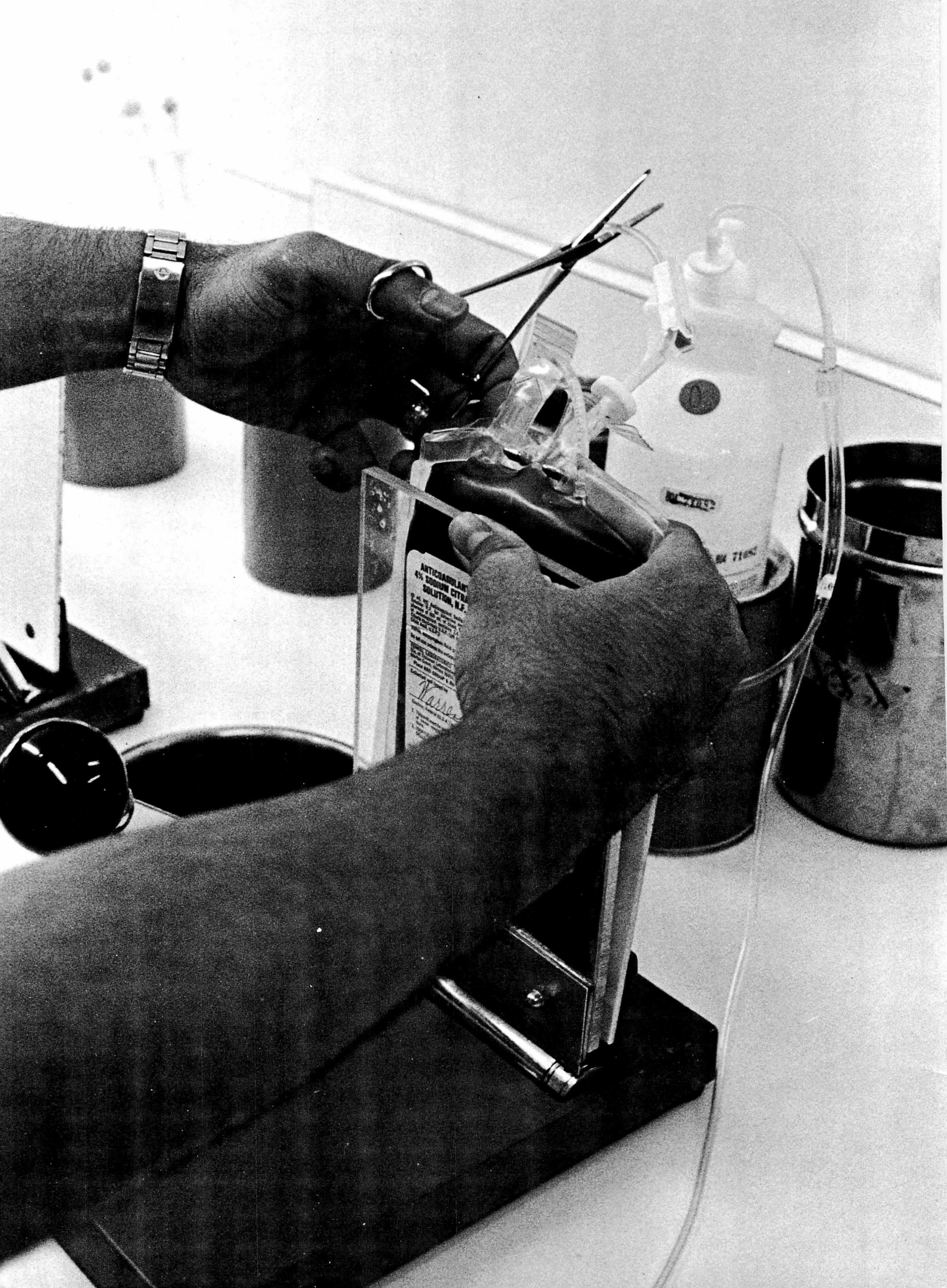


# **FDA** **CONSUMER**

DEC. 1975—JAN. 1976

## **Metric Measures And The Consumer**





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## This Month

**“H**abit is habit,” Mark Twain said, “and not to be flung out of the window by any man, but coaxed downstairs a step at a time.” Twain’s observation surely applies to our system of weights and measures. Ounces and pounds, quarts and gallons, and feet, yards, and miles aren’t going to be shucked off overnight in favor of grams, liters, and meters. But metric is coming—a step at a time. And once consumers learn to live with it, they may find they like it.

Metric advocates contend that familiarity—or habit—is about all our present system has to recommend it. They argue that the present system is difficult, if not downright irrational, because the units and sub-units of our basic measures seem to have been selected at random. The metric system, on the other hand, is based on units that divide rather neatly into smaller units, or build into larger ones, merely by multiplying or dividing by 10. There’s more on metric, and what it will mean for consumers, on page 20.

The metric system won’t change the way we count our money, of course. But a new program developed by the Department of Health, Education, and Welfare may change the amount of money consumers and taxpayers spend for certain prescription drugs. The idea is that if there is more than one brand of a certain drug, and the various brands are equally effective, the Federal Government will establish a maximum price that it will pay for that drug under its Medicare and Medicaid programs. In turn, this should help in *Holding Down Prescription Drug Costs* for all consumers, as we try to make clear beginning on page 8.

When it comes to consumer protection, minute measurements can take on enormous importance. If the issue is the possibility of vinyl chloride migrating from plastic packaging material into food, discovery of a few parts per million—or even billion—can be cause for concern and regulatory action. Just such findings, coupled with the knowledge that vinyl chloride has the potential to cause cancer, led FDA to propose a ban on certain food packaging made from vinyl chloride. The story on why FDA acted on polyvinyl chloride leads off this issue.

**Inside Front Cover Photo:** *An employee at a plasmapheresis center prepares to remove a bag of red blood cells from an extracting device after the plasma has been drawn off. For a report on how conditions at plasmapheresis centers have improved under FDA regulation, turn to page 11.*

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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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**Cover Design:** Jack Lefkowitz



# Consumer Forum

## Chiropractic Treatment

It was very appalling for me to read the article published in the October FDA CONSUMER on chiropractic x rays. I worked in a chiropractic clinic for 15 years and the wonderful results that patients received was glorifying. Patients would be carried in, as they were unable to walk due to back problems, and then to see them walk out was amazing.

If more people would consult with chiropractors instead of being overloaded with drugs, etc., how much better off people would be healthwise.

Articles such as the one in your October issue are very disturbing, especially when chiropractic does so much. I bet you editors have never received chiropractic adjustments and so how would you know the benefits?

C. Arnett  
Layton, Utah

*The October FDA CONSUMER published a letter from a physician questioning the use of full-spine x rays by chiropractors and a response giving FDA's position on this matter. The response pointed out that chiropractors, along with other groups licensed by the States to use x rays, are included in a wide-ranging FDA program aimed at reducing unnecessary exposure to radiation from diagnostic x rays. The response noted that "FDA does not have authority to determine the scientific validity or medical usefulness of chiropractic," and the response did not state or imply that FDA either endorses or condemns chiropractic treatment.*

## Aflatoxin and Peanut Butter

I'm writing as an individual connected with the peanut butter industry for many years and in regard to your "Consumer Forum" on page 3 of the FDA CONSUMER for September 1975.

The editorial stated the previous CONSUMER article on aflatoxin in peanut butter was misleading. Your statement to clarify the misleading article is also misleading. In fact you tend to indicate that aflatoxin in the samples of the five largest peanut butter firms were

negative "by chance" and beware since you wouldn't guarantee the peanut butter free of aflatoxin.

Now Shari Malamut feels that aflatoxin is present in the other five brands and probably in the five largest brands some of the time.

If you don't have any facts to publish, don't imply.

E. N. Henney  
Moraga, California

*The September issue of FDA CONSUMER published a letter from Shari Malamut asking about a newspaper article (not a previous FDA CONSUMER article) on aflatoxin in peanut butter. Ms. Malamut's letter said that the newspaper article "quotes FDA as saying that according to a survey made in 1973 five of the ten major peanut butter manufacturers produce aflatoxin-free products." Our response pointed out that the survey referred to in the article was a single sampling program, and such a sampling "does not guarantee that all lots produced by the same manufacturers will be aflatoxin free." We might add that FDA does not approve, endorse, or guarantee any food product.*

## Medicare and X Rays

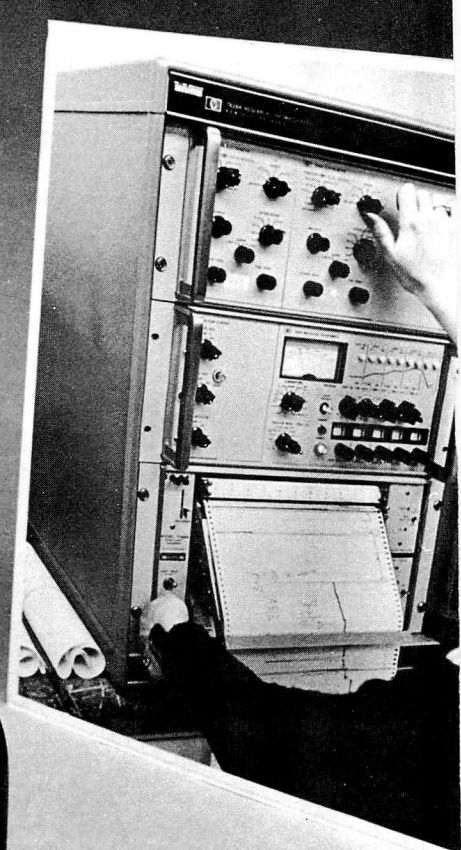
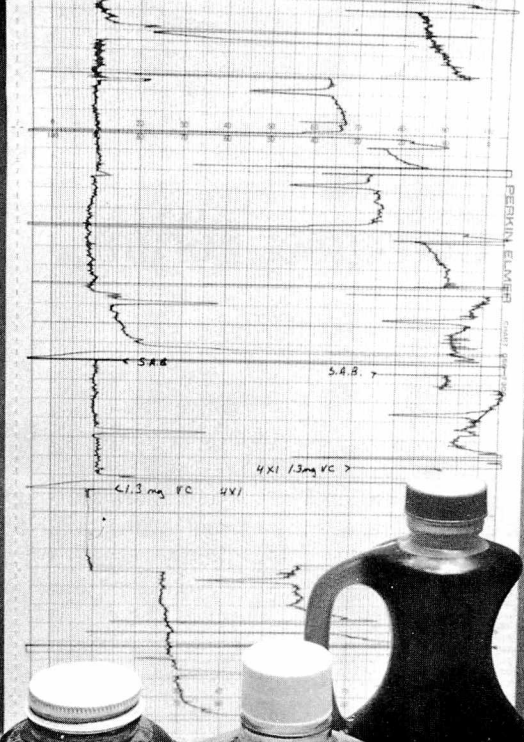
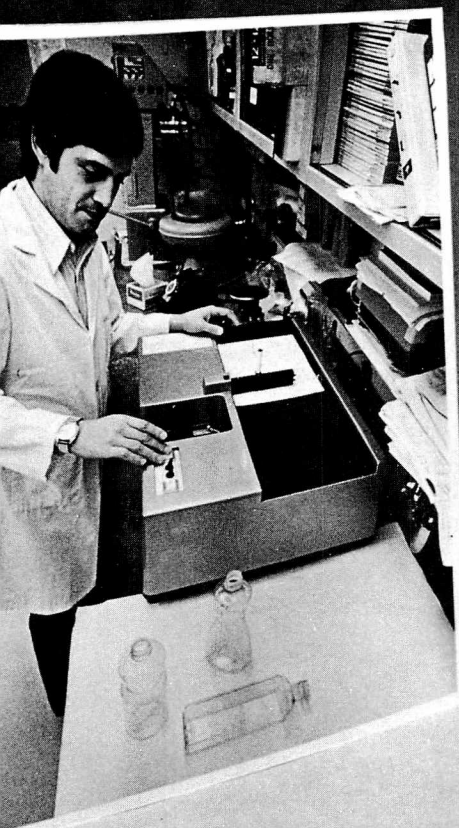
After reading the October FDA CONSUMER (page 3) I would like to add a comment to the discussion of chiropractic x rays.

Following a fall that affected my back, I have been taking a series of chiropractic treatments (my first experience) which appear to be helpful.

When I inquired about Medicare, I was told that patients of a chiropractic doctor could apply for this only if an x ray were taken. If this is true, it would seem that patients eligible for Medicare are being pushed into spinal x rays.

Charlotte Montgomery  
Westfield, N.J.

*The Medicare law permits payment for chiropractic treatment "only with respect to treatment by manual manipulation of the spine (to correct a subluxation demonstrated by x ray to exist). . . ."*



# Polyvinyl Chloride: Why FDA Acted

*FDA has proposed to ban certain food packaging made from vinyl chloride. The proposal is based on recent discoveries that vinyl chloride can migrate from the package material into the food, and that it has the potential to cause cancer.*

by Wayne L. Pines

Vinyl chloride, a major component of the widely-used food packaging material polyvinyl chloride, has joined the small but growing list of chemicals about which new scientific evidence has raised questions of safety. The list is growing as scientists refine their ability to detect minute quantities of chemicals, and as they take new looks at

*Laboratory instruments used to identify food packaging material made with vinyl chloride and to measure how much—if any—vinyl chloride has leached into food include an infrared spectrometer and a gas chromatograph. The spectrometer (at left in photo on opposite page) is used to identify polyvinyl chloride polymer in food packaging material. The chromatograph (at right in photo) is used to measure the amount of vinyl chloride that has leached from the packaging. The chart between the two instruments is typical of the "readouts" produced by the chromatograph to show the level of vinyl chloride in food packaged in a vinyl chloride container. In the foreground are some foods packaged in materials that may be made from vinyl chloride.*

older chemicals whose safety has long been taken for granted.

FDA's recent proposal to ban certain food packaging made from vinyl chloride was based on two new findings, both made since 1973. The first finding was that when some plastics are made from vinyl chloride, which is ordinarily a gas, some of the gas that is not converted to solid form can be trapped in the plastic and later migrate into food. The second finding was that vinyl chloride has the potential to cause cancer when inhaled, and studies indicate it may cause cancer when ingested.

Beyond the immediate question of vinyl chloride's potential danger to the American public lie numerous broader issues. The vinyl chloride case is a classic illustration of FDA acting on the basis of inconclusive but compelling new scientific evidence in its efforts to protect the public. It also is an example of a solution proposed by FDA that satisfies neither the affected industry nor some consumer advocacy organizations.

Vinyl chloride has been used since the 1940's as the key building block for solid plastics in the form of polyvinyl chloride. FDA estimates that in 1973, some 4.6 billion pounds of polyvinyl chloride resin was used in the United States.

Of this, some 300 million pounds was used for food packaging, making polyvinyl chloride second to polyethylene as the most common plastic used for food packaging. Polyvinyl chloride containers are used for foods such as honey, jelly, vinegar and other condiments, vegetable oil, and other products, as well as for "blister packs" for luncheon meats. It also is used as

a component of other food packaging, such as coatings in beer and soft drink cans, and as cap liners and gaskets for bottles and jars.

In addition, about 400 million pounds was used in 1973 for production of water pipe. Polyvinyl chloride also has a multitude of other uses: as packaging for drugs, cosmetics, toys, hardware, and other products; as a component in some medical devices; in covers for car seats; and for a wide variety of other products used in one way or another by virtually every American.

Polyvinyl chloride—as well as other less-used plastics made from vinyl chloride—originates with the vinyl chloride gas. The first step in the manufacturing process is the conversion of the gas into a resin. The resin is then blended with a number of other substances—such as plasticizers, stabilizers, or lubricants—to form a compound that is used to make the finished plastic article.

During this process, some of the vinyl chloride gas remains in its original form. Estimates indicate that less than 90 percent of the gas is actually converted into the solid plastic. Some of the remaining gas dissipates into the atmosphere. But some is trapped in the plastic, and can migrate gradually into food products with which it comes into contact.

Until 1973, no one suspected that vinyl chloride gas could migrate from plastic containers into food. In 1973, Schenley Distillers, which had been using bottles made out of polyvinyl chloride on a limited and experimental basis for alcoholic beverages, reported finding vinyl chloride in vodka, gin, and other



*The "blister packs" used to package processed meats often are made of polyvinyl chloride.*

distilled alcoholic beverages. The results of the Schenley migration studies were subsequently confirmed by FDA, and on May 17, 1973, the Agency proposed a ban on the use of polyvinyl chloride for bottling alcoholic beverages. The Treasury Department—which has certain regulatory authority over alcoholic beverages because of the Federal tax on them—terminated authority for the use of polyvinyl chloride bottles for alcoholic beverages.

FDA's 1973 proposal was based on the contention that no studies had ever been conducted to demonstrate the safety of vinyl chloride when ingested by people. Until then, there had been no need for such studies, as there had been no reason to suspect that vinyl chloride gas was present in polyvinyl chloride plastic so that it could migrate into food. The Schenley findings were followed quickly by a growing accumulation of data indicating that vinyl chloride could migrate from polyvinyl chloride bottles into nonalcoholic foods. For example, late in 1973 FDA received reports on analyses of vegetable oils packaged in polyvinyl chloride bottles showing the presence of vinyl chloride at levels of 1.6 and 6.5 parts per million (ppm). Results of other analyses disclosed varying levels of vinyl chloride in other products: mineral oil .074 ppm; a vitamin supplement, 1 ppm; and a mouthwash, .174 ppm.

In early 1974, the British Ministry of Agriculture, Fisheries, and Food reported finding vinyl chloride in concentrations ranging from .01 to .08 ppm in fruit squashes and from .01 to .04 ppm in cooking oils. The Canadian Health Protection Branch of the Ministry of Health and Welfare reported finding vinyl chloride ranging from .9 to 8.4 ppm in seven samples of apple cider vinegar. It also reported find-



ing vinyl chloride in samples of various wines, gin, and malt vinegar. Experiments showed that the highest levels of vinyl chloride were most likely to occur in alcoholic and fatty foods packaged in polyvinyl chloride bottles.

Early in 1974, a manufacturer of polyvinyl chloride resin reported a greater than normal incidence of liver cancer among its workers. Italian researcher Cesare Maltoni confirmed that vinyl chloride gas, when inhaled, could cause cancer. In April 1974, on the basis of this plus other reports, FDA proposed a ban on vinyl chloride as a propellant in cosmetic aerosols. It also proposed to require persons using or desiring to use vinyl chloride gas as a propellant in drug aerosols to prove that such use was safe. FDA's final order was published August 26, 1974, and manufacturers were asked to recall outstanding stocks of the aerosols.

The Environmental Protection Agency and the Consumer Product Safety Commission took similar ac-

tion to ban aerosols using vinyl chloride as a propellant in products under their jurisdictions.

Dr. Maltoni also had started a study to determine the effect of vinyl chloride when eaten by animals. The study involved introducing vinyl chloride in an olive oil solution into the stomachs of rats by means of a tube. The study was started with three groups, each consisting of 40 male and 40 female rats. Each group received the solution at a different dosage level. There was also a fourth group which received olive oil with no vinyl chloride, for use as a control.

After a year, examination of the rats that had died showed that one rat in the highest dosage group had cancer of the thymus. A rat in the middle dosage level group was found to have liver cancer. No tumors were reported among rats in the lowest dosage level group, or in the control group.

That experiment is continuing and is expected to be completed in early 1976. On the basis of the



preliminary findings, however, FDA concluded that, when complete, the study is likely to show that vinyl chloride can cause cancer when ingested.

FDA recognizes that finding cancer in two rats cannot be considered conclusive evidence. But no spontaneous cancers like the ones found by Dr. Maltoni have been reported in rats, nor had this type of cancer of the thymus and liver ever occurred spontaneously in Dr. Maltoni's rat colony. FDA concluded that preliminary data from the Maltoni study, combined with the data already available, were sufficient to warrant regulatory action to protect the public from ingesting vinyl chloride. FDA's proposal, as published in the September 3, 1975 *FEDERAL REGISTER*, presented a three-pronged approach to regulation:

- Plastics made from vinyl chloride gas could no longer be used to make bottles, blister packs, boxes, and other rigid and semi-rigid containers for food. Foods that have been packaged in such containers include vegetable oils, honey, vinegar, liquid vitamins, processed meats, and jelly.

- Flexible plastics made from vinyl chloride—for example, jar and bottle cap liners and gaskets, coatings for beer and soft drink cans, and wrapping for fresh meat—would continue to be allowed. This decision was based on the conclusion that the production process for flexible plastics drives out all detectable traces of vinyl chloride gas, so there is no reasonable expectation that any vinyl chloride gas can migrate from the flexible plastic into food.

- Continued use will be permitted of water pipe made from polyvinyl chloride since none of the chemical has been detected in samples of water drawn from operating potable water pipe. But FDA will require studies to demonstrate that the use of the polyvinyl chloride potable water pipe is indeed safe. If such studies are not conducted, FDA will not permit use of polyvinyl chloride pipe.

### You Can't Tell By Looking

FDA has been asked by consumers how they can detect packaging made from polyvinyl chloride and if there is a list available of foods packaged in it.

There is no way for a consumer to tell by looking at a plastic container whether it is made from polyvinyl chloride or some other plastic such as polyethylene, which is used even more commonly for food packaging than is polyvinyl chloride.

While FDA is responsible for assuring that food packaging is safe, neither the Agency nor the food industry keeps a list of the specific packaging materials used for each of the millions of separate food items available to the American consumer.

Many manufacturers, anticipating FDA's proposed ban, already have taken action to use plastics other than polyvinyl chloride for food packaging.

FDA's proposed ban on the use of rigid and semi-rigid plastics made from vinyl chloride would affect only a small amount of the total annual production. Of the 4.6 billion pounds of polyvinyl chloride resin used in 1973, only about 54 million pounds—slightly more than 1 percent—would be affected by the proposal. FDA assessed the economic and environmental impacts of its proposal and concluded that formal statement on these aspects of its actions would not be required. Such statements are required when a Federal Agency proposes to take an action that would have a substantial impact on the economy or the environment.

The Agency also decided that the public health hazard from polyvinyl chloride food packaging material is not so great as to warrant issuance of the regulations without an opportunity for public comment or to require the recall and destruction of food packaged in polyvinyl chloride containers.

FDA believes the evidence on migration is sufficient to require action against polyvinyl chloride packaging for other products under its jurisdiction, such as drugs and cosmetics, and proposed regulations are being drafted.

Sixty days from September 3, 1975, originally were allowed for public comment on the proposal on food packaging, and this was ex-

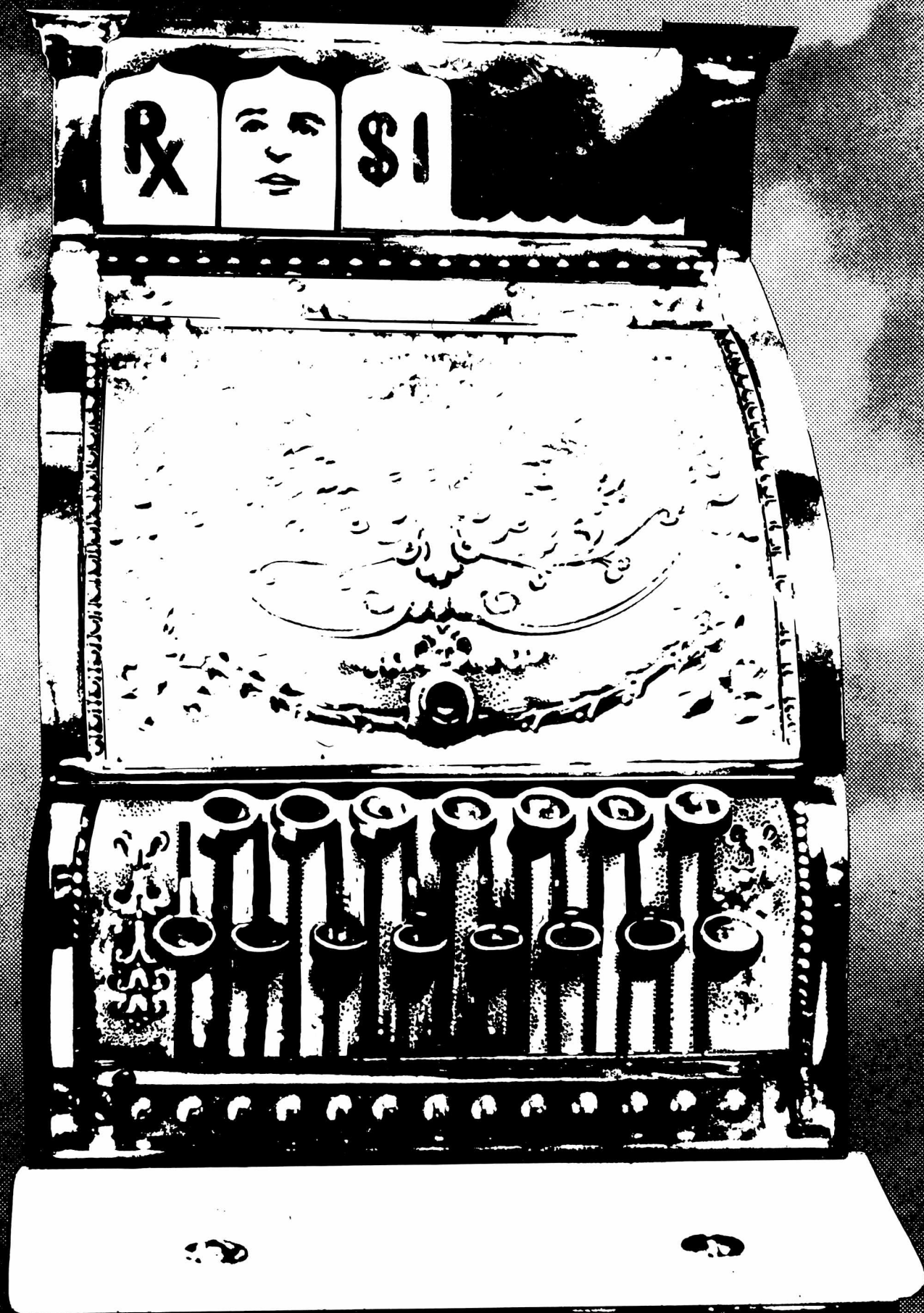
tended until December 12. After this period expires, FDA will consider the comments and issue a final regulation.

