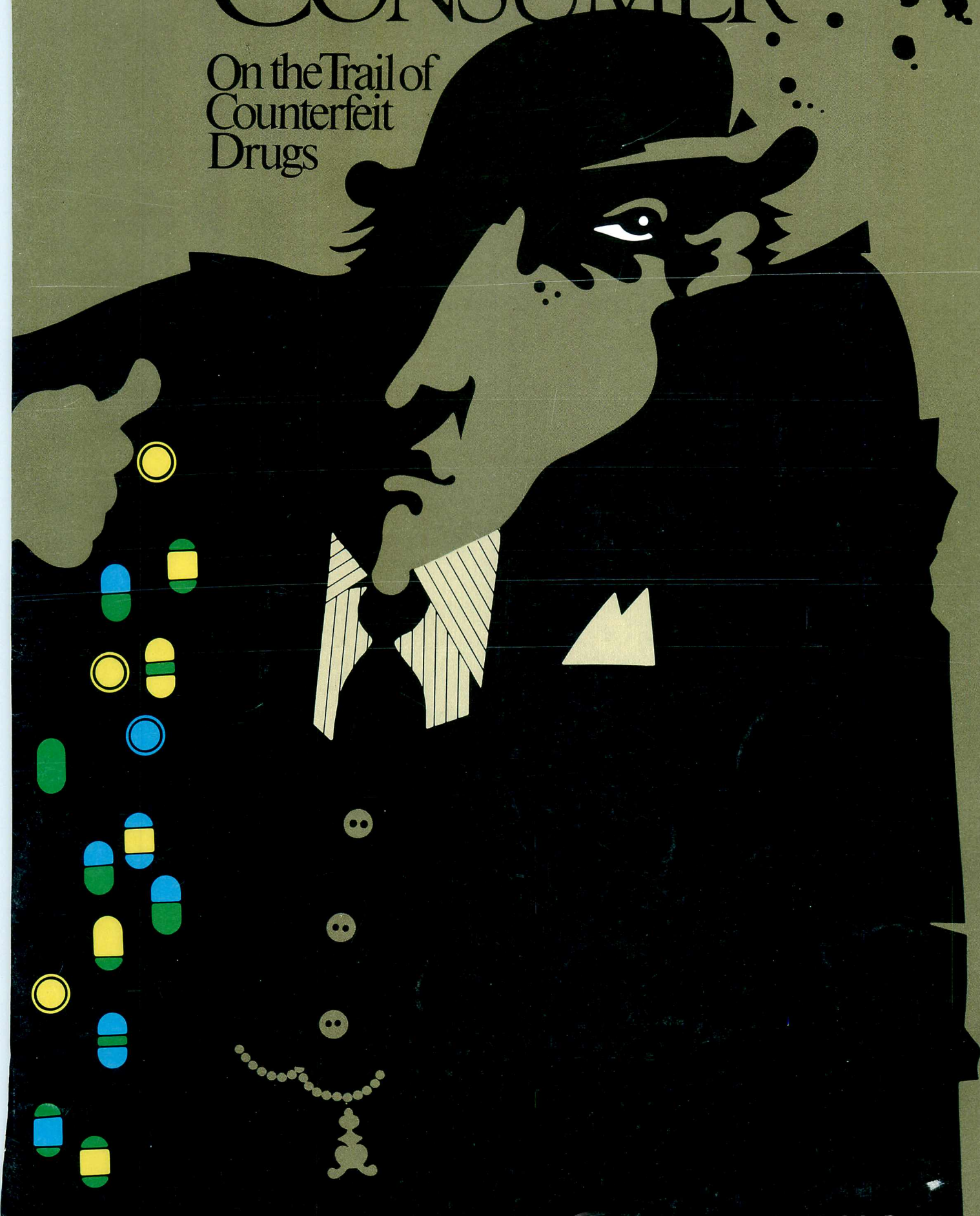


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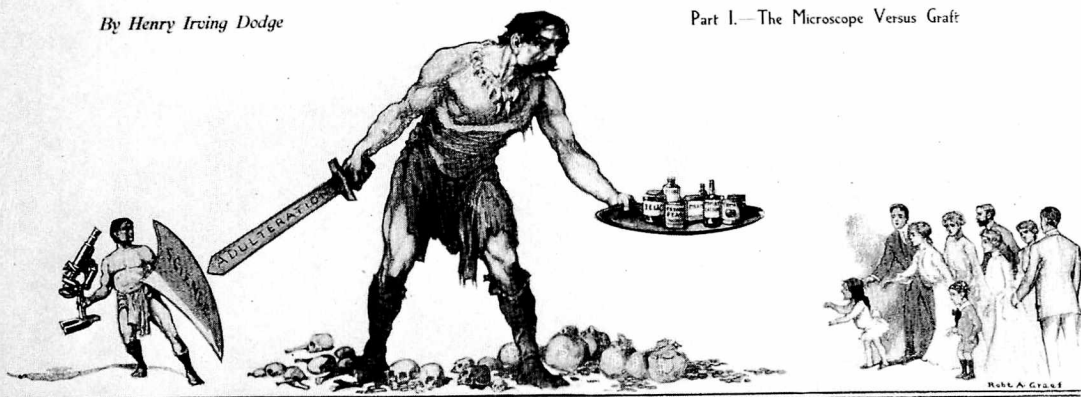
On the Trail of
Counterfeit
Drugs



The Truth About Food-Adulteration

By Henry Irving Dodge

Part I.—The Microscope Versus Graft



This is the First of a Series of Three Articles, Prepared with the Cooperation of Dr. W. D. Bigelow, Chief of the Division of Foods, United States Bureau of Chemistry. The Series is Therefore a Thoroughly Authoritative Account of This Most Dangerous and Ever-Growing Practice

FROM the time when man put money into the scales against his brother's life food-adulteration has obtained. Man's weakness was never expressed in form more mean than this. To poison for a patriotic purpose, or even for revenge, has the redeeming quality of romance, but to do it for money degrades the poisoner from the classic dignity of Borgias to the low condition of "Suicide Hall McGuirk."

Perhaps the romance that attaches to poisoning done for murder springs from the passion that prompts the act, the magnificent risk involved, and the picturesque, yet terrible, end of the tragedy. But where the motive is to cheat, the public singularly takes the act none too seriously. By the same token it would bludgeon a highwayman, yet laugh at the escape of a clever pickpocket. It exalts smartness above honesty, and cherishes the bird that feeds upon its vitals, or condones the fact with drowsy toleration. No matter what may be the source of this indifference, the fact is that the public has from a remote period, and does now more broadly than ever, tolerate the adulteration of food for purposes of gain.

Pliny says the Romans put mineral matter into their bread, and doctored their wines to the extent that it was hard to get a glass of the real stuff even in his time. Early Greece saw the danger, and sought to avert it by the appointment of food-inspectors. In the sixteenth century Englishmen tested ale by spilling some on a bench and sitting on it. If their leather breeches stuck to the seat they knew sugar had been added to it. There was nothing complicated about that method. It was not fraught with the arch mystery of chemistry—no blue flames or sulphurous smoke that bespoke the alchemist. Any boy could practise it, and doubtless many did unconsciously at times. It was a long call from then to 1850, when Hassel replaced the leather-breeches method with analytical chemistry, physics and the microscope, and made disclosures of food-adulteration that startled England into the passage and moderate enforcement of her first national food law.

Thirty years later the seed sown in Great Britain began to sprout in American consciousness. Massachusetts was the first to attempt to enforce food laws, and Minnesota and Ohio soon followed her example. About that time Dr. H. W. Wiley, Chief of the Division (now the Bureau) of Chemistry, began the investigation of foods on the American market. The public was apathetic, bored if you please, by the reiterated efforts of a few patriotic persons, and for more than ten years the movement progressed but slowly, only five states adding their moral support to the stand taken by the other three. In response to an awakened public sentiment, twelve states and territories have within the last six years joined the crusade against poisoned foods. The movement has now become a definite and effective organization. The Association of Official Agricultural Chemists, composed of all federal, state and municipal official chemists, has come into existence. The purpose of this body has been to apply chemical methods to the study of all agricultural products. It has

cooperated with Doctor Wiley, Chief of the Bureau of Chemistry, in his work, and has greatly advanced analytical methods for the examination of foods.

Doctor Wiley's efforts presently developed a regular food-examining branch of the Division of Chem-

istry, which was itself an offshoot of the Department of Agriculture, and when in 1901 it was made a bureau its most important arm was the food laboratory, the affairs of which were administered by Doctor Bigelow, five assistant chemists and a clerk. Three years later, by order of the Secretary of Agriculture, the food laboratory was made the Division of Foods of the Bureau of Chemistry, with a force of sixteen chemists, two clerks and five helpers. The growth of the Division of Foods is typical of that of the Bureau of Chemistry in all fields. From a humble, almost accidental, origin it has grown to be the most important arm of the bureau. In addition to the work of its regular staff the chief of the bureau devotes much detailed personal attention, especially in the establishment of standards of compositions of foods, experiments regarding the influence of preservatives on nutrition, and the enforcement of the foreign food law, which is under his immediate supervision.

Every means known to science has been used by the Bureau of Chemistry to detect food-adulteration. A drag-net, no respecter of persons, was cast for samples. Morse's Four Corners as well as Greater New York contributed to the catch. The corps of the bureau, typical of all other government corps, being drafted from all parts of the country, peculiarly lent itself to the work. When one of the clerks went to his home in San Francisco on a vacation he was accorded a few extra days and expenses, and directed to bring back with him samples of foods gathered from all parts of that section. The same with the man from Maine. Thus the whole nation was practically raked, and there was scarcely an article of food which did not contribute to the work of the Bureau of Chemistry. Dairy products, spices and condiments, alcoholic beverages, lard, baking-powder, sugar, confectionery, honey and beeswax, tea, coffee and cocoa preparations, canned vegetables, cereals and cereal products, preserved meat, fruits and fruit products, olive-oil, were all subjected to the test.

Doctor Bigelow on one occasion went into the shop of a small importer in New York, and asked for a sample of Rhine wine. "What brand have you?" he asked of the shopkeeper. "Any brand you desire," said the man; and after some talk he offered to put up a dozen cases of wine for his customer under the label of any one of a number of German wine-makers.

"Can you give me the ———'s liebfraunmilch?" asked the Doctor. The man went to a drawer and got the required label.

"Have you the cap?" "Yes, sir," said the man, producing it.

Later, going into the store of an alleged importer of wines in Philadelphia, Doctor Bigelow asked an Irish laborer who was temporarily in charge if he could give him a certain make of Rhine wine. The man replied that he did not know where their Rhine wine came from, but that the vineyard was somewhere in California.

A label which the Doctor secured read, "Old reliable coffee"—giving the manufacturer's name—"one pound, full weight. A compound of delicious drinking coffees, guaranteed to please those who like a full, heavy-bodied cup of coffee."

A LATE PORTRAIT OF DR. H. W. WILEY



CHIEF OF THE UNITED STATES BUREAU OF CHEMISTRY



DR. W. D. BIGELOW, CHIEF OF THE DIVISION OF FOODS, UNITED STATES BUREAU OF CHEMISTRY

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

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

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

Cover Design: Zeb Rogerson

FDA CONSUMER

Interferon: Trying to Live Up to Its Press

6

Early research indicated that interferon, a protein found in most body cells, might be the magic cure for cancer, the common cold and herpes infections. However, a more studied look at the substance reveals that it has a ways to go before delivering on such promises.

They're Growing Food Under Water

10

Fish farming has long been popular in some foreign countries, but now American entrepreneurs are getting more serious about the business. The outcome should be more catfish, trout and even Utah lobsters for the American palate.

New Commissioner Finds No Lack of Challenges— or Satisfaction

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An interview with Arthur Hull Hayes Jr., M.D., FDA commissioner since April, reveals his views on the drug approval process, food safety laws, sodium, the regulatory climate and a host of other subjects.

Blood Tests Give Inside Story

20

It takes only a drop of blood for doctors and technicians to analyze a variety of human ills. This article tells of the tell-tale clues that might be found in a drop.

Herpes Thrives on The Sexual Revolution

24

Genital herpes is a growing problem for people who are sexually active. The symptoms come and go, and the cure remains illusive.

Tips for the Salt-Conscious Consumer

27

Salt is 40 percent sodium and sodium has been linked with high blood pressure. But cutting down on sodium is more than ignoring the salt shaker, as this article points out.

Update

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Inside Front Cover: Lined up in perfect order, like soldiers at the ready, these bottles of interferon were part of a shipment of seven billion units of the rare substance provided to the National Cancer Institute by Meloy Laboratories in February 1981. What interferon is and how it may be used in cancer treatment is told in Interferon: Trying To Live Up To Its Press, beginning on page 6.

Update

Charges Challenged

Two recent articles in READER'S DIGEST have resulted in a number of inquiries to FDA about the safety of indoor lighting and outdoor tanning products. However, neither the Food and Drug Administration nor the companies making the products in question have been able to substantiate the factual basis of any of the health hazard charges made in the articles. Both articles were written by Lowell Ponte. FDA's concern with the articles was expressed in the following letter, addressed to the magazine's editor in chief:

Twice in the past six months, READER'S DIGEST has published articles by Mr. Lowell Ponte: *How Artificial Light Affects Your Health* (February) and *Sunbathing In A New Light* (July). Both stories were reported in other media nationally and resulted in considerable consumer and professional inquiries to the Food and Drug Administration.

Both pieces made sensationalistic statements about the cancer-causing potential of commonly used consumer products. In both cases, these statements and their implications contradict the state of science, especially about human exposure.

In particular, the sunbathing article totally ignored the comprehensive findings of a 1978 committee report whose members are the foremost authorities about sunscreens in the country. None of these experts has any knowledge of the unnamed scientists and unidentified research reports Mr. Ponte claims. FDA has written Mr. Ponte requesting documentation for his statements.

The readership of your publication is so large and its impact so great that the credibility of what is printed is of special concern. In the future, should Mr. Ponte provide manuscripts to READER'S DIGEST, we believe that they should receive better scrutiny and unsubstantiated statements should be verified with knowledgeable government or private sector officials.

PPI Study Completed

Last year FDA was about to embark on a three-year program to test the feasibility of providing patients with information leaflets on drugs, called patient package inserts (PPIs). How the program would work was outlined in Rx With a Dose of Info in the November 1980 FDA CONSUMER. FDA's program is "on hold" while the agency reviews its regulations, but another test of PPIs has been completed. Here are the results of that study:

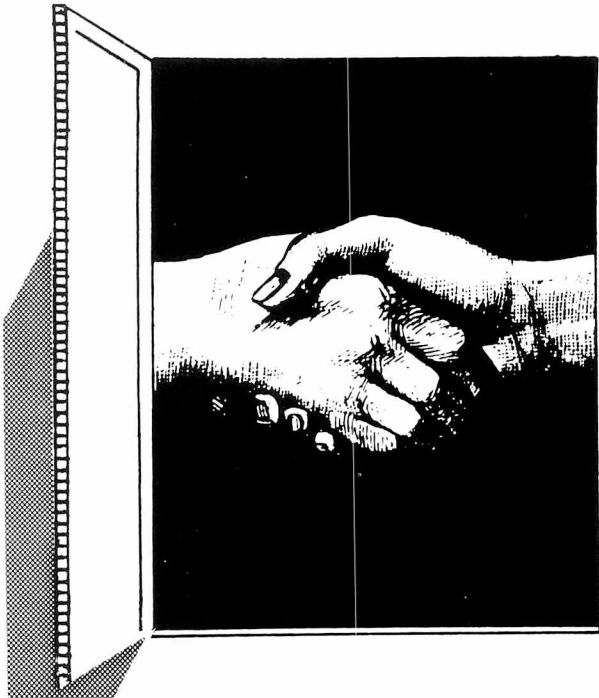
About 70 percent of patients interviewed said they read a patient package insert (PPI) that was included with their prescription in a survey completed for FDA by the Rand Corp. of Santa Monica, Calif.

There were more readers among first-time users of the drug but reading was not limited to the younger or more educated, according to the survey. Patient package inserts are leaflets for consumers describing a prescription drug's purpose, directions, precautions and side effects.

The Rand study was a three-year, \$525,000 project in which a sample of 1,821 people who had prescriptions filled at 69 Los Angeles pharmacies were interviewed. Subjects were given one of several PPIs, or they served in a no-PPI control group. They were interviewed by telephone two to three weeks after receiving their prescriptions and also were asked to respond to a mail questionnaire.

The drugs chosen for the study were erythromycin, an antibiotic; flurazepam, a sleeping pill; and estrogens, for menopausal symptoms. (Estrogen drugs are currently distributed with an FDA-required PPI. For the other two drugs, special PPIs were developed for the study.)

The study was reported by Rand scientists at an August 1981 meeting of the American Psychological Association in Los Angeles. Other principal findings:



- About half of the subjects said they kept the PPI, and 20 to 30 percent said they read it more than once.
- People who received PPIs could answer more questions correctly about how to use a drug, its interactions and contraindications, than those who did not get PPIs.
- Few respondents changed their minds about whether to take a drug after reading the PPI.
- Only 3 of over 2,000 prescriptions dispensed with PPIs were returned for a refund.
- PPIs did not generally increase side-effect reporting. People generally did not "imagine every side effect" listed in the leaflet, as critics of PPIs have predicted would happen. However, certain styles of presentation, in which the PPIs include many specific instructions, increased the reporting of side effects.
- People getting PPIs did not contact their physicians more often but were more likely to discuss

drug safety and side effects with physicians during these contacts.

- Patients reported that PPIs helped them to understand their drugs, to follow their doctors' advice and to know when to take their drug. The less educated respondents reported the most favorable reaction.

