacterials in deodorant bar soaps, antiseptics, cosmetics)	Diuretics (and antihy- pertensives)	chlorthalidone, furosemide, thiazides and combinations
Antibiotics	tetracycline and tetracycline derivatives: chlortetracycline, demeclocycline, doxycycline, methacycline, minocycline, oxytetracycline	Dyes	acridine, anthracene, eosin (lipstick), erythrosin, fluores- cin, methyl violet, methylene blue, orange red, rose bengal, toluidine blue, trypanflavin, try- pan blue
Anticonvulsants	carbamazepine, trimethadione	Estrogens and Proges- terones	mestranol and norethynodrel, diethylstilbestrol
Antidepressants	amitriptyline, desipramine, doxepin, imipramine, nortrip- tyline, protriptyline	Melanogenics (and in cosmetics)	furocoumarins (5-methoxy- psoralen, 8-methoxypsoralen, 4,5,8-trimethyl-psoralen)
Antidiabetic (glucose- lowering agents)	sulfonylureas (acetoexamide, chlorpropamide, tolazamide, tolbutamide)	Perfumes and Toilet Articles (essential oils in cosmetics)	Containing ethereal oils, oil of bergamot, oil of cedar, citron, lavender, lemon, lime, rose- mary, sandalwood
Antihistamines	diphenhydramine, prometha- zine, triprolidine, chlorphen- iramine	Tranquilizers	chlorprothixene, doxepin, haloperidol, loxapine, thi- othixene
Antimicrobials/Anti-in- fective agents	griseofulvin		phenothiazines: acetophena- zine, chlorpromazine, fluphen- azine, perphenazine, prochlor- perazine, thioridazine, trifluoperazine, trifluoproma- zine

huts used fluorescent sunlamps in an attempt to mimic sunlight. However, Andersen notes that the tanning industry's growth today is due to a new type of lamp that provides over 95 percent UV-A and less than 5 percent UV-B, which is very different from sunlight.

These new booths are being sold as "safer" than the earlier type. The answer to the "safer" question is unknown, Andersen says. UV-A directly may not cause cancer but it's possible that it can age the skin. "It is very likely that UV-A is associated with aging, but we have little proof, only guilt by association," is the way Andersen puts it.

Further, Andersen says there is no doubt that certain chemicals may increase a person's sensitivity to UV-A and cause problems. For example, medications may find their way to the cornea and join up with ultraviolet-A rays to increase the sensitivity of the eye and damage it. Likewise, certain drugs can increase sensitivity to ultraviolet rays found in sunlight and tanning booths, a fact that was noted in the most recent DRUG BULLETIN put out by FDA to some 967,000 health professionals.

UV-A is also used together with a psoralen derivative to treat severe psoriasis. However, the treatment is used on a selective basis because the combination can cause cancer. Psoralen has an interesting history in itself. One derivative of it that is widely used in perfumes for fragrance can also accelerate tanning. In fact the undistilled version of the derivative can cause women to develop darkened spots behind the ears and in other places where perfume is applied. After concern was raised about the psoralen derivative back in the early 1970's, American manufacturers voluntarily began using a version that doesn't produce the spots.

Some operators of the UV-A tanning booths also have been claiming that eye goggles are not needed for protection in their booths. Not so,

says Andersen. Eye protection is needed in either type of tanning hut, not only to prevent eye burn and other corneal irritations, but to eliminate any increased risk of cataracts.

Tanning booths started out about 2 years ago using 8 to 16 Westinghouse fluorescent lamps in a small booth in which the "tannee" stood up while getting bronzed. The huts featured speed, with from 1 to 15 minutes exposure.

Some of the newer unit booths use more lamps—a minimum of 16 and as many as 24, 36, or 48 of the UV-A lamps. The "tannee" lies on a bed with the lamps underneath or with lamps both underneath and above ("like a grilled cheese sandwich.") Minimum exposure time is on the order of 15 minutes; but the session may last as long as an hour.

Just how widespread the tanning industry has become is unknown, although the National Association of Sun Tanning has a mailing list upwards of 5,000. The growth of the industry worries more than FDA, which has the job of regulating the booths. Two specialists, Richard J. Wurtman, M.D., of the Massachusetts Institute of Technology, and Frederick Urbach, M.D., of the Skin and Cancer Hospital at Temple University's School of Medicine in Philadelphia, made their qualms known earlier this year in an issue of the NEW ENGLAND JOURNAL OF MEDICINE. They noted that the light source in the booths may "provide 10 times the irradiance of noon summer sunlight." In other hands, they point out, that amount of radiation is a "successful experimental tool for generating skin cancer in animals."

The two said it is the duty of doctors to "warn their communities about the very high medical price people may have to pay" for a little cosmetic skin color.

In a brochure produced by FDA's Bureau of Radiological Health, users of these "suntan closets" are warned that burns or eye injuries can result

if the subject is not careful and that the risk of skin cancer in later years is increased. Premature wrinkling of skin is another aftereffect noted.

The brochure also warns that tanning booths should not be used if a person burns easily. In other words, if you don't tan in the sun, you won't tan in a tanning booth. Still another warning concerns cold sores or herpes. Ultraviolet rays can upset the genetic control of dormant or developing cold sores, thus aggravating the infection.

Honoring time limits and wearing protective goggles are also stressed in the brochure, along with avoiding direct contact with the lamps.

Tanning hut operators don't usually promote the use of sunscreen products for their customers. But the customers should understand that to protect parts of the body customarily unexposed to the sun, it may be useful to use a sunscreen lotion on those parts to prevent burning during a tanning hut session.

A panel of outside experts reported to FDA 2 years ago that sunscreens can serve a useful purpose in scattering and blocking out ultraviolet rays. The panel, one of 17 reviewing over-the-counter drugs for the Agency, recommended that a sun protection factor, or SPF system, be adopted by FDA to tell sun bathers how effective a product is. SPF ratings, which are being included on lotion labels, range from 2 for people who seldom burn and who tan easily to 15 for people seeking a complete sunblock.

However, Andersen says it's questionable whether the use of sunscreens will reduce the risk of skin cancer. "It's a good working hypothesis but that is not proof," he says.

At any rate, if you want to be Joe or Josephine Cool, with that bronzed look that much of our culture says is attractive, remember it's the ultraviolet rays that give you that look—rays that can take their toll in years to come.

The Voice Of The Quack

Quackery thrives. It thrives because people want to believe there are simple cures for their ills and easy ways to correct their imperfections. The quack understands this and exploits it. His advertisements, as this article points out, are a mixture of mysticism, pseudoscience, and sensationalism.

by Roger W. Miller

The voice of the quack is not a harmless honk.

It is a voice that attempts to soothe, to assure the sick, the aging, or the foolish. What the voice really wants is to charm the money out of anyone—whether sick, growing old, or just plain hopeful.

Too often the quack succeeds, and Americans throw away hundreds of millions of dollars annually for a variety of products that can't possibly work. The money flows so fast that Federal and State investigators can't keep pace with all the quack operations.

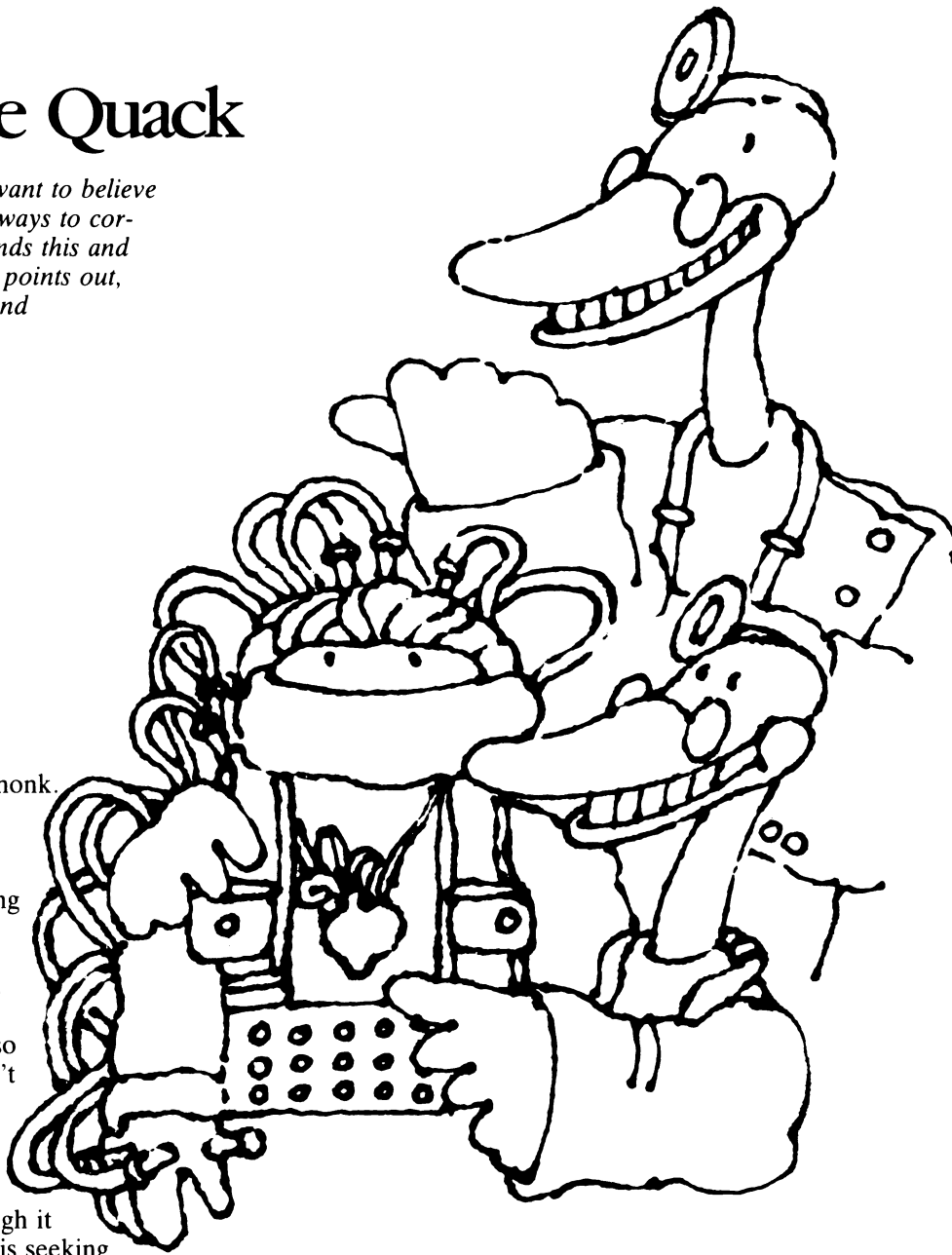
To an uninvolved observer, the quack's voice may give itself away, the advertisements being parodies of themselves.

Even in printed ads, the voice is shrill, though it may not sound that way to the person who is seeking help for real or imagined illnesses or shortcomings.

How does the quack manipulate the language so as to make the shrill sound melodious? A study of quack advertisements in some large circulation newspapers and magazines shows that the language of quackery is quite universal, almost as if every ad writer had taken the same correspondence course in Creative Quackery Ad Writing 101.

Such language often hints at the mystical. But unlike his Medicine Man predecessor, who invoked "nature" or the occult, today's quack is more likely to cloak his claims of knowledge about the unknowable in polysyllabic terms that, to the unwary, sound like major scientific milestones. Thus, "**an amazing breakthrough in medical technology**" has resulted in a product that "**reverses hereditary pattern baldness.**" Or "**clinical studies prove that**" you really can stop the aging process. What's more "**researchers have uncovered the secret that revolutionizes the science of breast development.**"

In the good old days, the typical source of a cure-all potion was supposedly some Indian chief who spent his time digging strange roots rather than scalping white men, or a venerable patriarch in a foreign land who



never left his high mountain village because he could maintain perpetual youth or health or both by just swilling his elixir. Today's Medicine Man is not above using the exotic in his promotion pieces. Indeed, sometimes he even combines the foreign with the scientific, as in "**Now from Europe comes a remarkable skin care breakthrough: cell therapy.**" However, instead of an Indian chief or a guru, the ads today are more likely to tout the "**discovery of an Olympic champion.**"

Sharing top billing with science in the get-well-quick ad business is Ma Nature herself. Whether taken orally, rubbed on, played with, or simply looked at, the quack products today are all "**natural.**" They're natural as in "**100 percent natural ingredients**" and "**works safe and naturally**" and "**Nature wants you to function perfectly.**"

But if Mother Nature and scientists are working feverishly to restore your health or youth, your diet is what's killing you, as these lines attest:

"Modern diets are poor in nutrition."