FDA's proposed course of action was opposed by the Society of Plastic Industries, which said the Agency had acted with "undue panic." On the other hand, the Health Research Group, a Washington-based consumer advocacy organization, said that FDA should have proposed a ban on all vinyl chloride food packaging materials. The Health Research Group had petitioned FDA to take that action on July 1, 1975, while the Agency was developing its proposed regulation.

In announcing FDA's proposed regulation, Commissioner of Food and Drugs, Alexander M. Schmidt, M.D., said: "FDA and the scientific community agree that vinyl chloride poses certain risks to human health. Furthermore, there are available alternatives to the materials we propose to ban for use in contact with foods. The risk is therefore one that as a nation we can avoid. It is on this basis that the FDA proposes to act."

Dr. Schmidt said the proposal offered "for consideration by the American public deals practically, positively, and constructively with the problem as we understand it."

*Wayne Pines is FDA deputy assistant commissioner for public affairs.*



# Holding Down Prescription Drug Costs

*A new program will establish maximum prices the Government will pay for certain prescription drugs dispensed to Medicare and Medicaid patients. This not only will reduce the costs of these tax-supported programs, but also is expected to hold down the price the general public pays for the same drugs. FDA's job will be to determine if different brands of the same generic drug are equal in their therapeutic effect, so a maximum allowable cost can be set for that drug.*

To a New Yorker the "Big Mac" is the Municipal Assistance Corporation. To a teenager, it is a giant hamburger. In April 1976, the "Mac" part will take on still another meaning—one with considerable significance to taxpayers and consumers of prescription drugs. MAC is shorthand for "maximum allowable cost"—the maximum price the Government will pay for certain drugs dispensed to patients in Medicare and Medicaid programs.

The Department of Health, Education, and Welfare, which developed the MAC regulations that are scheduled to take effect April 26, estimates that they will produce savings of \$60-\$75 million a year for the Federal and State governments by cutting the cost of prescription drugs under Medicaid and Medicare without reducing the quality or availability of the care provided under these tax-supported programs. In addition to these savings, it is expected that the setting of maximum costs for drugs under Medicare and Medicaid will reduce, or at least hold down, the cost of these same drugs for the general public as well.

Maximum allowable costs will be set for so-called multiple source drugs, which represent about one-fourth of the prescription drugs on the market today. Three-fourths of prescription drugs can be obtained only from a single manufacturer or source, and thus, each of these drugs is available to pharmacists and other retail dispensers at just one price. The remainder are those drugs that are available from more than

one source or manufacturer, and prices for the same drug under different brand names often vary widely. The maximum cost which will be established for these drugs will be the lowest price charged by any source from which the drug is "widely and consistently" available. For instance, one drug that could be on the MAC list is tetracycline, an antibiotic used to combat infections. It is manufactured by at least 50 different firms, and the price charged to retail druggists by one manufacturer may be four to five times as much as that charged by a competing supplier. The maximum allowable cost will not always be the lowest price charged by any manufacturer, however, because that company's product may not be "widely and consistently" available.

If it appears that a particular drug won't be available in some communities at the maximum price set for it, separate maximums will be established for these areas.

Maximum costs will be established in a series of steps beginning with a six member Department of Health, Education, and Welfare (HEW) Pharmaceutical Reimbursement Board which will select the multiple source drugs to be included. Also involved is a non-government advisory committee of 15 experts in pharmacy, pharmacology, medicine, pharmaceutical marketing, public health, and consumer affairs which will advise the Board on cost limits. This information will be published in the FEDERAL REGISTER with 30 days allowed for comment from inter-



will be established for that drug.

Another function of the Reimbursement Board will be to provide physicians and pharmacists with a list of the most frequently prescribed drugs along with the price a community pharmacy generally pays for each. The list, which will be updated periodically, will be organized so that physicians can compare the price of products which can be used interchangeably. It is this aspect of the program that will have the most benefit for the average consumer since, with this information, a physician can prescribe a drug that should produce the desired therapeutic results at the lowest cost to the patient.

The effort to hold down prescription drug costs under Medicaid and Medicare does not rest solely on the establishment of maximum payments for multiple source drugs. Under the MAC regulations, which were published in the *FEDERAL REGISTER*, July 31, 1975, payment for any prescription drug—whether it is available from one or a number of sources—will not exceed the lowest of:

- The maximum allowable cost

of the drug—if one has been established—plus a reasonable dispensing fee.

ested persons or organizations. During the 30-day comment period, interested parties also may request an oral hearing on each proposed limit. The drugs on the MAC list will be reviewed and the list revised regularly.

FDA's role in this process will be to determine whether different brands or formulations of the same generic drug are bioequivalent—that is whether they are equal in their therapeutic effect—so a maximum allowable cost can be set for that drug. A key factor in the Agency's decision will be its newly proposed regulations governing determination of the bioequivalence of drugs. The purpose of these regulations is to assure that prescription drugs that are intended for the same use can be used interchangeably. Once FDA has established that the various brands of a given drug are bioequivalent, the Reimbursement Board can establish the price to be paid for it under Medicare and Medicaid programs. If FDA finds that different formulations of the same generic drug are not equal in their therapeutic effect, no maximum allowable cost

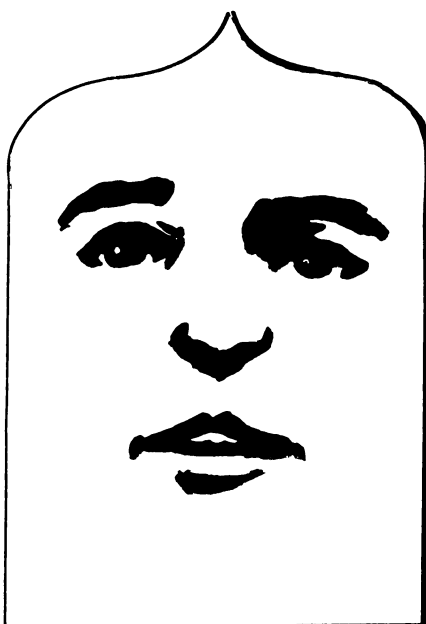


of the drug—if one has been established—plus a reasonable dispensing fee.

- The estimated cost of the drug to the pharmacy or other dispensing agent, plus a reasonable dispensing fee. (Estimated acquisition costs will be set by the appropriate State agency based on drug price information provided by the U.S. Department of Health, Education, and Welfare.)

- The provider's usual charge to the general public for the drug.

Instituting a cost-conscious reimbursement system for prescription drugs under Medicaid and Medicare is a step toward reducing increasing medical care costs without reducing the quality of that care, according to HEW officials. The regulations specifically provide that physicians will have freedom to prescribe the drug of their choice, regardless of cost. Physicians who want to prescribe a higher priced brand name can do so by certifying in their own handwriting that a particular drug is medically necessary. In such cases, the Government will pay the full cost of the prescribed drug.





# Making Blood Money Safe And Respectable

*FDA regulations have helped clean up the plasma industry and make the buying and selling of blood safer for all concerned. Paid donors are now selling their blood at commercial plasmapheresis centers at the rate of 14,000 pints a day.*

by Richard White

**T**hey sit in crowded waiting rooms from Miami to Los Angeles, waiting to earn a few dollars. They often have been stereotyped as seedy transients and alcoholics, but their ranks also include students,

moonlighters, and the unemployed.

They all have one thing in common, something that runs in their blood—and in yours.

It is called plasma, the thin yellow liquid composing more than half the volume of human blood, and these people are cashing in on it. In the U.S. medical marketplace, plasma has become a valuable commodity which paid donors now sell at the rate of about 15,000 pints per day.

Is it possible that so much life-sustaining fluid can be bought and sold safely?

The FDA believes that it can. In the past two years, the Agency has established guidelines to regulate the booming plasma industry and has licensed 250 plasma collection centers in 39 States. As a result, the thousands of people who regularly sell plasma can now breathe easier. And the plasma centers themselves are now gaining respectability in communities which once threatened to outlaw them.

Even with Federal regulation, the plasma industry may never live down its reputation as a kind of corporate leech preying on the poor.



Myths of what goes on in plasma centers abound and, as one plasma center manager admits, "There will always be a stigma attached to selling blood."

However, 1975 has been a year of extraordinary change for the U.S. plasma industry. Until the recent economic recession, the supply from plasma donors had never matched the industrial demand for raw plasma. Between 1970 and 1974, U.S. plasma centers doubled their total output and were offering bonus incentives to lure new donors. But in 1975, centers which previously depended on transients started drawing a steady middle-class clientele, lured in by the \$5-\$10 donor fees. New centers opened in such university towns as Columbus, Ohio, and Knoxville, Tennessee. By mid-summer 1975, many plasma warehouses were fully stocked for the first time, and many donor incentive programs were canceled.

Also, on January 1, 1975, FDA licensing of plasma centers took effect under regulations adopted by the agency in November 1973—the first set of Federal regulations aimed specifically at the plasma industry. Inspectors from the Bureau of Biologics began visiting plasma centers as early as July 1972, when the bureau joined the FDA. Many of the flagrant abuses which plagued the industry are being remedied as a result of annual FDA inspections of all licensed plasmapheresis facilities.

On July 1, 1972, the FDA took action to combat the number one health menace associated with plasma—the transmission of hepatitis B virus through the injection of plasma derivatives. A regulation adopted on that date required all plasma centers to institute the so-called second generation testing procedure for hepatitis in donor blood. Since

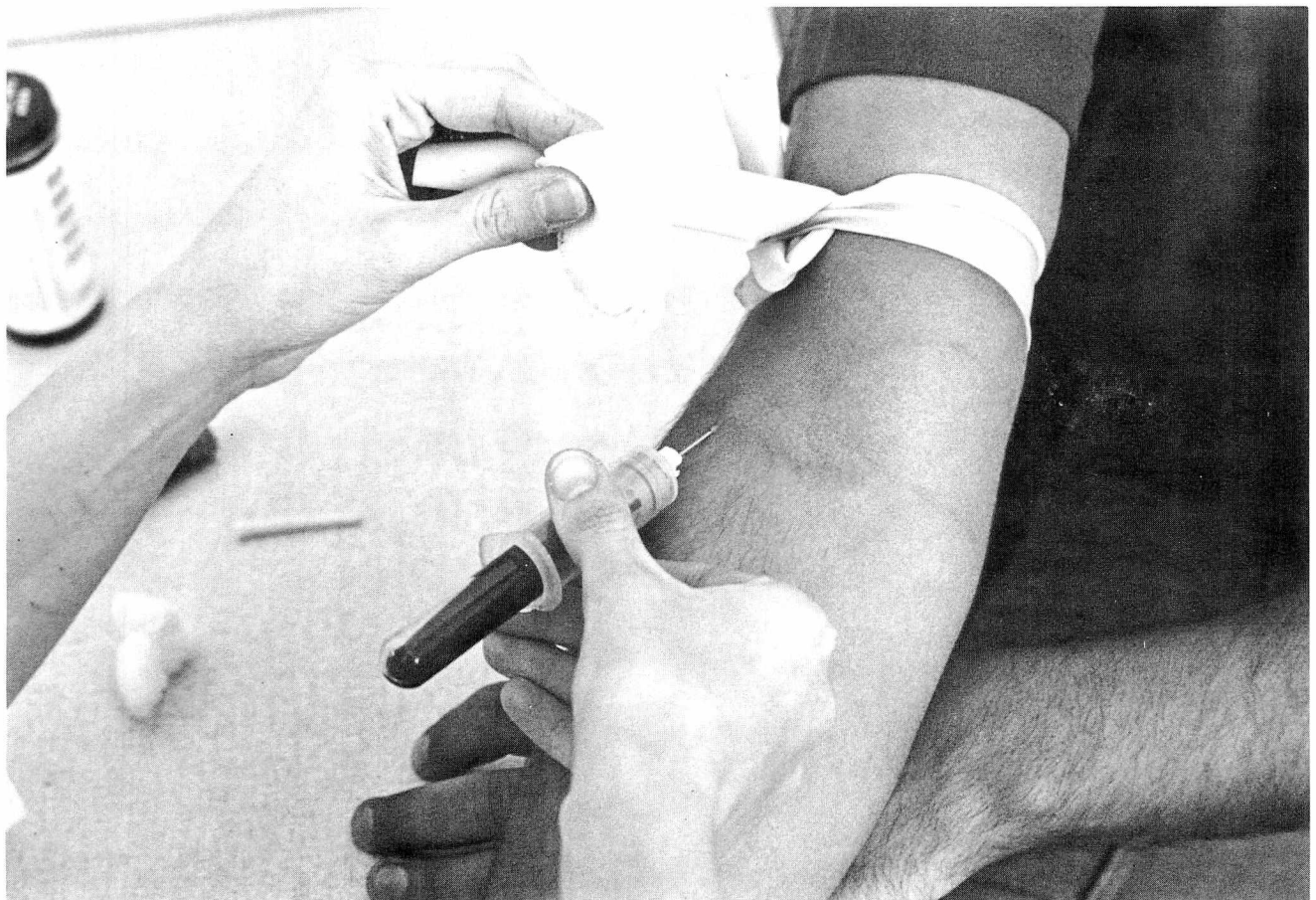
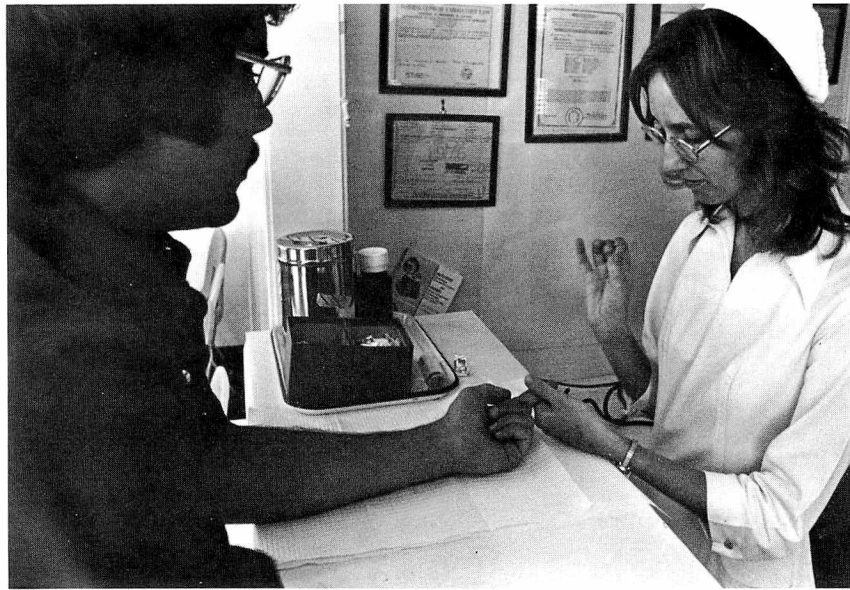
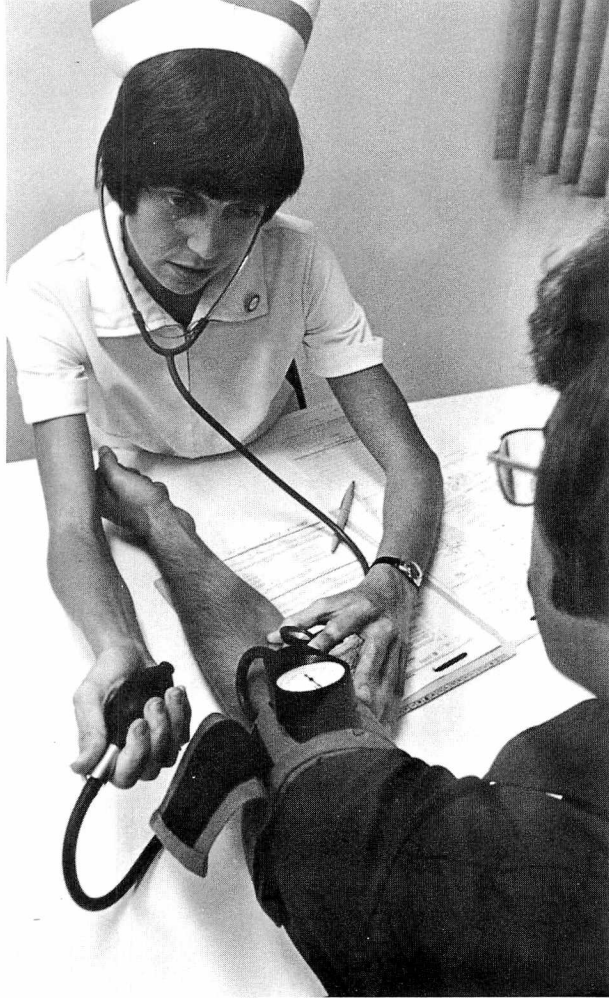
September 15, 1975, the FDA has required that all licensed blood and plasma be tested for the presence of hepatitis B by newer, more sensitive third generation procedures. The FDA's Bureau of Biologics estimates that this new procedure is 100 to 1,000 times more sensitive than second generation tests, and will reduce cases of hepatitis transfer through blood products by an additional 25-50 percent.

All FDA-licensed plasma centers in the United States practice plasmapheresis—the process of extracting whole blood from donors, separating the plasma from the red blood cells, and then returning the red cells to the donor. Plasmapheresis was performed in experimental laboratories as early as the 1920's and was practiced on a large scale during World War II by Howard University Physician Charles Drew, who organized a plasma supply line to beleaguered Britain.

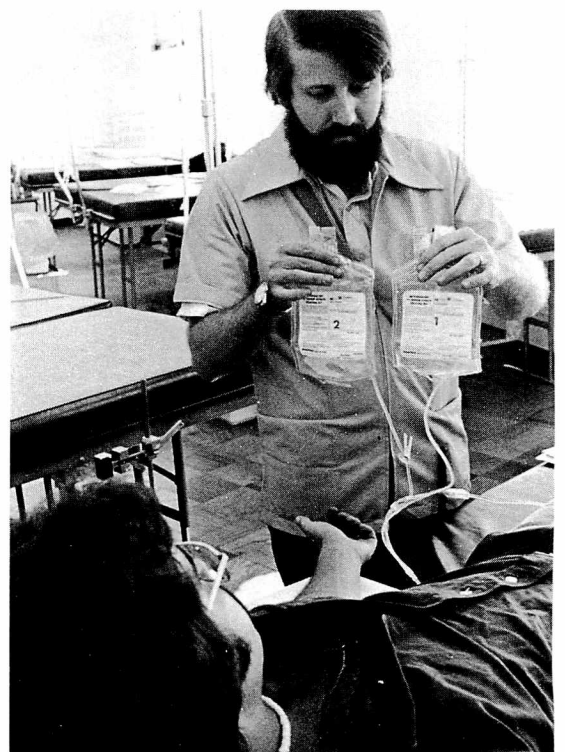
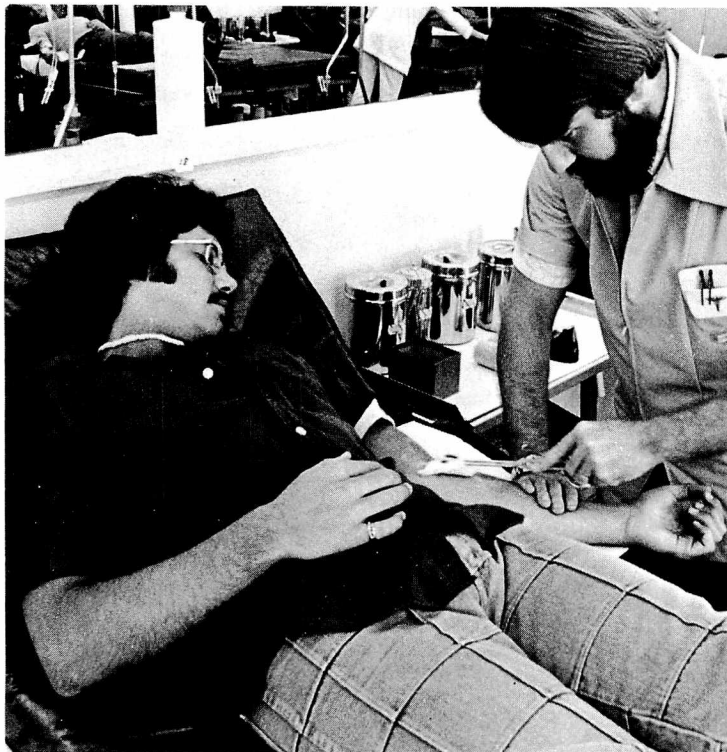
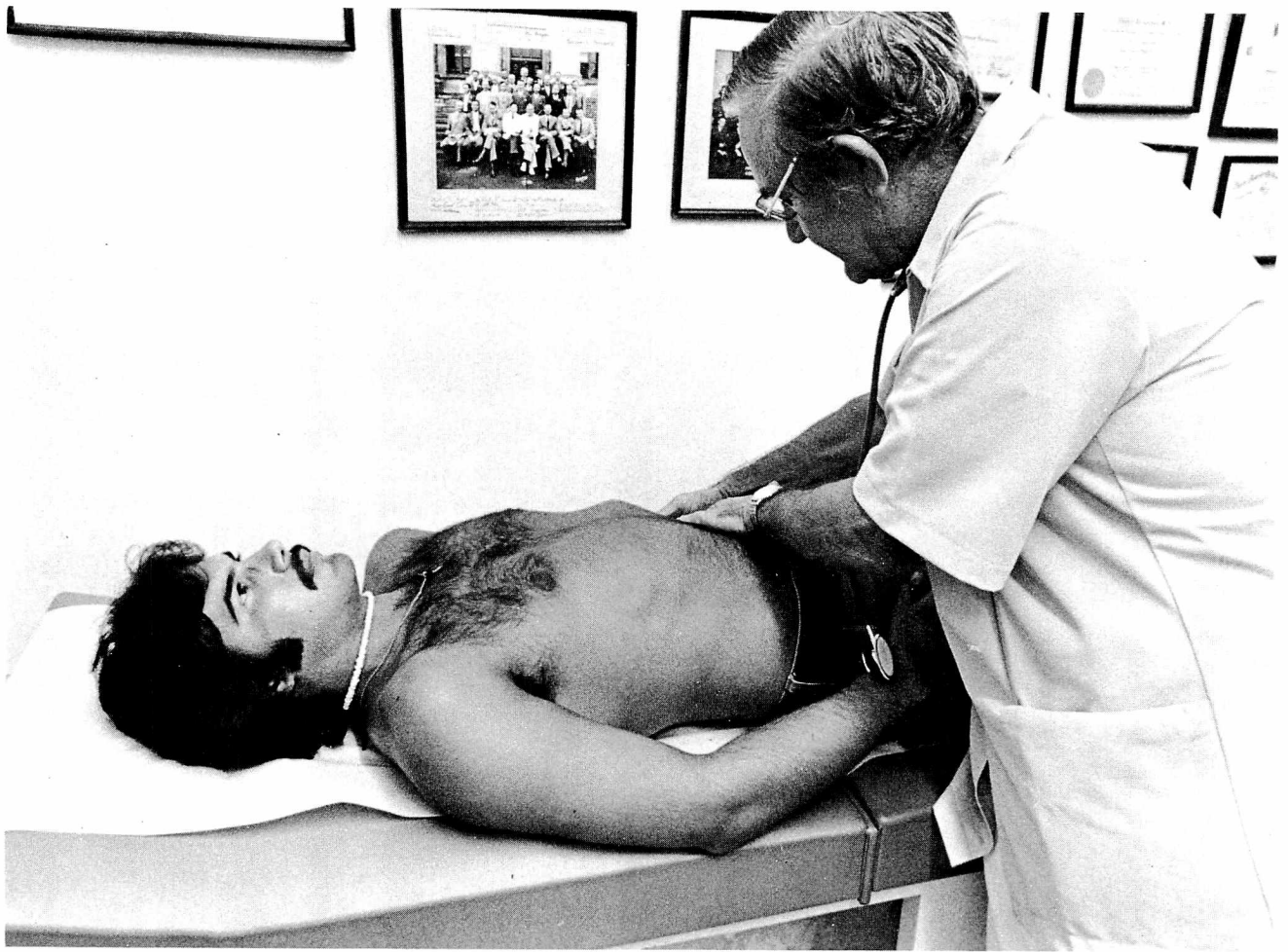
Even so, early plasmapheresis was unwieldy, relying on volunteer donors and bulky glass bottles for handling plasma. It was not until 1953 and the development of vacuum-seal plastic blood bags that the process became commercially feasible using paid donors. Simultaneously, scientists perfected a refrigerated centrifuge capable of separating plasma from red cells in minutes, and the safe and efficient collection of plasma became a practical possibility.