In a related matter, Merrell Dow Pharmaceuticals of Cincinnati, Ohio, has agreed to issue a **PPI on Bendectin**, as recommended by an FDA advisory committee. Bendectin is a prescription drug often prescribed for nausea and vomiting during pregnancy.

In a September 1981 press release announcing its decision, the firm said that it "feels patients need to have accurate information about the drugs they are taking. This is particularly important in pregnancy, where special care is always required." The press release said the company felt that the physician is the primary source of such information but that further study is needed.

Bendectin was one of the 10 drugs slated for the pilot PPI program.

Probe of Contraceptive

A number of contraceptive methods were described in Contraception: Comparing the Options in the July-August 1977 FDA CONSUMER. One not mentioned was Depo-Provera; FDA has not approved the additional use of this drug, now used in cancer treatment, as an injectable, long-lasting contraceptive. The situation regarding Depo-Provera could change, however, as the result of this recent FDA action:

FDA Commissioner Arthur Hull Hayes Jr., M.D., has named a public board of inquiry to weigh the risks vs. benefits of Depo-Provera, a controversial contraceptive. This is only the second time such a board has been convened.

Dr. Judith Weisz, professor and head of the di-

vision of reproductive biology in the department of obstetrics and gynecology at the Milton S. Hershey Medical Center, Pennsylvania State University in Hershey, will be chairman of the board. Other members are Dr. Griff T. Ross, associate dean of clinical affairs at the University of Texas in Houston; and Dr. Paul D. Stolley, professor, departments of medicine and research medicine, University of Pennsylvania School of Medicine in Philadelphia.

Depo-Provera has been manufactured and marketed by the Upjohn Co. of Kalamazoo, Mich., for the treatment of cancer of the endometrium (lining of the uterus) and kidney cancer. In 1967 the firm began tests to learn if the drug was also effective as an injectable, long-lasting contraceptive.

In 1974, shortly before FDA had planned to approve this new use for the drug, an additional review of the safety data raised a question about the incidence of cancer of the cervix among the women who participated in the Upjohn studies. For that reason, FDA stayed the approval.

An advisory committee set up to study Depo-Provera found no valid evidence that the drug is associated with cervical cancer, but indicated the possibility can't be ruled out. Therefore, in 1978, FDA told the firm the agency did not have sufficient information to determine whether Depo-Provera is safe for general marketing in the United States. The firm then requested a public board of inquiry.

Depo-Provera is approved for contraception in some other countries and is manufactured in several.

The board will consider:

- Whether, in comparison with other drugs approved for contraception, the benefits of Depo-Provera in the United States outweigh its risks under conditions of general marketing.
- Whether data from beagle dog and monkey

studies submitted by Upjohn indicate a potential risk of breast or endometrial cancer in humans from Depo-Provera.

- Whether the human data submitted by Upjohn can, as Upjohn claims, successfully refute the risk of human cancer suggested by the animal data.

- Whether an approval of Depo-Provera for contraception under general marketing conditions is likely to increase use of the drug as a contraceptive under conditions not stipulated in the approved labeling or is likely to increase its use for unrelated indications for which safety and effectiveness have not been established (for example, for hygienic purposes in mental retardees).

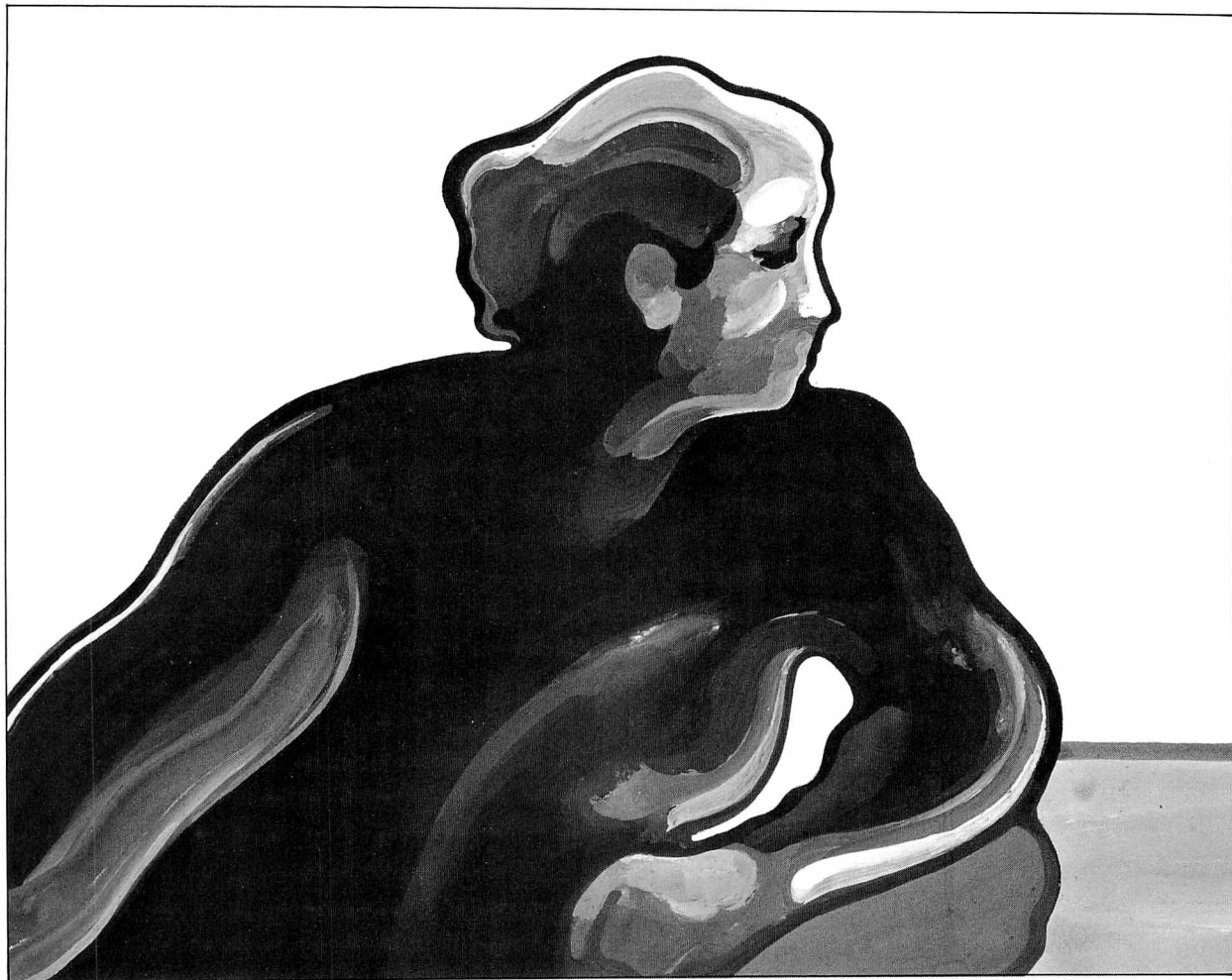
- Whether, in the event of contraceptive failure, use of Depo-Provera may increase the risk of teratogenic effects to a greater extent than would other systemic contraceptives.

- Whether, in view of Depo-Provera's adverse side effects or pharmacologic effect, estrogen therapy is likely to be prescribed in addition to Depo-Provera in a significant number of patients.

- Whether there are conditions of labeling and distribution controls that would permit marketing of Depo-Provera as a safe and effective drug on a limited basis. (There may be certain patients in the United States for whom benefits of Depo-Provera for contraception outweigh potential risks. This population, if it exists, may be very small and may not warrant general marketing of Depo-Provera for contraception.)

Fat Won't Melt

"Getting the fat off" appears to be a major obsession in the United States and consumers would appear to be willing to believe any theory or try any device to realize this objective (see Cellulite: Hard to Budge Pudge, FDA CONSUMER, May 1980). Here's a report on yet another product that promises miracles:



A nationwide promotion is under way in behalf of La Creme "body contour cream," aimed at women and being marketed by La Creme Inc., New York, N.Y., and Morristown, N.J. Advertisements claim that the product will "help melt away inches of unwanted bulge in just 60 minutes." The ads say, "Its gentle warmth penetrates deep into your skin and helps melt fatty deposits." Promotional literature distributed to retail stores and franchises (though not necessarily to consumers) also claims that FDA has approved or classified La Creme as a skin toner, tightener and smoother. In some locations, La Creme is demonstrated or sold with a form of body wrap. Customers are told that La Creme may be used under pantyhose while at work for the same effect as and in lieu of wrapping.

Consumers should be aware that:

- No known product can penetrate the skin and

melt away fat.

- La Creme, the product, has not been reviewed, analyzed or approved by FDA.

- FDA has received neither safety and efficacy data nor adverse reaction reports about La Creme. (Promoters claim La Creme's formulation was invented in California 12 years ago during arthritis research. FDA's Bureau of Drugs and Medical Devices and its Division of Cosmetics Technology have no record of any related correspondence.)

- FDA is looking into La Creme's marketing status under the law. The firm claims La Creme is a cosmetic.

- Any loss of inches that ensues after combining a cream product with a body wrap probably is due to a transitory "wristwatch band" pressure effect that will disappear soon after the wrap is removed. Any loss of weight from induced moisture loss will be regained as soon as the user eats or drinks.

There have been some impressive short-term results in some cancer patients, but the overall picture at the present time is that interferon is not the miracle cure many hoped it would be.

for alternative sources of the substance. One proved to be connective tissue cells called fibroblasts obtained from the penis foreskins of newly circumcised male infants. The cells are grown in culture and stimulated by a virus to produce interferon. Lymphoblastoid cells derived from lymphocytes, a type of white blood cell, provide the third source of virus-induced interferon. These three virus-induced interferons were designated Type I interferons.

Another type of interferon is produced by the T-lymphocytes (specialized cells that battle foreign substances in the body) when stimulated by antigens or mitogens, agents that trigger division of immune cells. This type of interferon was designated Type II interferon.

In the last few years interferon has been produced artificially by use of the techniques of genetic engineering. Simply put, this means a single gene that contains the genetic code for interferon is snipped from one cell and inserted into a harmless bacterium. This becomes a miniature factory turning out interferon as it multiplies.

As more of the precious interferon became available in the 1960s and 70s, research moved from the laboratory to the clinical setting. One of the earliest tests in humans, in 1972, pitted interferon against common cold infections. Carried out by a Stanford University team in association with investigators in England, the study produced impressive results, but the cost was prohibitive—\$700 for one squirt of an interferon-laced nose spray. The Stanford group

also found indications that interferon shortened the duration of herpes zoster (commonly called shingles) and chicken pox in patients whose immune systems were out of kilter. The effect of interferon on hepatitis B infection was also studied. Among other early studies were those of Israeli doctors who used interferon in eyedrops to combat the viral eye infection popularly called pink eye.

The first to come forth with evidence that interferon might work against cancer in humans was Hans Strander, a cancer specialist at Sweden's Karolinska Institute. He treated children with osteogenic sarcoma, a rare and often deadly form of bone cancer, and found they lived longer than expected. Strander also reported success in treating a number of cases of juvenile laryngeal papillomatosis, a disease that causes wart-like growths on the vocal cords.

Excited by Dr. Strander's apparent success, Dr. Jordon Gutterman of the M.D. Anderson Hospital and Tumor Institute in Houston, Texas, tried interferon on patients with advanced breast cancer, multiple myeloma and lymphoma. His initial results also were encouraging, enough so that in 1978 the American Cancer Society (ACS) decided to invest \$2.4 million to study interferon's effect on four types of cancer: melanoma, multiple myeloma, breast cancer and lymphomas other than Hodgkin's disease. A few years later ACS upped its allocation by \$3.4 million, making a total of \$5.8 million for this research.

The ACS decision to devote so much money to interferon research encouraged others to enter the field.

A number of pharmaceutical manufacturers, research firms and even two oil companies have budgeted millions for research and production of interferon. In April 1981 the National Cancer Institute (NCI) announced it was beginning studies of leukocyte interferon made by genetic engineering. The studies are designed to determine the range of doses of the new drug that can be safely used. Tests to determine anti-cancer effects will come later. The study is part of a larger investigation sponsored by NCI that began in mid-February in seven research institutions.

The NCI's sister agency, the National Institute of Allergy and Infectious Diseases, also supports research on interferon's effect on infectious diseases such as hepatitis, herpes virus infections and juvenile laryngeal papillomas.

Interferon is considered a biological product because one of its primary sources is blood cells and because it is intended to act through a specific immune process similar to an antitoxin. For this reason its regulation falls within the province of FDA's Bureau of Biologics. The bureau has already assembled the scientific expertise and is developing the instruments needed for this task. (See *rDNA: Tinkering With Nature To Make Drugs*, FDA CONSUMER, May 1981.) When the first product will be ready for licensing cannot be predicted, however, for there are many problems involved in interferon production that still must be solved.

For instance, there is the question of identity. Interferon is not a single entity. Not only are there several



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Interferon

Trying To Live Up To Its Press

Interferon is a protein found in most cells of the body. Early scientific research suggested that massive doses of the substance might be useful in the treatment of cancer, herpes infections and the common cold. Whether interferon will live up to its original promise remains to be seen.

by Annabel Hecht

A news magazine called it the big IF; in the scientific world the official abbreviation now is IFN. Either way, the subject is interferon, a substance that has raised the hopes of many that a "miracle cure" for cancer and the common cold is just over the horizon.

Unfortunately, early reports of success with interferon may have been overly optimistic. There still is much to be learned about how the substance works and whether it can really do all that is expected of it. It may be many years before FDA's Bureau of Biologics will be able to license an interferon product for human use. Yet, in spite of the gaps in scientific knowledge, products allegedly containing interferon are appearing in such places as health food stores.

Interferon is a protein, a natural substance produced by many cells in the body in response to some stimulus, such as a virus. Interferon has been called the body's Paul Revere. When it is released by cells that are under siege from a virus, interferon spreads to other cells to prepare them for attack by stimulating the production of what are called anti-viral proteins.

Credit for discovering interferon

goes to Alick Isaacs and Jean Lindemann, virologists at London's National Institute for Medical Research. The two shared an interest in learning why patients suffering from one virus-caused infection rarely came down with a second viral disease. In 1957 they found the answer: The first virus infection caused the cells to produce something that protected the body against the second infection. It was Lindemann who gave that something its name—a combination of "interfere" and "on," a suffix then in vogue among scientists for naming new genetic concepts.

Although interferon's anti-viral activity was what first brought it to the attention of the scientific world, it is now known to have a number of other effects on the body. For instance, it retards the growth of cells by slowing down cell division. Some of the cells most sensitive to this effect are essential to the immune system. Interferon seems to increase the activity of "natural killer cells," white blood cells that can kill enemy cells without involving other parts of the immune system.

In contrast to today's wide interest in interferon, the first reports of the Isaacs-Lindemann discovery barely made a splash. People were probably not aware of it, unless they happened to be comic strip fans. In a 1960 episode of the popular adventure series Flash Gordon, a spaceman infected by an extraterrestrial virus was saved by injections of interferon.

This lack of interest or awareness is understandable. Scientific research in the 1960s was hampered by inadequate supplies of interferon. The body itself produces only small

amounts and no one then knew how to coax the cells into producing more. In addition, interferon is generally "species specific," that is, mouse interferon usually is effective only in a mouse, while interferon produced by man usually is effective only in the human and one or two other species. Thus, the scope of research was necessarily limited.

The acute shortage of interferon was relieved in part by the work of Dr. Kari Cantell, a Finnish virologist who developed the first method of mass producing the substance, using leukocytes, which are infection-fighting white blood cells. They were obtained from blood donated to the Finnish Red Cross, since white cells are not needed for normal blood transfusion. Cantell found that by infecting the white cells with a virus—in this case the influenza-like Sendai virus that is harmless to humans—he could stimulate them to make interferon. The resulting solution was centrifuged to remove the white cells and partly purified to destroy the virus. Of what was left, something less than 1 percent was pure interferon.

Until recently the only major source of interferon was Dr. Cantell's Finnish laboratory, which is capable of producing some 400 billion units of IFN a year. Although this may seem like an ample supply, it actually is small, considering that a single dose daily may be more than a million units. (A unit is the amount of interferon that protects half of a cell culture in a laboratory dish from being destroyed by a test virus.)

At about the same time that Cantell was developing leukocyte interferon, other scientists were looking

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for alternative sources of the substance. One proved to be connective tissue cells called fibroblasts obtained from the penis foreskins of newly circumcised male infants. The cells are grown in culture and stimulated by a virus to produce interferon. Lymphoblastoid cells derived from lymphocytes, a type of white blood cell, provide the third source of virus-induced interferon. These three virus-induced interferons were designated Type I interferons.

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also found indications that interferon shortened the duration of herpes zoster (commonly called shingles) and chicken pox in patients whose immune systems were out of kilter. The effect of interferon on hepatitis B infection was also studied. Among other early studies were those of Israeli doctors who used interferon in eyedrops to combat the viral eye infection popularly called pink eye.

The first to come forth with evidence that interferon might work against cancer in humans was Hans Strander, a cancer specialist at Sweden's Karolinska Institute. He treated children with osteogenic sarcoma, a rare and often deadly form of bone cancer, and found they lived longer than expected. Strander also reported success in treating a number of cases of juvenile laryngeal papillomatosis, a disease that causes wart-like growths on the vocal cords.