"Modern food processing strips away many key nutrients from our diets."

"Most people do not manage to eat a well balanced diet."

To hear these ad writers talk, we should all be 7-foot-

Quack Language From A to Z

A	= Amazing (as in “ <i>amazing</i> breakthrough”)	N	= Natural (as in “Now there’s a <i>natural</i> way to lose those excess pounds.”), may also be used in the French form <i>naturel</i> ; also nutrients (as in “Your normal diet doesn’t provide the proper <i>nutrients</i> .”)
B	= Breakthrough	O	= On the spot (as in “Feel the texture of your hair change <i>on the spot</i> to silken smoothness.”)
C	= Clinical	P	= Painless
D	= Discovery, doctor (as in “ <i>Doctor</i> makes amazing <i>discovery</i> .”)	Q	= Quick
E	= Exciting, European, enzymes (as in “This <i>exciting European</i> discovery of new <i>enzymes</i> resulted from an amazing clinical breakthrough.”)	R	= Research, researcher, revolutionize (as in “ <i>revolutionize</i> the process of preventing baldness”); also remarkable (as in “_____ is a <i>remarkable</i> scientific discovery.”)
F	= Fantastic (as in “It was <i>fantastic</i> ; within 3 weeks the pain had left,” writes Mrs. Z. B. of Chatsworth, Calif.); also, formula, fast-working	S	= Secret, speed, safe
G	= Guaranteed	T	= Technology
H	= Home cure (as in “Now there’s an amazing <i>home cure</i> for arthritis, thanks to a fantastic scientific breakthrough accomplished in a Finnish laboratory.”)	U	= Uncover (as in “researchers <i>uncover</i> secret formula”)
I	= Instant, immediate, inexpensive, ingredient	V	= Vanish (as in “liver spots <i>vanish</i> miraculously”)
J	= Just (as in “The pain was gone in <i>just</i> 3 weeks,” reports B. Z. of Bellflower, Ill.)	W	= Wonder, works (as in “It really <i>works</i> .”)
K	= Know-how (as in “With a special brand of understanding and <i>know-how</i> , Dr. Strange was able to come up with this secret formula.”)	X	= X rays (as in “ <i>X rays</i> prove that arthritic calcium deposits are cleared up.”)
L	= Lose (as in “guaranteed to <i>lose</i> 3 pounds a night while you sleep.”)	Y	= Youthful
M	= Medical (also medically approved, medical technology); also miracle and miraculous	Z	= Zinc (as in “the mineral crucial to man’s prowess.”)

ers rather than the nearly 6-footers that we are (or the 5-footers of not too many generations ago who subsisted on nonprocessed foods).

In addition to being scientifically based on natural, such products are always *fast working*, *inexpensive*, *painless*, and *guaranteed*. Speed is important. The items have to go to work instantly or even sooner. (Some are believed to start working as soon as the buyer writes the check for them—a not too preposterous idea since the one reasonable defense left to a quack is that his product may work because his customers *think* it works.)

Inexpensiveness is a relative word. Quack items often run in the \$9.95 range. That may seem like a lot for a package of tea that will provide “*natural prostate rejuvenation*” (as if the prostate had a known function), but \$9.95 is less than the cost of a visit to a doctor’s office (where the prospective quackery victim would be told only that the prostate has nothing to do with sexual ability). Whatever the price, you can use your BankAmericard or Master Charge credit card. And there’s assurance of a full refund by returning the unused portion of the 100 teabags—if you’re “*unhappy in any way*” or if your prostate didn’t rejuvenate but still sits there and does nothing.

The products are typically promoted as being painless, although the annals of more than one court will show that some of these products have done physical harm to people. The real harm comes, however, because people rely on the quack’s product when they probably should be seeing a physician.

The guarantees may be stated clearly enough. But

most people who are made fools of don’t like to admit it, even to get their money back.

The quack ad writers often display a little scientific knowledge to explain the wonders their products perform. But the explanations don’t go very far. One, for a skin cream, reads: “*Basically, the process involves the use of cell cultures derived from embryonic tissues.*” Sometimes, the language is couched so as to deepen the mystery: “*Apparently what happens is . . .*”

The similarity in language in the ads is, to use a favorite word of the quacks, *amazing*. Words other than *amazing* that repeatedly find their way out of a quack’s mouth and into his advertisements are: *breakthrough*, *secret formula*, *natural*, *discovery*, *instant* or *instantly*, *safe*, *painless*, *medical*, *clinical*, and *research* or *researcher*. Several of them may hook right together, like railroad cars. Try it.

Also similar in language are the testimonials from “*satisfied*” users of the products. “*It really works!*” is the most often used testimonial. The speed at which the “*secret formulas*” work is also worthy of comment by Mrs. Satisfied and Mr. Convinced User.

Such is the language of quackery. Oozing with confidence. Friendly, willing to share a secret. Knowledgeable about the maladies of mankind. Cynical in confiding that the conventional medical system doesn’t provide help for “people like you.”

But the dulcet tones are dangerous, a siren’s song. Watch that friendly arm that drapes over your shoulder; it will lift your billfold when it is withdrawn.

Roger W. Miller is editor of FDA CONSUMER.

The Notebook

■ *FDA has withdrawn a proposal that would have permitted bread with only 25 percent fewer calories than regular bread to be labeled “**reduced calorie.**” The rule, proposed September 22, 1978, would have authorized an exception to the regulatory requirement that foods labeled “reduced calorie” be reduced at least one-third in calories. Comments from the baking industry and consumers indicated that it is possible to make a bread meeting the one-third calorie reduction requirement and this was confirmed by FDA tests. The Agency then decided that the proposed exception was not necessary nor in the best interest of the consumer. The special dietary food regulations governing labeling of reduced-calorie foods became effective July 1.*

* * * *

■ *The Department of Health and Human Services has mailed a free catalogue of comparative **price information on prescription drugs** to 500,000 medical and osteopathic physicians, pharmacists, and consumers who have asked for it. The catalogue, developed by the department’s Health Care Financing Administration, divides 184 of the most frequently prescribed drugs, plus aspirin and acetaminophen, into 16 therapeutic categories. Under each category the guide lists the generic and trade names for each drug, the marketer of the product, and the cost to the pharmacist for one day of therapy.*

The guide is expected to be updated every 6 months. It is intended to help physicians and pharmacists consider the cost of different drugs when they write or dispense prescriptions.

* * * *

■ *FDA has asked for data or comments on whether to impose restrictions on manufacturing and distributing overseas of nine **anorectic (appetite suppressing) drugs**: amfepramine, benzphetamine, chlorphentermine, chlortermine, fenfluramine, mazindol, phendimetrazine, phenmetrazine, and phentermine. The call for information followed a request to the Secretary of*

HHS from the Secretary General of the World Health Organization for assistance in determining whether any change would be justified in the status of the nine drugs.

* * * *

■ *Latest addition to the list of FDA standing advisory committees is the **Blood Products Advisory Committee**, established in June. Function of the committee is to review and evaluate data on the safety, effectiveness, and appropriate use of blood products intended for use in diagnosis, prevention, or treatment of human disease.*

* * * *

■ *The Radiation Policy Council, created by Executive order in February, has established a Task Force on Federal Occupational Radiation Exposure Regulations. Member agencies are the Departments of Commerce, Defense, Energy, Health and Human Services, Labor, and Transportation, the Environmental Protection Agency, the Nuclear Regulatory Commission, and the Veterans Administration. The Department of Labor heads the task force, which is to analyze and evaluate the regulation of **occupational radiation exposure** in terms of a uniform approach to keeping doses as low as possible; analyze and evaluate the present processes for development of Federal guidance and regulations on occupational exposure to ionizing radiation; and explore problems of implementation, including gaps in coverage and compliance.*

* * * *

■ *The Nuclear Regulatory Commission (NRC) issued a final rule (June 19 FEDERAL REGISTER) requiring medical licensees authorized to prepare radioactive drugs from radioisotope generators to test these drugs for a **contaminant called molybdenum-99 (Mo-99)**. In diagnostic nuclear medicine, the most widely used radioactive drug is technetium-99m (Tc-99m), which many hospitals and nuclear pharmacies obtain*

from a radioisotope generator. This is a shielded device containing Mo-99, the parent of Tc-99m. The Mo-99 is adsorbed on an alumina column arranged so that sterile saline solution can be fed through the column to wash out only the daughter radioisotope Tc-99m. Following a report from an NRC medical licensee, a joint NRC/FDA investigation revealed that if Mo-99 is improperly loaded on the alumina column or loaded on a defective column, greater than normal amounts of Mo-99 can break through the column and contaminate the Tc-99m.

* * * *

■ FDA has executed a Memorandum of Understanding with the **Federal Grain Inspection Service (FGIS)** of the U.S. Department of Agriculture establishing cooperative working arrangements the two agencies will follow in carrying out their responsibilities in the inspection and standardization of grain, rice, pulses (peas and beans), and food products. The agreement became effective April 15.

* * * *

■ The Environmental Protection Agency has proposed addition of seven waste products to its list of **hazardous wastes**, including distillation tar residues and activated carbon residues from the manufacture of veterinary pharmaceuticals. According to the notice published in the **FEDERAL REGISTER** these waste products contain high concentrations of arsenic—a highly toxic element. Arsenic contamination of ground and surface waters has resulted from the improper management of these and other process waste products.

* * * *

■ FDA has proposed that **allergenic extract products** be exempted from the expiration dating and stability testing requirements in the Current Good Manufacturing Practice regulations (CGMP's) for drug products. When the CGMP's were most recently

amended in 1978 seven manufacturers of allergenic extract biological drug products petitioned FDA to exempt their products because expiration dating periods for these products were already specified in regulations governing biological products and the kind of stability tests contemplated in the CGMP's were not yet appropriate for testing of allergenic products.

* * * *

■ If you recently bought an instrument that's supposed to **measure radiation leakage** from your microwave oven, don't rely on it, FDA warns. An evaluation of four widely advertised models revealed they were remarkably inaccurate and not capable of distinguishing levels of radiation that are below the Federal Performance Standard for microwave ovens from those that exceed the standard. The four instruments tested were: Micromate, Guardrod, Interceptor, and Microscan.

Unless the oven has been dropped or abused it is unlikely that radiation leakage in excess of Government guidelines will occur. If damage has occurred, these inexpensive instruments are not reliable for measuring leakage.

* * * *

■ The Food and Drug Administration has advised physicians to write "no refill" on **prescriptions for propoxyphene**, a frequently prescribed painkiller most commonly known as Darvon, Darvon-N, and Darvocet-N. In addition, the Agency suggested that physicians write their propoxyphene prescriptions, rather than calling them in to pharmacists.

In announcing the advisory in the **FDA DRUG BULLETIN**, which is circulated to one million health professionals, Dr. Jere E. Goyan, Commissioner of Food and Drugs, said: "Propoxyphene has been associated with a number of deaths, mostly resulting from deliberate overuse, abuse or suicide. There is a need for health professionals to keep this potential risk in mind when prescribing and dispensing the drug."

Investigators' Reports

Some Would Call It Buried Treasure

It was enough to make you cry in your beer or, if you are a member of a temperance organization, it was enough to make you smile for a week. For, buried in the prairie lands of Arkansas is enough beer to last a small-size city for weeks, perhaps months—over 153,000 gallons of it.

In the final week of May this year, some 68,000 cases of beer were packed into 15 railcars and traveling at high speed through eastern Arkansas. As the train, property of the Cottonbelt Railroad, headed through Hickory Ridge, a small town in the midst of cotton and soybean fields in Cross County, 22 cars jumped the tracks. Officials from the railroad later theorized that a broken wheel on one car was responsible.