Now, FDA-licensed plasma centers are found throughout the country, with concentration on the eastern seaboard, in the Deep South, and in California. Approximately half of all the centers lie in four States: Pennsylvania, Florida, Texas, and California. Los Angeles alone has a dozen centers; Beaumont, Texas, with a population of only 120,000, has three.

*Screening of a prospective donor at a plasmapheresis center includes the taking of his medical history, measurement of blood pressure and other "vital signs," and blood tests from samples drawn from a finger and a vein.*









*On a donor's first visit to a plasmapheresis center he is examined by a physician (top photo). Donors who continue to sell their blood to the center are reexamined periodically.*

*In the bleeding room (bottom photos), the donor's arm is made ready, blood bags are prepared and tagged, and the donor is asked to verify his name and other information on the bags.*

And with the centers have spread apprehension, myths, and misunderstandings about the plasma industry. Since several of these myths confuse plasmapheresis with whole blood donation (as for the Red Cross), it is appropriate to compare the two procedures.

A whole blood donation takes about 30 minutes, as many civic-minded volunteers know. After the donor is interviewed, tested, and found acceptable, the skin is punctured at a vein, approximately a pint of blood is withdrawn, and the donor is dismissed.

Plasmapheresis, however, can take up to two hours. After the pint of whole blood is withdrawn and the thin liquid plasma separated from the packed red cells, the cells are reinfused into the donor. In commercial plasmapheresis, this process is usually repeated to obtain a second pint of whole blood. The donor gets back all of his or her red cells and receives enough saline solution to replace the volume of lost plasma. The entire procedure is accomplished through one needle inserted into one vein in the arm.

The donor of whole blood is advised not to donate more often than once every eight weeks, because the body needs that long to restore red cells. Plasma, however, is restored in 12 to 24 hours, and FDA regulations allow an individual to donate twice a week. This means a plasma donor could give as many as 104 pints a year and, though some public health advocates find that frequency shocking, the FDA considers it well within the body's tolerance.

"When these regulations were written in 1973, they were supported by a massive amount of data," said Dr. Joel M. Solomon, deputy director of the Bureau's

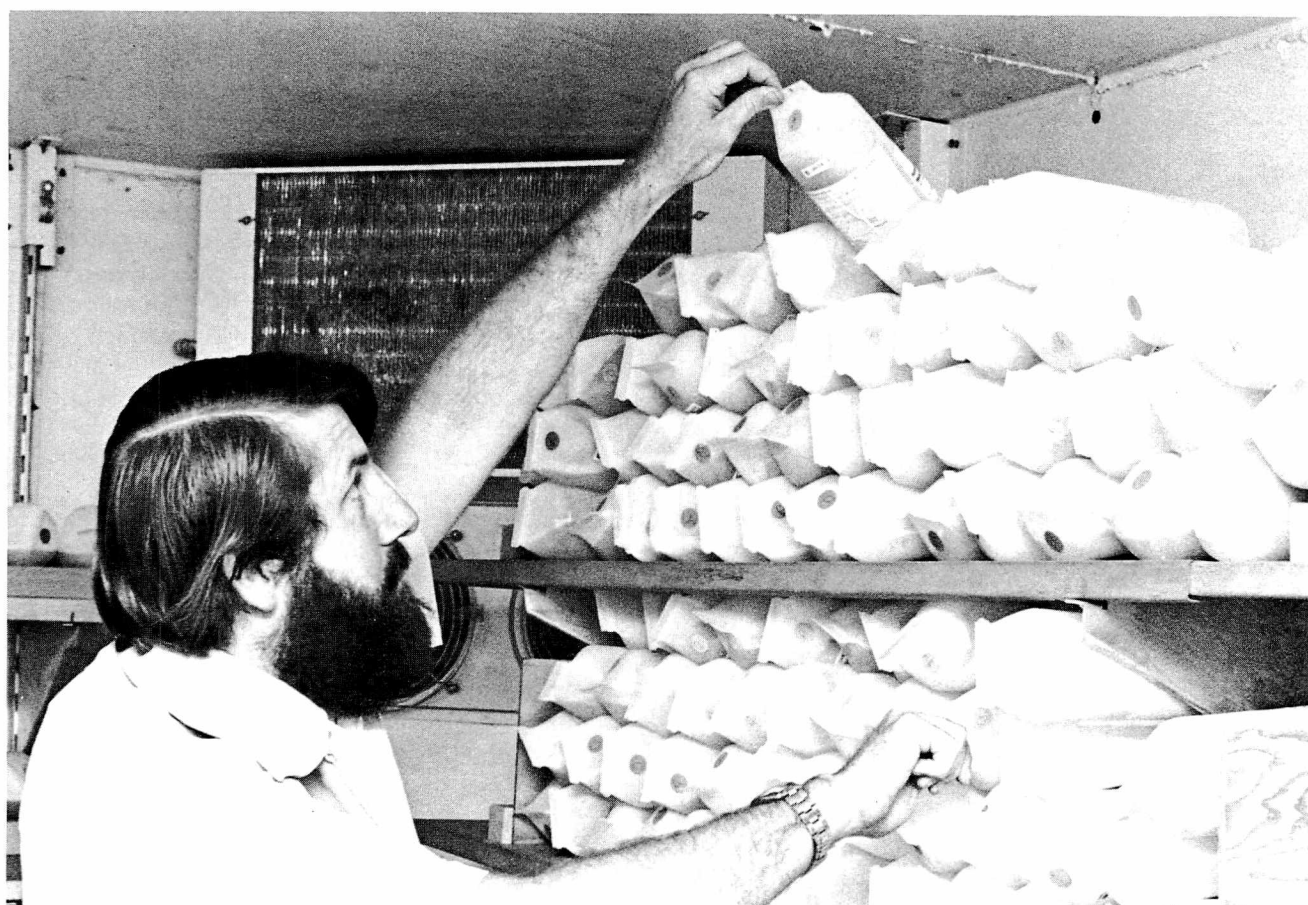
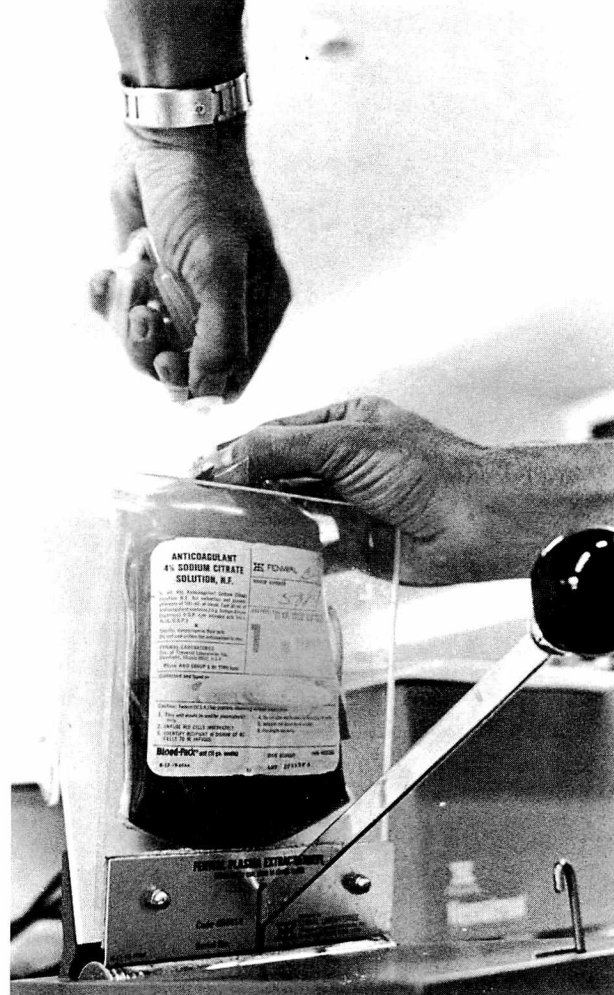
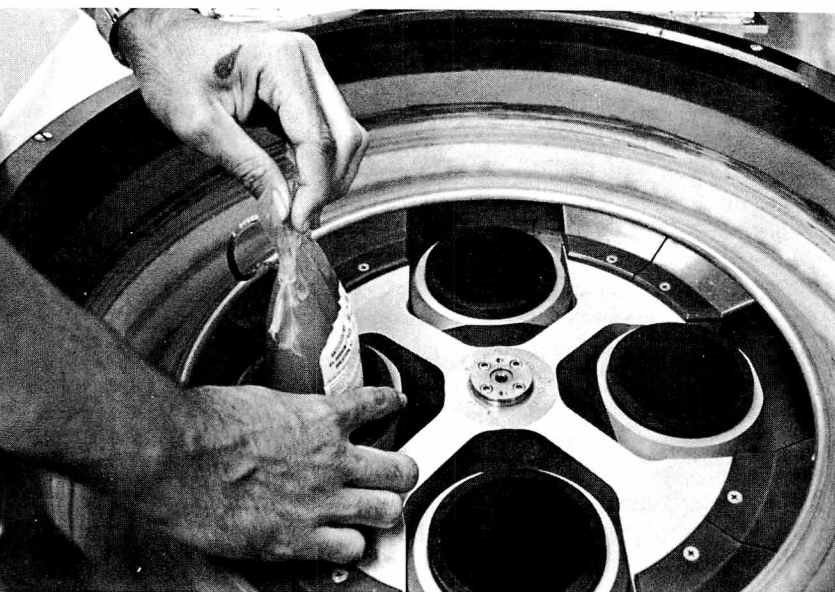
Division of Blood Products.

A common misconception is that plasma sold by skid row alcoholics is transported directly to local hospitals and transfused into patients. Unlike whole blood, plasma collected by plasmapheresis is not transfused in its raw form. Instead, it is frozen (plasma can be stored almost indefinitely frozen) and shipped interstate to fractionation facilities where trade name plasma derivative products are manufactured. Ironically, in light of the alcoholic-donor belief, each step in the fractionation of plasma proteins includes the addition to the plasma of ethyl alcohol.

The raw plasma collected by plasmapheresis, licensed by the FDA, and used in the manufacture of human medicines including gamma globulin, antihemophilic factor, and albumin products for treating patients in shock and those with life-threatening burns, is called "Source Plasma (Human)."

There is another popular belief—not entirely lacking in factual support—that U.S. health care would be better off if there were no paid blood donors. Much clinical research indicates that the incidence of hepatitis is greater among paid than volunteer donors. The American Blood Commission, which includes as members all the major blood banking organizations in the country, has urged the eradication of paid donors as a national health priority as recommended in the National Blood Policy of the Department of Health, Education, and Welfare.

It is unlikely at present, however, that the U.S. plasma industry could continue its current output (1.8 million liters obtained from plasmapheresis in 1974) without buying plasma from donors. While it is in the American tradition to



*Blood taken from a donor is placed in a centrifuge (top left photo) where the plasma is separated from the red cells by a spinning process.*

*Centrifuging causes the plasma to rise to the top of the bag and the red blood cells to settle to the bottom. The plasma is then drawn off (top right).*

*Plasma is stored in a freezer (bottom photo) to await use in the manufacture of medicines and diagnostic products.*

volunteer whole blood donation, plasma collected by plasmapheresis is a profit-making product, pure and simple. The pint of plasma a donor sells for \$5-\$10 moves onto the Source Plasma (Human) market at a rate of \$35-\$45.

In the regulation of plasma centers, then, the FDA's purpose is largely to protect the donor selling plasma as well as to ensure the quality of the plasma product.

The FDA's Source Plasma (Human) regulations require that each donor be examined by a qualified physician and certified to be in good health prior to his first bleeding. The physician must explain the risks of plasmapheresis and obtain the donor's written consent. At the time of each donation, the donor must be in good health, weigh at least 110 pounds and have normal temperature, blood pressure, and pulse. His hemoglobin and serum protein levels must meet FDA standards and he must be free from any evidence of respiratory disease or viral hepatitis.

The plasma center is required to establish a strict donor identification system (most use photographs) and test each donor once every four months for syphilis. The plasma itself may not be pooled; a center must store it in individual containers, and the storage facility must be kept at  $-20^{\circ}\text{C}$  or less.

All this may seem like more trouble than plasma is worth. But in the past decade, plasma has become an indispensable raw material in the production of drug products, and plasmapheresis now supplies more than 80 percent of U.S. plasma for these life-saving products. (The rest is obtained from stored whole blood which has lost red-cell potency and from placentas left over from childbirths.) Major pharmaceutical companies such as

Abbott Laboratories, Inc., and the Hyland Division of Travenol Laboratories, Inc., operate plasma centers across the Nation to insure a ready supply of acceptable plasma.

According to research by FDA's Bureau of Biologics, the bulk of Source Plasma (Human) is used to make serum albumin, a product used in treatment of shock from hemorrhage, trauma, infection, or surgery and to make antihemophilic factor for prevention and control of hemorrhage in hemophilic patients.

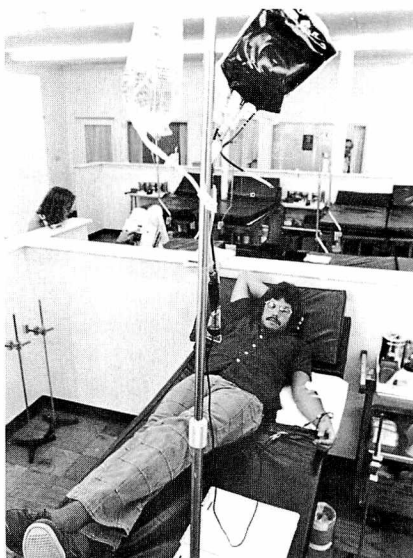
The plasma product gamma globulin, once used for immunization against polio and measles, is still important in supplying antibodies for treating such diseases as hepatitis, tetanus, and rabies. Also fractionated from plasma are other coagulation factors used to treat type B hemophilia, and fibrinogen for treatment of hemorrhage (although use of the latter, a notorious source of hepatitis infection, is declining).

When FDA inspectors began visiting plasma centers in 1972, they found that many of them were cutting corners to increase profits. In one such center, located in Tampa, Florida, a 58-year-old man died while selling plasma in February 1974. The FDA's investigation of his death, and the subsequent injunction suit filed against the center, revealed the kind of abuse that was plaguing the industry.

The man was allowed to donate plasma at that center, official reports showed, even though he was extremely sick and ultimately died of pneumonia in both lungs. The death occurred partly because the man had never been examined by the plasma center staff doctor, the FDA learned. Instead, according to the testimony of the plasma



*After the plasma has been drawn off, the donor is asked to identify the bag containing his red blood cells by the information on the label. The red cells are then mixed with an equal amount of saline solution from a second bag and reinfused into the donor.*



center manager, the staff doctor simply pre-signed copies of the medical examination forms.

Also, the manager said, the plasma center routinely falsified donor records, overbled donors in violation of FDA regulations, and sold plasma which reacted positively in hepatitis testing. It also practiced the dangerous technique known in the plasma business as "double-bagging," he testified. (FDA regulations require that the red cells from the first pint bag of whole blood be returned before the second pint bag can be withdrawn. Double-bagging means removing two bags, roughly a quart of whole blood before returning the red blood cells from the first bag.)

Plasmapheresis regulations adopted in 1973 permitted centers such as the above to continue collecting plasma after a license suspension—so long as the center did not market Source Plasma (Human). And since some lower-price plasma is sold for laboratory use (not for making human medicine), unlicensed centers were able to stay in the plasmapheresis business.

In 1974, however, the FDA proposed new regulations which would amend the definition of Source Plasma (Human) to include plasma designated for laboratory use, effectively requiring the licensing of all plasmapheresis centers. One result of this amendment, expected to be approved soon, will be to give the plasma donor protection in any center he visits. Another will be to permit importation of Source Plasma (Human) for any purpose only from licensed foreign firms. No longer will independent unlicensed foreign operators be permitted to export plasma collected by plasmapheresis to the United States for use in laboratory diagnostic products.



The Bureau of Biologics also is now scrutinizing the widespread practice of immunizing donors to increase antibody levels in their plasma. Usually, plasma centers pay donors a "bonus fee" to take a series of immunization shots. Some centers offer as many as four bonus programs, one each for tetanus, measles, whooping cough, and smallpox.

"Some of these procedures have been used for years to stimulate antibodies in donors, and yet there is insufficient research on the cumulative effects of this kind of stimulation," explained FDA's Dr. Solomon. "Our hope is that we can tighten up the guidelines for immunizations in order to insure donor safety and at the same time obtain further information on the effect of repeated immunization of donors."

As long as there is a valuable role to be played by plasma derivatives in conditions such as hepatitis, tetanus, rabies, and hemorrhage shock, the commercial centers which tap the body's plasma-producing capacity will continue to make an important contribution to the health of American citizens. FDA regulation of the plasma industry has driven a number of centers out of business, and most of the glaring violations found in the remaining centers are being remedied after several inspections.

With proper regulation, the image of the plasma industry may change. Selling plasma may never be as socially acceptable as visiting the Red Cross Bloodmobile. But it can be safe for the donor, and plasma from paid donors can be as important as donated whole blood in contributing to the health of patients.

*Richard White is a freelance writer.*

## **New Blood Labeling Regulations Proposed**

FDA has proposed that labels on all blood for transfusion be required to indicate whether the blood was collected from a voluntary or paid donor, and to state that blood from paid donors is associated with a higher risk of transmitting hepatitis.

The labeling proposal, which was published for comment in the November 14, 1975, *FEDERAL REGISTER*, is one of two new FDA actions intended to improve the quality of blood and blood products.

The other action makes final new standards for collecting, processing, and storing blood and blood products. The standards consist of Good Manufacturing Practices (GMP's) that will be required of all blood banks, transfusion facilities, and other blood-processing facilities.

"Both actions are parts of a continuing major FDA program to improve the quality of blood provided for patients in the United States," said Alexander M. Schmidt, M.D., Commissioner of Food and Drugs. "Our objective is to make sure that every American receives uniform quality of products and services from the nationwide blood-service complex."

Dr. Schmidt pointed out that until three years ago there was limited Federal regulation of blood products, with only about 250 licensed interstate blood banks subject to Federal standards. Since then, FDA regulations have been extended to cover all facilities that process blood, including those that operate only within a single State.

Dr. Schmidt said that the labeling requirement is needed because blood from paid donors is more likely to transmit hepatitis than blood from voluntary donors. Under these circumstances, he said, physicians and patients "are entitled to know the source of blood and its attendant hepatitis risk."

The new Good Manufacturing Practice Regulations cover licensed (interstate) and unlicensed (intrastate) facilities that process whole blood or plasma. The regulations require that all blood donations be tested for hepatitis by the most sensitive method; establish standards for performance of safety tests before administration of blood or blood components to patients; require immediate reporting to FDA of fatal reactions occurring from the donation or receipt of blood; require maintenance of standard operating procedure manuals; and extend record-keeping requirements for blood processing. Some of these requirements already apply to licensed facilities.

The new GMP standards were effective December 18, 1975.

**I**f you're a consumer—and who isn't—you may be thinking metric sooner than you think. But don't panic—chances are you've already been exposed to some parts of the metric system of weights and measures at one time or another and further indoctrination is likely to be just as gradual. Once you give it a fair try, once you get the hang of it, you may find you can think faster and more accurately in metric than in the system we use now.

U.S. consumers don't need to be told that they're putting more money where their mouths are, and they're getting more concerned about the budget bite for each mouthful. In Paris, Buenos Aires, Cairo, and Calcutta, and practically every other place in the world, consumers feel the same pain in the pocketbook when they buy food or drink, but they can usually figure

out the extent of it without a pocket calculator.

For this they are beholden to the metric system of weights and measures. Metric is now being used by ordinary consumers in almost every country in the world. Its simplicity in everyday use is that its units, subunits, and multiples of units for a given physical measurement—weight, capacity or volume, length or distance, area, or temperature—are based on factors of ten or tenths. Thus, no complicated mental arithmetic is needed to convert from one value to another or to relate these values to the decimalized money systems most countries have today. The decimal does most of the work, and no battery changes are necessary.

The basic unit in the metric system of weights is the gram, much smaller than the ounce we are used

# Metric Measures And The Consumer

*It will take some getting used to, but metric is a considerably simpler system of weights and measures than the one we use now. Because the metric system is based on units of 10, most consumers probably will find it easier to compare food costs when dealing in grams and kilograms than in ounces and pounds.*

to dealing with. You might have trouble telling whether an object weighs a few grams or several, but metric scales don't, and more precise weighing is possible than by the fractions of ounces you commonly see on some product packages.

There are about 28 grams in an ounce. A thousand grams make a kilogram, which comes out to a little over two pounds.

Suppose that at some future time you walk into the grocery and everything, or practically everything, is packaged by metric measure. Maybe you decide immediately that the first thing you'll want when you're at home recovering from the ordeal is a cup of coffee, so you put that at the top of your shopping list.

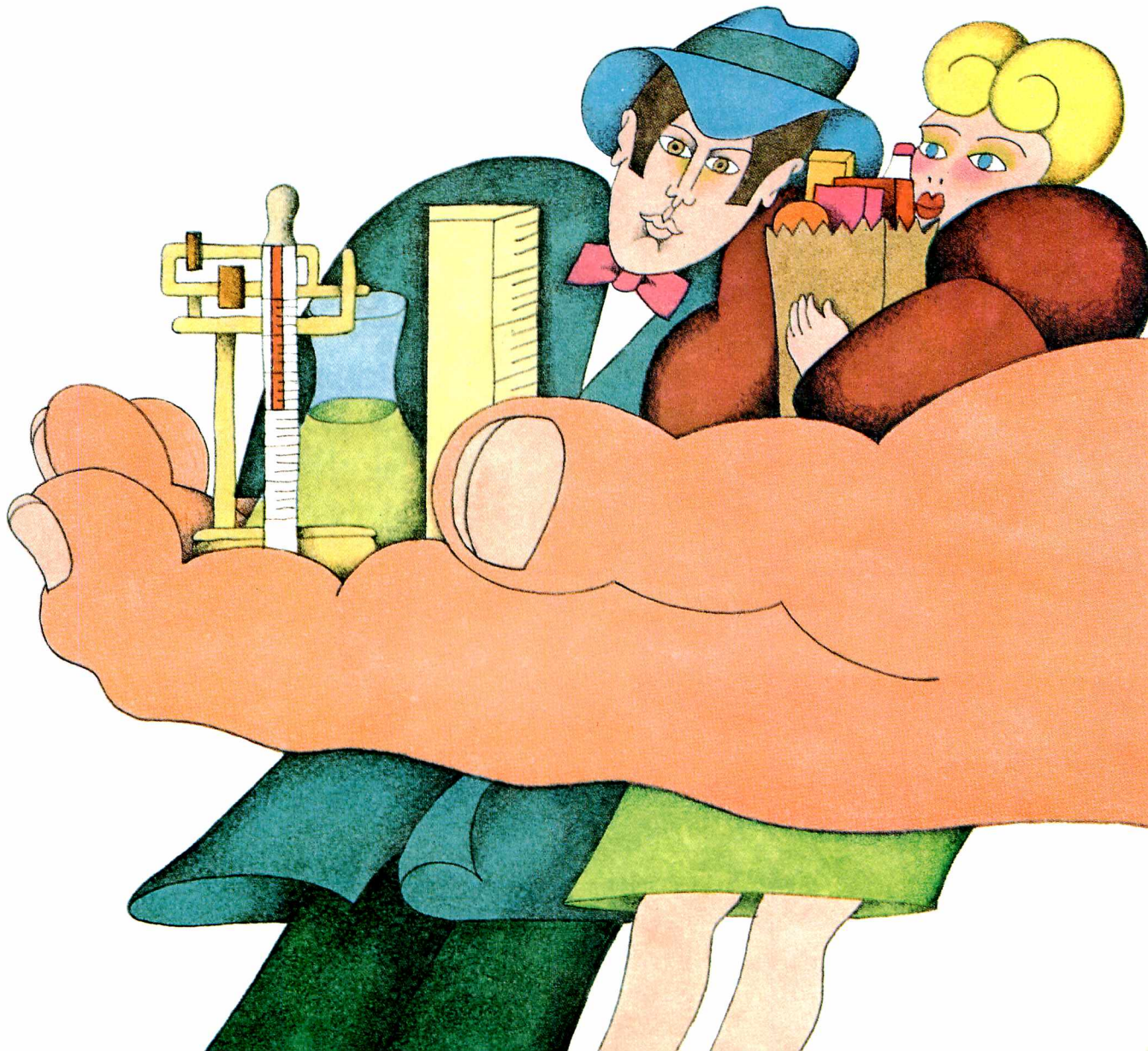
Let's say that a 1-kilogram (1,000-gram) can of coffee sells for \$2.25 and you want to know what it

costs in smaller amounts. Just keep an eye on the decimal as it moves one unit to the left each time you divide by 10:

1,000 grams (1 kg)	\$2.25
100 grams (.1 kg)	\$.225 (22.5 cents)
10 grams (.01 kg)	\$.0225 (2.25 cents)
1 gram (.001 kg)	\$.00225 (0.225 cent )

In the foregoing table the decimal moves to the left, to signify division—into tenths, hundredths, and thousandths. To multiply, you simply move the decimal in the opposite direction.