Excited by Dr. Strander's apparent success, Dr. Jordon Gutterman of the M.D. Anderson Hospital and Tumor Institute in Houston, Texas, tried interferon on patients with advanced breast cancer, multiple myeloma and lymphoma. His initial results also were encouraging, enough so that in 1978 the American Cancer Society (ACS) decided to invest \$2.4 million to study interferon's effect on four types of cancer: melanoma, multiple myeloma, breast cancer and lymphomas other than Hodgkin's disease. A few years later ACS upped its allocation by \$3.4 million, making a total of \$5.8 million for this research.

The ACS decision to devote so much money to interferon research encouraged others to enter the field.

A number of pharmaceutical manufacturers, research firms and even two oil companies have budgeted millions for research and production of interferon. In April 1981 the National Cancer Institute (NCI) announced it was beginning studies of leukocyte interferon made by genetic engineering. The studies are designed to determine the range of doses of the new drug that can be safely used. Tests to determine anti-cancer effects will come later. The study is part of a larger investigation sponsored by NCI that began in mid-February in seven research institutions.

The NCI's sister agency, the National Institute of Allergy and Infectious Diseases, also supports research on interferon's effect on infectious diseases such as hepatitis, herpes virus infections and juvenile laryngeal papillomas.

Interferon is considered a biological product because one of its primary sources is blood cells and because it is intended to act through a specific immune process similar to an antitoxin. For this reason its regulation falls within the province of FDA's Bureau of Biologics. The bureau has already assembled the scientific expertise and is developing the instruments needed for this task. (See *rDNA: Tinkering With Nature To Make Drugs*, FDA CONSUMER, May 1981.) When the first product will be ready for licensing cannot be predicted, however, for there are many problems involved in interferon production that still must be solved.

For instance, there is the question of identity. Interferon is not a single entity. Not only are there several

When the first product will be ready for licensing cannot be predicted, however, for there are many problems involved in interferon production that still must be solved.

types of interferon—i.e., virus-induced and antigen-induced—but there are also within each type several subtypes, each of which could have different effects on the body. (Recent efforts to make interferon using genetic engineering revealed that leukocyte cells have at least ten genes capable of producing the precious protein.) It is not possible at this time to determine whether interferon products made by different methods and by different manufacturers will have the same biological effect. If synthetic interferons were to be made by several companies, each could be distinctly different from one another since each may have been cloned from a different gene.

Then there is the question of purity. Early leukocyte, fibroblast and immune interferons used in clinical studies were 0.1 to 10 percent pure. Technology used for purification has improved and lymphoblastoid interferon used in clinical studies is now 10 to 50 percent pure. The genetically engineered interferon comes close to 100 percent purity. However, even this product has potential disadvantages, including the possibility that the gene used for splicing can mutate and produce an altered or inactive preparation. Lack of purity has led scientists in the past to question whether the interferon or some other substance is responsible for the good and the bad effects of these preparations. (Interferons can cause side effects such as headaches, fever, chills, nausea, hair loss and depression of the bone marrow's ability to make blood cells.)

Results of a British study comparing the effects of a partially purified leukocyte interferon with that of a purified preparation suggested that these side effects are caused by the interferon and not its impurities. The authors advised that because of these adverse reactions, interferon should not be used for trivial ailments.

Still another problem besetting interferon research has been the acute shortage of it, up to now, and its high cost. It is estimated that it costs \$20,000 to \$30,000 to treat one patient. The supply side of the picture looks brighter now as more U.S. firms have started production.

Whether all this expense will be justified remains to be seen. There have been some impressive short-term results in some cancer patients, but the overall picture at the present time is that interferon is not the miracle cure many hoped it would be.

"Interferon hasn't yet done anything better than any other cytotoxic (anti-cancer) drug," Frank Rauscher Jr., the American Cancer Society's senior vice president for research, told a seminar for news reporters in March. Yet, a month later, scientists meeting in Rotterdam agreed that the substance "will eventually find a permanent place in the limited armory of the cancer chemotherapist."

It is too early to know whether interferon will be effective in preventing virus infections, such as herpes, but there is "guarded optimism" for the use of interferon in the treatment of hepatitis B, according to Peter Newark, writing in the May 14, 1981, British journal *NATURE*.

In spite of the doubts raised in the scientific community, early reports of interferon's potential have made it a natural subject for exploitation. FDA has learned that some health food stores are selling a product allegedly containing 500 units of interferon in combination with vitamin A. No specific health claims are made on the label, which recommends one tablet a day to supplement the body's natural secretion of interferon. However, advertising suggests interferon is a "miracle cure" for cancer. There is no evidence to suggest these products have any value.

There also have been news stories about interferon treatment for cancer being offered in Mexico and Europe. The cost is a mere \$60,000.

Consumers who may be tempted to try such products with the hope they will have some health benefits should keep these points in mind:

- There is no interferon product licensed for medical use in the United States.
- Research on interferon is still in its infancy and scientists do not know at this time whether it will be useful in treating cancer and other diseases.
- It takes millions of units of interferon to cause an appreciable effect. There is no evidence that very small doses will do anything at all.
- The body produces interferon *only* when it is attacked by a disease. A healthy person does not need interferon.

Annabel Hecht is a member of FDA's public affairs staff.

Aquaculture

They're Growing Food Under Water

In this country aquaculture, or fish farming, got off to a late start, but now it has rounded the turn and is moving up fast. More and more entrepreneurs are developing the technology and marketing strategy to make the raising of fin fish, shellfish or crustaceans pay off. The payoff for the consumer promises to be an assured supply of desirable kinds at a time when traditional catches from the sea have just about reached their limit.

by Harold Hopkins



Anybody knows it's the American farmer who puts ham and eggs, pork and lamb chops, hamburger and pot roast, T-bones and chicken on the table.

But farmers who supply oysters, shrimp, catfish, and salmon steaks?

This too may come to pass in a big way in the coming years if a new business or occupation called aquaculture keeps up its present momentum. Aquaculture is not a misspelling of agriculture nor some lispy way of referring to the traditional tilling of the soil—it's farming water instead of land. In its broad meaning the word takes in plants, too, but in the United States we're not as high on edible seaweed and other such products as the people are in some countries. Here aquaculture is chiefly thought of as a way of domesticating—and improving the output of—the fishery trade, particularly those fishery products that over the years have been shown to be most in demand for the highest prices.

Putting what used to be "wild" fish, shellfish or crustaceans into "cultivation" of sorts may also result in improvement of their flavor, nutritional quality or safety as food. That's because of the undivided attention they get from the aquaculturist, who doesn't need to worry about fisherman's luck. He already has his catch. His concern is supplying the product to order and in the amount wanted, and getting the best price for it.

Hundreds of small to large U.S. aquaculture operations enjoy a ready market for all the oysters, clams, mussels, shrimp, prawns, crabs, crawfish, eels, catfish, trout and salmon they can haul out of the water. But neither they nor traditional fishermen are hauling out nearly enough today to meet the steady consumer demand, and 60 percent of our seafood is imported.

The nation's aquaculturists, if things go their way, plan not only to change all that but to make a plate of fried shrimp, catfish fillet, a salmon steak or clam chowder as familiar to Mr. and Mrs. America and their offspring as meat loaf, breakfast sausage, a Big Mac or Kentucky fried fowl. But they still have a long row to hoe to make it happen, or you might say, a lot of roe to sow.

The U.S. aquaculturist is essentially a new breed. He admires the technology of some other countries, Japan, for instance, where the culture of yellow tail and blue fin tuna, penned salmon and shrimp have reached a high state of efficiency, and he brings a good background of aquacultural science to his work, but he still has to apply that knowledge to conditions in the United States. He is not much impressed with the extensive overseas culture of such species as carp and milkfish, which offer little temptation to American palates. He is directing his brains, energy and capital toward carving out a share of the market for the high demand products.

If there is a demand for a fish, shellfish or crustacean,

the chances are good, or improving, that it can be planted, fed, tended and harvested in controlled or protected waters and trucked off to market by an operator wearing a ten gallon hat instead of a sou'wester. The "ocean rancher" of Oregon doesn't ride sea horses or herd sea cows. He deposits fertilized salmon eggs or fingerlings in a freshwater stream. From there the salmon make their way downstream to the "range"—the sea, that is—which they roam until they reach maturity. When in a few years the salmon has reached a size big enough for spawning—or becoming the centerpiece on a dining-room table—its homing instinct takes over and it returns unerringly up the same stream where it was released. There the rancher sits waiting at a convenient dam or "fish ladder" to capture the whopper and take it off to market.

Washington state laws don't permit ocean "ranching," but one large operation in that state buys salmon eggs or strips them from gravid females, fertilizes them in a bucket, hatches them in a tank, then raises the fingerlings in floating nylon net pens moored in the salt water of Puget Sound, using pelleted feed. They are harvested when they reach three-quarters of a pound, a size the company or its customers have decided is right for a dinner plate.

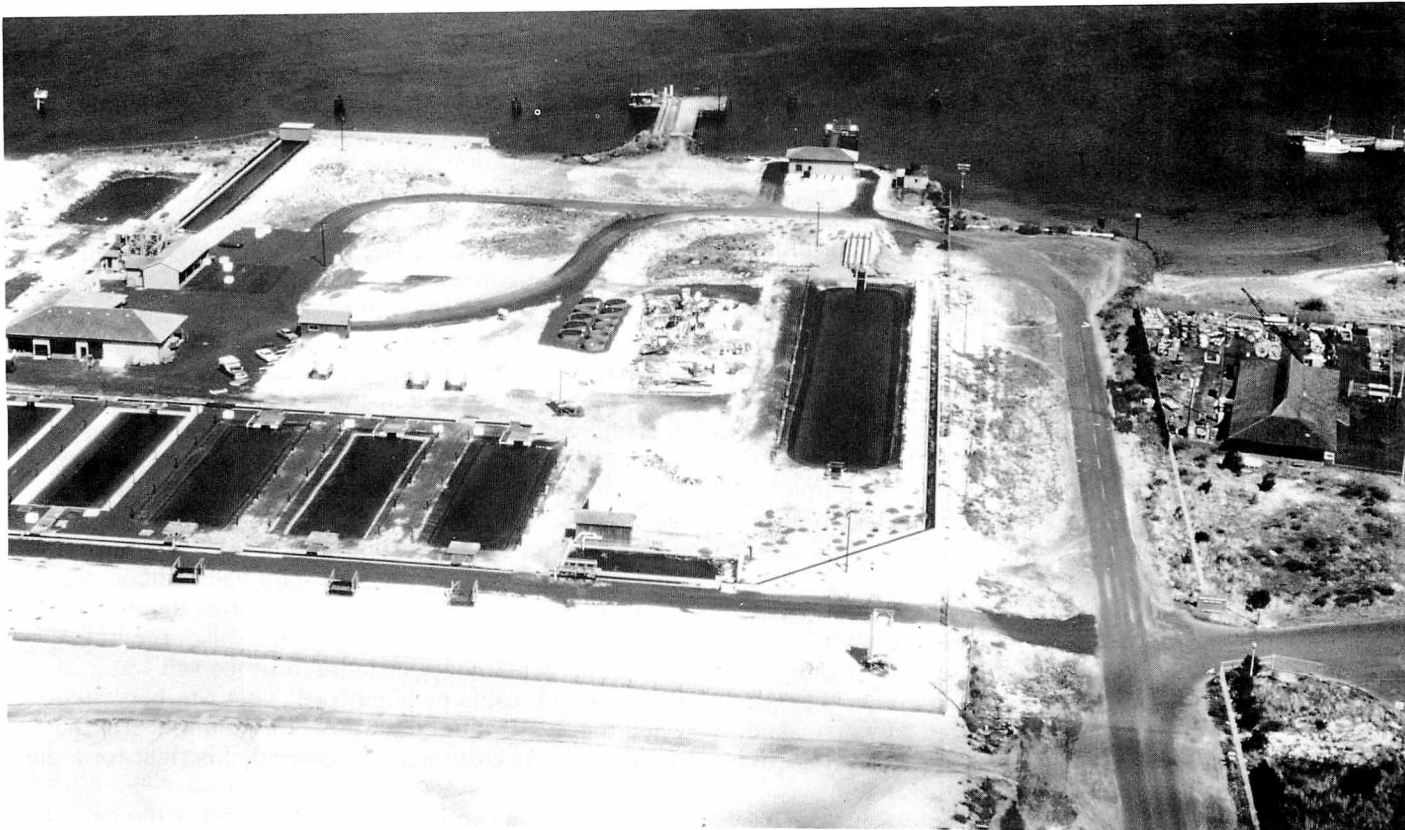
Aquafarming can be carried on wherever the cultured fish, shellfish and crustaceans can be made to feel at home. Depending on the species, this can be in coastal lakes or ponds and estuaries, or far inland in artificial ponds or raceways, flooded fields, even tanks. Since efficient and profitable raising of most species dictates complete or at least supplemental feeding, advances in aquaculture have been paralleled by the development of feed formulas that contain all the nutrients needed—in a form that the cultured species can and will eat. Fish that insist on their food being alive are not suitable for aquaculture.

Raw materials for aquaculture feeds are much the same as for farm animals—cereals and other grains, meat and fish scraps, plus whatever vitamin or mineral supplements may be needed, in meal or mash or pelleted form that will sink or float, dissolve quickly in water or remain solid for a time, whichever best fits the feeding habits of the particular species. Some species, grown in large numbers and crowded into confined areas, are subject to diseases and require medicated feed or the addition of pharmaceutical agents in the water in which the fish are grown.

Other species, such as oysters and clams, obtain their food from micronutrients suspended naturally or in solution in water. That makes it impractical to grow them very far from the sea. Researchers are looking for ways to incorporate these nutrients into water that otherwise would be unsuitable.

Utah is patently not the place to grow the luscious ocean delicacy that turns ladies into kittens, the Maine lobster. Or is it? Roger Mickelsen and Rex Infanter, a couple of young nutrition experts at Brigham Young University in Provo, decided a few years ago to experiment with breeding and growing lobsters in raceways, using water from Great Salt Lake. They weren't the first lobster culturers, just the farthest inland. Great Salt Lake's

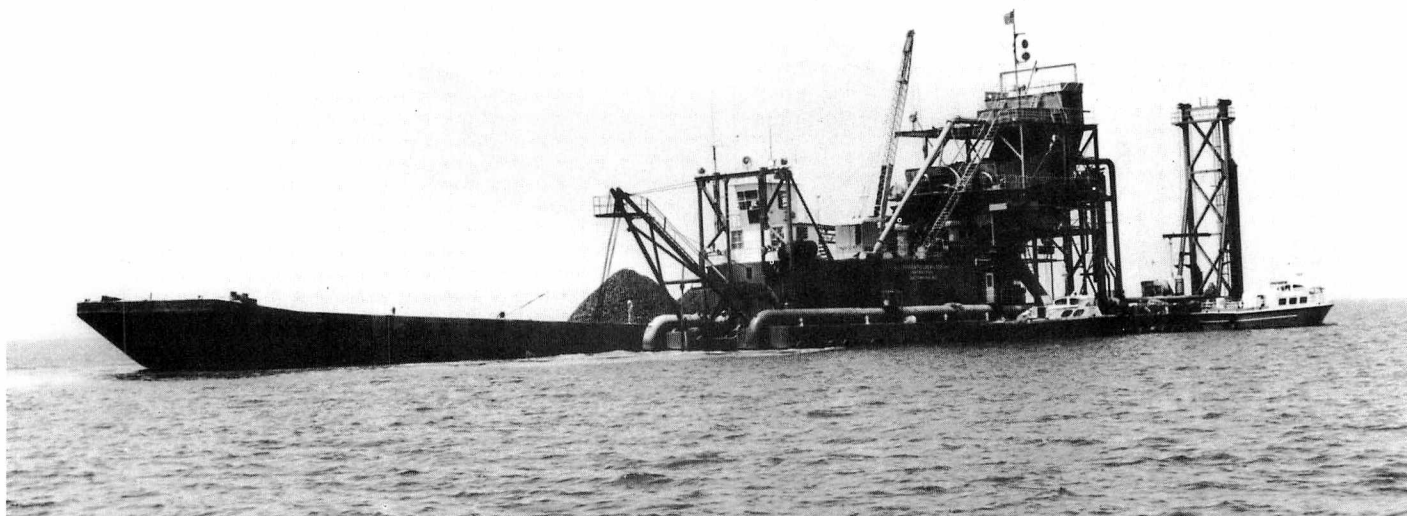
This teeming mass of eyes, stripes and fins are salmon fry, one of two species artificially spawned by Oregon Aqua Foods, an ocean-ranching subsidiary of Weyerhaeuser Co. They'll be released to make their way to the ocean and will return to the release point to spawn when mature. The silver salmon mature in 18 months at about 6 pounds, and king salmon in 4 years at 15 pounds.



Oregon Aqua Foods' salmon release and recapture site at the mouth of the Yaquina river at Newport, Ore., is a brief but significant stopping place for salmon fingerlings. They are put into the ponds shown in the foreground where they will be "imprinted" by the particular water, then released through pipes to swim to the ocean. They will return unerringly to the same spot at maturity, ready to spawn, and will be recaptured as they ascend a "fish ladder" connected to the building to the right of the pier.

At a University of Maryland oyster hatchery at Horn Point, mature oysters are placed in tanks as shown and conditioned to induce spawning. When the larval oysters are hatched, they are put into large containers and fed the algae culture medium from the jars shown until they can be planted or deposited in areas of water supplied with old shell and favorable to seeding.





water wasn't so great, but there was lots of salt handy, so they mixed their own water, the same as it's done for a living room salt water aquarium, and it worked.