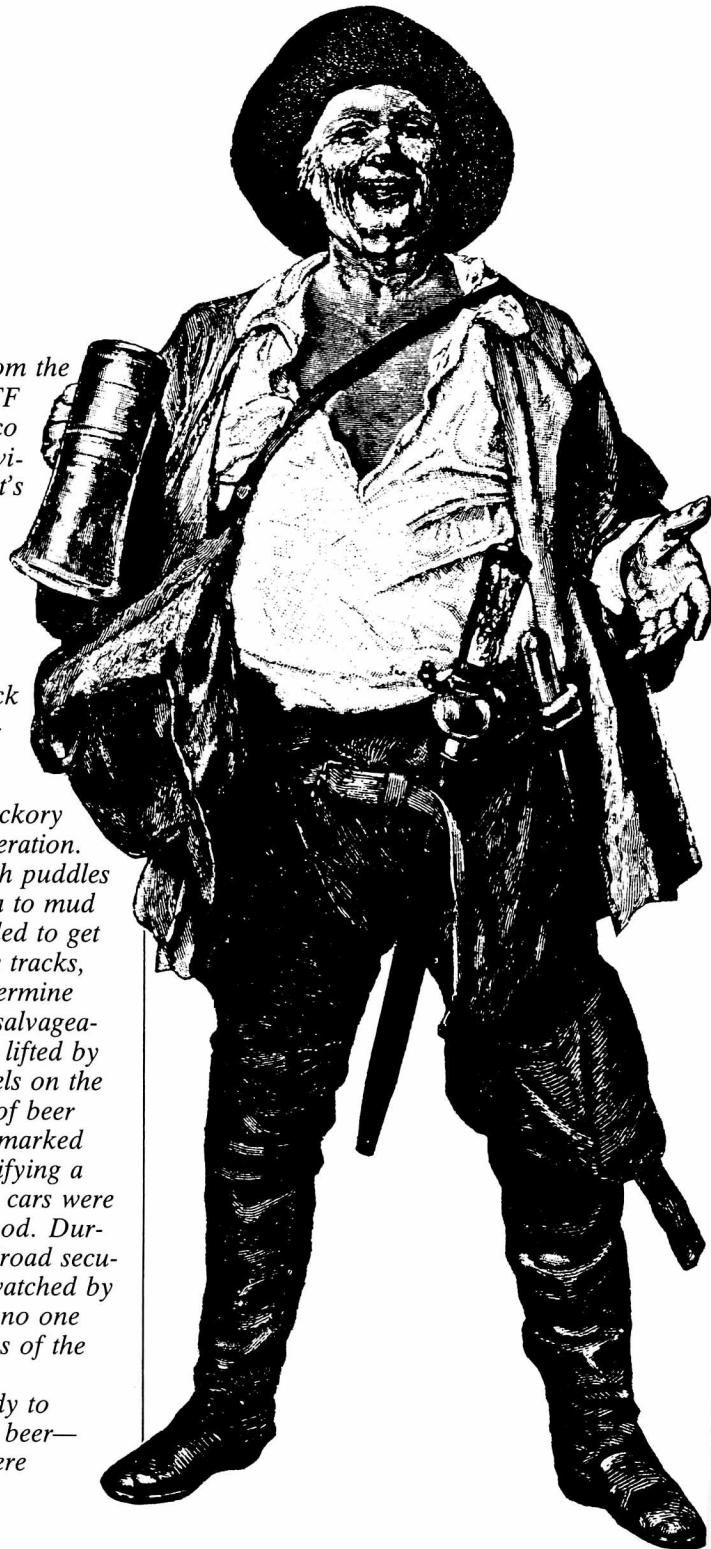
The crash, they say, was resounding. As the train left the tracks and plowed into the earth, the cars disengaged violently, smashed together. Some were shattered. Of the 22 cars, 15 were carrying the beer, and as the tops and sides of the boxcars splintered, the beer—in screw-top bottles and pull-top cans—cascaded onto the ground.

Laurie Sikes, Arkansas Health Department sanitarian for Cross County, got news of the wreck from Hickory Ridge police and headed out to survey the damage. In the next few days, coping with the wreck occupied not only Sikes but city police, railroad officials, representatives from the beer

company, and inspectors from the Treasury Department's BATF (Bureau of Alcohol, Tobacco and Firearms). Sikes' supervisor let the health department's central office in Little Rock know what was going on; and the supervisor there, in turn, passed on the word to FDA's Little Rock Resident Inspection Post chief, Ray McCullough. Both Little Rock offices wanted to be kept informed on the progress of salvaging.

It rained off and on in Hickory Ridge during the salvage operation. While rainwater mingled with puddles of beer and reduced the area to mud and railroad workers struggled to get most of the cars back on the tracks, sopping officials tried to determine how much of the brew was salvageable. The cars were repaired, lifted by crane, and set back on wheels on the tracks. Most of the cartons of beer were packed into them and marked by Sikes with red tags—signifying a State embargo. Many of the cars were then boarded up with plywood. During the entire operation, railroad security guards and city police watched by day and night to make sure no one made off with bottles or cans of the possibly contaminated beer.

Finally, the train was ready to move. About 7,000 cases of beer—pretty near a railcar full—were



deemed hopelessly damaged and were left behind to be destroyed by bulldozer in the sanitary landfill at nearby Harrisburg, Arkansas. The rest was sent on to Pine Bluff, Arkansas, the largest available train holding area, 70 miles away.

There the State Health Department's Jefferson County office took over—a three-person staff of Marcell Jones, Beth Sartain, and Bob Kemp. Working in relays, one manned the office while the others examined some 61,000 cartons of beer, then conferred with the beer manufacturing representatives, BATF officials, and members of the Arkansas Pollution Control and Ecology Department, which had some doubts about burying an essentially liquid product in a landfill designed only for solid waste.

The outlook for the beer turned gloomy. Some beer lovers may be willing to tolerate a little dirt, but breweries, according to Little Rock resident-in-charge McCullough, don't like to take chances with their product's reputation. They would just as soon have their brand name beer destroyed, rather than fall into the

hands of salvagers.

Destruction was the word given by the State investigators. During the wreck, the beer, although in cartons, had been battered, buffeted, and had set in rain and later in mud. In Pine Bluff, the heat had done its part, sending the temperatures in the railcars up to 110° or 120° F. The exteriors of the bottles and cans were frequently encrusted with dirt and the State inspectors felt that mud had probably got into many of the containers. Rinsing in chlorine solution—a technique frequently used to sanitize products after such wrecks—would be ineffective, State officials said, on products with screw tops or pull tabs.

Three railcars of the beer were eventually salvaged—in a slow process of separating the damaged and undamaged containers by hand. These were allowed to proceed—two railcars to California and one to Texas—and the Little Rock State supervisor gave McCullough the exact destinations. Under the Arkansas State Salvage Law, FDA must be notified when salvage goods cross State lines so the appropriate districts can watch for the

products at their destinations and alert the recipients that the products have been involved in an accident.

The rest of the beer was judged to be unsalvageable. After careful consideration of EPA-based regulations for landfills, which are designed to prevent contamination of soil and ground water, the Arkansas Pollution Control and Ecology Department gave permission for the rest of the beer—almost 50,000 cases—to be buried in a landfill about 10 miles from the train holding area.

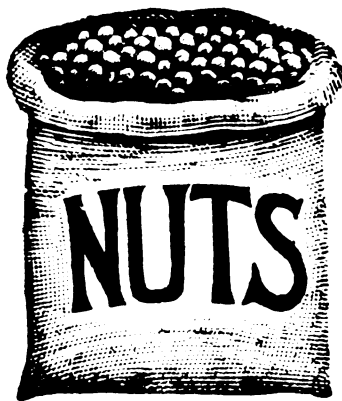
The dumping took 2 weeks, during which the Jefferson County staff spent each day supervising local warehouse employees hired by the railroad, who unloaded the cases of beer from the railcars and reloaded them onto a dump truck, then accompanied the truck to the landfill. The 20-mile round trip and the ever present smell of beer became monotonous, said Marcell Jones. But at least it wasn't as bad as the job of the BATF official, who had to remain at the dumpsite all day, every day, to watch the bulldozer grind over what must have seemed an endless supply of beer.

Investigators' Reports presents information on inspections, product seizures, court proceedings, and other administrative and regulatory actions by Federal, State, and local food and drug agencies across the country to provide health and economic protection to consumers of foods, drugs, cosmetics, and medical devices.

Taking Nuts to Court

The plaintiff in the case was the United States. The defendant was 13 cartons (more or less) of shelled almonds. The evidence was provided by FDA's **Seattle District** in its request for seizure.

Seizure—one of the legal weapons wielded by FDA to keep contaminated food products off store shelves and out of people's kitchens—is always directed against a specific adulterated product, never against the party responsible for the adulteration.



The case of the shelled almonds was typical. Seattle District investigators inspected Rogers Candy Co., Seattle, and found insects in the manufacturing plant. Accordingly, the investigators collected, in the random manner specified by the FDA Inspectors Operations Manual (IOM), approximately 1 pound of almonds from each of thirteen 50-pound cartons in storage. They also

collected copies of the product labels and the firm's shipping records. When the district laboratory found almost 10 percent of the almond samples were damaged by insects, the district went into action to keep the almonds from reaching unwary consumers.

On the basis of the investigators' evidence a U.S. attorney filed a complaint for forfeiture of the almonds in the U.S. District Court for the Western District of Washington. The judge signed the necessary legal documents, and a deputy U.S. marshal was subsequently dispatched to place under seizure the shelled almonds from the sampled lot. The 650 pounds of nuts were valued at \$1,200.

Beans, Rice, and Pigs

Some swine around Portland, Oregon, were eating higher on the hog—you might say—because of an inspection by FDA's **Portland Resident Post**.

A Portland investigator made a routine check of the warehouse facilities at Anzen Pacific Corp., Portland, an importer of oriental foods. Afterward, he told the firm's president there was an obvious rodent problem; that he had seen rodent pellets on numerous bags of rice and beans, on the floors, and even in the office supply room. Some foods, he said, were contaminated.

The president said he would get rid of the rodents. The immediate problem, however, was the already contaminated foods. The firm could choose to destroy the visibly contaminated products, the investigator said. Or—if the firm declined this action—the district might request a legal seizure.

The president suggested that the contaminated foods be diverted to animal feed—legally known as “constructive destruction.” The investigator stuck around to watch company employees separate bags of beans and rice with visible signs of contamination from other stored products. The following day he returned and observed as over 14,000 pounds of the 50- and 100-pound bags were loaded onto a truck, then accompanied the truck to the plant of a Portland animal feed manufacturer. The beans and rice were put in an area separate from other feed components and were eventually mixed in small amounts with the feed, ending up finally in the troughs of Portland area pigs.

Anzen Pacific subsequently cleaned its warehouse, improved its housekeeping practices, hired a new pest control firm, and instituted the practice of daily sanitation inspections.

Color Shows Drug ID

Early this year, a pharmacist made a report to the U.S. Pharmacopeia (USP) about a problem with a drug manufactured by Lederle Laboratories (Division of American Cyanamid) in Pearl River, New York.

The pharmacist noticed that some stocks of a drug labeled “Folvite Tablets” were the wrong color. Folvite tablets are orange; these pills

were white. The pharmacist set the questionable drugs aside and sent a Drug Defect Report to USP which forwarded a copy to FDA.

Pharmacists make over 5,500 reports a year through the Agency's Drug Defect Reporting Program. Through the program, implemented in 1971, FDA learns of many problems with drugs that might otherwise go unreported.

USP also sent a copy of the pharmacist's report to Lederle. The firm determined that the drug mistakenly labeled as Folvite—used to treat anemia—was actually another of its products, Artane, which is for the treatment of spasms associated with Parkinson's disease. The firm asked FDA's Bureau of Drugs for an evaluation of the problem and was advised that a recall of the product would be classified as Class II—indicating the drug was a possible hazard to consumers. A person taking the mislabeled drug would not be getting the needed Folvite, which is designed to correct a folic acid deficiency anemia, usually found in infants and pregnant women; also the person would unknowingly be taking Artane, a drug that commonly produces side effects such as mild confusion, insomnia, restlessness, and memory impairment. Artane has also been known to precipitate an attack of acute glaucoma in patients predisposed to open angle glaucoma.