Let's say flour costs \$.00044 per gram. That's not





much money, but a gram is not much flour either. So you want to know what larger amounts cost:

1 gram (.001 kg)	\$ .00044 (0.044 cent)
10 grams (.01 kg)	\$ .0044 (0.44 cent)
100 grams (.1 kg)	\$ .044 (4.4 cents)
1000 grams (1 kg)	\$ .44 (44 cents)

Comparison shopping when using the metric system is relatively easy when two package sizes vary in amount of contents. If a 1-kilogram (1,000-gram) jar of peanut butter costs \$1.95, and a 900-gram jar costs \$1.78, which jar gives you the most for the money? Since it's easy to find the cost of 100 grams of the 1-kg size (one-tenth of \$1.95 or 19.5 cents), you can

add this 100-gram cost to the \$1.78-cost of the 900-gram jar and the total is \$1.975, or 2.5 cents more for 1,000 grams than the larger size. It's not nearly as easy to figure out the best buy, when using the U.S. avoirdupois system, between a 1-pound (16-ounce) jar at \$0.79 and a 15-ounce jar at \$0.72, because of the difficulty in computing the cost of an ounce.

Some stores now are displaying shelf tags showing the unit price of packaged products. These tags usually state the cost of the item per ounce or pound, or per square foot for paper or similar goods. Unit pricing will continue to be helpful to consumers even after metric measurements are in general use.

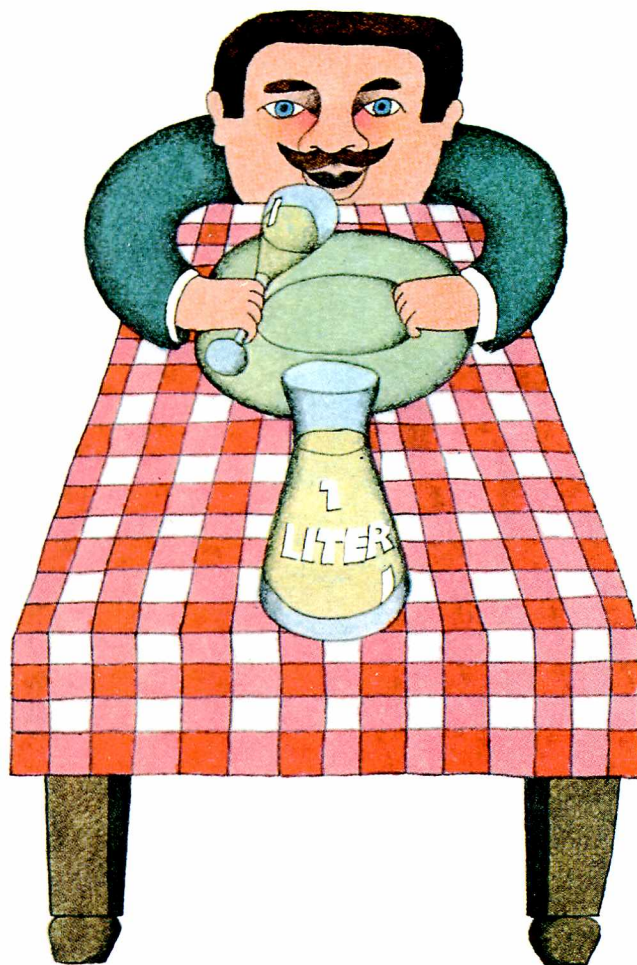
Along with weight, the consumer of food and drugs is most concerned about measurement of capacity or

## Some Common Metric Amounts and U.S. Equivalents



### Weight

Gram	0.0352 oz.
Kilogram (1,000 grams)	2.204 lbs. / 35.274 ozs.
Metric Tonne (1,000 kg.)	2,204.6 lbs.



### Volume

Liter (1,000 milliliters)	1.056 quarts
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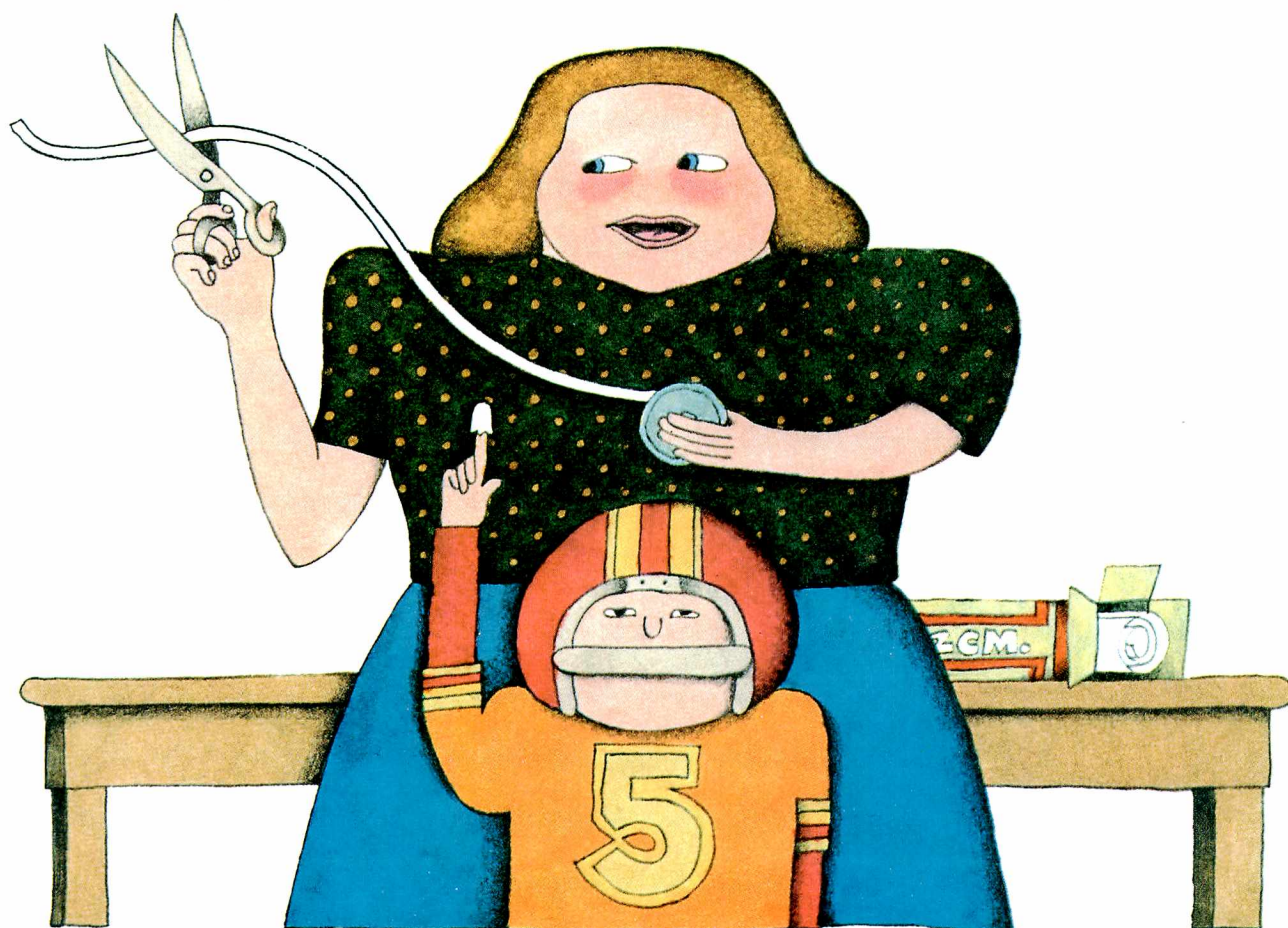
volume, in both liquid and dry measure. Here the patchwork of standards in the U.S. system of measurement, along with the difficulty of converting amounts of smaller units to larger ones (or vice versa) and of calculating costs, are enough to discourage all but the most persistent, methodical, and mathematically inclined shopper.

Capacity is based on cubed dimensions. In U.S. liquid measure the number of cubic inches in a gallon is 231. This breaks down to  $1 \frac{103}{128}$  cubic inches in a fluid ounce, and that number must be multiplied by the number of fluid ounces in a container to find the total number of cubic inches—or must be divided into the total cubic inches in a container to find the total fluid ounces. Try that on your abacus!

In the dry measure used for bulk amounts of such

products as grain or fruit, units range from 33.60 cubic inches in a pint to 2,150.42 cubic inches in a bushel. But the pints and quarts we use in dry measure do not correspond in actual capacity to those we use in liquid measure. Units of dry measure are sometimes verified by weighing, and because of the various densities of food commodities, the weights may vary for the same dry measure unit. The weight fixed by the U.S. Government for a bushel of wheat, for instance, is 60 pounds, and for a bushel of oats, 32 pounds. There are still other variations, and some States fix official weights that vary from the Federal standards.

The metric standard unit of capacity is the liter, for both liquid measurement and dry measurement such as that used for dry products in recipes. The liter



#### Length

Millimeter (0.001 meter)	0.03937 inch
Centimeter (0.01 meter)	0.3937 inch
Decimeter (0.1 meter)	3.937 inches
Meter (1,000 millimeters)	39.37 inches/3.2808 feet/1.1 yards
Decameter (10 meters)	393.7 inches/32.808 feet/11 yards
Kilometer (1,000 meters)	0.62137 mile/3280.8 feet



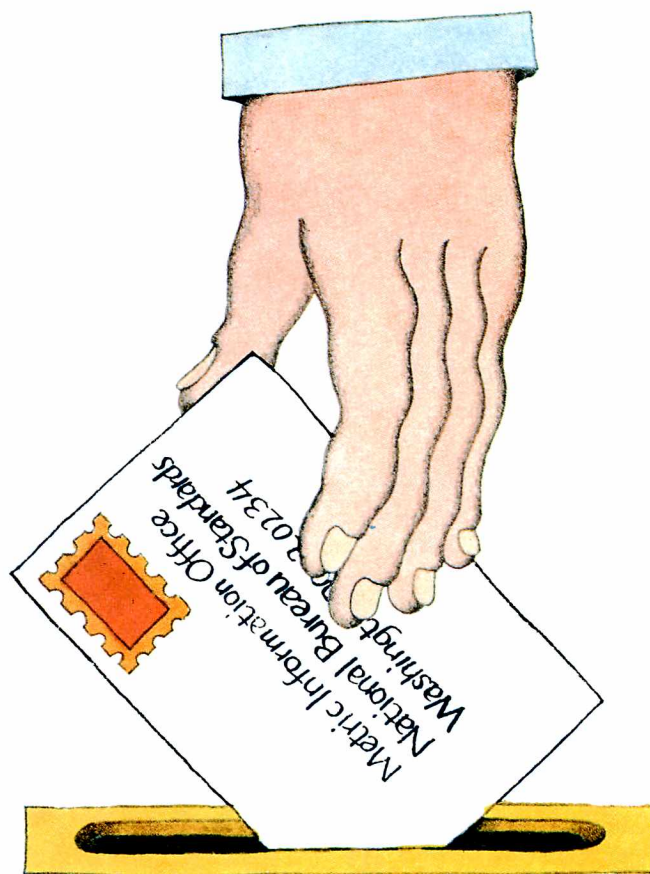
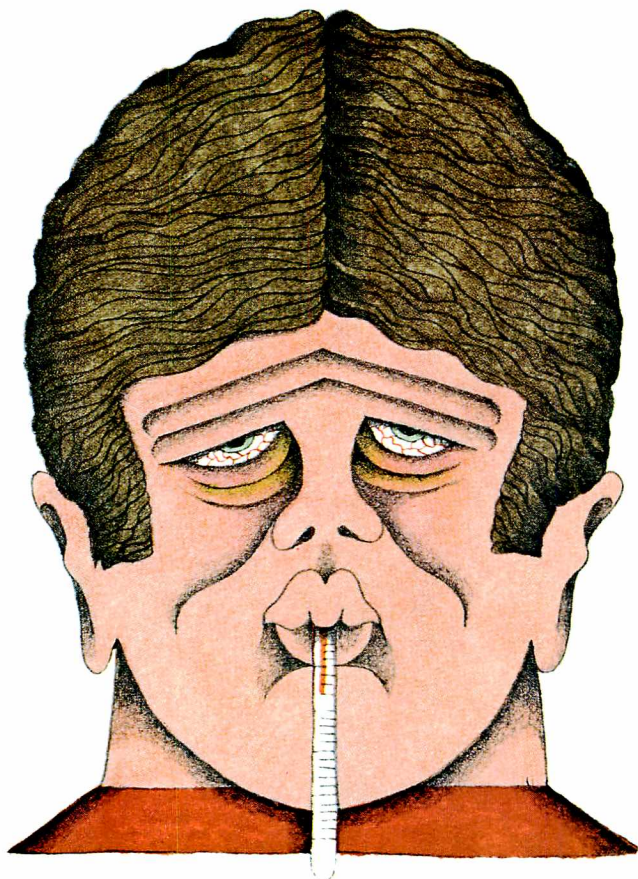
contains a little less than a U.S. dry measure quart and a little more than a U.S. liquid measure quart. The liter is derived from cubing a tenth of the metric unit of length, the meter. The meter (about 39.4 inches or 3.3 feet) is divided into thousandths (millimeters), hundredths (centimeters), and tenths (decimeters). The liter is equal to 1 cubic decimeter, or one-thousandth of a cubic meter.

Because of the metric system's simplicity and precision, its wide use, and its ready accommodation to decimal monetary systems, the number of countries officially going metric has increased steadily since the system was developed in France and adopted there in the 1790's (along with a decimal monetary system). The rate of adoption has been so rapid and complete (25 countries in the past 10 years) that today the

United States keeps lonely company with Brunei, Burma, Liberia, and Yemen as the only nations remaining officially uncommitted to general use of metric.

Although the marriage of metrication and decimalized money was made not in heaven but in 18th century France, those who have noted its widespread success feel that the sooner a similar match takes place in this country the better. U.S. proponents for joining the rest of the world are becoming increasingly vocal in urging official adoption of metric and in exhorting individual citizens, consumer groups—anyone who will listen—to think metric.

The difficulty in thinking metric when you are used to thinking in other terms is indeed the most immediate obstacle to incorporating metric into our economy and way of life. If you heft an object, a lifetime of



Temperature	Celsius	Fahrenheit
Water freezes	Zero	32
Water boils	100	212
Body temperature	37	98.6
Pleasant summer temperature	26.7	80

#### Educational Materials

Educational materials concerning the metric system can be obtained and specific questions concerning the system will be answered by writing to the Metric Information Office, National Bureau of Standards, Washington, D.C. 20234.

conditioning tells you to think of its weight in ounces or pounds, or fractions of them. Mentally converting this to the metric equivalent isn't easy. Many metric proponents believe it would be better—if you can do so—to forget ounces and pounds and think of what you're hefting only in terms of grams (tens or hundreds of them) or kilograms. Some suggest that one way to begin is by learning the metric weights, capacities or dimensions of familiar objects, containers, distances, and areas.

But the biggest and most discommoding obstacle is the long range one that would result from superimposing the metric system on an economy and culture in which most of the things we can see, touch, and feel are already laid out under a system that has worked—and still does. Wholesale change would require replacement of measuring instruments, machine tools, other equipment, and manuals and textbooks. Therefore, some aspects of the present system almost certainly will be with us long after the metric system comes into common use. It would be wasteful to discard many of the things we possess, even measuring tools and instruments, simply because they do not precisely fit metric standards.

Nevertheless, it's becoming increasingly obvious that the metric way of life is going to occupy a larger place in all our futures. Besides its intrinsic merits, metric is the only kind of commercial language in which our exporters may sell and trade their goods to the rest of the world so that there is no misunderstanding at either end of the transaction. For this reason, and because of the growing conviction that this country must and eventually will change over to metric, more and more companies are adding to their product labels the separate metric equivalent measure of contents after stating the ounces, pounds, gallons, fluid ounces, bushels, or similar measures required by law. Some companies have done so by consumer demand.

The Food, Drug, and Cosmetic (FDC) Act of 1938 requires that packaged foods, drugs, and cosmetics carry on their principal label panels the designation of contents in weight, measure, or numerical count "in terms likely to be read and understood by the ordinary individual under customary conditions of purchase and use." But the Fair Packaging and Labeling (FPL) Act of 1966 imposes additional requirements for labeling of food, nonprescription drugs, and cosmetics, including a provision that contents must be listed under the existing U.S. measurement system. These products are regulated as to labeling by both laws. Prescription drugs are exempted from FPL Act requirements and thus are regulated solely under the FDC Act.

Official adoption of the metric system would require congressional amendment of the FPL Act to specify metric label statements for food, nonprescription drugs, and cosmetics. FDA's regulations for food, nonprescription drugs, and cosmetics permit separate

additional statements of metric equivalents on the principal panel or other parts of the label and many manufacturers now carry such statements. The use of either the U.S. or metric system is permitted for label statements of the active ingredient strength of each dosage unit in packages of nonprescription drugs.

For prescription drugs, FDA regulations permit the use of either the U.S. or metric system for required labeling. The prescription drug industry generally has chosen to use the metric system, because of the greater need for precise measurements and because physicians and pharmacists, for whom most labeling is intended, are trained in the metric system by their scientific backgrounds. (The metric system is in almost universal use in the physical sciences in both this and other countries.)

FDA is, of course, well aware of the metric writing on the wall, and keeps this in mind for any appropriate new action or program. For example, its new regulations for nutrition labeling of foods and regulations to be adopted for dietary supplements are based on use of metric measurement for calculating the percentages of the U.S. Recommended Daily Allowances for nutrients per serving and for listing the quantities of certain nutrients. The compelling reason for using metric here is that the quantities involved are so small it would be confusing to calculate or declare them in the small fractions of ounces that would be necessary for accuracy.

An FDA advisory panel that reviewed over-the-counter laxatives for safety, effectiveness, and labeling claims has recommended that active ingredients in individual dosages of a container be listed on the label in metric measurement, and FDA is considering making this recommendation applicable to all categories of over-the-counter drugs.

FDA is beginning to encourage full and more conspicuous use of separate statements on labels of foods, nonprescription drugs, and cosmetics in metric equivalents of the required U.S. units.

One of the most critical aspects of a change to the metric system so far as it concerns the consumer would be the modest-to-extensive changes in packaging needed for most food and drug products to take full advantage of the system. Obviously, it is desirable not only for packages to be in sizes convenient to use but also for the contents to be in round metric numbers. This makes it easier for the consumer to determine the value of his purchase and to use the metric information for purposes such as determining the number of servings and recipes in a food package.

These changes could involve considerable costs to and effort by the industries concerned and would necessitate a familiarization period for both industry and the consumer, but once completed would be beneficial to all.

Two aspects of such changes present special difficulties. One, standardization of package sizes, involves

the food and drug industries as a whole as well as individual companies in any given industry. The other, standardization of can sizes, involves only the food canning industry.

Standardization of package sizes—that is, limiting the number of sizes to those that are most useful and lend themselves to easy calculation of costs—holds certain advantages for both industry and the consumer. Standardization can help the manufacturer keep his expenses down in practically all aspects of ordering, purchasing, processing, labeling, and distribution. It can help the consumer to familiarize himself with and begin using metric amounts—in other words, to think metric. Round numbers such as 10 grams, 100 grams, multiples of 100 grams, and 1 kilogram, and similar amounts in subunits of liters, would be a convenience to the consumer. So would simple portions of the kilogram, such as 50 grams (close to two ounces), 250 grams (close to a half pound), and 500 grams (close to a pound), and similar portions of the liter.

All these considerations apply to canned foods, but the canning industry also faces the formidable task of developing standards for heat treatment that will assure sterility or safety of the food product, based on the new container sizes and the kind and density of the particular food.

FDA cannot unilaterally impose standard package or container sizes on manufacturers; these standards must be worked out by agreement with trade groups representing a specific industry or group of industries. Some of this initial work is going on now on intra-government, intra-industry, and joint industry-government bases.

One recent move toward the metric system has been rulemaking by the U.S. Bureau of Alcohol, Tobacco Products, and Firearms to require standardized metric sizes for containers of domestic and imported wines by 1979. The Bureau, which under an inter-agency agreement with FDA has authority to establish most of the labeling requirements for wines, has at the request of U.S. winemakers designated seven metric sizes for all wines sold after 1978 except for those bottled before a certain date. During the interim period before full conversion existing bottles may be used. Whether old sizes or new, labels during the interim period will be required to state the quantity in both metric amounts and U.S. fluid ounces and decimal fractions of them. The Bureau has proposed similar regulations for distilled spirits.

The move toward adopting metric as a national policy is increasing in tempo. Legislation currently being considered by Congress would establish a United States Metric Board to plan, coordinate, and carry out a policy of encouraging and supporting increased use of metrication and voluntary substitution of metric measurement units in education, trade, commerce, and other parts of the economy. The board would encourage participation by these groups, look for ways

to promote efficiency and keep conversion costs down, and help in developing a broad program of education in the metric system for school children, college students, and the public.

The legislation does not propose a timetable or target date for going metric nationwide, but appointment of the board would provide a mechanism for moving deliberately in that direction. The board would include representatives of industry, labor, business, agriculture, commerce, the consumer, education, construction industry, science and engineering, State and local government, and others.

The manufacturing sector of the economy will be represented in the move to metric by the American National Metric Council, which would work with the United States Metric Board provided for in the legislation now before Congress. Although many trade organizations and individual companies and institutions have taken some initial action or expressed their intentions of moving toward metric, major commitments await Congressional enactment of the legislation to establish the Board and a national metric policy.

The metric system was born of the French Revolution, and was meant to be a system of fair dealing truly representative of and beneficial to the common people. Its developers, sick of manipulations of measures by kings as a way of imposing new taxes and customs, conceived of a system of measurements based on a constant of nature, instead of princely whim. The resulting meter, on which the rest of the system rested, was considered by the imperfect science of the time to be equal to one ten-millionth of the distance from the North Pole to the Equator. As has been shown since, it was not exact, but remarkably close.

The American Revolutionaries of the same period were tired of kings, too, but some of the new Republic's leaders became alarmed at the more radical excesses of the French uprising and the instability that accompanied it. With George III no longer in a position to collect taxes from them, they decided the old system of measurements developed in the mother country was worth keeping after all and would facilitate much needed trade. They settled for a decimal money system.

But the metric system found increasing support in the non-English-speaking world. By 1866 the United States sanctioned the metric system on a legal but not mandatory basis, and in 1875 signed a treaty to adopt it, but it was never put into common use.

Meanwhile, the metric system has continued to gain adherents. When the United States goes metric, all but 2/1000ths (that's 0.2 percent!) of the earth's population will be conducting their temporal affairs under the metric system. At that point, the system, as its Revolutionary developers intended, will truly be one that not only serves practically all the people, but takes the measure of all their works and institutions.



# Toward More Effective Drug Regulation



*Can the process by which drugs are approved for use be accelerated without weakening the safeguards that protect the public from dangerous or ineffective medicines? The Commissioner of Food and Drugs believes it can. He suggests modifying the system to permit some drugs to be approved for limited or conditional use. Drugs receiving such approval would be closely monitored by FDA and would be subject to quick recall.*

*by Alexander M. Schmidt, M.D.*

**A**s befits a subject of enormous importance to the well-being of the American people, there is continuing debate over the way drugs are developed and approved for use in the United States.

On one side are those who say that FDA *underregulation* permits manufacturers to pour powerful

new drugs onto the market without adequate testing.

Those holding the opposite view contend that FDA *overregulation* stifles drug development, for which the American public pays a heavy price: a slowing in the development of needed new drugs, denial to the American people of important new drugs already available in Europe, and damage to the American drug industry as foreign manufacturers surge ahead in new drug development because they do not face the burdens imposed by FDA.