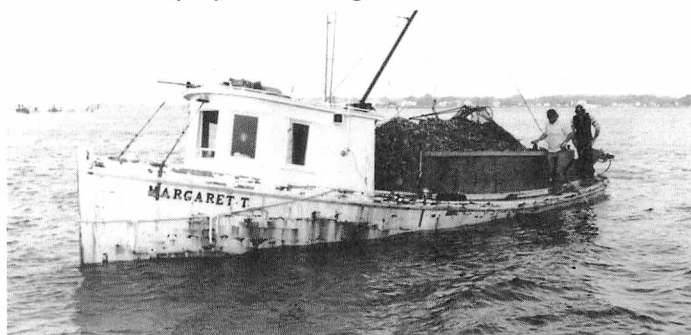
To circumvent the unpleasant (and unprofitable) habit lobsters have of dining on each other when not occupied with mating, Mickelsen and Infanter raise the crustaceans from hatchlings in little individual cages where they can't get at each other. Thus the lobsters nibble away at pelleted feeds until they've reached a big enough size to tempt that other nibbler, the consumer. That size is an optimum three-quarters of a pound, for restaurants obsessed with portion control, and they've got supermarkets interested, too. They believe they've got land lobstering down pat as an economically feasible proposition and are now trying to land an investor to help turn sweat into money.

Some conditions seem made for aquaculture. It's not unusual these days for a Southern farmer who wants bigger returns from his acreage to take advantage of a mild climate and plentiful rainfall by scooping out a pond of 2 to 5 acres for growing channel catfish. This opportunism probably began when farmers noticed how well random or stray catfish thrived in stock watering ponds, and started to cash in on the phenomenon. A Texas public utility power plant increases its revenues by raising catfish in cages suspended in water used to cool the power equipment. An aquafarmer in Idaho provides a warm environment for his catfish by constructing raceways filled with a proper mixture of cold water and hot water from geothermal springs nearby.

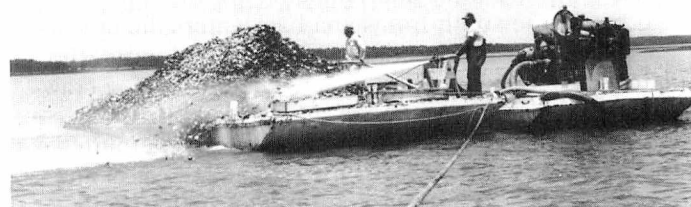
Catfish farming is restricted, you might say, to one breed of cat. No other catfish suitable for marketing will touch food that's not alive, but the channel cat will eat just about anything you throw at it, and grow to a 20-pounder doing it. Pioneer catfish farmers raised their fingerlings on doughballs, cornbread and other homemade mixtures, but nowadays instead of casting bread upon the waters most stick with the standard formulas developed by catfish feedmills that have sprung up.

In 1980 growers in the 10 biggest catfish raising states sold 88.5 million pounds of food fish, brooders and fingerlings for \$66.7 million and as of February 1981 had 63,000 acres of ponds in cultivation.

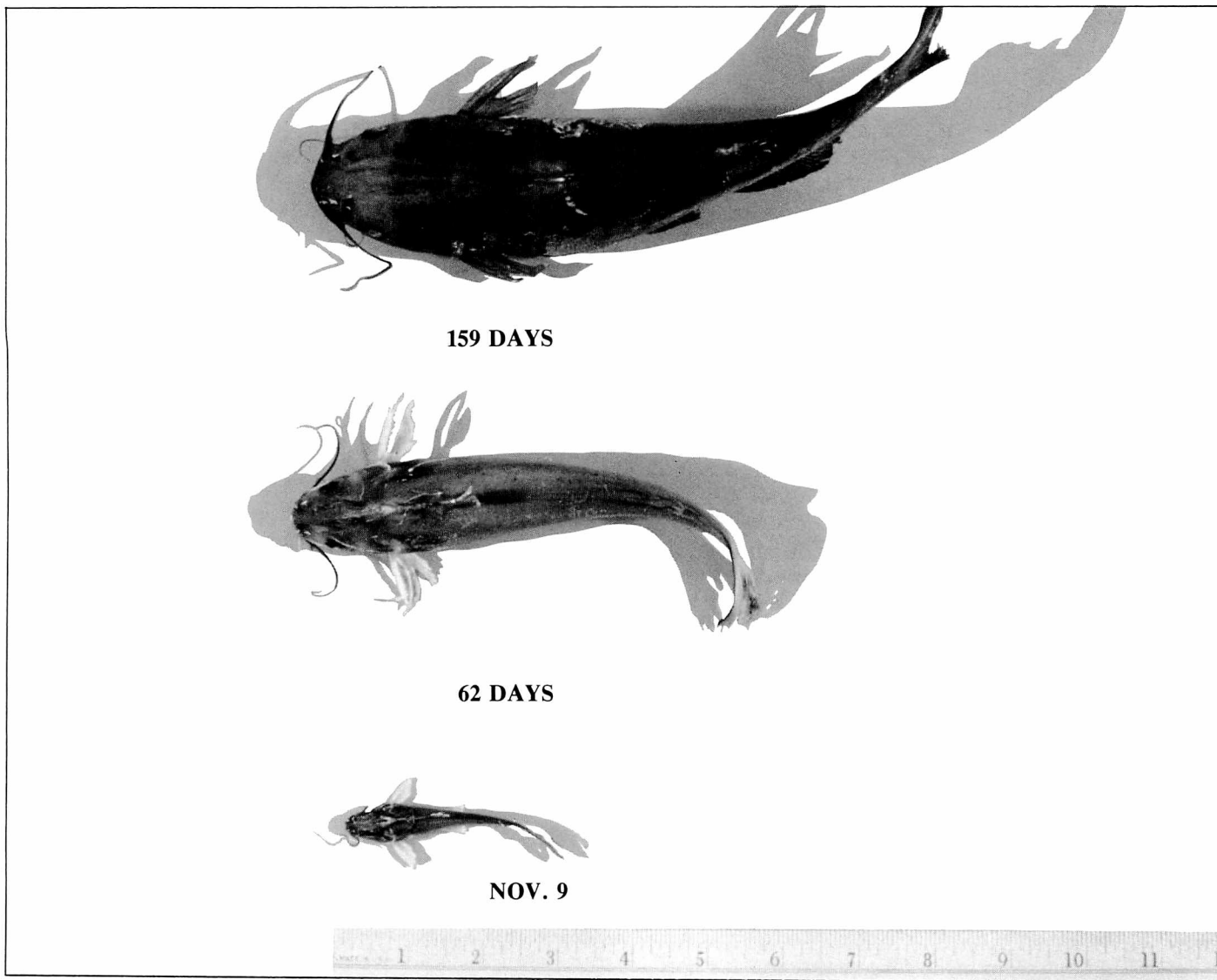
Shellfish breeding-planting programs are carried out along the Chesapeake Bay estuary system by Maryland's Department of Natural Resources, financed by a tax of 45 cents a bushel on oysters taken from public waters. Dredge vessels such as this take old shells from abandoned oyster banks or shoals, some of them prehistoric, and move them to a likely oyster seeding area.



After young oysters have made a good "set" by attaching to old oyster shells in the seed area, the resulting mix of shell and young oysters, called seed, is dredged up again by watermen hired by the state. The seed is moved to and redeposited in public waters, remaining there until ready for harvesting and marketing.



Juvenile hard clams in Chincoteague Bay, Maryland, don't attach to oyster or any other shells, but they do like the shelter and stability such shells provide on the bottom. Maryland's Department of Natural Resources buys empty shells from oyster shucking houses and scatters them in spots where young clams will snuggle up and grow to market size.



Water warmed by cooling of electric power plant equipment creates an artificial environment that alters the life cycle of caged catfish. The fish keep eating and growing through the winter. As a result, the Texas Electric Service Co., Fort Worth, produces a 10-inch, market-size fish in half the 18 months it takes nature to produce the same size fish.

Mississippi, Arkansas and Alabama are the top catfish states, but in the south Louisiana backwaters the crawfish is king. The native descendants of French colonists who settled the country thereabouts have been trapping crawdads for generations from open and wooded natural ponds and turning them into bisques, crawfish etouffé (tails sauteed in a butter-flour mixture called *roux*) and other robust dishes. Crawfish culture got under way a decade or so ago in response to demands by local restaurants and markets for predictable supplies of their favorites lasting into the off-season. As gourmets outside the state have learned of crawfish delights, the industry is opening up. More and more farmers, beset by idle labor and scarce cash in the fall and winter, have flooded their rice fields after the harvest to grow crawfish as a second

crop. To meet market demands the crawfish industry is processing the crustaceans by beheading them, freezing, packaging and storing the edible parts (the tail), and shipping the crawfish to distant markets instead of selling them alive by the sackful in the traditional way. Some 50,000 acres of flooded impoundments are devoted to this specialty in Louisiana, which produces 99 percent of the U.S. output.

Other freshwater species suitable for aquaculture are bass, trout and the shrimp-like crustaceans called prawns. Federal and state hatcheries supply millions of striped bass and largemouth bass fingerlings for stocking ponds, lakes and streams for public and fee fishing by sportsmen. That's aquaculture, too. Similarly, the coho salmon has been planted in some of the Great Lakes for game and commercial fishermen. Brook trout farming began over a century ago with hatcheries on the Eastern Seaboard.

Rainbow trout farming was introduced in the western United States before 1900 and since then there have been many refinements in breeding and feed formulas. In 1980 trout farmers in the leading production states of Idaho, Washington, California, Wisconsin, Georgia, Missouri and Pennsylvania sold 48 million pounds of foodsize trout

for \$38 million, Idaho leading with 89 percent of that total.

Prawns, on the other hand, are still in the experimental stage in the United States. The bulk of prawn aquaculture so far has been going on in Hawaii. Another freshwater species, the eel, is being cultured on a limited basis in this country, but Americans haven't developed the strong yen for them that exists in Japan, Europe and elsewhere, and thus the major markets for American eels are overseas. Since eels are spawned in the sea and then migrate to freshwater streams to grow to maturity before they return to the sea, they must be trapped while in "larval" form or as young elvers, and retained in ponds until they reach market size. The optimum methods for culturing eels are still being worked out, but the ready overseas market for them is attracting aquaculturists.

On a per capita basis the average American eats two pounds of shrimp a year. Shrimp culture technology has moved ahead rapidly in the past several years. There have been breakthroughs in captive breeding of some species and year-round production is now possible for shrimp larvae. In addition, pelleted feeds have been developed that supply all the nutrients shrimp need to grow, according to James P. McVey, an aquaculture technology expert of the National Marine Fishery Service of the U.S. Department of Commerce.

But shrimp farming has problems. Banks have been reluctant to make loans to this new industry. The amount of available coastal land in the warmer parts of the country is severely limited because of competing demands for recreation purposes and business and residential development. Hurricanes or other storms can play havoc with coastal impoundments and enclosures.

Shrimp aquaculturists are of two main types—those using coastal ponds and those using tanks or raceways. Marifarms, a 650-acre operation at Panama City, Fla., uses ponds and produces 500 pounds of shrimp per acre per year. Marifarms feed is supplied by the Ralston Purina Co., which itself owns the largest shrimp aquaculture operation in the world, in the Republic of Panama.

Those who use or plan to use tanks and raceways believe such operations are probably the only way shrimp culture can expand to any size. One aquaculture company executive noted that there are several hundred thousand acres of marginal land adjacent to estuary systems in Texas that would be ideally suited to shrimp culture and conceivably could supply all U.S. shrimp requirements.

The oyster industry is where aquaculture methods have been most widely adopted in the United States. Over 40 percent of the nation's oysters are cultured. Other shellfish cultured to a much smaller extent are clams, mussels and abalone. Oysters are not only much in demand but also are relatively easy to culture. Having no legs, fins or wings, oysters do not move about. They are dredged or tonged by oystermen from the same location year after year. They obtain food by pumping the water around them through their digestive tracts and retaining microscopic nutrients suspended or in solution in the water.

Thus, an oyster is unsafe to eat if the water it lives in is polluted by sewage outfalls, runoffs from industrial and agricultural wastes, and other contaminants. Oysters and other molluscan shellfish may become toxic if they feed on toxic marine dinoflagellates found in "red tides" responsible for paralytic shellfish poisoning. These facts

have long been known and oyster producing states and the federal government guard against the harvesting of oysters from polluted waters. As a consequence, the acreage of public and private waters for growing oysters is limited, and when oysters are harvested from these waters, the oystermen or state agencies "restock" the oysters in various ways.

The simplest stocking method is to dump empty oyster or clam shells into the waters. This gives oyster larvae something to attach to and remain until maturity. Watermen also obtain immature oysters from private or state hatcheries and dump them into the oyster waters for growth to maturity. Oysters also are grown by suspending oyster or clam shells in trays or racks from rafts or in metal frames, or tied to strings or wires suspended by long lines or cables in fixed positions. Oyster larvae attach themselves to these and stay there until they are mature enough to harvest. Under such conditions the oysters are under regular control and are lifted out of the water for cleaning off parasites or other unwanted materials. Although these systems are practiced in this country to a limited degree, they require considerable labor and are practiced much more extensively in Asia and some South American countries where labor is cheaper. On the Pacific Coast, oysters or other shellfish are often "planted" in areas where they can be harvested out of the mud flats by hand when the tide goes out.

Aquaculture received an important boost with enactment of the National Aquaculture Act by Congress on Sept. 26, 1980, which provided for a joint effort by several federal agencies to promote and foster water farming. The law aims at a "national aquacultural policy" and will be administered by three federal departments (Agriculture, Commerce, Interior) with cooperation from other government entities.

The law established a joint subcommittee on aquaculture, on which FDA is represented. The subcommittee has drawn up a National Aquaculture Development Plan making recommendations for development of aquaculture in this country, including government support activities.

The subcommittee in its report said that although technological capability in the United States is high, it hasn't been put to maximum use for aquaculture.

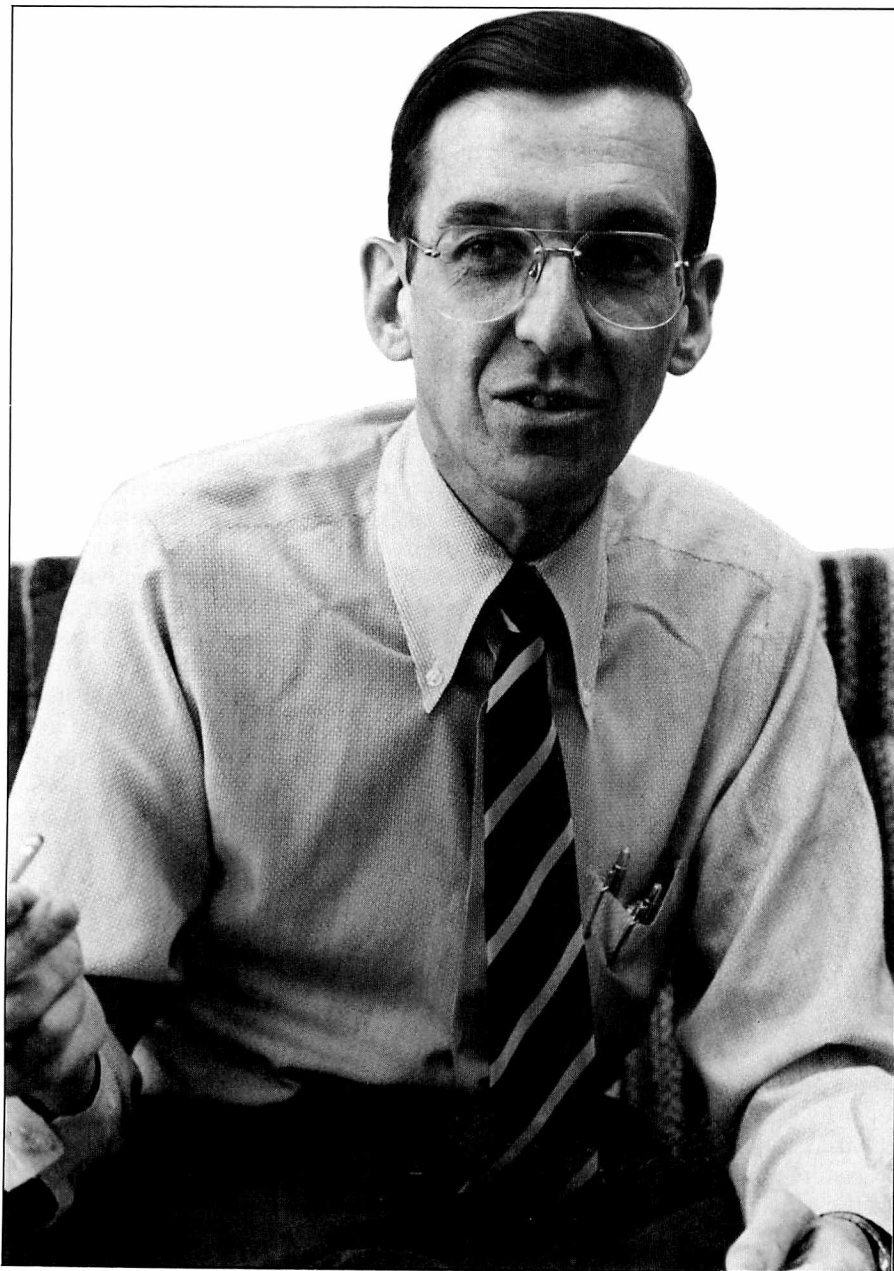
FDA is represented on the subcommittee because its shellfish sanitation consultants have had considerable experience with aquaculture in the shellfish industry; because of the agency's concern with safety and sanitation of seafood, whether caught by fishermen or produced by aquaculturists; and because medications used to protect the health of the species raised by aquafarming must be approved by this agency.