Lederle notified FDA's **New York District** of the problem and reported that the firm was unable to explain the error in labeling. Although Lederle had located only one box with mislabeled drugs, management said, it was recalling the entire lot in question. The New York District monitored the recall.

Illegal Antiquing

The mind may boggle at eggs reputed to be a hundred or a thousand years old, but such oddities are treated as just another species of food by FDA's **New York Regional Laboratory**. In fiscal 1980, the lab analyzed 12 samples of preserved duck eggs from the Orient—known alternately, poetically, and also inac-

curately as “Thousand Year Old Eggs” and “One Hundred Year Old Eggs”—and rejected them all.

A mud-like coating gives these preserved eggs the appearance of having been buried in the ground for a long period of time. This coating frequently contains high levels of lead, which apparently migrates through the shell into the albumin (egg white) and then through the membrane into the yolk. Inside the egg, the lead forms a sulfide, solidifying the albumin and yolk.

The eggs were imported from China, Hong Kong, and Thailand and were sampled prior to release into the domestic marketplace. Analysis found lead levels as high as 4,000 parts per million. The levels were highest in the albumin and decreased successively towards the interior of the eggs. None of the shipments was allowed into the country because of the excessive lead content.

Also in fiscal 1980, the New York lab analyzed 34 samples of salted duck eggs from China. Residues of the pesticides DDT, DDE, TDE, and BHC were found in 12 of the samples, and those shipments were not allowed to be marketed in the United States.

Pretty Poison

“Watch for these symptoms,” a **Buffalo District** investigator advised a rather shaken man, “and if you think you have them, go to a doctor—because you may have botulism.”

The man was one of three Buffalo residents who ate anchovy-stuffed olives suspected of being contaminated with two types of *Clostridia* bacteria. The men had obtained the olives from a food warehouse in Buffalo, but laboratory analysis indicated the olives had been contaminated during processing. The processor was Luis Cabezuelo, in Seville, Spain.

FDA's **New Orleans District** discovered the problem. During import inspections, an inspector noticed that some cans of olives were swollen, indicating inadequate processing. Canned products that are underprocessed may contain *Clostridium botu-*

linum bacteria, which produce the neurotoxins responsible for botulism (a frequently fatal disease).

Analysis by the **Dallas District Microbiological Laboratory** found no botulinal bacteria but did isolate *Clostridium tetani*, another anaerobic bacterium, from one can, and the products were not allowed into the country. Ingestion of *Clostridium tetani*, the bacterium that causes tetanus (or lockjaw), can also be fatal if the bacteria get into the bloodstream through a sore in the mouth or lesion in the stomach or gastrointestinal tract.

The anchovy-stuffed olives had been offered for import under the brand name Buleria. Fearing similar processing problems with previous shipments, FDA contacted firms distributing Buleria brand olives—two in Chicago and one in Waukesha, Wisconsin—which agreed to recall earlier shipments of the products. Another brand of anchovy-stuffed olives, also processed by the Spanish firm, was distributed by the Wisconsin company and was suspected of being underprocessed. FDA issued a press release warning consumers and restaurant owners to check for cans of “Imported Spanish Manzanilla Olives Stuffed with Anchovies” with brand names Buleria and Holsum, and to return them to the place of purchase *unopened*.

Meanwhile, FDA got a list of the firms that might have received shipments of olives from the three original importers. One of these was the Buffalo firm.

Buffalo District investigators went to the firm’s warehouse, located the single shipment of Buleria olives, and found that a small part of it was missing. The investigators explained the problem and asked the warehouse to hang onto the rest of the shipment—even though none of the cans were swollen or showed other evidence of contamination. They collected samples, which were sent to the Dallas lab, and then went out to track down the rest of the shipment.

One carton was found in possession of a Buffalo man and was returned intact. However, three men had each received—and partially con-

sumed—a can of olives. Buffalo investigators listed for them the symptoms of botulinal poisoning, which appear usually 18 to 36 hours after the toxin is ingested: dizziness, double vision, heaviness of limbs, and sometimes nausea.

The Dallas microbiological lab also found *Clostridia* bacteria in the Buffalo samples, confirming that the cans were underprocessed. Also, in the Dallas heat, the cans swelled up, indicating bacterial growth (which produces a gas.)

Under supervision by Buffalo District, the firm crushed the unopened cans in a compactor and buried them in a sanitary landfill.

The three men suffered no ill effects, other than anxiety. If the olives they ate were contaminated with *Clostridium botulinum*, it may have been the cold weather that saved them. In the cold New York climate, the bacteria must have failed to produce its dangerous toxins.

People Are Talking

People are speaking up, letting their complaints be known—and are making a difference. Following are examples:

A Cincinnati resident called FDA’s **Cincinnati District** to report finding bits and pieces of insects in Pot-O-Soup Chicken Noodle Soup Mix manufactured by Kroger Co., which has its headquarters in Cincinnati. The district relayed the complaint to the firm, then monitored the recall of 1,748 cases of the products.

Three other consumers went directly to the firm—again the Kroger Co.—with another complaint: metal shavings in chunk light tuna. Company officials notified FDA that, because of the complaints, they were recalling 1,162 cases of tunafish from five company warehouses in the Southern United States, and the district again monitored the recall.

A third complaint involved infant incubators manufactured by Ohio Medical Products, Madison, Wisconsin. An employee at the firm wrote the National Cancer Institute in Bethesda, Maryland, that the company had been using asbestos gaskets in

two models of infant incubators from 1944 to 1975. The writer was concerned that the asbestos fibers might damage the infants’ lungs.

The letter ended up in FDA offices, and investigators from the **Minneapolis District** went out to the firm. They confirmed that the report was accurate and learned that the company had conducted tests to determine whether the gaskets would release asbestos fibers into the atmosphere of the incubator. Company officials told investigators that although some fibers were released, the levels were far below those prescribed by OSHA (Occupational Safety and Health Administration) as acceptable for industrial workers, and thus posed no health hazard. The firm did manufacture asbestos-free gaskets that could be used as replacements but these, the investigators reported, were not energetically promoted.

At the district’s request, the company issued a letter—endorsed by the district—to medical facilities that had bought the incubators, pointing out the hazards of asbestos fibers and explaining that replacement gaskets made with nonasbestos materials were available. After a followup inspection, investigators reported that the firm received many more requests for the replacement gaskets than it had anticipated.

Nuts

In the December 1979-January 1980 issue of FDA CONSUMER an item in *Regional Reports* (page 30, under Region IX) stated that the American Pistachio Co., New York City, had declined to have samples of brazil nuts analyzed under the U.S. Department of Agriculture’s voluntary aflatoxin testing program. This was in error. The item should have read: “FDA’s Los Angeles District detained \$29,000 worth of shelled brazil nuts from Bolivia, which the American Pistachio Co., New York City, sought to import through the Port of Los Angeles. Analysis of the samples revealed contamination by aflatoxin, and the nuts were detained.” We apologize for this error.

Seizures and Postal Service Cases

FILED SEIZURE ACTIONS

charge violations of the Federal Food, Drug, and Cosmetic Act and are initiated based upon FDA recommendations. A seizure action is commenced by the filing of a complaint in the U.S. district court where the goods are located. A U.S. marshal is then directed by the court to take possession of the goods, removing the product from commerce, until the matter is resolved.

A total of 36 actions to remove from the consumer market products charged to be violative was reported in July. These actions included 9 of foods; all involved charges concerning contamination. Others included 4 of food additives, 22 of drugs (including 3 of veterinary), and 1 of a device/*in vitro* diagnostic product.

PRODUCT, DISTRICT & DATE FILED	FIRM & PLACE OF BUSINESS	CHARGES
FOOD/Contamination, Spoilage, Insanitary Handling		
Cornmeal, corn flour, and flour/U.S. District Court for the Northern District of Alabama 5/21/80	BMB Speciality Products, Inc./Decatur, Ala.	Held under insanitary conditions; contain rodent filth.
Dog food chunks, and other dog food stocks/U.S. District Court for the Western District of Virginia 5/20/80	Jones Wholesale Co., Inc./Bristol, Va.	Held under insanitary conditions; some contain rodent filth.
Filberts/U.S. District Court for the Eastern District of New York 1/10/80	Imported from Istanbul, Turkey.	Held under insanitary conditions.
Flour/U.S. District Court for the District of Puerto Rico 5/14/80	Shipped from New York, N.Y.	Contains insect filth.
Peanuts, shelled; and sunflower seeds/U.S. District Court for the Northern District of California 6/12/80	Quality Packaging, Inc./Hayward, Calif.	Held under insanitary conditions; some rodent contaminated.
Poppysseed, sesame seeds, bulghur wheat/U.S. District Court for the Southern District of New York 4/8/80	I. Grob & Co., Inc./Bronx, N.Y.	Held under insanitary conditions; poppyseed and sesame seeds contain rodent filth.
Red pepper, ground/U.S. District Court for the Eastern District of New York 2/15/80	Old Mansion, Inc./Richmond, Va.	Contains insect fragments.
Romano cheese/U.S. District Court for the Southern District of New York 4/14/80	Imported from Thiesi, Italy.	Insect contaminated.
Whole milk, dried/U.S. District Court for the Southern District of New York 4/10/80	Shipped from Reading/Pa.	Held under insanitary conditions.
FOOD ADDITIVES		
Bowls, agatized, wood/U.S. District Court for the Central District of California 6/13/80	Ellingers Agatized Wood, Inc./Sheboygan, Wis.	Contains the nonconforming food additive phenolic resin.
Calcium pangamate combination tablets, and apricot kernels/U.S. District Court for the Middle District of Florida 5/7/80	Synergy Plus/Union, N.J.; FoodScience Labs/South Burlington, Vt.; Earth Products/Marina Del Ray, Calif.	Calcium pangamate combination tablets contain the nonconforming food additive calcium pangamate and labeling fails to bear names of ingredients. Apricot kernels contain the poisonous or deleterious substance hydrocyanic acid (hydrogen cyanide) in such quantity as might render it injurious to health, and are accordingly unfit for food.
Mistletoe powder, mistletoe capsules, and mistletoe combination capsules/U.S. District Court for the Eastern District of Washington 4/25/80	J & P Industries, Inc., t/a Red Apple Herbs/Wenatchee, Wash.	Contain the nonconforming food additive mistletoe.
Tonic water/U.S. District Court for the District of New Jersey 6/3/80	Boller Beverages, Inc./Elizabeth, N.J.	Contains the food additive quinine in excess of 83 parts per million (ppm) quinine.
DRUGS/Human Use		
Allopurinol tablets/U.S. District Court for the Southern District of Florida 2/12/80	Premo Pharmaceutical Laboratories, Inc./South Hackensack, N.J.	New drug without an effective approved New Drug Application.
Allopurinol tablets, and other specified drugs/U.S. District Court for the Southern District of Florida 2/12/80	Pharmadyne Laboratories, Inc./Elmwood Park, N.J.	New drugs without effective approved New Drug Applications.
Allopurinol tablets, prochlorperazine capsules, and hydroxyzine HCl tablets/U.S. District Court for the Southern District of Florida 2/12/80	"	"