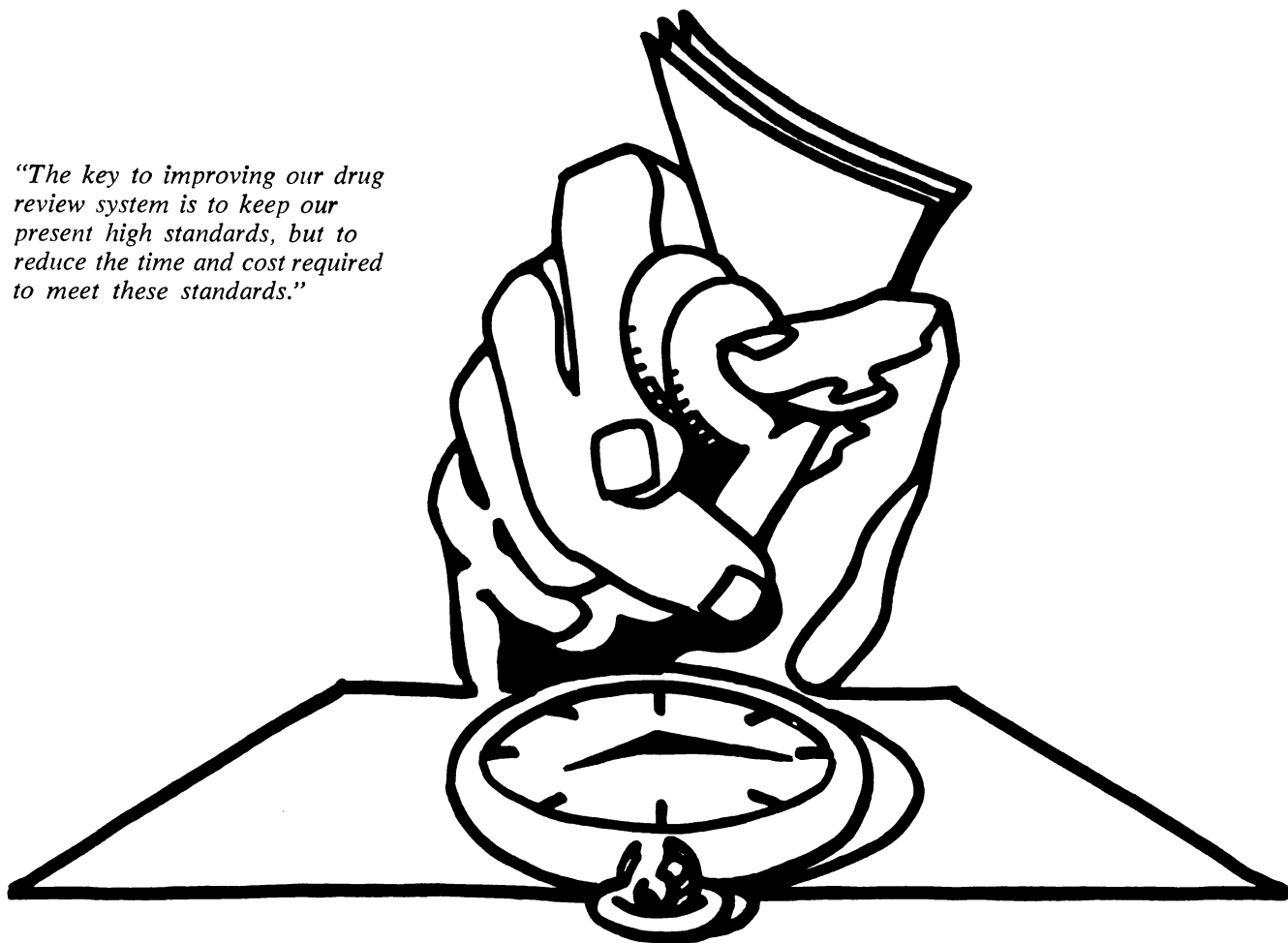
The debate traces back to the 1962 Drug Amendments to the Food, Drug, and Cosmetic Act. These amendments require that every drug sold in the United States must be demonstrated, by well-controlled, scientific studies, to be effective as well as safe. Proof that a drug would actually do what its maker claimed it would do—

i.e., “effectiveness”—had never before been a part of the law.

No responsible critic is likely to disagree with the intent of the 1962 Drug Amendments to insure safe *and* effective drugs. No critics are likely to argue for less safe or less effective drugs than the law requires. Nearly everyone also accepts the need for manufacturers to prove the safety and effectiveness of a new drug *before* marketing it for general medical use.

What is at issue is the efficiency of the procedures by which FDA is carrying out its responsibility under the law to assure that drugs are indeed safe and effective. Since there are so many areas in which we need new drugs—cancer, arteriosclerotic heart disease, diabetes, rheumatoid arthritis, most viral diseases—I have devoted considerable time to ways to make the drug approval process more sup-

*"The key to improving our drug review system is to keep our present high standards, but to reduce the time and cost required to meet these standards."*



portive of new drug development, while at the same time protecting the essential principles of safety and efficacy.

I have found two major areas of agreement between FDA and those who believe FDA is stifling drug development. First, the cost of drug development has indeed increased. No one can argue that it does not cost drug manufacturers money to comply with higher regulatory standards. Although I doubt that the cost is too high to permit a viable, competitive drug industry, it is quite clear under our free enterprise system that higher costs reduce industry's interest in trying to develop drugs with only a modest potential for profit. This seems a clear public loss, in that the study of relatively rare diseases and new drugs with which to treat them are the first to suffer from this situation.

I also agree that the time needed to develop a new drug has increased. Obviously, it takes time to meet the increased requirements imposed by the 1962 Drug Amendments. I agree it is desirable to

reduce the time needed for drug development to an absolute minimum. At the same time, it is essential not to act fast at the expense of proper proof of safety and effectiveness—proof that meets both legal and scientific requirements.

Above all else, the FDA does not agree—as some have charged—that our present standards of proof for drug safety and effectiveness are “too high.” Again, few reasonable people maintain that drugs should not be proved safe and effective before marketing, and few challenge the principle that substantial evidence from scientific studies is superior to medical opinion, however sincere, as proof of safety and effectiveness.

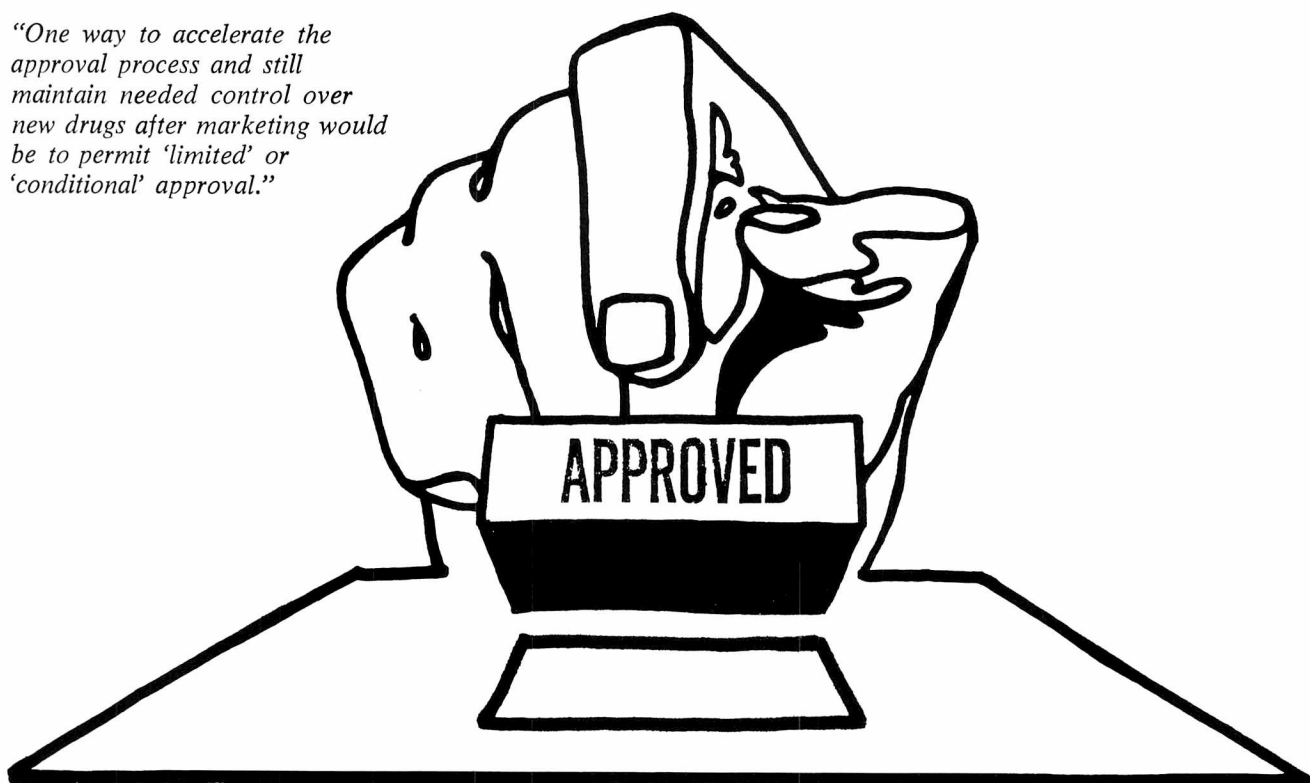
The key to improving our drug review system is to keep our present high standards, but to reduce the time and cost required to meet these standards.

There are several important reforms—some already underway, some we have only thought about, and some needing new legislation—which I believe can maintain, or even improve, the level of confi-

dence we have in our drug supply, while decreasing unnecessary delays and costs in adding still better drugs to that supply.

The major change involves devising a more flexible drug approval process. The main trouble with the present new drug approval system is inflexibility—in the main it is an all-or-nothing event: either a drug is not approved, or it is approved for use in the treatment of specified conditions by anybody with a medical degree. This has a number of basic deficiencies. For example, during the testing and approval process a drug is carefully monitored as to its effect on people, but it is tested on only perhaps 1,000 up to 2,000 individuals. After approval, the drug suddenly becomes available on prescription from any and all physicians to a potential population of 200 million. Since rare events by definition occur rarely, some side effects may not emerge until the drug is out on the market being used on thousands of people instead of hundreds, and largely out of FDA's control. We don't know who is

*"One way to accelerate the approval process and still maintain needed control over new drugs after marketing would be to permit 'limited' or 'conditional' approval."*



using the drug, on whom, in what medical environment, or with what results—good, bad, or indifferent.

If we today determine that an approved drug is a severe and imminent hazard, we can of course remove it from the market; but the definition of severe and imminent hazard is set by law and conditions meeting the definition are rare. The definition is so rare in fact that the authority has never been used. If there is no "imminent" hazard, but a drug in our judgment represents some hazard, we can go to court to remove it. But this may take years. So, since the approval process in practical terms represents our "last chance" for control, we properly tend under the present system to be conservative, to want all data in hand, to be absolutely certain of every detail before approving a drug. Hence, the approval process may be delayed.

One way to accelerate the approval process and still maintain needed control over new drugs after marketing would be to permit "limited" or "conditional" approval. The limits or conditions might

specify that a drug is approved for use only in hospitals, or only by certain specialists, or only by physicians who have taken specific training or who would agree to report results in a prescribed manner. Use of such drugs would be closely monitored by FDA, allowing the Agency to spot bad results early and be prepared to move quickly to remove from use those drugs which prove not to be worth the risk they impose.

This more flexible process involving limited approvals for limited use for a limited time must be coupled with a dependable system for gathering data on actual experience with a drug after it has been marketed.

Also, as part of this change, FDA must have greater power to remove drugs proved unsafe or ineffective after the initial approval. Present systems for reporting physician experience with drugs are abysmal, and FDA cannot cope with any issue of drug removal without facing almost certain legal challenge and delay.

I would not venture lightly into

this area. It does, indeed, approach the outer limits of where I think the FDA ought to be. This matter requires national debate involving physicians, lawmakers, regulators, and the general public. Almost surely, new legislation would be required. Certainly, any change to permit FDA to limit use of selected drugs as part of the approval process would require the fullest cooperation of physicians prescribing the drugs.

But, it is time for the debate to begin. I believe the debate will prove that these or similar changes are needed and must be made. They offer our best hope for earlier appearance in the United States of important new drugs. They offer new incentives to needed drug research by the American pharmaceutical industry. And they offer the best hope I can see to do both without compromising our present high standards for safety and effectiveness.

*Alexander M. Schmidt, M.D., is Commissioner of Food and Drugs.*

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# News Highlights

## Views Sought on Drug Labeling Petition

The Food and Drug Administration is seeking public comment on a petition which urges it to extend present requirements that certain prescription drugs be accompanied by labeling warnings written for consumers. The labeling would be given to the patient when a prescription is filled.

In announcing the action, Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, said that "FDA is publishing this petition to try to learn how consumers feel about the need for and usefulness of patient labeling and to see how we can strengthen the Agency's program to provide more information on prescription drugs to patients.

"FDA's long-standing policy is that consumers should be aware of the potential side effects from prescription drugs, and in many cases should actively participate with the physician in deciding on appropriate therapy," he said.

The petition urges additional label warnings because, it says, patients are not now receiving adequate information from physicians, or the information they do receive is misunderstood or forgotten by the patient.

FDA initiated the idea of patient labeling for prescription drugs in 1970 when it required such labeling for birth control pills. FDA said at that time that birth control pills were appropriate for patient labeling because they are prescribed for healthy women and because women should be aware of and watch for adverse reactions.

Since 1970, FDA has required patient labeling for an aerosolized asthma drug, and has proposed patient labeling for intrauterine contraceptive devices (IUD's). FDA is considering patient labeling for other products, such as hearing aids.

The petition specifically urges that written warnings accompany drugs that the petitioners say pose dangers to pregnant or breast-feeding women, such as hypnotics and tranquilizers, and drugs like amphetamines and chloramphenicol that the petitioners say have been overprescribed and can have serious side effects.

The petition was submitted by the Center for Law and Social Policy on behalf of Consumers Union of the U.S., Inc., Consumer Action for Improved Food and Drugs, National Organization for Women, Women's

Equity Action League, and Women's Legal Defense Fund.

FDA urged consumers to comment generally on the idea of patient labeling and to address themselves to how detailed labels should be, how labels should be presented and distributed, which drugs should receive priority attention, and how such labeling should be drafted and approved. Consumers were particularly urged to report their own personal experiences with patient labeling.

Comments on the petition may be submitted until March 5, 1976, to the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20852. The petition, originally filed with FDA on March 31, 1975, was published in the November 7 FEDERAL REGISTER.

## New Labeling Proposed for "The Pill"

FDA is circulating among consumer, industry, and professional groups a proposal to revise physician labeling for birth control pills.

Physician labeling is the information about prescription drugs that manufacturers are required by FDA to supply to physicians. The draft on which FDA is seeking comments before issuing a formal proposed regulation would require physician labeling on birth control pills to include the following new information:

- Women aged 40 or over should be urged to use methods of contraception other than "the pill" because of an increased risk of heart attacks. This recommendation is based on recent British studies which show that women over 40 taking "the pill" are about five times more likely to have heart attacks than women the same age not taking oral contraceptives.

- Some extremely rare birth defects, such as heart malformations and stunted limb development, have been reported more frequently in children whose mothers took female sex hormones in early pregnancy than in children whose mothers did not take sex hormones. Birth control pills contain the sex hormones estrogen and progestin, or progestin only. Any woman who has not taken "the pill" as directed should be checked for pregnancy if one menstrual cycle or period is missed, so that a developing child is not exposed to the increased risk of another month of sex hormones.

- Women who wish to become pregnant should consider waiting for about three months after discontinu-



ing "the pill" before conceiving. Data show there is a possible increased risk of spontaneous abortion in women who become pregnant shortly after discontinuing "the pill."

- Tests for pregnancy in which sex hormones are administered to the patient must no longer be used because of the risk of hormone exposure to the developing child. Tests using blood or urine samples are available to diagnose pregnancy.

- Nonmalignant tumors of the liver, which can be fatal due to internal bleeding, have been reported with the use of "the pill." This is an extremely rare finding.

FDA emphasizes that serious adverse effects associated with "the pill" are relatively uncommon, and that birth control pills remain a relatively safe method of contraception when taken properly. "The pill" continues to be the most effective method of birth control other than sterilization.

### **Warning Proposed on Oral Diabetes Drugs**

FDA has proposed that new warnings be required on the labeling of all oral antidiabetic drugs.

The proposed warnings would tell physicians that there may be an increased risk of cardiovascular death in diabetic patients treated with the oral drugs as compared to those treated by diet alone or by diet and insulin. The proposed new labeling states that the oral drugs should be used only by people whose symptoms of excess blood sugar cannot be controlled by diet and in whom insulin cannot be used.

Commissioner of Food and Drugs Alexander M. Schmidt, M.D., said that the "sole purpose" of the proposed new labeling is to inform physicians and their patients of the higher risk of serious side effects associated with the use of the oral antidiabetic drugs. "The FDA action in no way is intended to preclude the physician from exercising his own clinical judgment when dealing with individual patients," Dr. Schmidt said.

The proposed new labeling emphasizes that the patient not only should be informed of the advantages and potential risks of the oral hypoglycemics and of other kinds of therapy but should participate with his physician in the decision to use the drugs.

### **FDA Issues New Laser Safety Standards**

FDA has issued a new safety standard to prevent unnecessary consumer and industrial exposure to laser radiation. The standard takes effect July 31, 1976.

The standard establishes four classes of laser products according to the intensity of the radiation emitted and potential for producing harmful effects. The standard specifies safety features and warnings for those products capable of causing biological damage.

The laser standard is the first promulgated by FDA to require that warning labels be reproduced in cata-

logs and descriptive brochures, and the first to specify that specified symbols and colors be used with precautionary statements.

Surveys of laser products in educational and industrial use conducted by FDA in 1973 showed serious deficiencies in safety practices and in products.

About 30,000 lasers—devices that produce particularly concentrated beams of light—are used for educational purposes in U.S. colleges and schools. Growing at the present rate of about 18 percent annually, the laser industry projects total sales this year of \$310 million among its 150 manufacturers.

Many of the safety features required by the new standard are now in use or can be incorporated into present designs with minimal expense.

### **Manufacturer Recalls Sleep-Aid**

The manufacturer of Sominex 2 is recalling all outstanding stocks of the product and has halted its distribution and promotion. These actions were taken by the manufacturer, the J.B. Williams Co., Inc., New York, a division of Nabisco, at the request of FDA.

Sominex 2, a nonprescription drug sold nationally over-the-counter as a nighttime sleep-aid, contains a prescription drug, diphenhydramine.

The Food, Drug, and Cosmetic Act prohibits the sale of a prescription drug directly to consumers without medical supervision.

Under FDA policy, there are two ways in which a prescription drug can be switched to nonprescription status. One way is by petition to FDA. Such petition may be offered by the company selling the product, by the FDA Commissioner, or by any interested person.

The second way is through a program now underway to review the safety and effectiveness of all ingredients used in nonprescription drugs. In addition to recommending acceptable ingredients, formulations, and labeling for each major category of nonprescription drugs (laxatives, antacids, sleep-aids, etc.), the non-government scientists conducting the review are asked to recommend changes in the prescription and non-prescription status of various drugs.

If FDA formally agrees with an expert recommendation for changing a drug from one status to another, the switch may then be made by drug manufacturers.

In the case of Sominex 2, the non-FDA reviewers in the OTC program are recommending that diphenhydramine, the active ingredient in Sominex 2, be allowed for OTC use provided additional studies confirm the safety and effectiveness of the drug for such use. FDA has not yet acted on the recommendation, however, and the required studies have not yet been conducted. FDA, therefore, judged Sominex 2 to have been marketed prematurely, both in terms of the law and in terms of the scientific studies needed to confirm its suitability for the OTC market.

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# Regional Reports

## REGION II

New York District inspectors discovered that the S & M Sugar Co., Inc., Brooklyn, New York, a bakery warehouse, was storing food products under insanitary conditions. Numerous lots of bakery supplies were found defiled by rodents. At FDA's request the New York State Department of Health embargoed practically all food in the warehouse. Reconditioning of the goods took place under the direct supervision of the Department of Health and an FDA investigator. The corporation and its principal officer, Samuel Mernick, secretary-treasurer, pleaded guilty in the U.S. Court in the Eastern District of New York to one count of holding food under insanitary conditions and were fined \$1,000 each. Mernick's fine was suspended.

The first and only U.S. port of call for the S.S. *Lossi Bank* was at Brooklyn, New York, where her entire cargo of cocoa beans from New Guinea was unloaded. Inspectors from FDA's **New York District** found hundreds of insects, later identified as "Red Legged Ham Beetles," crawling on the surface of the bags. Since the cocoa beans had not been damaged, the lot of 23,540 bags, weighing 2.3 million pounds and valued at \$2.2 million, was allowed to be fumigated and was then released. Within a few days, inspectors found that the "Red Legged Ham Beetles" from the S.S. *Lossi Bank* had infested the cargo unloaded from another ship, the S.S. *Ru Yung*. Among these lots were 300,000 pounds of Indonesian black pepper and 250 bags of Indonesian nutmeg, which also required fumigation before being released.

When FDA's **Buffalo District** learned of an accident in the plant of an upstate New York chocolate manufacturer that resulted in possible contamination of his product, inspectors visited the firm and made suggestions that led to a \$60,000 modification of the plant. The firm had reported possible contamination of condensed milk by a solution used to clean equipment. Modifications of milk storage and cleaning systems, including physical isolation of cleaning equipment from other equipment containing milk, will make it unlikely that contamination will occur in the future.

The Buffalo District detained a variety of products offered for import because of laboratory findings of filth including insect parts and fragments, rodent hairs, and in some cases, rabbit and cat hair. Among the products ordered to be reexported were 800 cases of assorted macaroni, valued at almost \$4,500, of-

fered for import from Ontario, Canada; 25 cases of Italian Nectar destined for Cleveland, Ohio, via the Port of Buffalo; and a truckload of 3,000 cases of various types of cookies, valued at \$15,750, bound for Wisconsin from Peek Frean, Division of Associated Biscuits of Canada, Ltd., Toronto, Ontario.

As a result of its continuing survey of fish import shipments for mercury contamination, the Buffalo District refused entry into the United States of 480 pounds of fresh yellow pike fillets shipped by Hamilton Finlay Fish, Ltd., Hamilton, Ontario, Canada, and a second lot of yellow pike shipped from Freshwater Fish Market, Thunder Bay, Ontario, because of mercury contaminations.

In the wake of Hurricane Eloise, which caused extensive flood damage in Puerto Rico, FDA's **San Juan District** devised follow-up plans in cooperation with Commonwealth and local health officials. Joint investigations of regulated industries, including tuna canneries, drug manufacturers, a rum distillery, a large candy producer, and a host of retail and warehouse operations, showed extensive damage to firms and products. Identifying contaminations and arranging for the reconditioning or destruction of those lots involved took more than four weeks of concentrated joint FDA-State operations.

## REGION III

Girl Scouts and their families in central Maryland will have an increased awareness of good food habits if they follow suggestions in *The Many Faces of Food*, a guide for Scout leaders that includes FDA materials. Anne Lane, consumer affairs officer in FDA's **Baltimore District**, assisted in development of the guide. Attractively illustrated to appeal to young people, it suggests activities to be used by Brownies, Junior, Cadette, Senior, and Adult Scouts for obtaining merit badges. The program is being financed by a local restaurateur who is interested in better nutrition for youth.

## REGION IV

Automated Medical Laboratories, Inc., Miami, Florida, recalled over 20,000 liters of Source Plasma (Human), valued at \$500,000, manufactured by two of its firms, Orlando Plasma Corporation and Plasma Corporation of Clearwater. FDA's **Orlando District** investigators found inadequate hepatitis testing and

poor recordkeeping at the Orlando firm, which also conducted hepatitis testing for Plasma Corporation of Clearwater. The recalled plasma must be completely tested for hepatitis and approved by FDA before any of it can be used.

Steinfeldt-Thompson Co., Inc., Dania, Florida, a packer of canned, Spanish specialty food items, has obtained a Temporary Emergency Permit from FDA allowing it to distribute low-acid canned foods after a two-month hiatus in operations. The firm had been prohibited from making interstate shipments of low-acid canned foods produced at the Dania facility after an inspection by Orlando District investigators revealed significant deviations from Good Manufacturing Practice Regulations, including lack of approved scheduled process times, inadequate recordkeeping, inaccurate automatic temperature recorders, and lack of recall procedures. Products that had been packed before the time of inspection were placed under a stop-sale order by the Florida Department of Agriculture and Consumer Services. When a subsequent inspection showed that the firm had corrected the deficiencies it was granted the Temporary Emergency Permit. This permit can be revoked if the firm is again found to be in violation of FDA regulations.

Thirty-five thousand pounds of El Presidente brand frozen, peeled, and deveined shrimp, offered for import from El Salvador, was detained at the Port of Miami by Orlando District inspectors. Analysis of samples of the shrimp at FDA's mobile laboratory revealed decomposition. The shipment, packed by Pezca, S.A., and valued at \$35,000, was destined for Los Angeles.

When Hurricane Eloise's 130-mile-per-hour winds struck Florida's gulf coast in September, seven Orlando District investigators rushed to the western Florida Panhandle to assist State and county health officials. For three days, the FDA inspectors checked grocery stores, restaurants, drug stores, feed mills, grain storage elevators, and hospitals to dispose of unsafe foods, drugs, and cosmetics. The hurricane damaged approximately \$263,763 worth of food, \$5,000 worth of feed grain, and \$748 worth of drugs and cosmetics. Winds and rain caused the greatest damage in Fort Walton Beach and Panama City Beach, the two cities hardest hit, but flooding damage was minimized because the hurricane hit the coast during low tide. Many businesses used ice to preserve foods during periods of loss of electric power. Portable generators provided by military units provided power to food establishments on a rotating basis.

## REGION V

Thorough investigative work by FDA's **Chicago Dis-**

**trict** led to the discovery of over 2,000 liters of 15-year-old blood plasma in a public cold storage warehouse. The plasma was owned by Bishop Biologicals, Inc., Chicago, a bankrupt plasmapheresis center which had put the plasma in storage when the donor center and processing facility was closed and put up for sale. With the assistance of the Illinois Department of Public Health, the Government made a mass seizure of the plasma, valued at over \$62,000. The FDA charged that the product was adulterated and misbranded in that it was not manufactured in accordance with Good Manufacturing Practice Regulations and that the label lacked the name and address of the manufacturer, distributor, or packer; an accurate statement of the net quantity of contents; the name and/or quantity of the anticoagulant; and an indication that the products are not suitable for use in humans. The Department of Public Health placed the plasma under State embargo.