Although aquaculture is still in its infancy in this country, it seems obvious that it provides almost the only direction we can take to substantially increase the amount of fish, shellfish and crustaceans available for consumption. Overfishing and an increasing world population have sealed off the other major avenues. Right now aquaculture does not account for a significant share of the seafood we consume, but there is reason to believe that—the way things are going—the wave of the future may lie down on the aquafarm.

Harold Hopkins is editorial director of FDA CONSUMER.

New Commissioner Finds No Lack Of Challenges — Or Satisfaction

Arthur Hull Hayes Jr., M.D. became the 14th commissioner of FDA—starting with Harvey Wiley—on April 13, 1981. He promptly set forth some goals for himself and for the agency. In this interview with Wayne Pines, FDA's associate commissioner for public affairs, Dr. Hayes sets forth how he perceives his job and the agency, and what his goals are.



Q. *Dr. Hayes, during the first few months of your tenure you've spent a lot of time dealing with one issue, sodium. Why?*

A. There are two reasons. First, before I became commissioner one of my responsibilities was to direct the hypertension clinic at Hershey Medical Center, so sodium and its relation to hypertension has been one of my professional concerns for a long time. I've advocated for some time the need for more understanding of the relation between hypertension and the ingestion of sodium, and as a pharmacologist I've been interested in how sodium affects the action of drugs.

It really was a coincidence, though, that sodium also developed as an issue for FDA around the same time I was preparing to become commissioner. Congressman [Albert] Gore [D., Tenn.] had scheduled hearings on sodium before I even knew I was coming to Washington. The hearings were scheduled for April 14, which was to be my second day on the job. I didn't testify myself, but I did participate with my deputy, Mark Novitch, in developing the five-point plan that we discussed at the hearing.

The followup on that plan is very important to me and that's why I've spent so much time on this issue.

Q. *You advocate a voluntary approach to sodium reduction and labeling, rather than a mandatory approach. What does that tell us about your approach to regulation in general?*

"I'm very much in favor of regulation—when it's the best or only way to serve the public good and when the regulations are fair and effective. I'm only against bad and unnecessary regulation, and I hope everyone would be."

A. My general philosophy is that regulation through the use of mandatory rules should be used only when you can't accomplish the same thing by more efficient methods. In the case of sodium, for instance, if we were to start along the regulations route, it would be years before any final rules would become effective. That's just how long the process takes. And it seems to me if you want some results in the marketplace, there is a more efficient way to go about it, and that is to go to the food industry and say, "There's an important public health issue here, and you can do something about it." I believe it's entirely proper for government to go to industry to try to accomplish its objectives, rather than relying on the long and drawn out rulemaking process. And rulemaking often creates an adversary type relationship that I don't think is good for either the government or business. We're not necessarily on the opposite sides.

But there's a larger issue involved. I have watched over the years as government regulation has become more common. And what's happened is that industry no longer has the initiative to do anything different or to take the initiative itself. On many occasions people from companies or trade associations have told me they were afraid to try something new or to go beyond what the regulations required because they feared that FDA wouldn't approve it or that they would have to change what they were doing after FDA issued final rules. So they tend to sit on their hands

and do nothing. That's bad for our country.

Q. *What do you intend to do about it?*

A. What I'm trying to do is to tell industry, "You really don't have to be afraid of government. If you want to try something new and different in terms of labeling, we'll support you. We're not going to stand in the way of innovation. And we don't have all the good ideas."

Q. *Many of the officials appointed by the new administration indicate that they're opposed to federal regulations. Are you?*

A. I think that's a misrepresentation. I don't think this administration is uniformly opposed to regulation. There are some areas where perhaps there's been too much regulation, and we need to correct past excesses.

I believe that this administration favors good regulation. In the food and drug area, for example, there's a consensus that regulation is absolutely essential. The mushroom recall that occurred earlier this year is a good example. There were bad batches of mushrooms on the market. It was entirely proper for the government to step in and try to get those mushrooms off the market as quickly as possible. The same thing is true in the drug area. It is quite reasonable for the government to be in the business of approving new drugs before they are marketed. Individual consumers can't tell for themselves

whether a drug works or is safe.

The public has very high expectations for the foods and drugs it buys. It expects them to be safe and effective and most people don't even want to give it a second thought. They shouldn't have to. If you go back just a few years in history, it wasn't very long ago when there were really unsafe foods in the marketplace and our drugs weren't much more than alcohol and opium.

I don't want to undo all the progress that's been made in assuring people that their foods and drugs will be safe; what I want to do is to build on the record that industry and FDA have made.

I'm very much in favor of regulation—when it's the best or only way to serve the public good and when the regulations are fair and effective. I'm only against bad and unnecessary regulation, and I hope everyone would be.

Q. *Did you get any marching orders from the new administration before you became commissioner?*

A. Not in a general sense. Before I make a decision on very important matters, I discuss it with Secretary Schweiker and Assistant Secretary [Edward] Brandt. But I haven't had any differences with them and they've let me make the calls at FDA. I wouldn't want it any other way.

I find my discussions with the secretary and Dr. Brandt extremely useful. They are very much interested and involved in what FDA is doing,

"I think the commissioner has to concentrate on the large picture, the large issues, and that's the way I approach this job."

and that's good for the agency and for the public. They also support the agency strongly, and that's very important.

Q. *The secretary issued an order earlier in the year that required more department clearance of FDA regulations. Doesn't that mean greater involvement by the secretary's office in FDA decisions?*

A. Not really. That order was necessary because the Office of Management and Budget imposed new reporting requirements on all departments, and so the secretary's office needed to see more of what FDA was doing. What that order did, in effect, was to codify what had always been the relationship between the FDA commissioner and the HHS secretary. When I told the FDA Policy Board about the order, one of them said, "That really doesn't change anything." And I think that's correct. The law has always given the authority to enforce the law to the secretary, not the commissioner, so it's entirely appropriate that major new rules be reviewed by the secretary before they're issued. I expected that to be the situation before I came here.

Q. *How do you like the job so far?*

A. It's a lot more hectic than I ever imagined any job to be. There's a constant round of meetings and decisions and hearings and the like. I can keep busy 25 hours a day and still not do everything the job requires.

Q. *How do you spend your time, then?*

A. I think the commissioner has a few functions that must be performed. I am the representative of the agency to the outside world, to other agencies, to the Congress, to the industries and consumer groups, to the public, and so I must spend a lot of time on that. There are a few overriding issues that I have a particular interest in, like the drug approval process, sodium and hypertension, and food safety, that I spend time on. I want to make sure the agency is running well, so I spend some time, though not as much as I'd like, on that. Much of the management has to be delegated. I think the commissioner has to concentrate on the large picture, the large issues, and that's the way I approach this job. If I get bogged down in too much trivia, then I'd do nothing else all day, and I wouldn't really get anything done.

Q. *In the first few weeks, you said nice things about the FDA staff. Do you still feel that way?*

A. Absolutely. The staff here is great. They know exactly what they're doing and why. I have a great deal of confidence in the people who run FDA. In fact, in talking to some of my colleagues at other agencies, all of them have been impressed by the staff they inherited. The permanent senior staff in the federal government doesn't deserve all the criticism it gets.

It's too easy for a new manager, coming into an agency, to start fid-

dling with the people and the structure. That's the surest way not to accomplish anything. My style is to tell my staff what I want done, and then give them the time to do it. If they can't do it, then I have to do something about it.

Q. *Have you set any goals for yourself?*

A. I'm interested in sodium, and really want to see better labeling and a greater selection of foods than in the past. I want to see if we can change the food safety laws, many parts of which are outdated. I want to improve the drug approval process. It sometimes takes too long for drugs to be developed and approved. I don't think all of the fault lies with FDA, but the agency has to make sure its approval and review process is working properly.

I want to improve FDA as a scientific agency. I regard myself primarily as a scientist and I think all of our decisions have to be made on the basis of good science. People don't often appreciate that FDA still has to make decisions even when all the evidence isn't in. We don't have the luxury that people at universities have of deferring decisions until the last word is in. But we have to be sure that when we do make a decision, it's based on the best science available.

I would like historians to say that while I was commissioner we restored an appropriate balance between regulation and innovation, and gave back to industry some of the incentive it needs to move forward. At the same time, I'd like FDA to con-

"Modern science tells us that nothing can be risk free. There is no perfect food. We have to put some of these concepts into a law that's enforceable. It's not an easy task."

tinue to provide the same protections that the public wants and expects from the products we regulate.

Q. *Let's see if we can pin you down to some specifics. First, on sodium. What do you want to accomplish?*

A. My goal is to make it possible for people with high blood pressure to be able to select from a variety of foods, and buy foods that are low in sodium, and be able to understand from the label what the sodium content of foods is.

Q. *How much time are we talking about?*

A. I don't have a specific timetable yet, but in a few months I'm going to assess where we are, and then I'll decide how we're doing. This really is a chance for the American food manufacturers to show their willingness to work with us on a voluntary and cooperative basis. I hope it works. As a perennial optimist as well as realist, I expect it to.

Q. *What about the specifics on food safety?*

A. The food safety law is a hodgepodge. There's no uniformity. Different chemicals are regulated differently on the basis of nothing other than age or whether they're naturally part of a product or added. That doesn't make any sense from a health standpoint.

I'm working with the President's Cabinet Council on Food and Nutrition on this issue and I hope we can

develop some alternatives. My goal here, to be somewhat specific, is to write a law that provides the same measure of health protection that people expect, but that doesn't force irrational decisions because we can find one part per trillion of a contaminant in a food. Modern science tells us that nothing can be risk free. There is no perfect food. We have to put some of these concepts into a law that's enforceable. It's not an easy task.

Q. *What about new drugs?*

A. This is an area that truly merits special attention. For years we've heard the drug industry say there's a "drug lag." There are many reasons why some drugs are introduced into other countries before they reach the United States, and only some of them are attributable to FDA regulations.

Nevertheless, what we need is a comprehensive look at the entire issue. The Bureau of Drugs has been developing new procedures and we will follow through on that effort. I've appointed a special task force to look at the drug development and review policies, and I expect their recommendations by next March. And there's a congressional commission that's also looking at the process. So, by next year, I'm confident, we'll have some specific solutions.

Part of the answer lies within FDA. We have to streamline some procedures and reduce unnecessary paperwork. Part of the answer lies in better understanding by the public of how the process works. People can't

compare the amount of evidence required 20 years ago to get a new drug approved with what's now required. The standards are different. Nothing's the same as it was 20 years ago. Part of the answer lies with the industry, which has to do a better job of research and testing. And part of the answer lies with the research community. So there's a lot of work to be done here, and not only by FDA, though it's quite appropriate that we begin the study here.

Q. *How much time do you think can be shaved off the drug development process?*

A. I don't know—maybe a year, maybe more. I simply don't know.

Q. *One final question. You've been commissioner several months now. What qualities does it take to be the commissioner?*

A. You have to be a good scientist, so you can understand the issues. You have to be a good manager, so you can make sure things get done. You have to be a specialist in congressional relations and public relations and all sorts of other relations, because you spend a lot of time on that. You have to be diplomatic, because you're always resolving strongly held feelings by different people. All in all, it's a fascinating job. There's no limit to the work or the challenge or the satisfaction.

Blood Tests Give Inside Story

Blood, they say, is thicker than water. Actually, it is a tissue made up of water, cells, proteins and other compounds. When something goes wrong in the body, the delicate balance of these compounds goes awry. Measuring these changes in blood tests enables doctors to diagnose a variety of ills.

Few people have escaped that disquieting experience of watching a nurse draw what seems to be an enormous amount of their life's blood into a syringe. (Actually all that is lost is 2 or 3 teaspoons out of a blood supply of 4 to 5 quarts.)

Today blood tests are a routine part of most physical examinations. By studying the characteristics of the blood a doctor can determine whether the patient has a serious disease or condition or can rule out a suspected illness. While the patient is being treated, periodic blood tests may be made to monitor his recovery or check the levels of drugs in his system.

Blood, of course, is much more than a barometer of health. It is vital to life itself. As it makes its grand rounds through the body, blood carries oxygen, nutrients, vitamins and drugs to the cells and picks up, along the way, the waste products of cell metabolism. It transports hormones from the endocrine glands to appropriate receptor sites in the body. Blood defends the body against infection and other foreign invaders and helps maintain the environment by regulating the internal body temperature.

Although blood looks like a simple red liquid when it oozes from a cut on the finger, it actually is a tissue made up of a variety of living cells suspended in a substance called plasma.

Plasma accounts for more than half of the blood's volume and consists mainly of water plus plasma proteins and other organic and inorganic compounds. The major plasma proteins are albumin, the alpha, beta and gamma globulins, and fibrinogen.

The other organic compounds

include urea, uric acid, creatinine, amino acids, glucose, neutral fats and cholesterol. The inorganic compounds found in plasma are sodium, potassium, chloride, calcium, phosphate, sulfate and magnesium. These compounds are sometimes collectively called electrolytes because they conduct an electrical current.

About 45 percent of total blood volume is made up of the cells, or corpuscles. There are three types of blood cells: the erythrocytes, or red cells; the leukocytes, or white cells; and the platelets. Blood cells are unique, for unlike most other cells in the body, they are continually being replaced. As old cells finish their life span and die, new cells are being born and readied for their task in the blood stream. Only the cells of the skin have a similar capability.

Red blood cells are tiny round or slightly oval discs with the added characteristic of flexibility, making their passage through the tiniest blood vessel possible. They can't move by themselves, but are carried along by the flow. It is the red blood cells that carry oxygen from the lungs to the various cells in the body and pick up waste in the form of carbon dioxide. The main organic component of the red cells is hemoglobin. It is iron in the red cell—the "heme" in hemoglobin—that transports oxygen and waste. When their 120-day life span is completed, red cells break down and their iron is salvaged for future use.

There are five members of the white cell family: the three granulocytes—neutrophils, eosinophils, and basophils; and the lymphocytes and the monocytes. Each type of white cell plays some

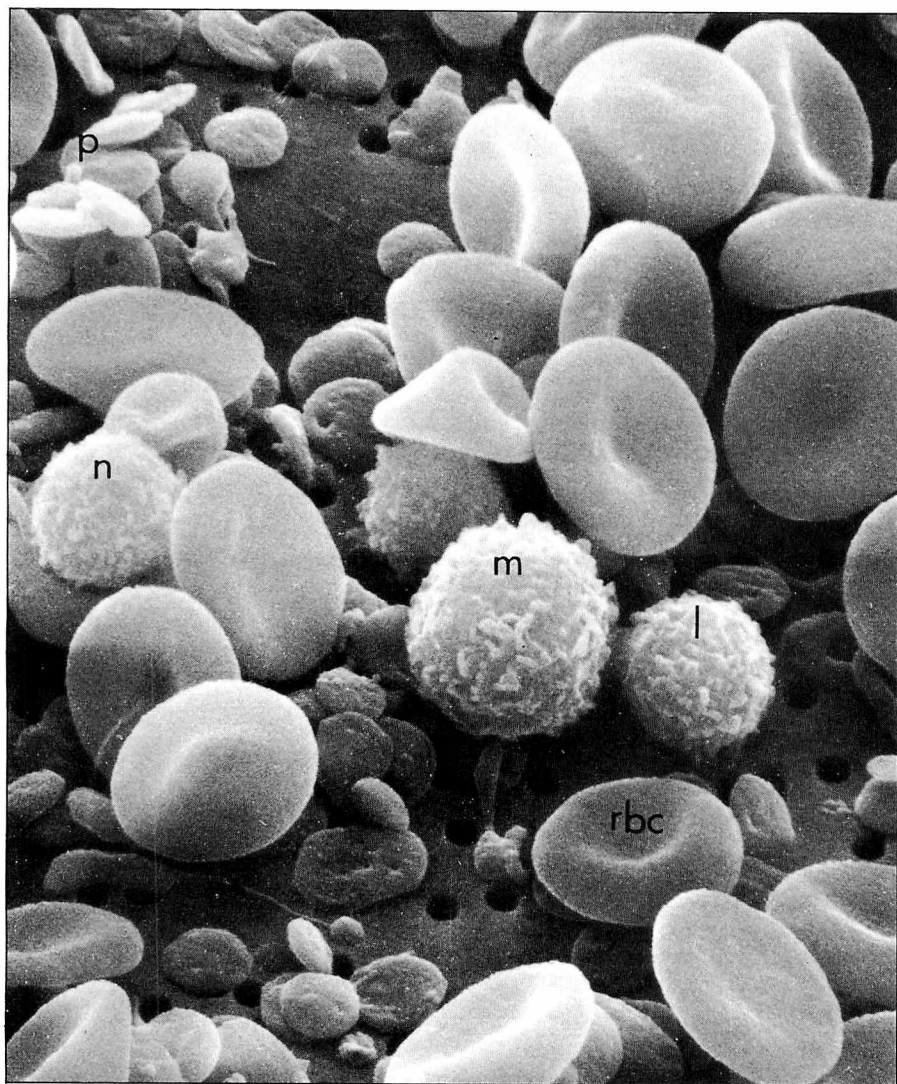
role in the body's defense system—gobbling up bacteria, stimulating the development of fever (a warning sign that infection exists), forming antibodies against foreign substances. These tasks are carried out in the tissues, rather than in the blood itself.

Platelets are the smallest of the formed elements in the blood, with a life span of 8 to 10 days. Platelets play an important role in blood clotting and in keeping blood from leaking out of injured vessels.

In normal healthy individuals, the blood circulates and recirculates uneventfully with all these cells and other constituents maintained in predictable and measurable concentrations. When something goes wrong, the balance may change. The number of blood cells may rise or fall; their appearance and behavior may change; the amount of enzymes, amino acids or other substances in the blood may increase. These changes are what the doctor looks for when a blood test is made.