PRODUCT, DISTRICT & DATE FILED	FIRM & PLACE OF BUSINESS	CHARGES
Betamethasone valerate cream 0.1%/U.S. District Court for the Southern District of Florida 2/12/80	Clay Park Laboratories, Inc./Bronx, N.Y.	New drugs without effective approved New Drug Applications.
Chlorpropamide tablets/U.S. District Court for the Southern District of Florida 5/12/80	Chelsea Labs Inc./Inwood, N.Y.	New drug without an effective approved New Drug Application.
Chlorthalidone tablets, doxine tablets, hydroxyzine HCl tablets, hydroxyzine pamoate capsules, and betamethasone valerate cream/U.S. District Court for the Eastern District of N.Y. 1/24/80	Premo Pharmaceutical Laboratories, Inc./South Hackensack, N.J.	New drugs without effective approved New Drug Applications.
Chlorthalidone tablets, hydroxyzine hydrochloride tablets, allopurinol tablets, diethylpropion HCl tablets, doxylamine succinate with B ₆ tablets, furosemide tablets, hydroxyzine pamoate capsules, and trimethoprim with sulfamethoxazole tablets/U.S. District Court for the Eastern District of New York 1/24/80	Pharmadyne Laboratories, Inc./Elmwood Park, N.J.	"
Chlorthalidone tablets, hydroxyzine HCl tablets, allopurinol tablets, furosemide tablets, hydroxyzine pamoate capsules, and trimethoprim with sulfamethoxazole tablets/U.S. District Court for the Middle District of Florida 2/8/80	"	"
Chlorthalidone tablets, and other specified drugs/U.S. District Court for the Middle District of Florida 2/12/80	"	"
Chlorthalidone tablets/U.S. District Court for the Southern District of Florida 4/8/80	"	"
Chlorthalidone tablets, and other specified drugs/U.S. District Court for the Southern District of Florida 5/1/80	"	"
Dioctyl sodium sulfosuccinate with casanthranol/U.S. District Court for the Western District of Kentucky 6/19/80	Pharmacaps, Inc./Elizabeth, N.J.	Manufacture not in conformity with current good manufacturing practice.
Doxine doxylamine succinate with pyridoxine HCl tablets, and hydroxyzine HCl tablets/U.S. District Court for the District of Arizona 3/17/80	Premo Pharmaceutical Laboratories, Inc./South Hackensack, N.J.	New drugs without effective approved New Drug Applications.
Furosemide tablets, hydroxyzine hydrochloride tablets, prochlorperazine capsules, hydroxyzine pamoate capsules, allopurinol tablets, diethylpropion hydrochloride tablets, chlorpropamide tablets, and trimethoprim with sulfamethoxazole tablets/U.S. District Court for the Eastern District of New York 4/16/80	Pharmadyne Laboratories, Inc./Elmwood Park, N.J.	"
Hydroxyzine HCl tablets, diethylpropion tablets, prochlorperazine capsules, hydroxyzine pamoate capsules, spironolactone with hydrochlorothiazide tablets, trimethoprim with sulfamethoxazole tablets, and chlorothiazide with reserpine tablets/U.S. District Court for the Eastern District of New York 2/6/80	"	"
Hydroxyzine hydrochloride tablets/U.S. District Court for the Southern District of Florida 2/12/80	Premo Pharmaceutical Laboratories, Inc./South Hackensack, N.J.	New drug without an effective approved New Drug Application.
Hydroxyzine hydrochloride tablets/U.S. District Court for the Southern District of Florida 2/12/80	Bolar Pharmaceutical Co., Inc./Copiague, N.Y.	"
Metronidazole tablets, and other specified drugs/U.S. District Court for the Southern District of California 5/9/80	Pharmadyne Laboratories, Inc./Elmwood Park, N.J.	"
Trimethoprim with sulfamethoxazole tablets, and other specified drugs/U.S. District Court for the Southern District of Florida 2/12/80	"	"

PRODUCT, DISTRICT & DATE FILED

FIRM & PLACE OF BUSINESS

CHARGES

DRUGS/Veterinary

DES implants for calves and steers/U.S. District Court for the Southern District of Texas 6/18/80	Cattle Feeders, Inc./Goliad, Tex.	New animal drug and no effective approved New Animal Drug Application in effect with respect to its use and intended use.
Foot rot ointment, Skin Ease, Cutibalm, and other veterinary drugs/U.S. District Court for the Southern District of New York 6/23/80	Goshen Laboratories, Inc./Goshen, N.Y.	Manufacture not in conformity with current good manufacturing practice. Some drugs are new animal drugs and no New Animal Drug Applications are in effect with respect to their use and intended use.
Wound powder, and scarlet oil/U.S. District Court for the Northern District of Iowa 5/12/80	Fort Dodge Laboratories, Inc./Fort Dodge, Iowa	New animal drugs and no New Animal Drug Application are in effect with respect to their use or intended use.

DEVICE/*In Vitro* Diagnostic Product

Calf serum for <i>in vitro</i> diagnosis/U.S. District Court for the District of Maryland 5/8/80	B & B Research Laboratories, Inc./Baltimore, Md.	Labeling is false and misleading as testing of product for mycoplasma and virus is dangerous to health when used in the manner suggested in labeling. Quality falls below its represented quality due to presence of protein precipitate. Circumstances of manufacture, packaging, and storage not in conformity with current good manufacturing practice.
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U.S. POSTAL SERVICE actions taken in medical cases as authorized in the Mail Fraud Statute (18 U.S.C. 1341) and/or the False Representation Statute (39 U.S.C. 3005) as reported by the Chief Postal Inspector.

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

- February 15, 1980: **Bettervision Eye Clinic**, Pacific Bldg., 16th & Jefferson, Oakland, California. Advertising and sale through the mail of the product "The Bates Method Eye Exercise Program," representing the ability to improve eyesight with eye exercises.
- February 15, 1980: **Nail Builder**, P.O. Box 9669, Atlanta, Georgia. Advertising and sale through the mail of the product "Liquid Protein for the Nails," representing the ability to "make the nail stronger and is adding the needed protein that stops cracking and splitting."
- February 26, 1980: **Quest Research**, P.O. Box 9669, Atlanta, Georgia. Advertising and sale through the mail of the product "Calorie Eliminator," representing the ability to "burn off more fat than if you ran 98 miles a week! Up to a full size smaller in just 5 days."
- March 11, 1980: **Casino de Nasis**, 256 S. Robertson, Beverly Hills, California. Advertising and sale through the mail of the product "Stamina Stay Hard," representing the ability to "increase the size of the penis with extra inches."
- April 4, 1980: **Indian Herb Co.**, 7907 S. Paulina, Chicago, Illinois. Advertising and sale through the mail of the product "Yelstrap." The product states in part, "it helps clean the kidney tracts of filth, waste, etc. Prevents getting up at nights, tried and approved by many, perfected by an old Indian Chief. It is also known to remove the slime, etc., that has accumulated in the kidneys and tract for years."
- May 13, 1980: **Indian Herb Co.**, 7907 S. Paulina, Chicago, Illinois. Advertising and sale through the mail of the product "Rheumatism Root." The ad states in part, "according to Botanical Guide & Reference Book, it is used in chronic rheumatism, dropsy and nervous afflictions, spasms, cramps, etc. Also, it is used as a gargle in diseases of the throat and indolent ulcers."
- May 28, 1980: **Cambridge Diet**, Garden Road, Monterey, California. Advertising and sale through the mail of the product "Cambridge Diet," representing the ability "to rapidly shed your excess pounds and actually lose up to 6 pounds in 48 hours."

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

- January 29, 1980: Against **Head Start**, P.O. Box 10064, Atlanta, Georgia. Satisfactory evidence was presented to the Postal Service that Head Start and their agents are engaged in conducting a scheme or device to obtain money by means of false representation. This firm was advertising the product "Vitamins for Nails." The ad stated in part "The facts, as you might guess, revealed that the better the diet the better the nail growth. Among important minerals, researchers found calcium, zinc, and manganese to be the most crucial to healthy nail development. Special vitamins and special minerals. Not in ordinary vitamin pills. Eleven ingredients in all have been put in one easy to take capsule, and when these nutrients were added to the diets of women who could not grow healthy nails, their nails grew like they never had before."
- February 14, 1980: Against **Zeldcoe**, Box 11155, Santa Ana, California. Satisfactory evidence was presented to the Postal Service that Zeldcoe and their representatives are engaged in conducting a scheme or device to obtain money through the mails by means of false representation with respect to the sale of the Health Restorer. The product guarantees to get rid of body pain with no medicine.
- February 22, 1980: Against **E.R.R. (E. R. Renner)**, P.O. Box 344, Cleveland, Texas. Satisfactory evidence was presented to the Postal Service that E.R.R. and their agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product "Salvation for Arthritis," representing the ability to cure arthritis.
- March 13, 1980: Against **Bettervision Eye Clinic**, Pacific Bldg., and 16th & Jefferson, Oakland, California. Satisfactory evidence was presented to the Postal Service that Bettervision Eye Clinic and their representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the Bates Method Eye Exercise Program. It states in part, "eye exercises that can safely correct most cases of poor eyesight so that glasses or contact lenses are no longer needed. It corrects poor eyesight by strengthening the eye muscles and relaxing the eyeball."

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Cashews, at Minneapolis, Dist. Minn.

Charged 8-1-79: while held for sale, the article contained insect filth; 402(a)(3). Consent decree authorized release to Hollander Trading Corp., New York, N.Y., for salvaging. (F.D.C. No. 62391; S. No. 79-203-089; N.J. No. 1)

Flour, at Las Vegas, Dist. Nev.

Charged 11-19-79: while held for sale in railcars, the article contained insects and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Union Pacific Railroad Co., Las Vegas, Nev., for salvaging. (F.D.C. No. 62681; S. No. 80-179-913; N.J. No. 2)

Flour, at Reno, Dist. Nev.

Charged 11-6-79: while held for sale, 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. 62677; S. No. 80-180-266; N.J. No. 3)

Flour, beans, animal feed, and other foodstocks, at Salisbury, M. Dist. N.C.

Charged 12-27-79: while held by Thomas & Howard Co., Inc., Salisbury, N.C., certain of the articles contained rodent and/or insect filth, and all of the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 62738; S. No. 80-164-322 et al.; N.J. No. 4)

Flour, and textured vegetable protein, at Rio Piedras, Dist. P.R.

Charged 4-3-79: while held by Productos Cuquis, Rio Piedras, P.R., the articles contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 62231; S. Nos. 79-157-743/5; N.J. No. 5)

Flours, special-blending, high-gluten, and whole-wheat, at Louisville, W. Dist. Ky.

Charged 8-23-79: while held by Linker Brothers Bakery Co., Inc., Louisville, Ky., the high-gluten flour contained rodent and insect filth, and all of the flours had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 62404; S. No. 79-131-927; N.J. No. 6)

Flours, all-purpose, and bread flour, at Columbia, Dist. S.C.

Charged 11-23-79, amended 12-12-79: while held by Munford, Inc., Columbia, S.C., the all-purpose flour contained rodent filth, and all of the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 62643; S. Nos. 79-229-623/5 et al.; N.J. No. 7)

Gelatin, ground, at Jersey City, Dist. N.J.

Charged 4-24-79: while held by Importers Service Corp., Jersey City, N.J., the article contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Burtonite Co., Nutley, N.J., for conversion into glue. Subsequently, the claimant decided against such conversion into glue, and a consent decree ordered the article destroyed. (F.D.C. No. 62262; S. No. 79-207-483; N.J. No. 8)

Mushroom stems and pieces, canned, Tiroo, at Miami, S. Dist. Fla.

Charged 9-14-79: when shipped by Industrias Internacionales De Alimentos, S.A., Santo Domingo, Dominican Republic, the article

was contained in swollen and leaking cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 62452; S. No. 79-141-151; N.J. No. 9)

Orange juice, canned, at Sioux Falls, Dist. S. Dak.

Charged 8-14-79: while held for sale, the article contained decomposed orange juice and was contained in swollen and leaking cans; 402(a)(3). Consent decree authorized release to Ben Hill Griffin, Inc., Frostproof, Fla., for salvaging. (F.D.C. No. 62401; S. Nos. 79-196-137/8; N.J. No. 10)

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

Charged 12-28-79: while held for sale, the article had been held under insanitary conditions; 402(a)(4). Consent decree authorized release to Standard Importing Co., Inc., New York, N.Y., for salvaging. (F.D.C. No. 62687; S. No. 80-161-996; N.J. No. 11)

Peppers, chiltepinas, at Phoenix, Dist. Ariz.

Charged 9-12-78: while held for sale, the article had been held under insanitary conditions at the plant of Bernard Peralta Co., Phoenix, Ariz.; 402(a)(4). The article was claimed by Bernard Peralta Co., Phoenix, Ariz., who denied the charge. The Government moved for summary judgment. The court granted the Government's motion for summary judgment and ordered the article destroyed. (F.D.C. No. 61880; S. No. 78-127-536; N.J. No. 12)

Rice, and pinto beans, at Chicago, N. Dist. Ill.