Over 2,600 Cincinnati consumers had an opportunity to find out how FDA does its job when the mobile laboratory of FDA's **Cincinnati District** was turned into a consumer education display. Shown during Law Observance Week, the laboratory display included exhibits and demonstrations of equipment used by investigators and typical contamination problems they may encounter. An audiovisual presentation was made also on over-the-counter drugs. Law Observance Week is sponsored by the Cincinnati Chapter of the Federal Bar Association.

## REGION VI

Inspections by FDA's **Dallas District** revealed that the Texas Grocery Co., Houston, was holding food under insanitary conditions which allowed it to become contaminated with filth. The corporation and three of its officers pleaded guilty to a one-count charge and were fined a total of \$1,500 by U.S. District Judge Allan B. Haney. The corporation and one officer, William Wuntch, were fined \$500 each, while two other officers, Israel Wuntch and Sidney Stoler, were fined \$250 each.

## REGION VII

After an inspection by FDA's **Kansas City Field Office** revealed widespread insect contamination in the Central Cash and Carry Wholesale Grocery, West Plains, Missouri, the parent company, Reed-Harlin Co., and two company officials, James E. Hard and Bobby G. Burns, pleaded guilty to a one-count sanitation charge. Magistrate Dennis Steward, sitting in the U.S. District Court for Western Missouri, fined the company \$100 and the officers \$50 each. Hard and Burns had pleaded guilty to a similar charge in 1972. As a result of the current action, the firm is

initiating steps to correct the insanitary conditions, including the hiring of a sanitation consultant and a full-time employee to implement corrective measures.

Inspection by the Kansas City Field Office of Sun Star Foods, Robb-Ross Division, Sioux City, Iowa, revealed active insect infestation of the peanut handling and manufacturing equipment used in making peanut butter and other peanut products. Confirmation of these findings by FDA laboratory analysis of the finished peanut butter product led to Government seizure of 68 cases of peanut butter, valued at \$500, shipped to a dealer in Minneapolis, Minnesota.

A routine Kansas City Field Office inspection of the Lander Co., St. Louis, Missouri, led to the voluntary recall of an antiseptic mouthwash. The firm had changed the formulation of a 20 percent alcohol antiseptic mouthwash, but failed to change the label accordingly.

Tracy Pharmacal Co., St. Louis, Missouri, was found to be in criminal contempt of court and was fined \$4,900 by Magistrate H. Kenneth Wangelin of the U.S. Court for Eastern Missouri. Kansas City Field Office investigators found that the firm had sold 341 vials of a drug called Prozyde that was under seizure due to misleading label claims. The fine is approximately twice as much as the firm's receipts from sales of the drug.

Approximately 200 different drug products were seized by the Government at Jamieson-McKames Pharmaceuticals, Inc., and Pharmacare Pharmacy, Inc., St. Louis, Missouri. The Kansas City Field Office charged that some drugs distributed by Jamieson-McKames and Pharmacare Pharmacy were substituted for brand-name drugs made by recognized national manufacturers. Some of the substituted drugs did not receive premarketing approval from FDA, as required by law.

The investigation was started earlier this year when a complaint was received from a pharmaceutical company that pharmacies owned by Jamieson-McKames or Pharmacare Pharmacy were substituting look-alike drugs when filling prescriptions for brand-name drugs made by the complaining company. Subsequently, similar complaints were received from two other pharmaceutical companies.

Jamieson-McKames owns at least 16 Pharmacare Pharmacies in Missouri. Jamieson-McKames products are distributed under the Pharmacare Pharmacy label.

The seizure climaxed an investigation by FDA into Jamieson-McKames' activities. The investigation task force was composed of FDA, the Office of the Missouri State Attorney General, the U.S. Postal Service, the Missouri State Highway Patrol, and the Missouri Bureau of Narcotics and Dangerous Drugs.

## REGION VIII

A shipment of over 1,000 natural bristle toothbrushes from China, valued at \$115, was refused entry into the United States at the Denver Port of Entry when inspectors from FDA's **Denver District** found they contained nits, insect webbing, insect eggs, and insect excreta. The brushes, which had been consigned to a Denver import-export firm, were returned to the U.S. Customs Service for disposition.

Judge Fred Winner of the Federal Court in Denver, Colorado, denied a request by Marian G. Ogelvie, Golden, Colorado, for a Temporary Restraining Order to restrain FDA and the U.S. Department of Health, Education, and Welfare from interfering with the importation and receipt of Laetrile for her use. After oral argument of the case Judge Winner denied the request on the basis that a similar case in Oklahoma was being considered by the 10th Circuit Court of Appeals in Denver and the decision in that case would be binding on him. In the Oklahoma case, being appealed by FDA, the court declared that it is illegal for the Agency to interfere with the distribution of Laetrile for personal use. Laetrile is an unapproved drug derived from apricot kernels and promoted as a cure for cancer.

## REGION IX

Over 100 different lots of raw materials and finished products valued at an estimated \$37,000 were seized by a U.S. marshal at Lura-Glo Products, Inc., Oakland, California, a manufacturer of drugs, cosmetics, and dietary supplements. The firm has a long history of violations of FDA's Good Manufacturing Practice Regulations. There have been previous seizures by FDA's **San Francisco District** of articles manufactured by the firm and the State of California had revoked the firm's manufacturing license. The owner of the firm had advised FDA some time ago that he was selling the business but recent inspection showed he was still manufacturing drug products with virtually complete disregard for good manufacturing practices. San Francisco District representatives assisted the marshal with seizure, inventory, and transfer of the goods—enough to fill two large trucks—to a public storage warehouse. All products of obvious interstate origin were seized by the marshal, representing about 90 percent of the material on hand. The State of California embargoed the remaining 10 percent.

## REGION X

Univar Corp., doing business as Centennial Mills, Portland, Oregon, and its responsible officials, entered into a consent decree of permanent injunction in U.S. District Court for the District of Oregon as a result



of a charge by FDA's **Seattle District** office that the firm was continuing to process and hold foods under objectionable conditions and practices despite repeated warnings. The firm, one of the largest of its kind in the Northwest, mills and distributes wheat flour, and packages and distributes wheat products, dry beans, rice, and popcorn.

Under the consent decree, Centennial Mills shut down for two weeks until it brought its milling and processing operations into compliance with FDA regulations by establishing an effective sanitation control program, eliminating insects and vermin from its facilities and equipment, cleaning and renovating its facilities and equipment, and selecting a qualified individual to be responsible for maintaining the facilities, equipment, and operations in a sanitary condition.

The decree also required that all foods stored within the facility be examined for filth, and any food found to be contaminated either be destroyed or otherwise brought into compliance with the Federal Food, Drug, and Cosmetic Act. The firm is permanently enjoined from distributing foods which are adulterated which means, in effect, that if there are any further violations the firm could be held in contempt of court.

FDA's Seattle District organoleptic experts sniffed and a U.S. marshal seized approximately 52,138 pounds of frozen salmon, valued at about \$54,000, in Seattle, Washington, because of the presence of decomposed fish. The fish had been shipped from Alaska and was being stored in public cold storage warehouses for the account of Traco, Inc., Seattle.

Alert workers unloading wheat in Salt Lake City, Utah, started a chain of events ending with Government seizure of approximately 208,160 pounds of bulk wheat at Ammon, Idaho. The wheat, originally offered into interstate commerce by JMJ Elevator Co., Iona, Idaho, was sampled and seizure recommended by FDA's Denver District after Peavey Co. in Salt Lake City notified the office that workers unloading the grain from a railcar detected the presence of "pink" wheat. The "pink" wheat results from the use of a poisonous treatment, such as mercury, on seed wheat for fungicidal or other purposes. Such seed can be hazardous to humans and animals if eaten. The wheat was subsequently returned to the Ammon, Idaho storage site where seizure of the lot was initiated by the Seattle District.

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## State Actions

### Aflatoxin in Corn

Two FDA districts cooperated with the North Carolina Department of Agriculture in the investigation of insect-infested lots of cornmeal, leading to the voluntary destruction of 1,400 pounds of cornmeal and 4,200 bushels of corn, by Lakeside Mills, Inc., Kinston, North Carolina, because of aflatoxin contamination. Routine inspection of the mill by a State Department of Agriculture inspector revealed the insect infestation. Samples of the corn and cornmeal made from it were collected by Alan R. Moore of FDA's Raleigh Resident Post, while the New Orleans District laboratory assisted with the analysis of the samples, which disclosed high aflatoxin levels. The

Department of Agriculture embargoed the corn and cornmeal and two hundred pounds of cornmeal were returned from trade. Destruction of the merchandise, valued at \$18,000, was witnessed by the Department of Agriculture inspector. Aflatoxin is a toxin produced by a mold that grows on corn and other grains and that can be spread by insects.

### Bacteria in Bottled Water

Fleming Foods Co., Inc., Topeka, Kansas, recalled all outstanding stocks of its Rainbow Brand Bottled Spring Water. The voluntary recall was initiated when the Missouri State Division of Health found a high bacteria count in the bottled water.

### Milk Contamination Traced

When analysis of milk samples collected on a routine basis on a farm in eastern Long Island, New York, revealed contamination by the pesticide dieldrin, an investigator from FDA's New York District traced the source of contamination to the dairy herd. Informed of the findings, the Suffolk (New York) County Health Department condemned all milk produced by this herd. Dieldrin accumulates in the fatty tissue of the animal and could result in a persistent and continuous milk contamination. In an effort to save the herd, the cows are being treated individually. If the dieldrin residues cannot be eliminated, the Health Department will order that the animals be sacrificed.

# Seizures and Postal Service Cases

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

A total of 25 actions to remove from the consumer market products charged to be violative was reported in October. These included 18 seizures of foods: 2 involved charges concerning poisonous and deleterious substances, 15 involved charges concerning contamination, and 1 involved charges concerning economic and labeling violations. Other seizures included 1 of color additive, 2 of drugs, and 4 of medical devices.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>FOOD/Poisonous and Deleterious Substances</b>		
Almonds/Jacksonville, Fla. 9/16/75	Valley Almond Growers Coop/Winters, Calif. (M,S)	Contain the added poisonous and deleterious substance aflatoxin.
Frog legs/Chicago, Ill. 9/23/75	Imported from India.	Contain the added poisonous and deleterious substance viable <b>Salmonella</b> microorganisms.
<b>Contamination, Spoilage, Insanitary Handling</b>		
Beans, pinto/San Miguel, N.Mex. 10/16/75	San Juanito Chile Products/San Miguel, N.Mex. (D)	Held under insanitary conditions; insect and rodent contaminated.
navy; black peppercorns/Carrollton, Tex. 10/6/75	Arrow Industries, Inc./Carrollton, Tex. (D)	Held under insanitary conditions; rodent contaminated.
Clam fry mix; flour; rye flour/New Bedford, Mass. 10/10/75	National Wholesale Co./New Bedford, Mass. (D)	Insect and rodent contaminated.
Cottonseed flour/Ponce, P.R. 10/9/75	Rovira Biscuit Corp./Ponce, P.R. (D)	Insect contaminated.
Crabmeat, canned/Seattle, Wash. 9/23/75	Imported from Taiwan.	Decomposed; insect and rodent contaminated.
Flour, wheat/Mayaguez, P.R. 8/27/75	Sucrs. de Esmoris & Co., Inc./Mayaguez, P.R. (D)	Held under insanitary conditions; insect contaminated.
Honey/Onsted, Mich. 10/9/75	Morton Quality Products/Newark, Del. (S)	Sugars and starches have been substituted in part for honey.
Peanuts, shelled, Spanish/Chicago, Ill. 9/22/75	Beatrice Caramel Apple Co./Chicago, Ill. (D)	Moldy.
Popcorn/Greeley, Colo. 10/17/75	D & D Bean Co./Imperial, Nebr. (S)	Held under insanitary conditions; insect contaminated.
Pumpkin seed/City of Industry, Calif. 9/2/75	El Molino Mills/City of Industry, Calif. (D)	Held under insanitary conditions; insect contaminated.
Rice/Mayaguez, P.R. 10/9/75	Corp. de Importacion y Distribucion/Mayaguez, P.R. (D)	Insect contaminated.
Shrimp, canned/Detroit, Mich. 9/15/75	Washington Crab Producers, Inc./Westport, Wash. (P); Peter Pan Seafoods/Seattle, Wash. (S)	Decomposed; prepared and packed under insanitary conditions.
headless, frozen/Oakland, Calif. 10/15/75	Valley Frozen Foods, Inc./Port Isabel, Tex. (P); Penguin Frozen Foods, Inc./Northfield, Ill. (S)	Insect contaminated; shrimp heads, fish, and crab shell have been substituted for headless shrimp.
Wheat/Murray, Utah 8/20/75	Howard Petracek/Jennings, Kans. (M,S)	Rodent contaminated; false and misleading labeling, since the reused bags bore the names of unrelated products, manufacturers, and net weights.
Salt Lake City, Utah 8/20/75	"	Rodent contaminated; false and misleading labeling, since the reused bags bore the names of unrelated products, manufacturers, and net weights; some unlabeled bags lacked the common or usual name of the article.
<b>Economic and Labeling Violations</b>		
Oyster stew, canned/Seattle, Wash. 9/23/75	Tillamook Oyster Co./Tillamook, Oreg. (M,S)	Short weight.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>COLOR ADDITIVE</b>		
Cherries, Maraschino/Gretna, La. 10/22/75	Zatarain's, Inc./Gretna, La. (M,S)	Contain FD&C Red No. 4 in excess of prescribed tolerance.
<b>DRUGS/Human Use</b>		
Contact lenses, Rx 56/Cleveland, Ohio 9/19/75	Rynco Scientific Corp./Floral Park, N.Y. (M,S)	New drug without effective approved New Drug Application.
lens blanks; and cellulose acetate butyrate beads/Floral Park, N.Y. 8/7/75	Rynco Scientific Corp./Floral Park, N.Y. (D)	False and misleading claims representing and suggesting that there is substantial scientific evidence consisting of adequate and well controlled studies for the article's intended uses, or the article was otherwise generally recognized as safe and effective by qualified experts; inadequate directions for use and not exempted therefrom since articles are new drugs without effective approved New Drug Application; processed in an unregistered establishment.
<b>MEDICAL DEVICES</b>		
Accelatron devices/Snyder, Tex. 8/14/75	Donald G. Smith/Snyder, Tex. (D)	Misbranded; false and misleading therapeutic claims; inadequate directions for use.
Acuflex acupuncture device, Pro-Med auriculotherapy device/Munhall, Pa. 8/21/75	Jaesic Industrial Co., Inc./Wixom, Mich. (M); Professional Medical Distributors, Inc./Wixom, Mich. (S)	False and misleading therapeutic claims, including (Acuflex) claims for gastritis, internal organ diseases, muscular conditions, conjunctivitis, and (Pro-Med) claims of conformity with FDA safety, manufacturing, and labeling regulations; inadequate directions for use.
Diapulse devices/San Antonio, Tex. 9/18/75	Diapulse Mfg. Corp. of America/New York City, N.Y. (S)	False and misleading therapeutic claims; inadequate directions for use.
Therapuncteur and Punctoscope devices/Oklahoma City, Okla. 8/20/75	Medi-E-Prise/Orlando, Fla. (S)	False and misleading claims for peripheral disorders, most algia cases, plantar pains, osteomyelitis, fistulated abscesses, ulcers, eczema, shingles, etc.; inadequate directions for use.

## 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)

- July 22, 1975: **Cornwell Associates** and **The Insider's Mailbox**, 620 Kinderkamack Road, River Edge, New Jersey 07661; **The Insider's Mailbox**, 595 Madison Avenue, New York, New York 10022; **The Insider's Mailbox**, 380 Madison Avenue, New York, New York 10017. Advertising and sale through the mail of the "Astronauts' Diet" represented as the healthiest food plan ever invented for weight loss.
- August 11, 1975: **United Medical Supply**, P.O. Box 4823, North Hollywood, California 91607. Advertising and sale through the mail of the sexual device, the "Commander," representing the ability to maintain an erection for a lengthy period of time.
- August 12, 1975: **Citrus Farms**, 4040 East McDowell Street, Phoenix, Arizona 35008. Advertising and sale through the mail of a grapefruit diet pill representing the loss of weight.
- August 12, 1975: **Willpower**, Drawer G., Hawthorne, California 90250. Advertising and sale through the mail of an antiseptic mouthwash representing a loss of weight when used before a meal by reducing the sense of taste, and, therefore, causing a loss of appetite.

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

- July 24, 1975: Against **Dietsch Distributors**, R.D. No. 1, Sheboygan, Wisconsin. Advertising and sale through the mail of an ointment for the relief of arthritis.
- August 5, 1975: Against **Ruthie and Ace Products**, 130 West 42nd Street, Suite 1305, New York, New York 10036. Advertising and sale through the mail of "Mexican Spanish Fly" and "The Russian Fly" represented as sexual stimulants.
- August 15, 1975: Against **Cosmetics Laboratories**, 1030 Windsor Parkway, Atlanta, Georgia 30319. Advertising and sale through the mail of cosmetic capsules containing vitamin "E" to prevent wrinkles and youth restorer formula; and, vitamin "E" shampoo for increasing circulation, increasing vasodilation, and for aid in scalp conditioning.

# Notices of Judgment

## NOTICES OF JUDGMENT on Seizure Actions

### FOOD/Poisonous and Deleterious Substances

#### **Barley**, at St. Cloud, Dist. Minn.

Charged 1-7-75: when shipped by Bowdon Grain Co., Bowdon, N. Dak., the article contained the pesticide chemical malathion, in excess of the prescribed tolerance; 402(a)(2)(B). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60165; S. No. 80-983 H; N.J. No. 1)

### FOOD/Contamination, Spoilage, Insanitary Handling

#### **Basil**, at Chicago, N. Dist. Ill.

Charged 3-25-75: while held by Action Warehouse, Inc., Chicago, Ill., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 60301; S. No. 98-727 H; N.J. No. 2)

#### **Bean sauce, canned, and canned Hoi Sin sauce**, at Brooklyn, E. Dist. N.Y.

Charged 1-27-75: while held for sale, the articles were contained in swollen and leaking cans; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 60180; S. Nos. 42-667/8 H; N.J. No. 3)

#### **Bean sauce, canned, and soy sauce**, at New York, S. Dist. N.Y.

Charged 3-11-75: while held for sale, the articles were contained in swollen and/or leaking cans; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 60218; S. Nos. 44-207/10 H; N.J. No. 4)

#### **Beverages, carbonated, 7-Up, Crush Grape, and Royal Crown Cola**, at Wichita, Dist. Kans.

Charged 3-6-75: while held by Seven-Up Wichita Bottling Co., Inc., Wichita, Kans., who prepared the articles using ingredients shipped in interstate commerce, the articles contained particles of mold and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized destruction of the beverages and return of the cases and bottles to the dealer. (F.D.C. No. 60253; S. Nos. 75-743/5 H; N.J. No. 5)

#### **Candy pacifiers, Lic-A-Nip**, at Chattanooga, E. Dist. Tenn.

Charged 4-8-75: when shipped by Paul Spitz Co., Inc., Bronx, N.Y., the article was unfit for food, since it was prepared in a manner and in a shape which could present choking and aspiration hazards to infants and small children, who were likely to use the article; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60254; S. No. 60-550 H; N.J. No. 6)

#### **Cereal, breakfast**, at Camden, Dist. N.J.

Charged 11-20-74: while held by Alfred Lowry & Bro., Inc., Camden, N.J., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60075; S. No. 55-598 H; N.J. No. 7)

#### **Corn syrup solids**, at Christiansted, Dist. V.I.

Charged 3-19-75: while held by Island Dairy, Inc., Christiansted, St. Croix, V.I., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 60277; S. No. 25-525 H; N.J. No. 8)

#### **Crabmeat, canned**, at St. Paul, Dist. Minn.

Charged 3-7-75: while held for sale, the article contained decomposed crabmeat; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60256; S. No. 63-947 H; N.J. No. 9)

#### **Cracker meal**, at Hato Rey, Dist. P.R.

Charged 5-23-75: while held for sale, the article contained insect filth; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 60376; S. No. 22-725 H; N.J. No. 10)

#### **Flour**, at St. Thomas, Dist. V.I.

Charged 5-28-75: while held by Bootsma's Bakery (Pieter Bootsma), St. Thomas, V.I., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 60362; S. No. 25-066 H; N.J. No. 11)

#### **Flour**, at St. Thomas, Dist. V.I.

Charged 5-28-75: while held by East End Bakery, St. Thomas, V.I., the article contained rodent filth and was held under insanitary conditions; 402(a)(3),

402(a)(4). Consent decree ordered destruction. (F.D.C. No. 60363; S. No. 25-069 H; N.J. No. 12)

#### **Flour, cake mix, fig bars, batter mix, and various other foods in bags, cartons, and bales**, at New Orleans, E. Dist. La.

Charged 2-25-75: while held by P.A. Menard, Inc., New Orleans, La., some of the articles contained rodent filth and all were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60235; S. No. 55-007 H et al.; N.J. No. 13)

#### **Flour, potato chips, sugar, chocolate, rice, and other food stocks**, at St. Paul, Dist. Minn.

Charged 1-10-75: while held by Simon & Co., Inc., St. Paul, Minn., some of the articles contained rodent filth, and all the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60161; S. No. 64-228 H et al.; N.J. No. 14)

#### **Ginger, allspice, fennel seeds, cinnamon bark, and cocoa beans**, at Brooklyn, E. Dist. N.Y.

Charged 3-27-75: while held by Lorraine Trading Corp., Brooklyn, N.Y., the articles (except the allspice and cinnamon bark) contained insect and/or rodent filth, the allspice contained decomposed allspice berries, and all the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60296; S. Nos. 44-844/6 H; N.J. No. 15)

#### **Milk**, at Caguas, Dist. P.R.

Charged 3-11-75: while held for sale, the article was decomposed; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60257; S. Nos. 25-042/3 H; N.J. No. 16)

#### **Mushrooms, dried**, at Countryside, N. Dist. Ill.

Charged 4-24-75: while held for sale, the article contained insect filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60345; S. No. 99-078 H; N.J. No. 17)

#### **Mushrooms, dried**, at Oakland, N. Dist. Calif.

Charged 2-19-75: while held for sale, the article contained insect and rodent filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60194; S. No. 26-959 H; N.J. No. 18)

#### **Peas, black-eyed, canned, Kitch-N-Kraft**, at Highlands, S. Dist. Tex.

Charged 2-25-75: while held by SMS, Div. Hi-Port Industries, Inc., Highlands, Tex., the article had been prepared under insanitary conditions; 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 60231; S. No. 89-564 H; N.J. No. 19)

#### **Peach halves, canned**, at Brooklyn, E. Dist. N.Y.

Charged 10-14-71: when shipped by Fruitful Valley Sun, Inc., Dinuba, Calif., the article, labeled in part "Connoisseur . . . Fancy Freestone Halves White Nectar Peaches . . . Heavy Syrup . . . Packed for Jules Weber, Inc., Brooklyn, N.Y.," contained insect larvae, insect parts, and insect excreta; 402(a)(3). The shipper claimed the article, as original processor and guarantor to the purchaser of the article, and denied the charge. The claimant moved to change the venue to California, which motion was denied. The Government served written interrogatories and requests for admission on the claimant. George Noroian (sales manager of Fruitful Valley Sun, Inc.), Dinuba, Calif., as owner of the article, moved that he be substituted for Fruitful Valley Sun, Inc., which substitution was granted. The Government moved for partial summary judgment so as to narrow the factual issues to the key fact of whether or not the test results, of Dr. George York of the University of California at Davis and of FDA Entomologist Thomas L. Schwarz, showed that the article consisted of any filthy substance.

The court granted partial summary judgment deeming a number of facts to be established, including the following facts: the article (900 cases each containing 12 30-ounce cans of peach halves) was a substantially uniform mass; the 96 cans selected from the lot by FDA was a random sample which was fairly and reasonably representative of the lot, as was the portion (15 cans) of the sample tested by FDA Entomologist Thomas L. Schwarz; the tested portion of the sample of peaches (35 cans used in initial test of August 30, 1971, by FDA Entomologist Thomas L. Schwarz; 30 cans tested July 5, 1973, by Dr. George York of the University of California, at Davis; and 15 cans tested on February 7, 1975, by Thomas L. Schwarz) were fairly and reasonably representative of the article; that "filthy," under Section 402 of the Federal Food, Drug, and Cosmetic Act, had its ordinary and usual





meaning, including insect larvae and insect parts; and the current defect level for canned peaches was an average of 5 percent wormy or moldy first by count or 4 percent if a whole larva or equivalent was found in 20 percent of the cans. Thereafter, the case came on for trial by the court. The court found for the Government saying:

"At the trial evidence was offered to show that three tests were made on the peaches, two by the United States and one by the claimant. The first test was made on behalf of the United States, on August 30, 1971, by Thomas Schwarz, an entomologist for the FDA, who examined thirty-five of the ninety-six cans appropriated by the FDA as samples. . . . In the ten cans with the code number NP718682 Schwarz found that five of them contained a whole moth larva and that nine of them contained insect excreta pellets with a range of three to thirty-seven pellets and an average of 11.9 pellets per can. He found a whole moth larva in eleven of the twenty-five cans stamped with the number NP72GN22, and in four of the cans he found two larvae. In addition he found in twenty-two of the twenty-five cans insect excreta with a range of one to sixty-seven pellets and an average of 18.9 pellets per can. The libel stems from this information.