Blood for testing purposes is usually taken from a vein in the arm. This is called venous blood. If for some reason it is not possible to get venous blood, or if only a small amount is needed for a single test, the tip of the finger, edge of the ear, the big toe or heel may be pricked to get what is called peripheral blood. When the required amount of blood is drawn, it is delivered as quickly as possible to the laboratory for analysis. What happens to it there depends on what the patient's doctor wants to know.

A routine examination usually calls for a total blood cell count, a differential count of the different types of white cells, and an



These objects that look like tid-bits in a candy dish are really blood cells magnified 4,700 times under the scanning electron microscope. Visible in this picture are red blood cells (rbc), several white cells, including a monocyte (m), lymphocytes (l), and a neutrophile (n). The tiny disc-shaped cells are platelets (p). (Photo courtesy of the National Institutes of Health)

examination of a blood smear (a thin film of blood on a glass slide) to detect abnormalities in the cells. The amount of hemoglobin in the blood is measured and the ratio of red cells to the total blood volume is determined. The latter test is called the hematocrit. The erythrocyte sedimentation rate, i.e., the time it takes the red cells to fall toward the bottom of a special tube, and the prothrombin or clotting time are also measured.

Among the things the doctor might learn from these tests is whether the patient has anemia. This would probably be the case if the red blood count, hemoglobin and hematocrit were low in comparison to an established standard. Anemia can be caused by several different factors such as blood loss, damage at the cell production end of things, and accelerated destruction of mature cells. Thus, close examination of the red cells in the blood smear is needed to diagnose the exact cause of a particular patient's anemia. A blue-gray tint to the cells would indicate that they are immature and would signal increased cell production. Small pale cells occur with iron deficiency anemia.

An increase in the total number of red cells, and consequently, the total volume of cells (hematocrit), is referred to as polycythemia and is due to a variety of conditions.

The rate at which the red cells fall in the erythrocyte sedimentation test increases in certain inflammatory diseases, such as rheumatoid arthritis, chronic infections and diseases of the connective tissues.

White cell counts can go up if the patient is under stress, but are usually the result of some disease or

suggests the patient may have liver or bone disease or some form of cancer. High levels of bilirubin, a byproduct of hemoglobin metabolism, also points to liver disease. Disorders of the plasma proteins may be seen in patients suffering from acute bacterial infections or viral hepatitis. Albumin is decreased in some kidney disease, liver damage, chronic infections and third degree burns. High cholesterol levels signal possible

that are made in a day. Thirty years ago hematology tests were all performed manually, according to William K. Young, laboratory director of the Public Health Service Outpatient Clinic in Washington, D.C. Writing in *LAB WORLD* (December 1980) Young said, "Counting chambers, blood-diluting pipettes, monocular microscopes, stain preparation, slide washing and tube preparation were all part of those days' work."

coupled with computers that record all of a patient's test results in one convenient form.

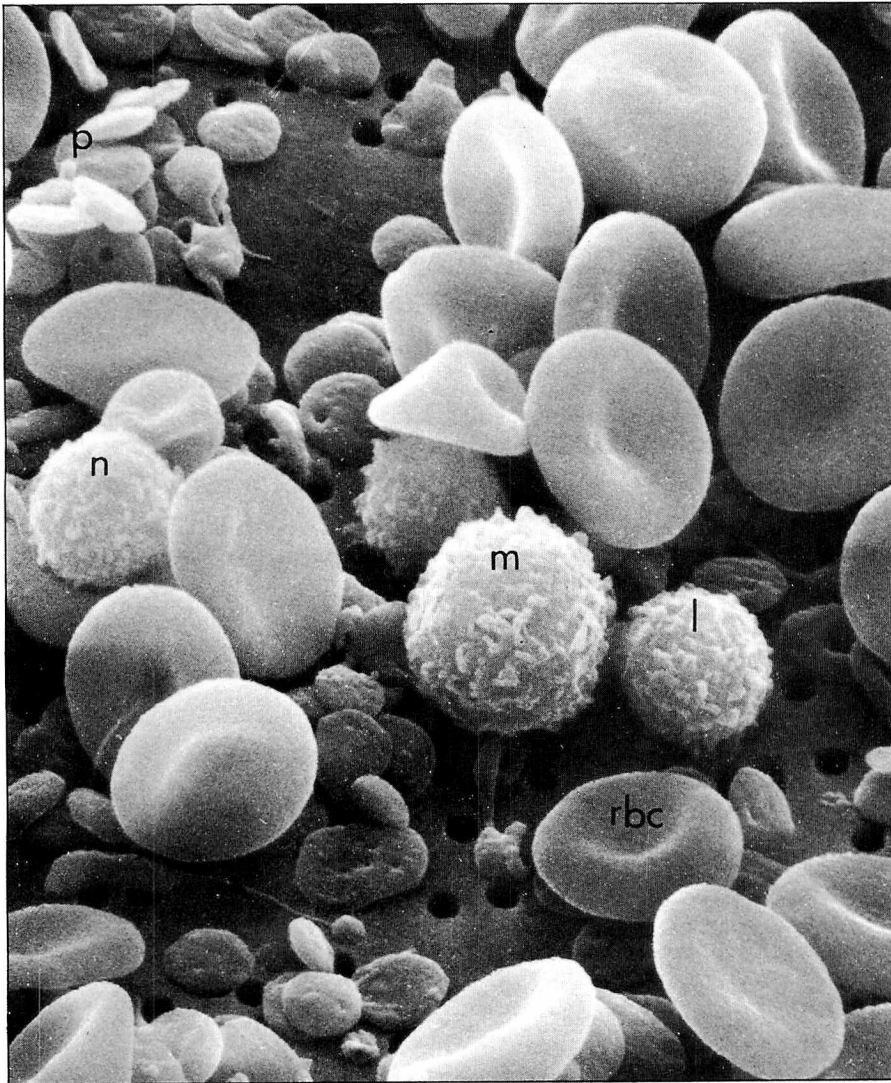
Blood-testing equipment, whether manual or automated, is regulated by the Food and Drug Administration under the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

—Annabel Hecht

A prick of the patient's finger is all that's needed to obtain blood for testing purposes. (Photos by Arthur Hall III).

This maze of tubing is the heart of SMAC—short for Sequential Multiple Analysis Computer. This multi-chan-





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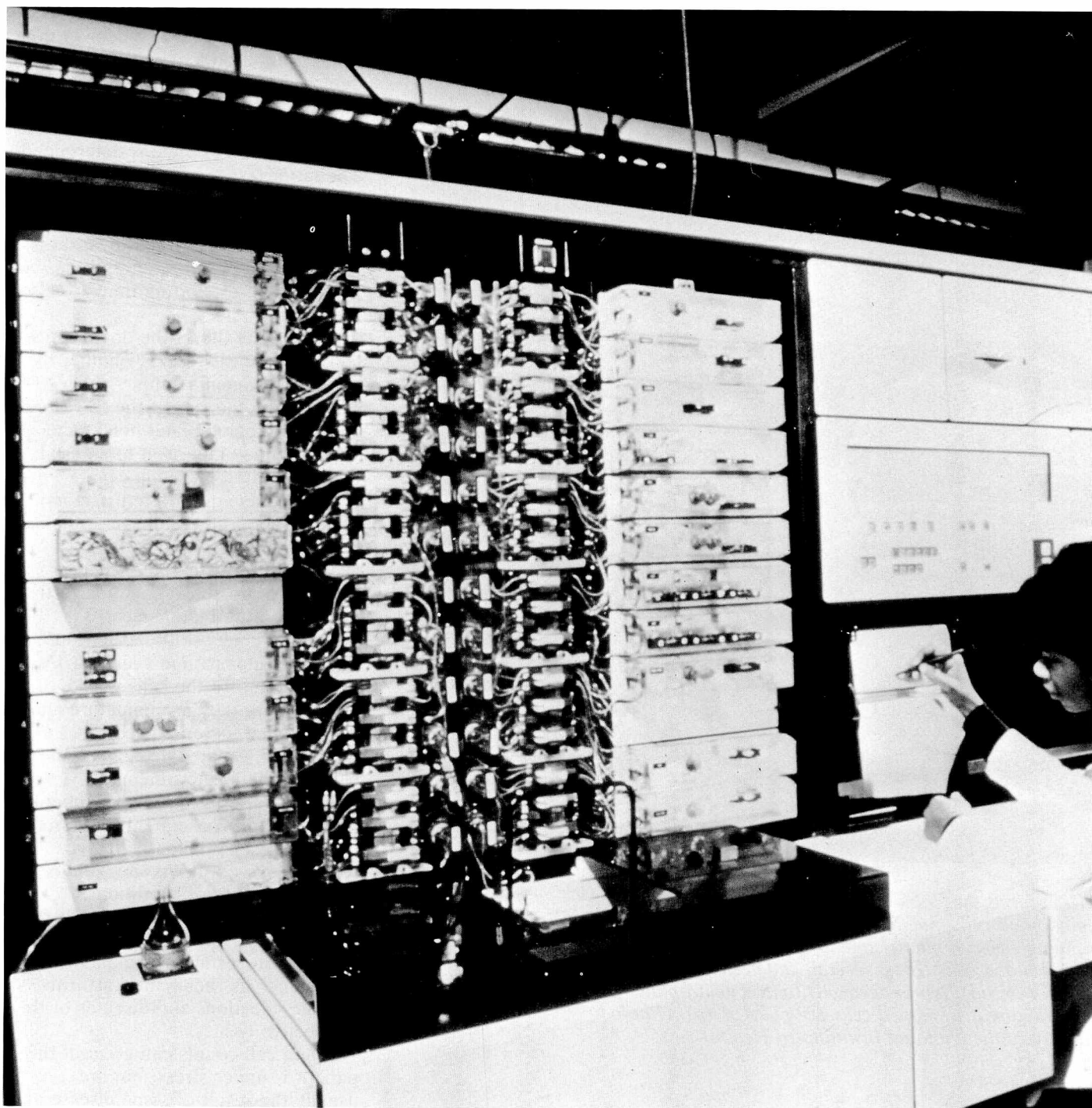
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This maze of tubing is the heart of SMAC—short for Sequential Multiple Analysis Computer. This multi-channel analyzer can measure the levels of 20 different elements in a single sample of blood serum.



exposure to certain drugs and chemicals.

An abnormal growth of white blood cells and a decrease in platelets are characteristic of leukemia. A persistently elevated platelet count tells the doctor the patient may have a condition called thrombocythemia. Increased prothrombin, or clotting time, may point to cirrhosis of the liver.

The study of the characteristics of blood cells, called hematology, is carried out in a hematology lab. Whole blood is used for these tests. Only the serum is used in the clinical chemistry lab to check the status of amino acids, enzymes and other constituents of the blood. Serum is the liquid portion of the clotted blood after the cells have been removed.

A standard chemical analysis of blood serum might include measurement of uric acid, calcium, alkaline phosphatase, bilirubin, proteins, albumin, cholesterol, glucose, urea nitrogen, sodium, potassium and chloride. The doctor might learn many things from these tests. For example, the patient may have gout, if the serum uric acid is elevated. Or hyperparathyroidism should be suspected if the calcium level is up. High levels of alkaline phosphatase (an enzyme important in digestion) suggests the patient may have liver or bone disease or some form of cancer. High levels of bilirubin, a byproduct of hemoglobin metabolism, also points to liver disease. Disorders of the plasma proteins may be seen in patients suffering from acute bacterial infections or viral hepatitis. Albumin is decreased in some kidney disease, liver damage, chronic infections and third degree burns. High cholesterol levels signal possible

heart problems, while abnormal amounts of glucose are a sure sign of diabetes.

Urea nitrogen, a byproduct of the breakdown of protein in the body, is measured in a blood test called BUN (for blood urea nitrogen). When levels of this substance are high the doctor will look for kidney failure. Congestive heart failure can also raise urea nitrogen levels. The balance of the blood electrolytes (sodium, potassium, chloride) may be upset if the patient has kidney failure, emphysema or an overdose of salicylates such as aspirin.

These are some of the tests that can be done in the hematology and chemistry laboratories. Other scientific skills also may be brought into play when blood needs to be analyzed. For instance, it takes a microbiologist to determine what antibiotic to use to fight a particular infection. A toxicology lab will handle blood samples from patients who have been exposed to harmful chemicals or drug overdoses. An immunology lab is concerned with blood typing and such tests as the AFP (alpha-fetoprotein) test, the first of several procedures to diagnose certain birth defects.

How these tests are done depends to some extent on the size of the laboratory and the number of analyses that are made in a day. Thirty years ago hematology tests were all performed manually, according to William K. Young, laboratory director of the Public Health Service Outpatient Clinic in Washington, D.C. Writing in *LAB WORLD* (December 1980) Young said, "Counting chambers, blood-diluting pipettes, monocular microscopes, stain preparation, slide washing and tube preparation were all part of those days' work."

The chemistry lab of that period was akin to "an alchemist's workshop," Young noted, "with the boiling solutions, comparative blocks and huge quantities of glassware."

In small laboratories and doctors' offices, blood tests are still done by technicians peering through microscopes at slides and counting chambers (special glass slides marked off in a grid to aid in cell counting). There have been improvements, of course (for instance, microscopes now have two eyepieces instead of one).

But for large facilities where many tests are made, sophisticated instruments do much of the work automatically. There are devices that count the various blood cells using electronic impulses or laser beams. The same machine also can measure the hemoglobin and hematocrit using tiny portions of the same blood sample.

Multi-channel analyzers can perform 20 or more different chemical tests on a minute amount of serum as it is pumped through a maze of spaghetti-like plastic tubing. Or, if the doctor needs the results from a single analysis quickly, there are instruments that can provide the answers fast. All the lab technician has to do is inject the sample and push a button. Many of these instruments are coupled with computers that record all of a patient's test results in one convenient form.

Blood-testing equipment, whether manual or automated, is regulated by the Food and Drug Administration under the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

—Annabel Hecht



Herpes Thrives On The Sexual Revolution

A highly contagious, sexually transmitted disease whose symptoms sometimes come and go without warning—that's genital herpes. Cases have increased in recent years, and so far there is no effective treatment. Until the answer to herpes is found, prevention is still the best bet.

by Louise Fenner

When herpes viruses come to visit, they stay forever. Some people are hardly troubled by these unwelcome guests, while others suffer the misery of repeated attacks. A type of herpes has come to be, for many people, a lifelong souvenir of the sexual revolution.

"Oh, it was so horrible," remembers a 28-year-old lawyer who suffered her first attack of herpes about 5 years ago. "It wasn't a time when it was a 'popular' little disease. I didn't know what it was. One doctor thought it was infected hair follicles. It took forever to get it diagnosed as herpes." She still has episodes of herpes about once a month, but they are becoming increasingly milder.

Somewhere between 5 and 20 million people in the United States are estimated to have the "popular little disease"—genital herpes—and possibly half a million new cases occur each year. Exact numbers are elusive because genital herpes is not routinely reported to the Centers for Disease Control as are some other sexually transmitted diseases. However, CDC has found through surveys of venereal disease clinics that the incidence of genital herpes is increasing, particularly among 15- to 30-year-olds, and other sources agree.

Herpes is different from venereal diseases such as syphilis and gonorrhea in an important way. Unlike the others, herpes cannot be cured or even effectively treated. Once the virus invades the body, nothing will evict it. The symptoms, usually painful genital blisters or sores, may occur only once, or they may return again and again. In between these episodes, the viruses remain dormant

and hidden within a cluster of nerve cells in the body. Herpes can be transmitted to others through intimate sexual contact when the infection is in its active stage, which in most cases is signaled by the presence of symptoms (although they may sometimes be hard to detect).

The culprit responsible for most cases of genital herpes is the herpes simplex virus type 2. It is one of a family of five herpes viruses that causes a wide range of human ills, including chicken pox, shingles, infectious mononucleosis and birth defects such as mental retardation. In this family is another herpes simplex virus—type 1—which produces cold sores and fever blisters on the mouth and face (oral herpes) and can occasionally attack the genital area. Estimates of the number of oral herpes sufferers start at 40 million.

Herpes simplex infections may result in serious complications. The viruses can cause severe localized or systemic infections in newborns and in people whose immune systems are weakened by disease or medications, such as organ transplant or cancer patients. Type 1 sometimes attacks the eyes, or even on rare occasions reaches the brain and causes deadly encephalitis. Babies born to women whose birth canals contain genital herpes sores may suffer fatal infections or brain or eye damage. Women who have had genital herpes appear to have a greater risk of developing cancer of the cervix than women who were never infected.

The symptoms of genital herpes usually appear in a victim within 2 to 10 days after contact with a person who has an active infection. The first sign may be a minor rash, itching or

a tingling sensation in the genital area, possibly accompanied by a burning sensation after urination or a vaginal discharge. Within a few hours, one or more small red bumps or fluid-filled blisters usually develop in or on the sex organs. The lesions are full of virus that can be transmitted to partners who come in direct contact with them. People also experience other symptoms, such as swollen lymph glands, fever, headache, aching muscles or a "sickly" feeling.

Within a week or two the sores dry up, crust over and finally disappear. The viruses are not gone, however; they are simply dormant. They travel down nerve pathways from the skin to a cluster of nerve cells (ganglia) near the spinal cord, and here they make camp. (A similar retreat occurs after an attack on the lips or mouth, but the viruses lodge in nerve cell clusters near the brain.) The viruses may remain in this dormant state forever, or something may trigger them to reactivate and travel back to the skin's surface for a renewed attack. Recurrences of active infections are very unpredictable—how many people suffer from them, or how often, is simply unknown.