Charged 1-19-79: while held for sale by La Preferida, Inc., Chicago, Ill., the articles contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. Following the dealer's unsuccessful attempt to recondition the rice, the dealer withdrew and the decree was amended to substitute Producers Rice Mill, Inc., Stuttgart, Ark., as claimant. (F.D.C. No. 62110; S. No. 79-177-581; N.J. No. 13)

Rice, and salted codfish, at Aguada, Dist. P.R.

Charged 3-14-78: while held by Irma Hernandez, Inc., Aguada, P.R., the articles contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61659; S. Nos. 78-147-637/8; N.J. No. 14)

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

Charged 8-2-79: while held for sale, the article contained decomposed fish; 402(a)(3). Consent decree authorized release to Dressel-Pacific Inc., Anchorage, Alaska, for salvaging. (F.D.C. No. 62397; S. No. 79-176-600; N.J. No. 15)

Salmon, dressed, frozen, 4 seizure actions, at Seattle, W. Dist. Wash.

Charged 8-24-79, 8-2-79, 8-29-79, and 10-9-79: while held for sale, the articles contained decomposed fish; 402(a)(3). Default decrees ordered destruction. (F.D.C. Nos. 62379, 62400, 62435, 62542; S. Nos. 79-212-033, 79-212-101, 79-212-409, 79-176-845; N.J. No. 16)

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

Charged 9-6-79: while held for sale, the article contained decomposed fish; 402(a)(3). Consent decree authorized release to Trans Asiatic, Inc., King Salmon, Alaska, for salvaging. (F.D.C. No. 62439; S. No. 79-212-405; N.J. No. 17)

Shrimp, frozen, at Boston, Dist. Mass.

Charged 9-21-79: when shipped by Mitsubishi Corp., Tokyo, Japan, the article, labeled in part, "Summit Quick Frozen Shrimp Processed and Packed by Suvarndurg Fisheries, Harnai . . . Product of India," contained insect filth and had been prepared, packed, or held under

insanitary conditions; 402 (a) (3), 402 (a) (4). Default decree ordered destruction. (F.D.C. No. 62455; S. No. 79-196-872; N.J. No. 18)

Sugar, macaroni products, salt, beans, spices, and other foodstocks, at Baltimore, Dist. Md.

Charged 4-25-80: while held by Pastore's Wholesale Grocers, Baltimore, Md., two lots of macaroni products contained rodent filth, and all of the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 62847; S. No. 80-232-503 et al.; N.J. No. 19)

Valerian root, yohimbe bark, fennel seed, and other herb barks, stems, roots, and powders, at Philadelphia, E. Dist. Pa.

Charged 5-25-78: while held by Penn Herb. Co., Ltd., Philadelphia, Pa., those articles which were foods had been held under insanitary conditions—402(a)(4); the articles which were drugs had been held under insanitary conditions—501(a)(2)(A); and one lot of yohimbe contained rodent filth—501(a)(1). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61779; S. No. 78-143-907; N.J. No. 20)

FOOD/Economic and Labeling Violations

Buffalo meat and vegetable protein combination patties, dried, at York, Dist. Nebr.

Charged 10-3-77: when shipped by Smokey's Smokehouse, Spanish Fork, Utah, the article, some jars of which were unlabeled and some labeled in part "Buffalo Jerky . . . Grumpy's Buffalo Chips . . . Grumpy's Buffalo Jerky Co., York, Nebraska . . . Ingredients . . . sodium nitrates, sodium nitrite," the article contained the nonconforming food additives sodium nitrate and sodium nitrite—402(a)(2)(C); while held by Grumpy's Buffalo Jerky Co. (Robert Nielsen), York, Nebr., who was labeling the article, certain plant proteins (i.e., textured vegetable protein and hydrolyzed vegetable protein) as well as water and monosodium glutamate had been substituted in part for buffalo (bison) meat—402(b)(2); the names "Buffalo Jerky" and "Buffalo Chips" are not the common or usual names for a product composed of buffalo meat (bison), water, plant proteins, preservatives, and other ingredients (which were ground and chopped into round patties)—403(i)(1).

The articles were claimed by the dealer who denied the charges and filed a motion for a preliminary injunction against the Government. The Government moved for summary judgment, and the claimant also moved for summary judgment. The parties entered into a stipulation of facts and, following a hearing, submitted the matter for determination.

The court found for the Government saying:

"The United States of America brought this action seeking to condemn certain food substances pursuant to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Sec. 301, et seq. (hereafter referred to as 'the Act'). The United States Marshal seized the substances identified in the complaint and the owner intervened to file a claim for return thereof. Each party filed a motion for summary judgment, the parties entered into a stipulation of facts . . . and the matter has been submitted for determination following a hearing.

"At issue is a food substance made from the following ingredients: buffalo (bison) meat, textured vegetable protein, hydrolyzed vegetable protein, salt, spices, flavoring, sodium erythorbate, sodium nitrate, sodium nitrite, potassium sorbate, water, and monosodium glutamate . . . These ingredients are combined into dark brown patties of meat packaged in jars and labeled as set out at Paragraph 3 of the stipulation.

"The government seeks to have these food substances condemned . . . The parties have by their stipulation agreed that this court has jurisdiction over the instant action, that the food substances at issue are 'articles of food' within the purview of 21 U.S.C. Sec. 334, and in effect, that the food substances have been shipped in interstate commerce in their present condition. The questions presented for

determination on summary judgment are whether the food substances are adulterated or misbranded within the meaning of the Act.

"The government contends that the food items are adulterated within the meaning of 21 U.S.C. Sec. 342(a)(2)(C) because they contain sodium nitrate and sodium nitrite; that the food items are adulterated within the meaning of 21 U.S.C. Sec. 342(b)(2) because certain plant proteins have been substituted in part for the principal ingredient—bison meat; and that the food items are misbranded within the meaning of 21 U.S.C. Sec. 343(i)(1). The government must prevail on at least one of these allegations to permit the condemnation.

"The government contends that the food substance at issue is adulterated within the meaning of 21 U.S.C. Sec. 342(a)(2)(C) . . .

"In determining whether the food substance at issue is adulterated within the meaning of 21 U.S.C. Sec. 342(a)(2)(C), the court must first determine whether the food substance contained a 'food additive' within the meaning of 21 U.S.C. Sec. 321(s). The definition of 'food additive' consists of two elements: (a) the substance must become a component or otherwise affect the characteristics of the food and (b) the substance must lack general recognition among experts as being safe under the conditions of its intended use. The parties have stipulated that the food substance does contain as component parts the items sodium nitrate and sodium nitrite. The affidavits submitted by the government adequately support the conclusion that the use of sodium nitrate and sodium nitrite in conjunction with processing bison meat is not generally recognized among experts as being safe. While the claimant points to other uses of sodium nitrate and sodium nitrite which have been recognized as being safe, these examples are not comparable to the use in this case and so do not refute the government's showing or raise a factual dispute as to whether the use of these products in bison meat is generally recognized as safe. Accordingly, the court finds that both elements of the definition of food additives have been met.

"The claimant contends that these substances are approved for use under the Federal Meat Inspection Act, thus exempting them from the definition of food additives contained in 21 U.S.C. Sec. 321(s) and precluding a determination that the product is adulterated within the meaning of 21 U.S.C. Sec. 342(a)(2)(C). The government responds that this exception is inapplicable since the Meat Inspection Act applies only to meat food products which are defined by 21 U.S.C. Sec. 601(j), . . . Contrary to claimant's assertion that only added substance and not the meat to which it is added must be subject to the Meat Inspection Act, the exemption contained in 21 U.S.C. Sec. 321(s) provides that the use must be 'in accordance with a sanction or approval granted pursuant to the Meat Inspection Act'. The approval relied on by claimant is found at 9 C.F.R. Sec. 318.7(c)(1), which provides in part: '. . . the following substances may be added to products: common salt, approved sugars . . . sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite . . .' 'Products' as used in this regulation are defined at 9 C.F.R. Sec. 301.2(w) as 'Any carcass, meat, meat byproduct, or meat food product, capable of use as human food.' The terms 'carcass', 'meat', 'meat byproduct', and 'meat food product' all are defined at 9 C.F.R. Sec. 301(a)(ss) through (vv) in terms of cattle, sheep, swine, goats (sic) and equines only. Thus the issue is whether bison meat is within the purview of the Meat Inspection Act when the term is not specifically included. Only if it is will the use of sodium nitrate and sodium nitrite here be 'in accordance with a sanction or approval granted pursuant to the Meat Inspection Act.'

"The parties have referred the court to no reported cases regarding the applicability of the Meat Inspection Act to buffalo meat. An early Missouri case, *State v. Crenshaw*, 22 Mo. 457 (1856), does stand for the proposition that buffalo, although domesticated, are not cattle within the meaning of a statute making it a crime to 'wilfully and maliciously kill, wound or maim any cattle of another.' As the policies underlying the Missouri criminal statutes and the Meat Inspection Act are quite different, we do not consider this case to be controlling. We, therefore, turn to the purpose and the language of the Federal Meat

Inspection Act to resolve the issue.

"The Meat Inspection Act is, by its very terms, designed to protect the health and welfare of consumers: 'by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.' 21 U.S.C. Sec. 602. As such the Meat Inspection Act is not intended to derogate from any authority conferred by the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. Sec. 679. Rather, the Meat Inspection Act creates a separate area of concern—meat and meat byproducts for human consumption—over which the Department of Agriculture is given additional powers in the interest of protecting the public health and welfare.

"The Meat Inspection Act specifically delineates the food products subject to its provisions, listing only foods derived from cattle, sheep, swine, goats and equines. Other food products are regulated under the Food, Drug and Cosmetic Act. In view of the safeguards of testing and regulation of ingredients set forth in the comprehensive regulations promulgated pursuant to the Food, Drug and Cosmetic Act, the court finds that food products derived from bison meat will be adequately regulated for the protection of the public health and welfare under either the Food, Drug and Cosmetic Act or the Meat Inspection Act. In the absence of a congressional determination to include bison meat within the more limited coverage of the Meat Inspection Act, this court is unwilling to judicially extend the provisions of the Meat Inspection Act to do so. Accordingly, the court finds that the government correctly seeks to apply the provisions of the Food, Drug and Cosmetic Act to the food products at issue in this case. Therefore, the exception to the definition of food additives contained in 21 U.S.C. Sec. 321(s) for substances used in accordance with a sanction or approval granted pursuant to the Meat Inspection Act is not applicable.

"Having determined that sodium nitrate and sodium nitrite are food additives within the meaning of 21 U.S.C. Sec. 342(a)(2)(C), the court now turns to the question of whether or not these additives are 'unsafe within the meaning of Section 348 of this Title.' Under the provisions of Section 348, a use is deemed to be unsafe for purposes of the Act unless an exemption is granted by the Secretary of Health, Education and Welfare upon proper application or unless the use is in accordance with a regulation prescribed by the Secretary. The language of the statute establishes a presumption that the food additives are unsafe unless one of the exceptions is established. The court has carefully examined the regulations promulgated by the Secretary but has been unable to identify any regulations which are applicable to the instant use of the food additives sodium nitrate and sodium nitrite. The claimant has failed to demonstrate either an exemption or investigative use or a regulation permitting such use. Accordingly the court finds that the claimant's use of the food additives sodium nitrate and sodium nitrite are not approved by the Secretary and, therefore, are unsafe within the meaning of Section 348 of Title 21, United States Code.

"Having determined that the food product at issue is a food which contains a food additive which is unsafe within the meaning of Section 348, the court now finds that this food product shall be deemed to be adulterated within the meaning of 21 U.S.C. Sec. 342 (a)(2)(C) and subject to seizure pursuant to 21 U.S.C. Sec. 334. As a sufficient basis exists pursuant to 21 U.S.C. Sec. 342(a)(2)(C) for the condemnation of the food products seized by the United States Marshal, this court does not address the alternative allegations of adulteration and misbranding which have been argued by the government."

The claimant appealed. In denying the claimant's appeal, the Court of Appeals said:

"In this appeal Robert Nielsen d/b/a Grumpy's Buffalo Jerky Co. seeks review and reversal of an order of the district court which concluded that the food product buffalo jerky was adulterated within the meaning of 21 U.S.C. Sec. 342 and subject to seizure pursuant to 21 U.S.C. Sec. 334 due to the fact that the product contained an unsafe 'food additive' within the meaning of 21 U.S.C. Sec. 348.