"On March 30, 1972 the Commissioner of Food and Drugs published for the first time in 21 C.F.R. § 128.10 a notice announcing that the FDA had established maximum acceptable tolerance levels for natural and unavoidable defects in food not hazardous to health, copies of which levels were obtainable upon request. Until then these unpublished tolerance levels were employed for the purpose of enabling the FDA to determine whether or not to file a libel and have served the same purpose since publication. For canned peaches the defect tolerance level is 'Average 5 % wormy or moldy fruit by count or 4 % if a whole larva is found in 20 % of the cans.' Some time prior to November, 1972, the claimant requested and received a copy of the defect tolerance levels referred to above.

"In November, 1972 the claimant requested, for testing purposes, a duplicate set of sample cans of peaches and, accordingly, the FDA on January 8, 1973, shipped to the claimant thirty of the ninety-six sample cans. On July 5, 1973, at the request of the claimant, Dr. York, a biochemist engaged in extension food technology at the University of California at Davis, tested each of the thirty cans of peaches \* \* \* and he found through his tabulations that there were a total of ten insect fragments in eight of the cans tested. No examination of the individual peach halves for worminess or moldiness was made prior to their maceration although both claimant and Dr. York had copies, at the time, of the FDA tolerance levels for natural and unavoidable defects.

"Because Schwarz's August 30, 1971 test on the thirty-five cans of peaches did not include an examination of the peach halves for worminess, as required by the published defect tolerance levels, he was instructed to test fifteen additional cans. On February 4, 1974 he individually tested each of the fifteen cans \* \* \*. This examination revealed that six of the fifteen cans (40%) contained a total of nine whole insect larvae or their equivalent but Schwarz did not tabulate every insect fragment but rather only complete heads whether or not attached to a body. Schwarz also microscopically examined each peach half for evidence of the past presence of an insect either on or in the peach halves such as tunnelling, embedded insect fragments, and insect excreta. Thirteen of the one hundred and forty-three halves (9%) were found to have such evidence.

"On May 1, 1974 the claimant, in order to retest the peaches in conformity with the published defect tolerance levels as interpreted by the FDA, requested a second set of sample cans which was denied. Because of this denial claimant moved, at the trial, to dismiss the libel which was also denied on the ground that there was no statutory authority requiring the delivery of two sets of sample cans to the claimant and for the further reason that the claimant was not misled since at the time of its first test it had in its possession the defect tolerance levels. \* \* \* At the trial it was established by a preponderance of the evidence that the peaches in question did contain matter constituting 'filth' as that term is used in the statute. The results of the two tests performed by Schwarz and the one performed by Dr. York all reveal that the cans of peaches are contaminated by varying amounts of insect larvae and insect fragments. Since it has been long established, and the parties agree, that insects, insect larvae, and insect fragments are 'filth' within the meaning of 21 U.S.C. § 342(a)(3), . . . the only remaining questions raised by the claimant are: (1) the correctness and adequacy of the testing methods used by Schwarz, and (2) the amount of 'filth', in the form of insect larvae and insect fragments required for a violation of 21 U.S.C. § 342(a)(3).

"At the trial the claimant attacked the tests employed by the United States in

determining the existence of 'filth' as that term is used in 21 U.S.C. § 342(a)(3). The parties agree that the entire sample of ninety-six cans taken by the FDA from the nine hundred cases of canned peaches were selected at random and were fairly and reasonably representative of the defendant peaches. There was no evidence that the form of testing or the methods used were either improper or incorrectly performed by Schwarz who was a qualified expert with much experience in examining food for insect contamination. The claimant claims that Schwarz's second test on the canned peaches was not in conformity with a proper interpretation of the published defect tolerance levels for canned peaches which provide for:

'Average 5 % wormy or moldy fruit by count or 4 % if a whole larva is found in 20 % of the cans.'

The FDA has interpreted this phraseology to mean, and we agree, that the defect tolerance level is violated by an average of 5 % wormy or moldy fruit by count and if a whole larva is found in 20 % of the cans then it is violated if 4 % wormy or moldy by count. The claimant contends that the tolerance level is violated only when the total number of insect larvae in the entire sample equals 5 % of the total number of individual peach halves in the entire sample, and, if a whole larva is found in 20 % of the cans, it is violated if the total number of insect larvae equals 4 % of the total number of peach halves. The flaw in this contention is that it fails to observe the wording of the tolerance level in that it does not take into account or measure the peach halves for worminess or moldiness.

"We cannot accept the test of Dr. York as compared to the second test of Schwarz because the former failed to take into account or measure the peach halves for worminess while the latter did so. **The Webster's Third New International Dictionary** defines 'worm' to mean an 'insect larva' and the term 'wormy' to mean 'attacked or burrowed by worms.' Schwarz measured worminess in the individual peach halves by evidence of the visitation to the fruit by insect larvae such as tunnelling, embedded fragments, and excreta which appropriately indicated the extent to which, if any, a particular piece of fruit was attacked or burrowed by insect larvae. Therefore, we find that all of the testing methods were proper and adequately designed to yield results consistent with a proper interpretation of the FDA defect tolerance levels for canned peaches. \* \* \*

"In the absence of any authority to escape the statutory language concerning adulteration, the court must search for a *de minimis* standard and in doing so is compelled to rely, in the absence of any fixed standard, upon the expertise of the Secretary, whose guidelines we believe represent a proper and reasonable defect tolerance level for canned peaches. Since the results of Schwarz's second test reveal the existence of more than double the amount of 'filth' deemed by the FDA to be natural and unavoidable we conclude that more than a *de minimis* amount of 'filth' was present in the canned peaches and that they were 'adulterated' within the meaning of 21 U.S.C. § 342(a)(3).

"We cannot close without a comment on the claim that the FDA guidelines were not published until after the peaches were canned and consequently the producer was compelled to can such peaches without such guidelines and, accordingly, that the peaches were condemned without due process. . . . The absence of notice to the producer, however, would under no circumstances justify the distribution to the public of contaminated or adulterated food particularly since no evidence has been offered to show that such notice might have been instrumental in preventing such contamination. Indeed, the majority in **United States v. 449 Cases, Containing Tomato Paste**, [212 F.2d 567 (2d Cir. 1958)], decided, in effect, that the failure of the Administrator to comply with the Administrative Procedure Act by publishing in advance the standards of permissible contamination was not a defense to the condemnation proceeding. Whatever remedy, if any, the producer has against the United States under these circumstances it does not lie in this proceeding.

"Therefore, it is ORDERED that the 900 cases of canned peaches be condemned."

The claimant filed a notice of appeal, but failed to comply with the requirements to docket his appeal; accordingly, the appeal was dismissed. (F.D.C. No. 57518; S. No. 83-062 E; N.J. No. 20)

**Peas, dried**, at New York, S. Dist. N.Y.

Charged 11-29-74: while held for sale, the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to Graham Co., Inc., New York, N.Y., for salvaging. (F.D.C. No. 60048; S. No. 42-896 H; N.J. No. 21)

**Peppers-tomato preparation with rice, canned**, at New York, S. Dist. N.Y.



Charged 3-20-75: while held for sale, the article was unfit for food, since it was contained in swollen cans; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 60252; S. No. 43-683 H; N.J. No. 22)

**Pistachio nuts**, at New York, S. Dist. N.Y.

Charged 4-1-75: while held for sale, the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to Midwest Nut & Seed Co., Inc., Chicago, Ill. (F.D.C. No. 60248; S. No. 44-040 H; N.J. No. 23)

**Potatoes**, at Conroe, S. Dist. Tex.

Charged 2-18-75: while held by Manuel Rogers Produce Co., Conroe, Tex., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 60201; S. No. 89-562 H; N.J. No. 24)

**Salmon, dressed, frozen, and frozen, dressed sablefish**, at Brooklyn, E. Dist. N.Y.

Charged 4-11-74: while held for sale, the articles contained decomposed fish; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59713; S. Nos. 73-483/4 G; N.J. No. 25)

**Salt**, at South Boston, W. Dist. Va.

Charged 3-12-75: while held by Camp Chemicals Corp., t/a Keystone Mills, South Boston, Va., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60275; S. No. 112-100 H; N.J. No. 26)

**Sesame seeds**, at Brooklyn, E. Dist. N.Y.

Charged 4-7-75: while held by D. Rosen Co., Brooklyn, N.Y., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to Consolidated American Co., New York, N.Y., for salvaging. (F.D.C. No. 60313; S. No. 44-168 H; N.J. No. 27)

**Sesame seeds and annatto seeds**, at San Juan, Dist. P.R.

Charged 10-9-74: while held by Nieves Hermanos, Inc., San Juan, P.R., the articles contained insects and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60000; S. Nos. 23-145/6 H; N.J. No. 28)

**Spaghetti and other macaroni products**, at San Sebastian, Dist. P.R.

Charged 5-14-74: while held by Juan Bautista, Rivera Warehouse, San Sebastian, P.R., the articles contained insects, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59770; S. Nos. 23-262/5 H; N.J. No. 29)

**Wheat and chick peas**, at Brooklyn, E. Dist. N.Y.

Charged 2-18-75: while held by Joseph Fragola, Inc., Brooklyn, N.Y., the wheat contained rodent filth, and all the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60213; S. Nos. 44-043/5 H et al.; N.J. No. 30)

**FOOD/Economic and Labeling Violations**

**Tomatoes, canned, Yacht Club**, at Hopkins, Dist. Minn.

Charged 3-24-75: when shipped by M & R Sales Corp., Oak Park, Ill., the article fell below the standard of quality for canned, peeled tomatoes; since the article contained excess tomato peel; 403(h)(1). Consent decree authorized release to NCC Food Corp., San Jose, Calif., for reprocessing. (F.D.C. No. 60298; S. No. 63-991 H; N.J. No. 31)

**VITAMINS/SPECIAL DIETARY FOODS**

**Vinivita vitamin B12, folic acid, ferrous fumarate, and vitamin B1 & B2 combination tablets**, at Birmingham, N. Dist. Ala.

Charged 1-16-75: while held by King Pharmaceutical Co., Inc., Birmingham, Ala., who was repackaging the article from bulk, the article contained less than 50 percent of the declared amount of vitamin B1; 501(c). Default decree ordered destruction. (F.D.C. No. 60148; S. No. 115-862 H; N.J. No. 32)

**FOOD ADDITIVES**

**Chubs, dressed**, at Brooklyn, E. Dist. N.Y.

Charged 6-3-75: when shipped by Bell's Fishery, Mackinaw City, Mich., the article contained the nonconforming food additive dieldrin; 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 60368; S. No. 10-131 H; N.J. No. 33)

**Onion rings, breaded, frozen**, at Old Monroe, E. Dist. Mo.

Charged 8-13-75: while held by Sun Ring Foods, Div. Tamara Foods, Inc., Old

Monroe, Mo., who manufactured the article using onions shipped in interstate commerce, the article, labeled in part "Continental Frozen Breaded Onion Rings . . . Packed for Continental Coffee Company . . . Chicago, Illinois," contained the non-conforming food additive iodine—402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 60442; S. No. 76-175 H; N.J. No. 34)

**ANIMAL FEED**

**Corn for animal feed use**, at Pittsfield, S. Dist. Ill.

Charged 3-12-75: while in transit, the article was held under insanitary conditions, since the barge containing the article sank in the Illinois River, at Pekin, Ill.; 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 60258; S. No. 98-501 H; N.J. No. 35)

**DRUGS/Human Use**

**Amphetamine and barbiturate combination tablets and capsules**, at Lancaster, E. Dist. Pa.

Charged 3-15-74: while held for sale by Dr. Henry J. Glah, Jr., Lancaster, Pa., the labeling of the articles lacked adequate directions for use and the articles were not exempted therefrom, since the articles were new drugs without effective approved New Drug Applications; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 59650; S. No. 83-682 G et al.; N.J. No. 36)

**Drugs stocks, including A-D kelp tablets, charcoal tablets, cough syrup, castor oil, camphorated oil, boric acid powder and nasal drops, and drug components, senna, ginger, cascara, and gentian**, at Hammond, N. Dist. Ind.

Charged 4-30-75: while held by Indiana Botanic Gardens, Inc., Hammond, Ind., the circumstances used for the manufacture, processing, packing, and holding of the articles failed to conform with current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 60341; S. No. 87-225 H et al.; N.J. No. 37)

**Liver, iron, and vitamin combination injection**, 3 seizure actions, at Bay Shore, E. Dist. N.Y., Valley Stream, E. Dist. N.Y., and Flushing, E. Dist. N.Y.

Charged 10-22-74, 10-22-74, 10-22-74: while held for sale after manufacture by Bel-Mar Laboratories, Inwood, N.Y., who manufactured the article using a liver extract which had been shipped in interstate commerce, the article's strength differed from its represented strength, since the article was more than 40 percent subpotent as to cyanocobalamin activity; the label's declaration "Each 2 ml. contains: Liver Injection equivalent to 20 mcgm. Cyanocobalamin per ml. .067 ml." was misleading since it did not clearly state the amount of cyanocobalamin activity in each recommended dose; and the labeling of the articles seized at Bay Shore and Valley Stream contained the misleading statements "Not intended for treatment of pernicious anemia" and "For Maintenance use in pernicious and other macrocytic anemia," which statements were inconsistent with each other; 501(b), 502(a). The articles were claimed by the manufacturer who denied the charges and asserted that the articles were not being held for sale at the time of seizure since they were in quarantine at the time of seizure. The parties served written interrogatories on each other. Subsequently, the claimant consented to decrees of condemnation ordering the articles destroyed. (F.D.C. Nos. 60016, 60020/1; S. No. 41-243 H; N.J. No. 38)

**Plasma, human**, at Miami, S. Dist. Fla.

Charged 4-22-75: when shipped by Ralph Fields, from Smyrna and Adell, Ga., the circumstances of the article's manufacture, processing, packing, and holding failed to conform to current good manufacturing practice; the article's label lacked the name and place of business of the manufacturer, packer, or distributor; lacked an accurate statement of the quantity of contents; lacked the established name of the drug; and the article's labeling lacked adequate directions for use—501(a)(2)(B), 502(b)(1), 502(b)(2), 502(e)(1), 502(f)(1); and, while held by I.H.S. Miami, Inc., t/a Edison Blood Plasma Center, Miami, Fla., the circumstances of the article's holding failed to conform to current good manufacturing practice—501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 60326; S. No. 38-709 H; N.J. No. 39)

**Prozyde foreign protein and sodium iodide injectable**, at St. Louis, E. Dist. Mo.

Charged 5-22-73: when shipped by Myers-Carter Laboratories, Inc., Glendale, Ariz., the article was a new drug without an effective approved New Drug Application; and while held by Tracy Pharmacal Co., St. Louis, Mo., who had packaged and labeled some of the article which had been shipped in bulk, the labeling of the article, including the bulk package insert and the repacked carton inserts, contained false and misleading claims for the common cold, coryza, rhinitis, sinusitis,



acute and chronic influenza, tonsillitis, pharyngitis, bronchitis, chronic arthritis, respiratory tract infections, and laryngitis; and the labeling of the article in repackaged cartons was also false and misleading, since the statement on the label on the vials in said cartons, "Prozyde Each 1 cc. contains Purified Proteins 5%, Sodium Iodide 0.02 grams, Iodinated Peptones (equivalent to Free Iodine) 0.1 Mgm. . . . Tricresol 0.3%" was inconsistent with the statement on the carton insert "Protein-Iodide Composition A sterile injectable solution containing in each 2 cc. highly purified Foreign Protein 0.04 grams and Sodium Iodide 0.08 grams . . . Phenol 0.5% (as preservatives)"; 505(a), 502(a). The article was claimed by the dealer-repackager who denied the charges. The Government served written interrogatories on the claimant and moved for summary judgment.

In granting the Government summary judgment and ordering the article destroyed, the court said:

"This action was instituted by the United States on May 22, 1973, with the filing of a Complaint For Forfeiture seeking seizure and condemnation under 21 U.S.C. §334(a) of a certain quantity of drugs known as 'Protein-Iodide Injection' (herein known as 'Injection'). . . . Pursuant to the Complaint, a Warrant for Arrest of Property was issued ordering the seizure of the quantity of 'Injection.' The drugs were seized at the Tracy Pharmacal Company of St. Louis and now constitute the jurisdictional res.

"Notice of the seizure was duly published and Tracy Pharmacal Company filed a claim of ownership of seized drugs.

"The pivotal issue before this Court is whether the seized drug, 'Injection' is a 'new drug'. As the claimant admits that no approval of a new drug application with the Food and Drug Administration is now or has ever been in effect for the seized article, then such product may not be introduced into interstate commerce if it is found to be a 'new drug' within the meaning of 21 U.S.C. 321(p) and it must be condemned pursuant to 21 U.S.C. 334.

"Title 21, Section 321(p) of the United State Code provides in part:

The term 'new drug' means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a 'new drug' if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use.

In light of the above provision, the crucial issue, more comprehensively stated, is whether the drug 'Injection' at the time of its seizure, was generally recognized by experts in the field, as safe and effective for use under the conditions prescribed, recommended or suggested in the labelling thereof. If 'Injection' was not generally recognized as safe and effective, then the drug was subject to being classified as a new drug, and as such could not be shipped in interstate commerce without the prior approval of a new drug application.

"The labelling statements for 'Injection' show that it is intended for use in the cure, treatment and mitigation of sinusitis, chronic arthritis and respiratory tract infections such as bronchitis, tonsillitis, influenza, coryza, laryngitis and pharyngitis. The statements further indicated that the drug should be injected subcutaneously or intramuscularly and that its dosage generally for adults is 2cc. daily for acute non-specific infections of the upper respiratory tract.

"The thrust of the Government's motion for summary judgment are the affidavits of Dr. Goronwy Broun, Dr. Jack Zuckner and Dr. J. Russell Little, all experts on internal medicine, which establish that the composition of the drug is such that it is not now, nor has it eve[r] been, generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested in its labelling. Moreover, the affiants state that to their knowledge there are no published scientific studies which indicate that 'Injection' or a drug of this combination is either safe or effective when used for the aforementioned illnesses. The experts further indicate that a well-[ ]controlled clinical investigation to establish the safety and effectiveness of 'Injection' is necessary.

As 'Injection' is not generally recognized as safe and effective, it is [a] new drug within the meaning of 21 U.S.C. 321(p). . . .

"In addition, the absence of published medical or scientific studies as to the safety and effectiveness of 'Injection', or a drug of this combination, is proof that

the drug is not generally recognized among qualified experts as safe and effective and, therefore, is a new drug. . . . It follows that such drug is liable for seizure and condemnation pursuant to the provisions of 21 U.S.C. §334. (F.D.C. No. 59211; S. No. 47-772 G; N.J. No. 40)

**Quinidine sulfate tablets**, at Sacramento, and Fresno, E. Dist. Calif.

Charged: 6-13-74: while held by several consignees in the State of California after manufacture by H.R. Cenci Laboratories, Inc., Fresno, Calif., from ingredients shipped in interstate commerce, the circumstances of the article's manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice; 501(a)(2)(B). The manufacturing corporation and its president H.R. Cenci, claimed the article, denied the charge, and moved for summary judgment. The claimants subsequently withdrew their motion for summary judgment. Ultimately, a consent decree authorized release to the claimants for reconditioning. (F.D.C. No. 59801; S. No. 25-904 H; N.J. No. 41)

#### DRUGS/Veterinary

**Zirobee B-complex combination injection, two lots of Bee-Tops vitamin C and B12 combination injection, Cyanocobalamin injection, U.S.P., and Bee-Tops Plus vitamin C and B12 combination with pangamic acid injection**, at Hialeah, S. Dist. Fla.

Charged 2-4-75: while held by Zirin Laboratories, Int'l., Inc., Hialeah, Fla., (who had labeled the Zirobee injection, the Cyanocobalamin injection, and one lot [C. No. 021902] of Bee-Tops injection), the Zirobee injection contained more vitamin B12 and less iron than it purported to possess, and such lot of Bee-Tops injection contained more niacinamide than it purported to possess; the Cyanocobalamin injection (which was in unlabeled vials, whose previous vial labels reading "Vitamin B-12 Cyanocobalamin Injection U.S.P. . . . 1000 MCG Per cc" had been removed by the dealer) contained less than such labeled amount of cyanocobalamin; the labeling of the other lot (C. No. 021901) of Bee-Tops injection contained false and misleading claims concerning ascorbic acid for animals, when ascorbic acid was neither essential to the listed species nor was ascorbic acid deficiency known to occur in such animals; and the labeling of the Zirobee injection failed to bear adequate directions for use—501(b), 501(c), 502(a), 502(f)(1).

When shipped by Bio-Dyne Industries Corp., Inglewood, Calif., one lot (C. No. 021901) of Bee-Tops injection and the Bee-Tops Plus injection (which lots were accompanied from the shipper by the dealer's labels) contained less vitamin B12 and (such lot of Bee-Tops injection only) vitamin B6 than they purported to possess; and the Bee-Tops Plus injection was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to the use and intended use of such drug; and labeling of such lot of Bee-Tops injection and the Bee-Tops Plus injection contained false and misleading claims concerning ascorbic acid for animals, when ascorbic acid was not essential to the listed animal species; 501(a)(5), 501(c), 502(a). Default decree ordered destruction. (F.D.C. No. 60190; S. No. 425 G et al.; N.J. No. 42)

#### MEDICAL DEVICES

**Diapulse electromagnetic energy generator**, at Chicago, N. Dist. Ill.

Charged 3-28-75: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the article's accompanying treatment chart and leaflets contained false and misleading claims for infections, fractures, bone and tissue healing, smooth-muscle spasms, bursitis, arthritis, low back pain, headaches, wound healing, and stimulation of the reticuloendothelial system; and the article lacked adequate directions for use for the article's intended purposes and neither adequate directions for lay use, nor adequate information for use by licensed practitioners, could be provided; 502(a), 502(f)(1). Default decree ordered destruction. (F.D.C. No. 60288; S. No. 97-398 H; N.J. No. 43)

**Diapulse electromagnetic energy generators**, 2 seizure actions, at Texarkana, W. Dist. Ark., and at Gatesville, W. Dist. Tex.