In general, recurrences tend to be less severe than the first experience. Sores may not be as painful and may disappear sooner. It is not clearly understood what triggers a recurrence, but physical or emotional stress such as sunburn, fever, menstruation, sexual intercourse, dietary changes and emotional upset can launch an oral or genital herpes attack in some people. However, a recurrence can also appear without any apparent stimulus.

Symptoms may sometimes be so subtle during a recurrence that they are not noticed—for example, a small red bump or tender area—yet the virus can still be transmitted to others. Women may develop lesions inside the vagina or on the cervix that go undetected. (The incidence of this is not known, but it appears to occur less often than external lesions.) People who are alert to any preliminary signals of a herpes attack, such as a tingly or itchy sensation on the skin before a sore develops, may know in time to avoid infecting others. Some studies have found that even at this early stage, signs of infectious herpes simplex virus may be found on the skin's surface.

(Continued)

HERPES?

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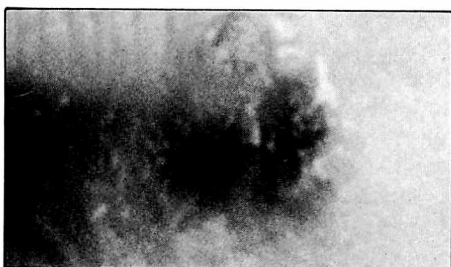
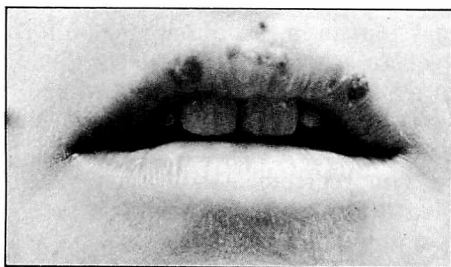
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Ads promoting herpes remedies crop up in popular magazines and newspapers, but let the buyer beware. There is no effective treatment yet on the market. When an answer is found, it will probably make the front page rather than the classified section. This ad was in ROLLING STONE magazine.



Lesions from a herpes simplex infection often last one to two weeks after symptoms first appear. Scabs have formed over the week-old cold sores shown here, and it will be several days before they disappear completely.

Because there is no effective therapy for herpes, prevention is extremely important. This means avoiding any contact with infected areas via intercourse, kissing, oral sex or other forms of touching. Oral sex can transmit the virus from one location to another, and both herpes simplex viruses types 1 and 2 can attack any area of the body. Most genital herpes is caused by type 2, but type 1 is involved in about 15 percent

of the cases. Conversely, type 2 is involved in about 10 percent of adult oral herpes cases. There is no consensus on whether the use of condoms helps reduce the risk of transmitting herpes, since their protective effectiveness has not been proven. The viruses are smaller than the pores in some condom materials and could conceivably pass through.

Although a herpes simplex infection is usually no more than a big annoyance to an adult, it can be devastating to a newborn infant. The newborn usually acquires the infection at birth from a mother who has active genital herpes. (The baby's chances of being infected are at least 50 percent.) In the United States, approximately one out of every 7,500 babies is infected with herpes during the birth process.

The chances for a baby so infected aren't good. Some 50 to 60 percent of newborns with herpes simplex virus infections die, and half to two-thirds of the survivors suffer permanent visual or neurological damage. Although at least one drug is being tested, there are no proven therapies for the affected newborn. If the mother has an active genital herpes infection at the time of delivery, the method for preventing infection in newborns is delivery by Caesarean section.

Women infected with genital herpes appear to have at least a four times greater risk of developing cervical cancer than those not infected with the virus (some risk estimates are twice as high). However, Richard Hamilton, M.D., says in *THE HERPES BOOK* that "it is important to keep in mind that no cause-and-effect relationship has been proven. Genital herpes is not considered a precursor of cervical cancer; it is simply one of several factors correlated with increased risk." Dr. Hamilton and other medical authorities advise women with genital herpes to have routine cervical cancer checks (PAP smears), preferably twice a year.

As a virus-caused disease, herpes presents special difficulties to scientists looking for an effective treatment. Viruses—unlike bacteria—survive and reproduce by living inside cells of the body. The problem is to find an agent that can cross the cellular membrane and attack the virus without harming the cell itself. Furthermore, when it is dormant, the

herpes simplex virus is virtually untouchable inside its hiding place in the nerve cell clusters. Apparently, neither antiviral drugs nor the body's own immune system can reach it. When the viruses do emerge, antibodies and other partners in the immune system often cannot stop them from launching an attack.

Some signs do point to progress. Three drugs are approved by FDA for herpes keratitis (an eye infection) and one of these, vidarabine, is also effective against herpes encephalitis. Several antiviral drugs are being tested on various types of herpes virus infections, as is interferon, an antiviral agent normally produced by the body. Some research is also geared toward bolstering the immune system to do a better job against herpes virus invaders, such as vaccines made from inactivated viruses. However, the possible connection between herpes viruses and cancer is a factor that vaccine developers must deal with, because the introduction of additional viruses into the body could conceivably be dangerous.

Basic research into the nature of herpes viruses and the diseases they cause is also going on around the world. In the United States, several federal agencies are involved, predominantly the National Institutes of Health, FDA and the Centers for Disease Control. FDA is also responsible, through its drug approval process, for assuring the safety and effectiveness of any new product to treat or prevent herpes.

Gerald Quinnan, M.D., director of the herpes virus branch in FDA's Bureau of Biologics, agrees with many researchers that the tenacious herpes simplex virus will be difficult to eradicate from human hosts. However, most genital herpes victims would be grateful for any progress, even if, in his words, "probably the best that could be hoped for in the foreseeable future is a situation where a topical agent is useful in reducing the severity of a herpes episode when it occurs."

Quinnan is sympathetic. "I have phone calls from all over the country," he said, "from people who want to do anything to get relief for what they consider an intolerable problem that's gone on for years."

Louise Fenner is a member of FDA's public affairs staff.

Tips For The Salt-Conscious Consumer

Sodium is an ever-present element in the human diet, and although it's vital to good health and nutrition, most Americans consume more of it than they need. However, cutting down on salt alone—the major source of sodium for most people—may not be enough. The smart consumer, as the following article suggests, will do some homework and learn how to pick those foods that are low in sodium and to avoid those that are high in the substance.

by Chris Lecos

Let's face it. Limiting the amount of sodium in one's daily diet is not a simple task. The sodium-conscious consumer just has to be knowledgeable—and disciplined—about the foods he or she eats.

It means working closely with a doctor or a professional dietitian or both to plan a proper diet if sodium restriction is critical in the treatment of high blood pressure or other diseases.

It means learning which foods are high and which low in sodium, and it especially means knowing that cutting down on sodium intake is not just a case of avoiding salt, although regular table salt—sodium chloride—is the largest single contributor of sodium to the human diet.

It means a longer time shopping in the supermarket to check food labels and ingredient lists for clues to sodium content, if the information is indeed there. And it means knowing how to read a nutrition label and ingredient list. Sometimes a sodium ingredient is identified by its proper chemical name. At other times a general term is used, such as brine or salt pork.

Most foods sold today do not tell

the consumer on the label how much sodium they contain, although FDA surveys indicate that the number of foods that do is rising. In 1977, for example, 7.5 percent of the dollar volume of foods sold involved products whose labels disclosed sodium content. By 1979, an FDA marketing survey showed the number had increased to 13.4 percent.

All right, then, why not turn to commercially available salt substitutes and buy only foods that are labeled clearly as being salt free or low in sodium content? Here again, some homework and a little knowledge help, perhaps along with some advice from the family doctor.

Potassium chloride is the main ingredient in most salt substitutes. Ammonium chloride is present in some. Other chemicals are added to enhance flavor, modify the bitterness that too much potassium chloride can impart, promote free flowage, prevent lumping and add bulk.

Salt substitutes can be used by the normally healthy person with no apparent ill effect, but most health experts, including those at the Food and Drug Administration, urge consumers on sodium-regulated diets to use only those substitutes that a family physician says can be used. A doctor also may want to limit the amount of the substitute that should be used with a meal. Substitutes composed of potassium or ammonium salts can be harmful to persons with kidney or liver diseases and certain heart disorders. Unfortunately, some people on sodium-restricted diets who might ordinarily benefit from using salt substitutes may be sensitive and susceptible to extra loads of potassium.

Like sodium, potassium is a mineral element and is essential for many body processes, including water balance, nerve impulse conduction and transmission, heart action and the function of some enzyme systems. A "safe and adequate" daily intake of sodium for healthy adults is 1,100 to 3,300 milligrams; for potassium, it's 1,875 to 5,625 milligrams for those who follow a normal activity pattern. These figures are the estimates of the Food and Nutrition Board of the National Academy of Sciences/National Research Council. Because sodium and potassium are widespread in the food supply, most people generally consume more of

these two elements than they really need.

Both sodium and potassium have an important role in maintaining the electrolyte composition of body fluids. The healthy person loses sodium and potassium in urine, feces, perspiration and tears from a good cry, but the loss is replaced through absorption of these ions from dietary sources. A reduction in the level of ions in the diet is balanced by a subsequent reduction in the level of the ions in excreted urine. The more sodium and potassium eaten or drunk, the more ions excreted in the urine. The kidneys, operating under hormonal influences, perform this balancing act. Disease, however, can interrupt this check and balance system.

It is estimated that 23 to 60 million persons have specific diseases or disorders that may require control of sodium or potassium or both in the diet. Excess sodium in these persons can increase the amount of water in the body tissues, causing swelling or a condition called edema. Sodium-restricted diets are necessary for patients who also are being treated for various heart, liver and kidney ailments, or for hypertension or high blood pressure. In many instances, control of sodium intake also may require a modification in the intake of other elements, including potassium.

Although studies suggest an association between high sodium intake and the onset of hypertension (high blood pressure), a condition that afflicts an estimated 34 million Americans, it has not been conclusively established that sodium consumption is a major factor in the cause of hypertension. The evidence is strong enough, however, for most members of the medical and scientific communities to conclude that a substantial portion of the U.S. population that is genetically or otherwise predisposed to hypertension would benefit from a reduction in dietary sodium.

The sodium-conscious consumer also has to be wary of products promoted as being salt free. That does not mean they are sodium free. Although the product does not contain salt, or sodium chloride, it can have other sodium compounds such as sodium citrate, sodium saccharin, monosodium glutamate (MSG), baking soda and baking powder. For example, in the case of one brand of po-

SODIUM TERMS TO LOOK FOR ON LABELS

Sodium ascorbate	Disodium inosinate
Sodium citrate	Disodium guanylate
Baking soda	Sodium ferrocyanide
Sodium chloride	Sodium triosulfate
Sodium caseinate	Celery salt
Sodium acid pyrophosphate	Sea salt
Sodium phosphate	Disodium dihydrogen pyrophosphate
Sodium aluminum	Sodium hexametaphosphate
Sodium bisulfite	Sodium gluconate
Disodium phosphate	Sodium nitrite
Sodium iron pyrophosphate	Sodium erythorbate
Sodium benzoate	Sodium nitrate
Garlic salt	Baking powder
Calcium disodium EDTA	Anhydrous disodium phosphate
Sodium carboxymethyl cellulose	Sodium biphosphate
Monosodium glutamate	Salt pork
Sodium preservatives	Brine
Trisodium citrate	Dioctyl sodium sulfosuccinate
Sodium aluminosilicate	Onion salt
Sodium stearyl-2-lactylate	Sodium hydroxide
Sodium propionate	Sodium metaphosphate
Sodium saccharin	Sodium thiosulfate
Sodium tripolyphosphate	Flour (self-rising)
Sodium alginate	

tato chips that was being promoted as having no added salt. FDA noted that one ounce of the chips contained 175 milligrams of sodium. That is a "significant amount . . . for any consumer on a sodium-restricted diet," FDA said in a letter to the manufacturer. The agency has indicated that claiming some products with sodium in them as being "salt free" is, in effect, misbranding.

The fact is that most people are getting more than enough sodium from the food they eat and the water they drink or use in the foods they prepare. Sodium is in most food and water either because it is a naturally occurring mineral element, or because it was added either during the manufacturer's processing or during the preparation of the meal in the home.

Most community water supplies contain varying amounts of sodium because it is naturally present or because it is added by the use of "softeners" in hard water areas. That can

mean sodium also is being consumed in coffee, tea and beverages prepared from local water supplies. The amount of sodium in drinking water varies all over the country. The consumer who needs to know usually can find out how much sodium is in the water from the local health or water department or from a local chapter of the American Heart Association. One can control the amount of sodium, and especially salt, that is added in the home. However, consumption of amounts naturally present in the food and those added by a manufacturer can be controlled only by knowing how much sodium is in a specified product. And that is not easy for many people.

For example, it is estimated that about 55 percent of the foods Americans eat are processed and that most of these foods do contain salt or some other kind of sodium ingredient. A 1978 FDA marketing survey of 1,155 national brands showed that 1,031 had ingredient lists on the la-

bels and, of the latter, 786 (or 76 percent) listed sodium as one of the ingredients.

The ingredient list, of course, does not tell how much of a particular substance is added. Its principal value is that it tells which ingredients are in a product and the ingredients are listed in descending order so that the ingredient present in the greatest amount is listed first, the next greatest second, and so on down the list. If a consumer were to shop only among the 1,031 national brands with ingredient lists, he would find that less than 6 percent state the actual amount of sodium on their labels, according to FDA's marketing data.

This does not mean that a sodium-conscious consumer faces an impossible task. Widespread publicity on sodium intake has made many Americans much more aware of it. A 1980 FDA survey of 1,500 shoppers, for example, revealed that 68 percent were trying to reduce their sodium intake. More information is available today from physicians and other health organizations and the number of reliable diet and nutrition books with numerous meal planning ideas is growing. The U.S. Department of Agriculture has published a handy 35-page booklet called "The Sodium Content of Your Food" that lists the average amount of sodium found in 789 different beverages, fruit juices, dairy products, eggs, fish, meat, poultry, fruits, grain products, legumes and nuts, soups, sugars and sweets, vegetables, condiments and other products, as well as selected nonprescription drugs. (See the inside back cover of this issue for information on how to obtain copies of the booklet.)

FDA's current efforts on sodium have focused on its announced plans to expand its activity in the public education of consumers about sodium, especially salt intake, and to encourage the food industry to act voluntarily to reduce the sodium in thousands of foods processed and sold in the United States. These FDA efforts are being coupled with proposed regulatory changes that have been drafted and that are designed to get industry to list sodium content on many more foods than is done at present.

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

Consumer Forum

Aloe Vera Council Defends Its Practices, Product



The July/August issue of FDA CONSUMER presented your readers with information about the use of aloe vera in an article which was biased, inaccurate and economically damaging to thousands of small businesspersons who grow or market aloe vera products. It is hoped that you will offer this correct and balanced view of aloe vera in the next issue of FDA CONSUMER. . . .

. . . aloe vera companies decided in January, 1981, to form the National Aloe Science Council. The main purpose of the council is to gather data on the history, growth and use of aloe vera products, conduct scientific research, hold scientific and technical conferences and disseminate news and information about the people, plants and products involved in the aloe vera industry. . . .

Despite the fact that aloe vera has been marketed as a home remedy long before 1938 when the Food and Drug Amendments grandfathered such products, the FDA has yet to issue a final decision regarding acceptable ingredients and labeling for such OTC [over-the-counter] aloe vera products. Until they do, drug products containing

aloe vera can continue to be sold.

This fact should be made clear to the public, which has recently been confused by an FDA press release which mistakenly gave the impression that aloe vera products are unsafe or potentially harmful.

The toxicity of aloe is completely misunderstood by FDA regulators and journalists as well. Aloe is a naturally occurring plant which yields two main fractions for human use: the resin, which is an effective laxative; and the pulp-gel which is used as a juice in beverages, and topically as a treatment for minor abrasions and burns. The two are distinctly different as to their side effects. The first, with higher doses, can elicit all the side effects customary with irritant laxatives, while the second has no known side effect with any reported use. . . .

What the author of the FDA CONSUMER article did not understand is that aloe vera gel as a drink is prepared from the water-colored inner pulp of the leaf which is entirely separate, physically and chemically, from the bitter yellow resin which is adjacent to the outer skin. . . . (Continued)

The properties of the two are entirely different. The yellow resin is a liquid with strong cathartic action. The inner pulp is water-colored gel held in thin walled cells. It has no cathartic action. It does contain all essential amino acids, many vitamins, complex sugars and a wide range of trace minerals. And thus, contrary to the article, does have nutritive value.

The greatest mischief, indeed widespread economic harm, resulting from the article and the attendant press release is the reference to aloe vera products being distributed through pyramid type operations. The major aloe vera manufacturers and distributors who sell the majority of aloe vera in the United States, are responsible companies which sell their products through legitimate marketing programs. They are the ones who formed the National Aloe Science Council and adopted a strong Code of Ethics. They are also the ones tarnished by such pyramid scheme references.

J. Robert Brouse
Managing Director
National Aloe Science Council, Inc.
Bethesda, Md.

FDA lauds any effort by an industry to police itself. However, the agency would be less than responsible if it did not warn the public about "exaggerated and unsubstantiated claims" that products derived from the aloe vera plant can cure or alleviate such conditions as colitis, bursitis, glaucoma, hemorrhoids, boils, arthritis, acne, etc.

As to making clear to the public that drug products containing aloe vera can continue to be sold to the public, the article did just that. It pointed out that until the agency makes a decision on recommendations made to it by expert panels, "drug products containing aloe vera can continue to be sold."