"We have carefully considered the arguments which appellant has

made, including the argument that a substance cannot be declared an unsafe 'food additive' in one context, but acceptable in another use, and the argument that the Meat Inspection Act, which approves certain uses of sodium nitrates and sodium nitrites, should be construed to include 'buffalo' meat within its terms, although buffalo is not expressly listed.

"After reading the appellant's citations of authority, and reviewing the affidavits submitted, we conclude that the district court did not err in its well-reasoned opinion and affirm on the basis of that opinion."

The claimant's petition for a writ of certiorari in the Supreme Court was denied, and the article was ordered destroyed. (F.D.C. No. 61433; S. No. 77-0-349; N.J. No. 21)

Peanut butters, smooth, and crunchy, at Dallas, N. Dist. Tex.

Charged 8-7-78: when shipped by Portales Valley Mills, Inc., Portales, N. Mex., the labels of the articles, which were labeled in part "Rivendale Natural Style Peanut Butter . . . Smooth [or "Crunchy"] Dist. By Rivendale Natural Foods, Inc., Dallas, Texas," displayed the name and place of business of the distributor and the ingredients statements inconspicuously due to their insufficient height, since such statements were less than 1/16 inch high—403(f); and the articles were also in violation of the Fair Packaging and Labeling Act, since the quantity of contents statements appearing on principal display panel areas of more than 5 square inches were in a type size less than 1/8 inch high—15 U.S.C. 1453(a)(3)(C)(i); and the quantity of contents statements were expressed as "Net Wt. 1 lb. 12 oz. (28 oz.)," instead of "Net Wt. 28 oz. (1 lb. 12 oz.)"—15 U.S.C. 1453(a)(3)(A)(i). Consent decree authorized release to Rivendale Natural Foods, Inc., Dallas, Tex., for relabeling. (F.D.C. No. 61879; S. No. 78-114-503; N.J. No. 22)

FOOD ADDITIVES

Coconut beverage concentrate, at Naguabo, Dist. P.R.

Charged 12-15-78: while held by Coco Rico, Inc., Naguabo, P.R., who manufactured the article using interstate potassium nitrate, the article, labeled in part "Extracto Concentrado . . . Coco Rico, Inc., Santurce, Puerto Rico," contained the nonconforming food additive potassium nitrate, and the article's label lacked a quantity of contents statement; 402(a)(2)(C), 403(e)(2).

The article was claimed by the manufacturer. The claimant moved for permission to ship the article to a foreign country. The Government opposed such motion and moved for summary judgment. The Government served written interrogatories on the claimant. The court denied the motions of both the claimants and the Government, saying in part:

"Claimant has now filed counter-affidavits controverting the basic facts upon which the [Government's] motion for summary judgment is based, alleging, in essence, that misrepresentations as to the nature and foreign destination of the article w[ere] never made to the government's agents, that the article is not 'unsafe' as alleged by plaintiff, and that the locally destined goods comply with all the requirements of the Food and Drug Administration.

"In view of the fact that there is controversy over material issues in fact, the Court hereby rules as follows:

1. Claimant's Motion for Permission to Ship Goods to a Foreign Country is hereby Denied.
2. Plaintiff's Motion for Summary Judgment is hereby Denied.
3. The case is hereby referred to the U.S. Magistrate for resolution of all matters dealing with discovery."

After two motions were filed by the Government to compel the claimant to answer the interrogatories, the U.S. Magistrate gave the claimant 12 days to answer the interrogatories or suffer dismissal of their claim. Ultimately, the claimant agreed that the court condemn the article and order the article's destruction. (F.D.C. No. 61920; S. No. 78-147-986; N.J. No. 23)

Rice, at Woodside, E. Dist. N.Y.

Charged 3-1-79: while held by Daiei Trading Co., Inc., Woodside, N.Y., the article contained the nonconforming food additive Dursban, and the article had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 62170; S. No. 79-161-247; N.J. No. 24)

Tea, herbal-blend, at Burbank, C. Dist. Calif.

Charged 10-31-79: while held for sale, after manufacture using interstate mistletoe leaves and stems, the article contained the nonconforming food additive mistletoe; 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 62651; S. No. 79-171-410; N.J. No. 25)

DRUGS/Human Use

Aspirin tablets, enteric-coated, at Troy, E. Dist. Mich.

Charged 3-11-80: when shipped by Tablicaps, Inc., Franklinville, N.J., the circumstances used for the article's manufacture and processing failed to conform with current good manufacturing practice—501(a)(2)(B); and the article's labeling was false and misleading as to the article's expiration dates, since the manufacturer had inadequate data to support such dates—502(a). Default decree ordered destruction. (F.D.C. No. 62730; S. Nos. 79-185-273/7; N.J. No. 26)

Betamethasone valerate cream, chlorthalidone tablets, and other specified new drugs and their components, at South Hackensack, Dist. N.J.

Charged 12-26-79: while held by Premo Pharmaceutical Laboratories, Inc., South Hackensack, N.J., who manufactured the finished drugs using various interstate components, the articles were new drugs without effective approved New Drug Applications—505(a); and the articles' labeling lacked adequate directions for use and were not exempted due to their new drug status—502(f)(1). Default decree ordered destruction. (F.D.C. No. 62733; S. No. 80-188-814 et al.; N.J. No. 27)

Chlorothiazide with reserpine tablets, furosemide tablets, diethylpropion hydrochloride tablets, hydroxyzine pamoate capsules, and trimethoprim with sulfamethoxazole tablets, at Monroe, M. Dist. Ga.

Charged 1-31-80: when shipped by Pharmadyne Laboratories, Inc., Hackensack, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). Default decree ordered destruction. (F.D.C. No. 62780; S. No. 80-208-542 et al.; N.J. No. 28)

DRUGS/Veterinary

Crown Foot-Rot Liquid, and another dichlorophene combination liquid for foot-rot and ringworm in cattle and horses, at Rockford, N. Dist. Ill.

Charged 3-5-80: when the 27-case lot of Crown Foot-Rot Liquid was shipped by Anchor Labs., St. Joseph, Mo., and while the other lots of dichlorophene combination liquid were held for sale after manufacture by Roberts Laboratories (t/a Crown Chemical Co.), Rockford, Ill., using interstate components, the articles were new animal drugs and no approval of a New Animal Drug Application was in effect with respect to their use or intended use—501(a)(5); and the circumstances used for the manufacture, processing, and holding of a 67-case lot of the liquid, manufactured by Roberts Laboratories, failed to conform with current good manufacturing practice—501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 62843; S. No. 79-177-269 et al.; N.J. No. 29)

PrimaLac "5" concentrate for livestock, at Clarksdale, W. Dist. Mo.

Charged 3-14-80: while held by Prairie States Enterprises, Inc., Clarksdale, Mo., who manufactured the article using interstate *Lactobacillus* culture, the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to its use and intended use for aiding "proper microbial balance in the intestinal tract" and for "improved efficiency"; 501(a)(5). Consent decree authorized release to the manufacturer for relabeling. (F.D.C. No. 62881; S. No. 80-184-198; N.J. No. 30)

MEDICAL DEVICES

Traceray III x-ray systems, 5 seizure actions, at Albany, N. Dist. N.Y.;

Rome, N. Dist. Ga.; Sterling Heights, E. Dist. Mich.; St. Louis, E. Dist. Mo.; and St. Louis, E. Dist. Mo.

Charged 11-16-79, 10-19-79, 10-5-79, 10-2-79, & 10-2-79: the articles, which had been manufactured by Western States Supply, Ltd., Pueblo, Colo., were dangerous to health when used as directed, because the articles would emit radiation beyond the pre-set exposure time—501(j); the accompanying labeling was false and misleading in claiming compliance with the regulations' standards, and in claiming that the devices would deliver the radiation exposure selected and in accordance with ranges stated in the instruction manual—502(a); and the articles' quality fell below their purported quality—501(c). Consent decree authorized release to the possessors for reconditioning. (F.D.C. Nos. 62459, 62484, 62504, 62506, & 62507; S. Nos. 79-107-955, 79-158-374, 79-120-713, 79-165-601, & 79-123-476; N.J. No. 31)

Transfer bags for blood, Venotrans, at Pontiac, E. Dist. Mich.

Charged 2-22-80: the article, which had been imported from Italy by Venospatial, Inc., New York, N.Y., was accompanied by letters containing false representations that FDA had approved the marketing of the article, and was labeled with outer and inner labels that lacked adequate directions for use, and was not exempted as a prescription device due to failure to state the method of use and due to failure to bear adequate information for use by licensed practitioners—502(a), 502(f)(1); the article's labeling lacked adequate warnings against unsafe use because the labeling failed to state that the article was not intended for human use—502(f)(2); and the article lacked an approved premarket notification application—502(o). Default decree ordered destruction. (F.D.C. No. 62835; S. No. 79-182-759 et al.; N.J. No. 32)

NOTICES OF JUDGMENT on Criminal Actions DRUGS

Raymond A. Biernacki (on behalf of Central Florida Research, Inc., t/a Northern Florida Research Center, Daytona Beach, Fla.), acting in S. Dist. N.Y.

Charged 10-20-78 by grand jury: that, in a matter within FDA's jurisdiction, material facts were falsified, concealed, and covered up; fictitious and fraudulent statements and representations were knowingly caused to be made and used; and false writings and documents were knowingly made and used; that, in furtherance of the above scheme, the defendant contracted and agreed with Vicks Divisions Research and Development, Mount Vernon, N.Y., to perform certain specified clinical research pursuant to the project's protocol and instructions; that the defendant represented that 120 identified subjects had been examined, tested, and observed; and he knowingly submitted final reports, patient report forms, and data sheets for persons who were in fact never examined, tested, and observed pursuant to the project's protocol and instructions; 18 U.S.C. 1001/2.

The defendant moved for dismissal of the indictment against him on the grounds that venue was improper and that the indictment was barred by the statute of limitations. In ruling for the Government, the court said:

"It is undisputed that the defendant, former owner and operator of the Northern Florida Research Center in Daytona Beach, Florida, contracted with Vicks Divisions Research and Development ('Vicks') to perform certain clinical research to test the safety and efficacy of 'NyQuil', an over-the-counter drug, and certain of its components. The test data and the final report were allegedly to be used or referred to by Vicks in its submissions to the U.S. Food and Drug Administration concerning the product in issue. Vicks is located in Mount Vernon, New York. The indictment charges that the defendant violated Title 18 U.S.C. Sections 1001 and 2 in that he unlawfully, willfully, and knowingly made false and fraudulent statements relating to the clinical tests and submitted them to Vicks.

Venue

"Section 3237(a) of Title 18 of the United States Code provides that any offense against the United States which was begun in one district and completed in another, or which was committed in more

than one district, may be prosecuted in any district in which the offense was begun, continued, or completed. In prosecutions involving false statements, venue has been construed as proper not only where the false statements or documents were prepared but also at the place where they were ultimately delivered.

"The defendant, however, contends that the crime of which he is accused was completed, if at all, when he delivered the allegedly fraudulent test results in Florida to William Burke, a Vicks officer. Burke had travelled from Mount Vernon, New York, to visit the defendant's research center in Daytona Beach, Florida. Therefore, defendant argues, since the crime was completed in Florida it would be improper to bring this indictment in New York.

"In support of this contention, defendant cites *United States v. Flaxman*, 304 F.Supp. 1301 (S.D.N.Y. 1969). There, the defendant was charged with aiding and abetting others in falsifying and misrepresenting material facts in an application for a loan to the Veterans Administration ('VA'). He filed the application with a prospective lender which was located within the venue of federal courts in the Eastern District of New York. Although federal regulations required that the lender deliver the application to the VA office in Queens County which is in the Eastern District of New York, the lender instead sent the false application to the VA office in Manhattan which is in the Southern District of New York. Apparently, the Manhattan VA's office had regularly accepted such applications in spite of federal regulations.