Charged 10-2-74 and 1-22-75: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' labeling lacked adequate directions for lay use and adequate information for use by licensed practitioners could not be furnished; 502(f)(1). Default decrees ordered destruction (except for some electronic components released to William F. Floyd, M.D., Gatesville, Tex.). (F.D.C. Nos. 59994, 60149; S. Nos. 88-864 H, 9-023 H; N.J. No. 44)

**Electro-sedation sound wave generator**, at Brinkley, E. Dist. Ark.



Charged 4-22-75: when shipped by Tri-Tronics Laboratory, Inc., Euless, Tex., the accompanying leaflets, booklet, and return postcard contained false and misleading claims for nervous tension and stress, harmful tension, psychosomatic illnesses and insomnia, relief from pressures of daily living, reactive depression, acute physical discomforts of bursitis, severe muscle cramps, tennis elbow, ankylosis, neuritis, depression, high blood pressure, peptic ulcer, and anxiety; the labeling lacked adequate directions for use and lacked adequate information for use by licensed practitioners for such purposes; and the labeling lacked adequate warnings against unsafe use; 502(a), 502(f)(1), 502(f)(2). Default decree ordered destruction. (F.D.C. No. 60331; S. No. 54-498 H; N.J. No. 45)

**Isotron electric, muscle stimulator**, at Orlando, M. Dist. Fla.

Charged 4-28-75: when shipped by Sportron, Inc., Fullerton, Calif., the accompanying brochure, leaflets, letters, and newspaper reprint contained false and misleading claims to develop, strengthen, and tone muscles, to rehabilitate patients suffering from muscle and nerve injuries, to be absolutely safe for all uses, to be painless, a 20-minute treatment to be equivalent to 2 hours vigorous weight lifting, and to be effective for stroke, spinal cord injuries, chronic low back pain, cardiac disease, polio, muscle impairment, poor circulation, insomnia, and loss of appetite; and the labeling lacked adequate directions for use and lacked adequate warnings against unsafe use; 502(a), 502(f)(1), 502(f)(2). Default decree ordered destruction. (F.D.C. No. 60330; S. No. 14-629 H; N.J. No. 46)

**PROPHYLACTICS**

**Prophylactics, rubber**, at Columbus, M. Dist. Ga.

Charged 3-26-75: when shipped by M & M Rubber Co., Kansas City, Mo., the article, labeled in part "Transparent Spartans Prophylactics . . . Distributed By M & M Rubber Co., Kansas City, Mo., . . . Sold For the Prevention of Disease Only," fell below its purported quality, and the label statement "Sold For the Prevention of Disease Only" was false and misleading, since the article contained holes; 501(c), 502(a). Default decree ordered destruction. (F.D.C. No. 60276; S. No. 3-329 H; N.J. No. 47)

**COSMETICS/BEAUTY PRODUCTS**

**Long Nails methyl methacrylate monomer fingernail lengthening kits**, at Salt Lake City, Dist. Utah.

Charged 10-9-74: when shipped by C.E.B. Products, Inc., (formerly Dark Eyes Co.), Chicago, Ill., the article contained the poisonous and deleterious substance methyl methacrylate monomer; 601(a). Default decree ordered destruction. (F.D.C. No. 59948; S. No. 80-135 H; N.J. No. 48)

**NOTICES OF JUDGMENT on Criminal Actions**

**FOOD**

**Affiliated Foods, Inc., and Byron P. Woodbury**, president, St. Joseph, V. Dist. Mo.

Charged 9-18-74: flour, pancake mix, and sugar were held in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). The defendants pleaded not guilty. The case came on for trial. The defendants moved to dismiss the action on the grounds that the Government had failed to deliver a written list of all its witnesses 10 days prior to trial. The court reserved its decision, but excluded the testimony of Government witnesses whose names had not been supplied to the defendants and excluded the sample collection report. Thereupon, the defendants moved for acquittal on the grounds that the Government had failed to relate the evidence presented, to the defendants. The court granted that motion and ordered the defendants **acquitted**. (F.D.C. No. 59837; S. No. 46-872 G; N.J. No. 49)

**Beaver Valley Baking Co., and Rudolph J. Fabyanic**, partner, New Brighton, W. Dist. Pa.

Charged 4-3-75: flour was exposed to contamination by insects by being placed in insect-contaminated processing equipment, was held under insanitary conditions in a building accessible to insects, and was contaminated with insect filth; 402(a)(3), 402(a)(4). Nolo contendere pleas; fines. (F.D.C. No. 60010; S. No. 67-551 F et al.; N.J. No. 50)

**Francoeur Baking Co., Inc. and Fernand G. Francoeur**, president & treasurer, at Nashua, Dist. N.H.

Charged 8-14-74: flour was held in a building accessible to insects and was contaminated with insect filth; 402(a)(3), 402(a)(4). Nolo contendere pleas; fines. (F.D.C. No. 59726; S. No. 15-141 G; N.J. No. 51)

**Martin-Glover Co., and Leo M. Rowan**, secretary & general manager, San Angelo, N. Dist. Tex.

Charged 8-20-74: black-eyed peas (count 1), popcorn (count 2) and cracker crumbs (count 3) were held in a building accessible to rodents, and were exposed to contamination by rodents; and the black-eyed peas and popcorn were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation to all counts; fine. Guilty plea by individual to counts 1 and 2; fine suspended, and probation. (F.D.C. No. 59730; S. No. 37-283 G et al.; N.J. No. 52)

**Morse's Foodmart, Inc., and Philip F. Feldman**, president, Mattapan, Dist. Mass.

Charged 2-27-75: cheese, flour, pretzels, toaster pastries, and pancake mix were held in a building accessible to rodents, and all the articles, except the pancake mix, contained rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine and probation. Guilty plea by individual to the count involving the toaster pastries; probation. (F.D.C. No. 59884; S. No. 16-480 G et al.; N.J. No. 53)

**Queen City Smoked Fish Co., Inc., and Theodore Lipsky**, president, Cincinnati, S. Dist. Ohio.

Charged 9-26-74: sablefish were prepared as smoked sablefish under insanitary conditions, whereby the sablefish might have become contaminated with filth and whereby the sablefish might have been rendered injurious to health, contrary to regulations relating to current good manufacturing practice in manufacturing, processing, or holding of smoked and smoke-flavored fish; 402(a)(4). Guilty plea by corporation; fine. Nolo contendere plea by individual; fine. (F.D.C. No. 58591; S. No. 26-336 F et al.; N.J. No. 54)

**Shryack-Wright Grocery Co., and Edwin F. Bruns**, secretary-treasurer, Sedalia, W. Dist. Mo.

Charged 10-15-74: candy (count 1) and cracker meal (count 2) were held in a building accessible to insects and were contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Guilty plea by individual to count 1 only; fine suspended and probation. (F.D.C. No. 59729; S. Nos. 48-756 G & 48-759 G; N.J. No. 55)

**Tracy Pharmacal Co., at St. Louis, E. Dist. Mo.**

Charged 9-5-75 in an application to adjudge criminal contempt: that, while Prozyde foreign protein and sodium iodide injectable (which had been seized by the U.S. Marshal in a forfeiture action—See N.J. No. 40 above) was in the custody of the court at Tracy Pharmacal Co., the defendant made thirteen sales of the seized Prozyde injectable to consignees in Illinois, six sales to consignees in Missouri, and twenty sales to consignees in other States. In finding the defendant guilty of the contempts, the court said:

"By an application filed September 5, 1975, by the United States Attorney, Tracy Pharmacal Company was charged with forty-nine counts of criminal contempt of the authority of this Court, in violation of 18 U.S.C. § 401(3). Each count alleges a sale by the Company of certain drugs under seizure by the United States Marshal in a forfeiture action previously before this Court, being cause number 73C339(3), such sales constituting a disobedience to a lawful writ or process. On September 5, 1975, this Court issued its order to the Company to show cause why it should not be held in criminal contempt.

"On September 15, hearing was held on the Court's Order To Show Cause, the defendant Tracy Pharmacal Company being represented by its attorney, Joseph H. Mueller, and its president, Thomas E. Fleming. By statements volunteered by both Mueller and Fleming, the Company admitted the allegations contained in the Government's application and attached affidavit by Michael B. Clapper, an investigator for the Food and Drug Administration, concerning the sale by the Company of the seized drugs. The Company offered information in mitigation, concerning the circumstances of the unlawful sales, so as to satisfy this Court that such disobedience did not constitute an open and direct intent to defy a lawful process. Information was further offered regarding the gross amount of sales realized by the Company by reason of its sale of the seized drugs.

"WHEREFORE, having fully examined the premises of the Company's admissions, the Court finds Tracy Pharmacal Company guilty of said contempts charged in the forty-nine counts of the application, and

"IT IS HEREBY ORDERED that the Tracy Pharmacal Company pay as a fine to the United States of America the sum of Forty-Nine Hundred Dollars (\$4,900.00), to be payable forthwith." (F.D.C. No. 59211A; S. No. 20-261 H et al.; N.J. No. 56)





#### NOTICES OF JUDGMENT on Injunction Actions

**Kaufman's Bakery, Inc., and Samuel Freeman, president, Buffalo, W. Dist. N.Y.**

Charged 6-25-74: that the defendants were engaged at their bakery at Buffalo, N.Y., in holding, after shipment in interstate commerce, flour and other raw materials for use and sale in bakery products, in distributing such bakery products in interstate commerce, and in holding for sale bakery products containing components shipped in interstate commerce; that such flour, raw materials and bakery products were prepared, packed, and held under insanitary conditions; that FDA inspections had disclosed a number of specified insanitary conditions; and that the defendants had been warned of the insanitary conditions existing in the bakery; 402(a)(4). A consent decree of permanent injunction enjoined the complained of violations, and it also enjoined: placing in the defendants' bakery any food shipped in interstate commerce; introducing into interstate commerce bakery products prepared, packed, or held at the bakery; and preparing, packing, and holding in the bakery and distributing from it, any bakery products containing components shipped in interstate commerce, unless and until a number of specified conditions were met, including a thorough cleaning and repair of the bakery, the elimination of all rodent and insect filth, the storage of raw material on pallets or racks off the floor and away from the walls, the establishment of a sanitation control program, the examination and certification of the bakery by a qualified person selected by the defendants, and the bringing into compliance of the food on hand at the bakery. Subsequently, the defendants moved to vacate the permanent injunction on the grounds that all of the acts required by the injunction had been performed and it was no longer equitable for the injunction to have prospective application. The matter was adjourned for approximately nine months. Thereafter, the Government consented to the granting of the defendants' motion, on the grounds that the defendants had substantially complied with all the terms and conditions of the decree. Accordingly, the decree of injunction was vacated and the complaint dismissed. (Inj. No. 674; S. No. 104-401 H et al.; N.J. No. 57)

**St. Albans Cooperative Creamery, Inc., and Isadore M. Yandow, president, and Ryle K. Dow, general manager, St. Albans, Dist. Vt.**

Charged 6-18-74 in complaint for injunction: that the defendants were engaged at their plant at St. Albans, Vt., in manufacturing, preparing, packing, labeling, and holding for sale, nonfat dry milk, and in introducing into interstate commerce nonfat dry milk; that the defendants also delivered, in Vermont, nonfat dry milk for use in processing cheese or other such foods, which were shipped in interstate commerce; that the nonfat dry milk contained penicillin in excess of the prescribed tolerance of zero; that FDA inspections of the defendants' plant disclosed that the plant received fluid milk contaminated with penicillin from individual producers and that nonfat dry milk produced at the plant contained penicillin; and that defendants were well aware that their activities were in violation of the law; 402(a)(2)(D). A consent decree of permanent injunction enjoined the complained of violations, and enjoined the interstate distribution of any of the defendants' milk products, and the intrastate distribution of such milk products which were intended for use in the processing of cheese or other food for human use which was to be distributed interstate, unless and until the defendants established certain procedures to sample and analyze their products and to destroy or bring into compliance articles containing penicillin, and unless and until all such foods on hand at the defendants' plant were analyzed and any penicillin-contaminated foods were destroyed or brought into compliance. (Inj. No. 670; S. No. 108-363 H et al.; N.J. No. 58)

#### NOTICES OF JUDGMENT on Miscellaneous Actions

**Protamide proteolytic enzyme injection, & judicial review of denial of a hearing on proposal to revoke its New Drug Application, Washington, Dist. Columbia.**

Petitioned 9-18-72 by Cooper Laboratories, Inc., Bedford Hills, New York, against the FDA Commissioner in suit for judicial review: that the firm petitioned for review of FDA's order denying a hearing and withdrawing the approval of the firm's New Drug Application for Protamide injection for neuritis, herpes zoster, and ophthalmic herpes zoster; that there were genuine issues of fact which required the holding of a hearing; that the FDA Commissioner had incorrectly applied the principles of summary judgment; and that shifting the burden of making a prima facie case from FDA to the petitioners was a denial of basic administrative fairness; and that the only FDA regulations that could justify a summary denial of a hearing to the petitioners, were regulations that were "precise." The court of appeals affirmed the actions of the FDA saying:

"To be marketed in interstate commerce under the Food, Drug and Cosmetic Act, a drug must generally be covered by a 'new drug application' (NDA) approved by the Food and Drug Administration (FDA). In 1944 the FDA approved an NDA for Protamide, an injectable colloidal solution of denatured proteolytic enzyme, upon a finding that the drug was safe for human use, and Protamide was thereafter marketed for symptomatic treatment of herpes zoster (popularly known as shingles), ophthalmic herpes zoster, tabes dorsalis, and neuritis. The 1962 amendments to the Act required the FDA to withdraw approval from any NDA where 'substantial evidence' of the drug's effectiveness was lacking, 21 U.S.C. § 355(e)(3) (Supp. II 1972), and placed the burden of coming forward with such evidence on the drug companies. After several FDA requests, Cooper Laboratories, the maker of Protamide, submitted various documents purporting to establish the drug's effectiveness. Having analyzed this submission, the FDA on August 25, 1972 withdrew approval from Cooper's NDA, finding that the proffered materials did not constitute substantial evidence of efficacy. On appeal Cooper asserts that the Administration should have granted it a hearing before acting.

"The 1962 amendments define 'substantial evidence' as 'consisting of adequate and well-controlled investigations, including clinical investigations,' . . . a standard explicated in considerable detail by FDA regulations promulgated in 1970. . . . While the amendments speak of FDA action 'after due notice and opportunity for hearing,' 21 U.S.C. § 355(e), the Administration has established summary procedures for finding a drug ineffective where the applicant's proffered evidence clearly does not include 'adequate and well-controlled investigations' and thus does not raise a 'genuine and substantial issue of fact' requiring a hearing. The Supreme Court has recently construed these procedural regulations and declared them lawful. The narrow question before us is whether the FDA's recourse to summary procedures was proper, given the evidence submitted to the Administration by Cooper. We find that it was and affirm the FDA's order of August 25, 1972 in all respects.

"After a searching examination of Cooper's evidentiary submission, of the FDA's characterizations of it, and of the regulatory provisions invoked in those characterizations, we are convinced that the Administration has located for each item of evidence at least one deficiency (and usually many such) which conclusively disqualifies the item 'in light of the pertinent regulations.' . . . As noted below, the Administration could well, and should, have drafted a more detailed and informative order. But the document's purport is everywhere plain. The case with which it deals is not, we think, a close one.

"As Cooper does not claim that its affidavits and testimonial letters constitute 'adequate and well-controlled investigations,' our inquiry focuses on the nine medical studies. These fall into three groups: the unfavorable, the uncontrolled, and the poorly controlled.

"We conclude that Cooper 'has not tendered any evidence which on its face meets the statutory standards as particularized by the regulations.' [Weinberger v.] Hynson, [Westcott & Dunning, Inc.,] 412 U.S. at 620. (Emphasis in original.) A hearing in this case 'would be an exercise in futility,' id. at 621, for

[n]o amount of examination and cross-examination can change the scientific studies and the data reported into something they are not.

**Upjohn Co. v. Finch**, 6 Cir. 422 F.2d 944, 955 (1970). Cooper has never indicated, either to us or to the FDA, exactly what a hearing would accomplish in this case. It is always conceivable, of course, that there exists information about the submitted studies which Cooper failed to include in its submission. But, for two reasons, this speculative possibility does not entitle Cooper to a hearing. First, the FDA's regulations clearly provide that 'the report of the results' of a study must itself demonstrate the study's compliance with the regulations. . . . If evidence *dehors* the report is crucial to showing the study's compliance with regulations, the applicant should at the very least advert to the evidence when submitting its application. Second, Cooper has never, at any stage in these proceedings, suggested what, if any, outside information exists on these studies. The reports submitted were merely clipped from old medical journals; they dealt with studies completed between 13 and 26 years ago. Scientists customarily publish their experiments in such a form that colleagues can ascertain from the published report itself whether minimally acceptable methods of control, observation, and analysis were employed. Absent specific contrary indications, the FDA is justified in assuming conformance with this custom. \* \* \*

"While the FDA's order removed Protamide from the commercial market, the drug is apparently eligible for an investigational exemption. If Cooper is genuinely



serious about testing this drug in a proper fashion, that route to progress remains fully open. But we do not perceive how the new research, or proper administrative assessment of it, would be advanced by holding a hearing at this point on old and clearly inadequate medical studies. . . .

"While we sustain the FDA's action in this case, we are not pleased with the draftsmanship displayed in the instant order. Given the facts here, and given that the order does show full understanding of the applicable regulations and a conscientious examination of the submitted studies, we have been willing to take the plain meaning of the Administration's language. Where the order implied a proposition, we allowed the implication and proceeded to assess it. Where the order clearly invoked the substance of a regulatory provision, we did not demand chapter and verse citations. In future, however, we shall apply a stricter rule of construction to Administration orders associated with summary action.

"We shall expect the FDA to make its criticisms express and detailed, and to cite precisely to the pertinent regulations and evidentiary flaws. The regulations are extensive and technical; submitted evidence is typically abstruse and voluminous. Courts cannot efficiently shoulder their heavy burden of review under *Hynson* unless the Administration's orders make utterly transparent why each piece of submitted evidence fails the particular regulatory provisions relied upon. If a regulatory provision or a piece of evidence is fairly open to several interpretations, the Administration must explain and defend its chosen interpretation. On occasion, interpretational differences between the FDA and the applicant will, under the *Hynson* standard, be insoluble without a hearing or some other orderly procedure for exchanging views. The FDA cannot, however, escape such procedures by issuing a cursory order which obscures the differences."

The firm petitioned for a rehearing by the court. The court voted to deny a rehearing; and Judge Leventhal (who had dissented from the original appeal, but now voted against a rehearing) concluded that "It is my perhaps optimistic judgment that the net result of this case will be confined to the facts presented. I should like to give notice, however, that the requirements of fair procedure voiced in my dissent are still part of my working kit of judicial review, and that if my present estimate does not prove to be optimistic, I shall not hesitate to call upon the court for a full dress reconsideration. (Misc. No. 201; N.J. No. 59)

**Tetracycline capsule manufacturer and his alleged subversion by planted spies and other conspirators**, suits for damages, injunction, and other relief, New York, S. Dist. N.Y.

Charged 7-13-71, and amended 7-30-71, by William Broder, Brooklyn, N.Y., against FDA District Director Weems Clevenger, the New York State Board of Pharmacy, and the New York State Assistant Attorney General Fred Nack: that Weems Clevenger (with the New York State Board of Pharmacy and the Assistant Attorney General) was conspiring through a private detective agency, to destroy William Broder's business Generic Formulae, Inc., and to revoke at a formal hearing scheduled for July 28, 1971, the State pharmaceutical registration for Generic Formulae, Inc.; that the defendants should be enjoined from such actions; and that the plaintiff should be awarded damages plus costs. Upon the plaintiff's affidavit, the court issued an order to show cause. The plaintiff also moved for a stay of the New York State hearing, which motion was denied.

Thereafter, there was a New York State hearing concerning Generic Formulae, Inc., at which William Broder failed to appear, although his firm was fined. At a subsequent hearing before the Federal court, it became clear to the court that the plaintiff personally had no standing; that his corporation, of which he was 100 percent owner, might have a cause of action in the New York State courts, if any of the charges were valid; that a corporate claim should be litigated through the services of a lawyer, and that the plaintiff personally had no Federal claim on which relief could be granted. Accordingly, the action was dismissed.

Charged 8-9-72 by William Broder, t/a American Telcaps, Inc., Brooklyn, N.Y., against New York State Comptroller Arthur Levitt, Bristol-Myers Co., E.R. Squibb & Sons, Inc., District Director Weems Clevenger, and twenty-eight other defendants in suit for damages: that American Telcaps Co., a firm owned and operated by William Broder, was engaged in the manufacture and sale of tetracycline capsules; that the court had jurisdiction because the alleged acts involved violations of the Sherman Antitrust Act which prohibits all conspiracies in restraint of trade; that the New York State Comptroller had cooperated with the conspiracy to have Broder fail to pay the deficiency in his State income tax, and with other conspiracies; that Bristol-Myers Co. and other major drug firms had conspired to monopolize the sale and manufacture of tetracycline and to destroy plaintiff; that Weems Clevenger participated in an entrapment attempt to have the plaintiff dispense tetracycline

capsules; and a number of other allegations. In dismissing the complaint, but also denying to the defendants protection against further suits by the plaintiff, the court said:

"This *pro se* action is the seventh in a series of related actions instituted by plaintiff William Broder, all of which allege a conspiracy involving several drug companies, a detective agency, and various officials of federal and state government. In these actions, Mr. Broder claims that the conspirators range from neighbors, former employees, and the Brooklyn Public Library, to large downtown law firms, various staff members and a judge of this Court. Sketchily described in the complaints, the conspiracy's alleged purpose is to destroy the plaintiff's business, American Telcaps Co., and to prevent him from manufacturing the drug tetracycline. In the instant action, Mr. Broder names thirty-two defendants and seeks damages in the amount of \$10,950,000. It is not known from the complaint the time the alleged conspiracy was formed, the overt acts proving it, nor the actual effect on the plaintiff and his business. The instant motion before the Court is for dismissal on the pleadings, or in the alternative summary judgment in favor of 13 of the defendants, as well as other relief. The plaintiff has motions for contempt, a motion to compel answers to interrogatories, and entry of a default judgment against one defendant before the Court as well.

"The responding papers, motions, and affidavits of these representative defendants (some of whom have been unsuccessfully sued by plaintiff in other similar actions), in seeking summary judgment, go unchallenged, unanswered and uncontradicted by plaintiff. They state that the present claim of plaintiff is related to all previous claims and that *res judicata* applies. As to those defendants herein who have been defendants in related cases which have been disposed of by motions, this Court agrees. Plaintiff himself admits the relatedness of all his actions and in fact states in his complaint that this instant action is the same as a prior one (in which summary judgment was granted for the principals of the alleged conspiracy, against plaintiff), but for the new defendants added here. \* \* \* In view of the uncontested affidavits in support of defendants' motions for summary judgment, the complete insufficiency of plaintiff's complaint, and in the interests of justice, defendants' motion for summary judgment is granted with costs as to all the defendants named by plaintiff in the instant action, and the action is accordingly dismissed.

"However, several defendants, in light of their past experiences with plaintiff, seek protection from further harassing and equally meritless suits which plaintiff may institute. Their affidavits document that the plaintiff, having lost one suit, merely initiates one after another, without remedying the flaws considered fatal by the Court in his previous suits. The plaintiff has yet to state a cause of action upon which relief can be granted, and from the viewpoint of former and present successful defendants who are haunted continuously by the possibility of further meaningless, expensive, and time-consuming litigation, an anti-suit injunction against Mr. Broder, forcing him to accept the finality of judgment against him in his purported cause of action is understandably sought.

"However, the Courts are extremely wary of blocking the litigant's door under our judicial system. . . . Of course, denial of such a drastic remedy does not leave defendants completely vulnerable. The defense of *res judicata* may be applicable in any subsequent action on the same cause of action, and the assessment of costs against plaintiff for instituting harassing and hopeless litigation remains a continuing possibility. (Misc. No. 199; N.J. No. 60)

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

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

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Alexander M. Schmidt, M.D., *Commissioner of Food and Drugs*  
Washington, D.C., December 1, 1975



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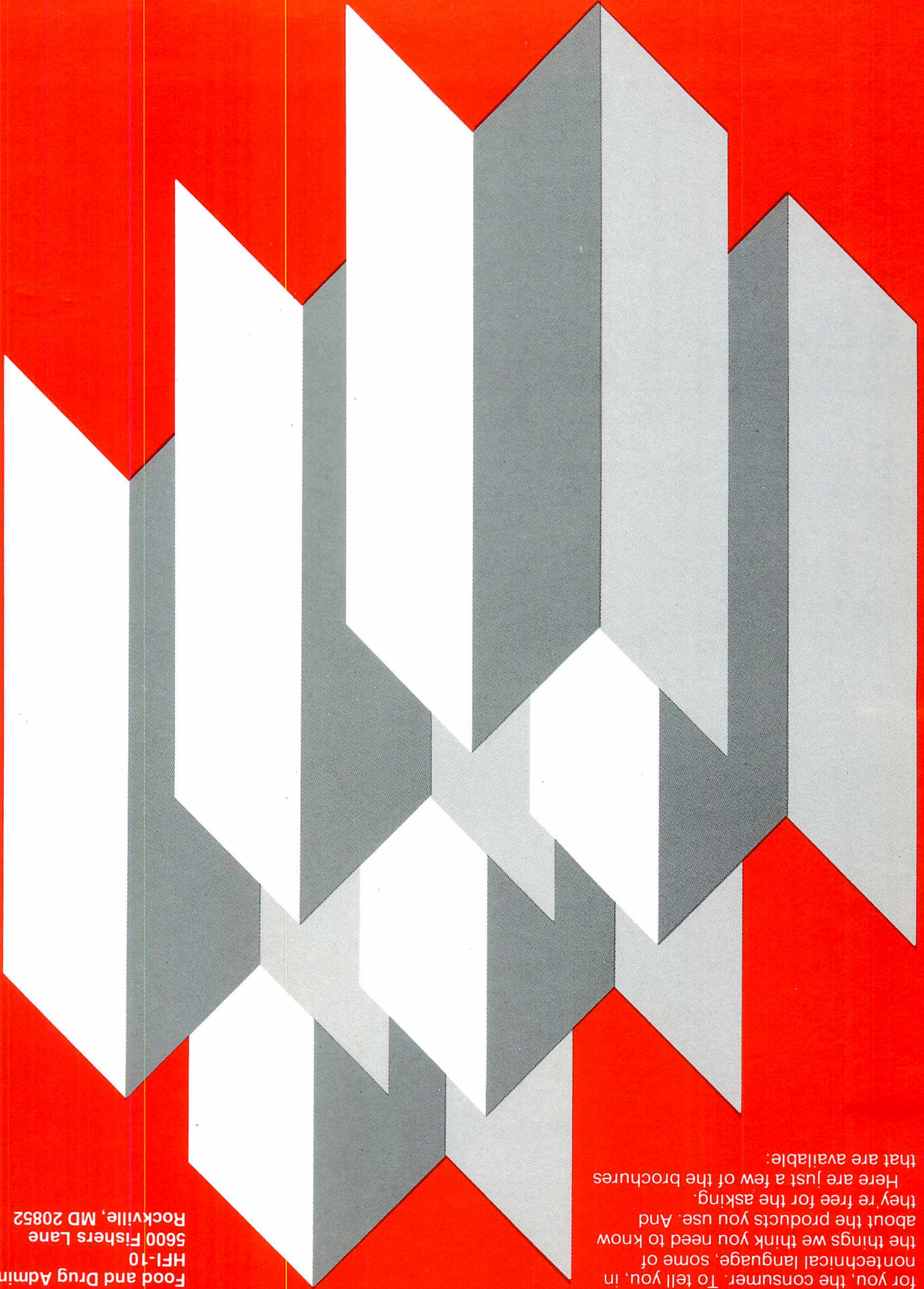
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