"Upon being indicted in the Southern District of New York rather than the Eastern District, the defendant moved for dismissal of the indictment on the ground of improper venue. The court acknowledged that the crime had not been completed until the forms had passed into the VA's office in Manhattan, *id.* at 1303, but dismissed the indictment. In dismissing the indictment, the court stated that a denial of the motion would have had the effect of denying the defendant his sixth amendment rights because of a government agency's failure to comply with its own regulations. This result would be improper particularly since the defendant had neither acquiesced in this violation of the regulations nor foreseen its occurrence. The court further noted that had the defendant caused the application to be sent to the VA's office in Manhattan, venue would have been proper in the Southern District of New York.

"Assuming for the purpose of disposing of this motion that the government's allegations are true, the Court finds that the defendant must have intended that the report be reviewed by Vicks or could have reasonably foreseen that the report could eventually be presented to Vicks' offices in Mount Vernon, New York. Thus here, the defendant was actively involved in the transmittal of the report to Vicks' offices located in the Southern District of New York, unlike the defendant in *Flaxman*. Venue is properly laid in the 'whole area through which [the] force propelled by an offender operates,' *United States v. Candella*, 487 F.2d 1223, 1228 (2d Cir. 1973) (citing *United States v. Johnson*, 323 U.S. 273 (1944)), therefore, in this instance proper venue included Mount Vernon which is within the Southern District of New York. Accordingly, the Court denies defendant's motion for dismissal of the indictment on the grounds of improper venue.

Statute of Limitations

"The Court finds that the indictment herein is not barred by the statute of limitations. Section 3282 of Title 18, United States Code, provides a five-year statute of limitations for the filing of indictments. The indictment in this action charges that the defendant made false statements to Vicks on or about October 23, 1973. If the crime was completed on that day, then the government's filing of the indictment on October 19, 1978, was timely. Defendant alleges, however, that the crime was committed, if at all, on October 12, 1973, when the reports in issue were completed. While the defendants are entitled to show at trial that all the elements of the crime were completed on October 12, 1973, resolution of this issue involves factual questions which are properly determined at a trial and not in a pre-trial motion to dismiss the indictment. . . . Accordingly, defendant's motion to dismiss the indictment on the ground that the indictment is barred by

the statute of limitations is denied."

Subsequently, the defendant pleaded guilty and was fined \$10,000 and placed on 3 years probation. (Misc. No. 465; N.J. No. 33)

Bucks County Research Institute, Inc., acting in the S. Dist. N.Y.

Charged 9-13-79: that, in a matter within FDA's jurisdiction, material facts were falsified, concealed, and covered up, fictitious and fraudulent statements and representations were knowingly made and used, and false writings and documents were knowingly made and used; that, in furtherance of the above scheme, the defendant contracted and agreed with Vicks Divisions Research and Development, Mount Vernon, N.Y., to perform certain specified clinical research; that the defendant represented that a specified physician was one of the qualified medical investigators who would conduct the examination of the study's patients; that the defendant knowingly submitted final reports and patient report forms in which the signature of such physician was forged and made without authorization; and that the defendant knowingly submitted final reports and patient report forms for work purporting to have been performed by such physician, but was, in fact, work which had been performed by an individual lacking proper qualifications and credentials; 18 U.S.C. 1001/2. Guilty plea and \$10,000 fine. (Misc. No. 465; N.J. No. 34)

James L. Fiore, Jr. (Secretary of Bucks County Research Institute, Inc., Washington Crossing, Pa.), acting in S. Dist. N.Y.

Charged 9-13-79: that the defendant unlawfully conspired to commit offense against the United States; that, as a part of the conspiracy, the defendant did the following: contracted with Vicks Divisions Research and Development, Mount Vernon, N.Y., to perform studies and clinical research concerning over-the-counter drugs, made an arrangement securing clinical research studies and projects by the direct and indirect payment of funds to a former employee of Vicks Divisions Research and Development, and made an arrangement (by such payments) to submit final reports and patient report forms that did not comply in all respects with protocol and instructions; that, as a further part and object of the conspiracy, the defendant would submit clinical confirmation and data (which might lead to the adulteration and misbranding of certain interstate over-the-counter drugs) which such employee would accept and inadequately review; that, in furtherance of the conspiracy, the defendant committed overt acts in the Southern District of New York by submitting certain final clinical study reports concerning four specified over-the-counter drugs; 18 U.S.C. 371. Guilty plea; 3 years probation and a \$1,000 fine. Special probation conditions included: payment of the fine in a lump sum; payment of the fine imposed on Bucks County Research Institute, Inc., in installments; and cessation of any role, directly or indirectly, in the operation of a medical laboratory. (Misc. No. 465; N.J. No. 35)

NOTICES OF JUDGMENT on Injunction Actions

J. B. Gottstein & Co., Inc., Barnard J. Gottstein, president, and **Douglas E. Dubois**, general manager, Anchorage, Dist. Alaska.

Charged 10-12-77 in a complaint for injunction: that the defendants had been engaged at their warehouse in Anchorage, Alaska, in holding for sale various interstate foods, including rice, sugar, flour, crackermeal, tomato juice, pepperoni, watermelons, lentils, and brown rice; that rice, crackermeal, pepperoni, and brown rice contained rodent filth; that all such foods had been held under insanitary conditions; that FDA's inspections disclosed a number of specified insanitary conditions and practices; and that the defendants had been warned of insanitary conditions and practices; 402(a)(3), 402(a)(4).

A consent decree of permanent injunction enjoined the complained of violations and enjoined any further warehousing operations (except for limited operations for 14 days or less) unless and until a number of measures were taken to assure that food was not contaminated with filth, and unless and until all foods on hand were examined and all contaminated food was destroyed or otherwise brought into compliance. (Inj. No. 807; S. No. 77-07-506 et al.; N.J. No. 36)

Clancy J. Meyer, t/a The New Health Food Store, Bellingham, W. Dist.

Wash.

Charged 9-30-77 in a complaint for injunction that the defendant had been engaged at his store in Bellingham, Wash., in receiving (after shipment in interstate commerce) labeling, and selling glandular concentrates; that FDA inspection disclosed the display of certain glandular concentrates (e.g., Dr. Kelley's Bald Mountain Pancrezyme tablets, Raw Heart tablets, Raw Brain tablets, Multi-Gland Concentrate tablets, and Mixed Gland Concentrate with bonemeal tablets); that also displayed on the store's shelves in juxtaposition to the glandular concentrates were leaflets entitled "The New Health Food Store Clinical Notes on the Effective Uses of Raw Gland Material," used as promotional literature and containing false and misleading therapeutic claims for conditions such as hypotension, edema, capillary engorgement, cerebral accidents, hypoglycemia, heart muscle functions and tone, kidney conditions, hypertension, all degenerative and debilitating diseases, serious anemias, impotency, menopause, cystic fibrosis, tuberculosis, leukemia, serious injury, blood loss, hypoadrenia, colitis, and ulcers; that such leaflets were acquired by the defendant and were periodically reproduced by him for display at his retail store to accompany the glandular concentrates; that the defendant had been warned on a number of specified occasions; that the defendant had written that he would continue to sell such articles and to use the above leaflets; that the FDA inspections had shown that the glandular concentrates' labeling (i.e., the promotional literature) contained false and misleading claims for use for diseases, since there was a lack of sound scientific knowledge that the glandular concentrates were safe and effective for their intended uses; and that the labeling of the glandular concentrates lacked adequate directions for their intended uses; 502(a), 502(f)(1).

Though the defendant denied any violations of the law and denied that raw glandular concentrates were drugs, a consent decree of permanent injunction was entered permanently enjoining a number of specified acts with respect to glandular concentrates, including the distribution of the defendant's promotional literature or substantially similar literature, or receiving, labeling, and holding for sale the glandular concentrates unless and until all promotional literature in defendant's possession containing therapeutic claims for glandular concentrates was destroyed. (Inj. No. 805; S. No. 77-71-929 et al.; N.J. No. 37)

Port of Seattle, and the port commission president, vice president, secretary, assistant secretary, port commissioner, general manager, marine terminals manager, and Terminal 20 superintendent, Seattle, W. Dist. Wash.

Charged 4-18-75 in a complaint for injunction: that the defendants operated four warehouses at Terminal 20, Seattle, Wash., and held for sale interstate food; that some of the food contained rodent and bird filth and was held under insanitary conditions; that FDA's eight inspections disclosed a number of specific insanitary conditions; that the defendants had been warned of the insanitary conditions and that, despite such warnings, continued to hold foods under the conditions charged, failed to rid the warehouses of pests, failed to make necessary reports, and failed to rid the warehouses of spilled foods and debris attractive to rodents, insects, and birds; 402(a)(3), 402(a)(4).

The court denied a motion for a preliminary injunction, saying:

"The Food and Drug Administration here seeks a preliminary injunction directed against the Port of Seattle in connection with the storage of food and food products at certain warehouses maintained and operated by the Port of Seattle. The motion of the government for preliminary injunction was first heard by this Court on May 5, 1975. The hearing was continued until May 30, 1975, in order that the Court might consider what, if any, steps had been taken by the Port to correct the conditions of which the government complained in seeking a preliminary injunction. On May 30, 1975, the Court considered additional affidavits filed by the government and by the Port, listened to further argument of counsel, and then went with counsel and with representatives of the Food and Drug Administration and of the Port to view the warehouses complained of.

"In light of the affidavits filed by the government the Court had

expected to find old, ill-kept and poorly-maintained warehousing facilities. To the contrary the Court found modern facilities which gave every appearance of being very well maintained.

"To the Court's untutored eyes there was no physical condition which was in obvious need of correction.

"The Court saw much evidence of efforts taken by the Port to minimize bird and rodent intrusion. The Court observed that many areas were screened; many rodent traps and bait boxes were in place; white lanes had been painted along the perimeter of the warehouses to mark off the areas upon which materials were not to be stowed; and many spaces which might potentially harbor rodents had been filled with concrete. The Port has recently adopted a comprehensive sanitation program for Terminal 20 and has retained an independent sanitation consultant for the express purpose of consulting with and advising the Port as to means of minimizing bird and rodent intrusion. Since May 5, 1975, the Port has spent approximately \$39,000 in furtherance of sanitation program activities at Terminal 20.

"By closing the warehouse doors, keeping them closed, sealing up all spaces around the doors, and stopping the movement of cargo into and out of the warehouse, defendants might be able to prevent the intrusion of a single bird or rodent into the warehouses. These measures would at the same time effectively shut down the use of those warehouses for their intended purpose of storing cargo.

"The government seeks a preliminary injunction from this Court restraining the defendants from placing any articles of food in defendants' warehouses T-3, T-5, W-1 and W-3 at Terminal 20 unless and until defendants have taken certain measures that 'will assure' that said articles are not contaminated by rodents, insects, or birds. In the Court's opinion the words 'will assure' require that measures be adopted which will unfailingly prevent contamination by rodents, insects or birds.

"The Court is unwilling to grant such an injunction until it has heard evidence that there are means available to defendants which will unfailingly assure that there can be no bird, insect or rodent intrusion into any one of the warehouses.

"Under the terms of the preliminary injunction proposed by the government, defendants could be held in contempt of the Court's order if a single bird or insect or mouse entered one of the defendants' warehouses and contaminated foodstuff stored in that facility.

"This Court is unwilling to issue an injunction, either preliminary or final, in this cause which is broader than the Court would be prepared to enforce by contempt proceedings. The injunction sought by the government cannot be granted in the absence of testimony as to the feasibility of measures, available to defendants, which will attain the perfection sought by the government. Accordingly, the motion by the plaintiff for a preliminary injunction is denied."

Subsequent FDA inspections found no conditions that would warrant injunctive relief. Accordingly, upon stipulation of the parties, the action was dismissed without prejudice and without assessment of costs to either party. (Inj. No. 696; S. No. 20-662 H et al.; N.J. No. 38)

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, HHS.

Published by direction of the Secretary of Health and Human Services.

Jere E. Goyan, *Commissioner of Food and Drugs*
Washington, D.C., October 1, 1980

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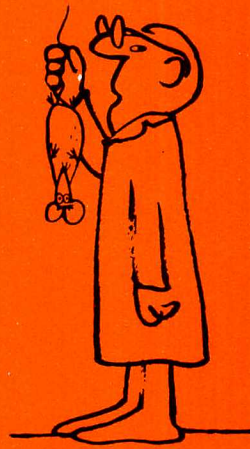
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