The article pointed out that two expert panels have advised FDA and its regulators that further tests should be made before aloe vera is declared safe and effective for treatment of minor burns, cuts and abrasions or for the treatment of minor vaginal irritations. Further, as the article noted, another expert panel advised FDA and its regulators that the pharmaceutical aloe be allowed sparingly in laxatives. However, it was also noted that other experts, including the American Medical Association and the American Pharmaceutical Association, contend that aloe should not be used in laxatives because it is unpredictable and sometimes violent.



JOHANNES NOTH, *The Black Death*, 1925

Plague Treatment Questioned

I should like to call your attention to one and possibly two significant errors in your very interesting article on plague [*Plague . . . Still a Potential Peril*], in the May 1981 issue of FDA CONSUMER. On page 8, the statement made—"The most effective drug in treating plague is streptomycin, usually given orally for up to 14 days." To the best of my knowledge, streptomycin is never given orally, and is effective only when given parenterally (by injection). While streptomycin could be the "most effective drug," it is probably not the drug of first choice in treating plague.

Harold C. Anderson, M.D.
Sunnyvale, Calif.

Dr. Anderson is correct in that streptomycin is not administered orally. However, according to Dr. Allan Barnes, chief of the Plague Branch of the U.S. Centers for Disease Control (CDC), it is the preferred treatment for plague, usually administered intramuscularly, sometimes intravenously. Other drugs, such as tetracycline and chloramphenicol, are sometimes used instead of or in addition to streptomycin in treating plague. The decision on which treatment to use is, of course, made by the attending physician's assessment of the individual patient and the circumstances of the case. Interestingly, most of the drugs used to treat plague are older generation antibiotics and are often hard to obtain when needed, according to Dr. Barnes. For that reason, CDC has been conducting research to find newer, more readily available antibiotics to combat the dread disease.

The Notebook

The Notebook: a potpourri of items of interest to consumers, gathered from FDA press releases, FEDERAL REGISTER notices, and other news sources. Publication dates of FEDERAL REGISTER items, designated FR, are included to aid readers who want further information.

■ Monitoring of heart conditions and activation of defibrillator treatment by phone; diagnostic kits for home use that measure cholesterol; electromagnetic energy that regenerates nerve tissue; lasers that treat warts; devices that control hormone production; anti-cancer drugs that act directly on the tumor with no side effects. These are some of the technologies a group of 190 scientists from within and outside FDA predict might emerge over the next 5 to 15 years. A total of 168 technologies are identified, more than a third of which will probably require FDA attention by 1982. The predictions, made in a study initiated in the fall of 1980, have been published in "**Forecast of Emerging Technologies**" by FDA's Office of Planning and Evaluation. Copies are available from NTIS, Input Branch, 5285 Port Royal Rd., Springfield, Va. 22161. Ask for PB 81-227-290. The cost is \$11.

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■ **Promazine** and **promethazine** drug products have been exempted from a requirement that a precautionary statement concerning elevated serum prolactin levels be included in physician labeling of neuroleptic drugs. Initially, FDA had no evidence that the two drugs did not raise prolactin levels (FR September 8).

* * * *

■ Advertising expenditures for **OTC external medications** will jump from \$459 million in 1979 to \$695 million by 1982 and to \$1 billion by 1985, according to a new market report by Frost and Sullivan Inc., market analysts, New York City. Product sales, which were \$2.2 billion in 1980, will increase to \$2.5 billion in 1982 and to \$2.9 billion in 1985. Except for hemorrhoid remedies, eye lotions, decongestants and athlete's foot products, new product activity "is intense," the report says. Twenty-five new products have been introduced since 1975 with 11 in the skin care category.

■ FDA has issued guidelines on the preparation of **compressed medical gases** that specify practices and procedures manufacturers can follow to comply with the blanket good manufacturing practice regulations (GMPs) for human and veterinary drug products. When these drug GMPs were revised in 1978, the agency indicated specific regulations would be developed for medical gases. Such regulations are no longer deemed necessary (FR August 18).

* * * *

■ FDA has executed a Memorandum of Understanding (MOU) with the U.S. Department of Agriculture to conduct a cooperative research program in connection with the use of **drugs and feed additives** in the diets of non-ruminant animals. Under the agreement that became effective July 21, FDA will provide experimental animals, feed and drugs, cages and brooders, and USDA's Science and Education Administration will provide space and some animals (FR August 18).

* * * *

■ Philadelphia and Dallas will be the sites of two new FDA regional **small business service desks**. Since 1979 FDA has had such desks in East Orange, N.J., Chicago, Ill., Santa Ana, Calif., and Atlanta, Ga., to help small firms obtain information and guidance concerning regulatory requirements.

* * * *

■ FDA says it is reviewing a recently published study on the increased risk of heart attack associated with the taking of **birth control pills** to determine whether the agency should require revision of physician and patient labeling. The study, published in the August 20 NEW ENGLAND JOURNAL OF MEDICINE, suggests that the increased risk of heart attack persists after the pill is discontinued.

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(Continued on following page)

■ Fish contaminated by **dioxin** have been found in Saginaw Bay, bordering Michigan on Lake Huron, and FDA has sent an advisory to Michigan Governor William G. Milliken about the health significance of this finding. It noted that fish with an average of 25 parts per trillion (ppt) or less of dioxin residues pose no serious health concern, but those averaging 25 to 50 ppt should be eaten only twice a month by area residents, who might ordinarily eat a large amount, and only once a week by sport fishermen, who would eat them only occasionally. A few samples of fish averaging 50 ppt or more of dioxin were collected from Saginaw Bay and the Tittabawassee and Saginaw rivers. Fish with these levels of dioxin should not be eaten. Most samples contained less than 25 ppt of dioxin, and for this reason FDA sees no need to set federal legal limits for fish distributed in interstate commerce.

* * * *

■ Expected off the press in late October is the second edition of FDA's "**Approved Prescription Drug Products With Therapeutic Equivalence Evaluations**," more familiarly—if imprecisely—known as "The Generic Drug List." The list is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. The price of \$45 (domestic) and \$56.25 (foreign) includes cumulative monthly updates for a year.

* * * *

■ FDA has issued a final rule amending the standards of identity for **enriched bread, rolls, buns, enriched flour and enriched self-rising flour** by deleting minimum and maximum requirements for iron enrichment and establishing single-level requirements for each food. Effective July 1, 1983, the new levels of enrichment will be: 12.5 milligrams per pound for bread, rolls and buns and 20 milligrams per pound for flours. These levels allow for enriched bread to be made from enriched flour without further adjustment (FR August 28).

* * * *

■ **NOTES FROM THE MARKET BASKET:** The quality standard for **bottled drinking water** has been

amended to include a quality level of 0.10 milligram per liter maximum for total trihalomethanes. Trihalomethanes, organic compounds that are derivatives of methanes, are introduced into drinking water by the reaction of naturally occurring substances with chlorine (FR August 14). . . . At the same time, FDA affirmed that it considers whey and certain modified whey products to be generally recognized as safe (GRAS) as direct human food ingredients and hydrogen peroxide to be GRAS for use as an antimicrobial agent in cheesemaking and whey processing (FR September 4).

* * * *

■ **FROM OTHER REGULATORY AGENCIES:** The Drug Enforcement Administration has proposed that **N-ethylamphetamine** be put in Schedule I of the Controlled Substances Act. The drug is a central nervous system stimulant that has a high potential for abuse and no currently accepted medical use (FR September 10). . . . In response to petitions from General Electric Company and the Health Industries Manufacturers Association, the Federal Communications Commission has proposed to exempt medical devices used in hospitals from its computing devices rules designed to eliminate **radio frequency interference**. Among other things, the petitions noted that labels required by FCC would cause confusion among users and FDA inspectors and might actually require manufacturers to violate FDA labeling requirements (FR September 8). . . . The **Canada Department of Consumer and Corporation Affairs** has targeted several areas "of immediate concern" in which it would be making "routine examinations," according to a report in **FOOD CHEMICAL NEWS** (August 24). Cited in a memo to food trade associations and consumer groups were (1) foods recommended for treatment, prevention or cure of disease; (2) foods containing insignificant or negligible levels of vitamins, minerals or protein being labeled or advertised "in a manner that suggests otherwise"; (3) failure to list ingredients in descending order of proportion by weight; and (4) use of the word "natural" to describe foods that have undergone man-induced physical or chemical changes during manufacture.

Investigators' Reports

Dead Fish, Deadly Fish

Dead fish bobbed up and down in the warm Caribbean waters and washed up on the shores of the Dominican Republic. There were thousands of them. On the west side of the Mona Channel, on the island of Hispaniola, Dominican Republic health officials tried to figure out what was killing the fish. On the east side, on the island of Puerto Rico, FDA's San Juan District wondered if the fish were toxic and if a peril to human health existed.

Newspapers in the Dominican Republic had reported that two people and a number of animals had died from eating the fish, and the district sent an investigator to the Dominican Republic to check out these reports. The district learned from other Puerto Rican health agencies that nine people were admitted to the hospital in Mayaguez after eating marinated fish that had been caught locally. The patients were vomiting and suffering from abdominal pain, diarrhea, fever and headache, but no diagnosis had been made. At the hospital's request, an investigator collected samples of fish the patients had eaten so the district lab could analyze them for pesticides and heavy metals.

As a precaution, FDA advised the San Juan customs office that all fresh fish coming in from the Dominican Republic should be sent to the district's lab, where samples would be tested for pesticides and heavy metals before release into the marketplace. But no one really knew whether such tests would detect the problem or what the problem was. Fishkills like the one in the Mona Channel had been reported off the coasts of Belize and Mexico's Yucatan Peninsula, as far north as the Bahamas and as far south as the island of Curacao. Authorities in the Dominican Republic had hypothesized that illegal dumping of chemical wastes had taken place or that an unusual form of Red Tide (a phenomenon associated with paralytic shellfish poisoning and fishkills) was

in the water, but both theories were discounted by the Environmental Protection Agency's office in San Juan. (For more information on Red Tide, see Investigators' Reports in the December 1980-January 1981 issue of FDA CONSUMER.) FDA confirmed that one person in the Dominican Republic died after eating fish, but it was uncertain whether the death or the illness of the nine people in Mayaguez was related to the fishkill in the Mona Channel. To further complicate matters, an EPA investigator told the FDA district staff that there was a report of a fishkill in the waters off Honduras and that people coming in contact with the water, but not the fish, had suffered diarrhea, headaches and fever.

Analyses of the fish showed no evidence of pesticides or heavy metals. The National Oceanic and Atmospheric Administration lab in Maryland also found nothing amiss in samples of fish. The Puerto Rico Department of Natural Resources tested samples of ocean water for temperature, salinity, oxygen and plankton content and found nothing that would account for the fishkills. That department eventually put forth the theory that the recent passage of Hurricane Allen had caused excessive turbulence in the water, reducing the oxygen supply, and that the fish had suffocated. Since there had been no recent reports of other fishkills or illness, this was adopted as the official explanation. The patients in Mayaguez were released from the hospital, their illness undiagnosed, and San Juan district reported that no additional fish would be sampled unless the circumstances changed.

Circumstances changed several months later and provided insight into the possible cause of the illnesses. In March 1981, an epidemiologist at a hospital on the island of St. Croix called the district office to report that approximately 40 people had gotten sick after eating red snapper. The

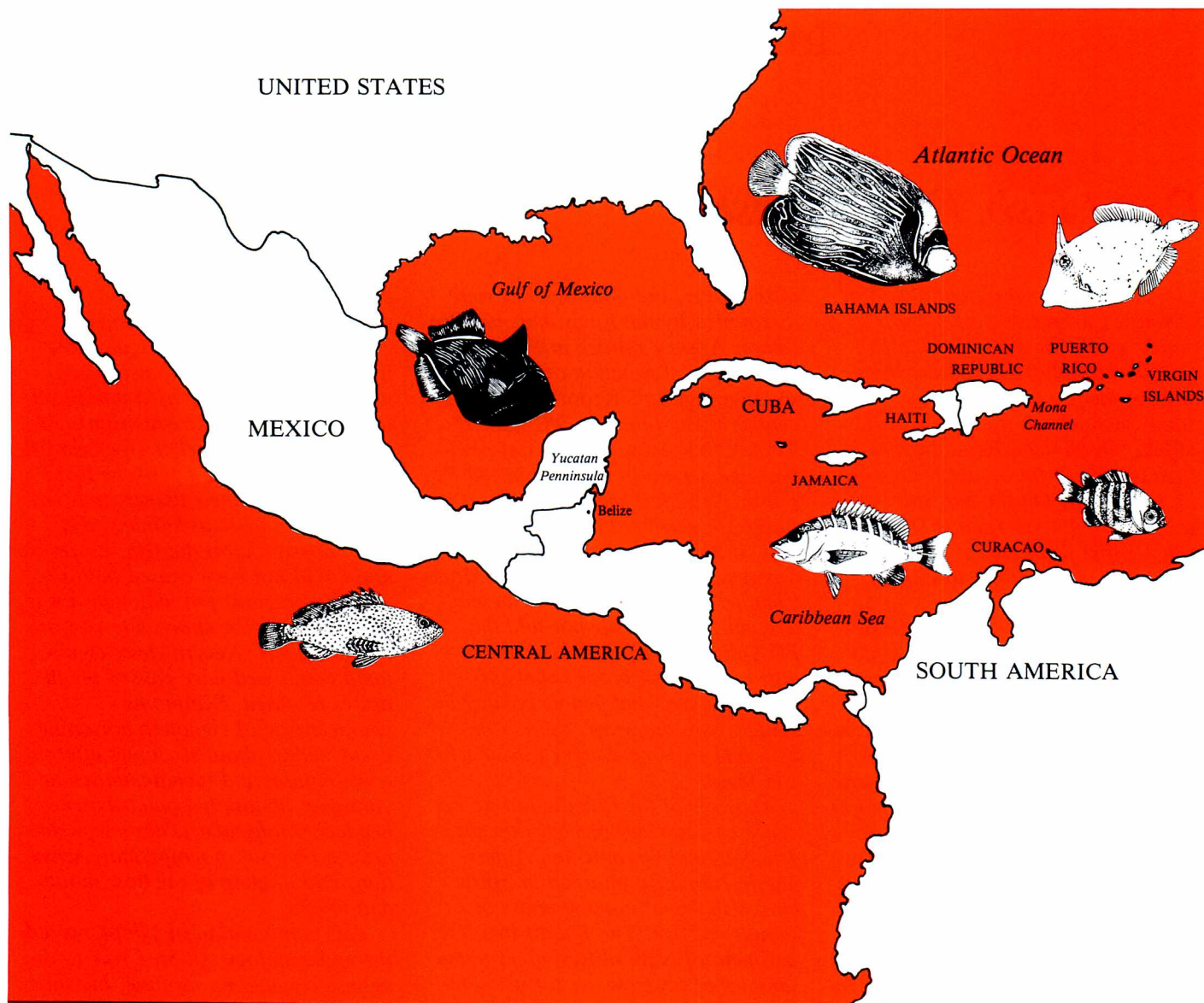
cause, the epidemiologist said, appeared to be ciguatera poisoning.

Ciguatera poison, or ciguatoxin, like paralytic shellfish poison, is a neurotoxin produced by a dinoflagellate (a tiny algae-like organism). As fish eat the dinoflagellates—or eat fish that have eaten the algae—the toxin accumulates in their tissues, thus rendering them toxic to humans. The toxin doesn't harm the fish, however, and could not have caused the fishkills the previous fall although it was too late to do the analysis to confirm this positively. Nevertheless, ciguatoxin could well have caused the illnesses reported. Symptoms characteristic of ciguatera poisoning occur within about six hours after consumption and include nausea and vomiting, abdominal pain, diarrhea, headache, muscular aches and weakness, a reversal of temperature sensation, and tingling of the lips, mouth and tongue.

This combination of symptoms led the epidemiologist in St. Croix to diagnose ciguatera poisoning, but this tentative diagnosis was based only on symptoms, since the hospital did not have the facilities to test for the toxin.

Accordingly, an investigator from San Juan district flew to St. Croix to collect samples and the full story. He learned that all the patients involved had eaten red snapper caught by a fisherman from Ponce, P.R. The man had been fishing off St. Barts, one of the smaller Virgin Islands, and his luck had been sensational; he had reeled in about 750 pounds of red snapper, then had to stop because his boat engine was acting up. He iced the fish to prevent spoilage and headed for St. Croix, the closest place where repairs could be made. Since the boat would have to be docked for some time, he sold the fish to street vendors and restaurants on the island. Soon after, people began reporting in large numbers to the hospital.

The investigator tracked down the remainder of the red snapper, col-



lected samples and issued a warning against further eating of the fish. The samples were sent to labs in Hawaii and St. Thomas, the Virgin Islands.

Although ciguatera poisoning has been known in various regions of the Caribbean and Pacific for centuries, the toxin—or toxins—that causes it is still very much a mystery. The dinoflagellate involved has tentatively been identified as *Gambierdinus toxicus* and appears to spawn and flourish following major oceanic disturbances and destruction of coral reef. A storm such as Hurricane Allen could have created the conditions in which the tiny organism thrives.

Currently there is no proven method that can be used commercially for the detection of ciguatoxin. Several universities are conducting studies to develop such a test, including the University of Hawaii and the College of the Virgin Islands. The lab in Ha-

waii was able to confirm that the samples of red snapper contained ciguatoxin.

Meanwhile, the number of people in St. Croix that fell ill with symptoms associated with ciguatoxin rose to 69. The Puerto Rico Department of Natural Resources warned people through radio announcements, newspaper articles and posters that locally caught fish might be poisonous. The warnings led to more reports of ciguatera poisoning that might otherwise have gone undiagnosed, as happened the previous fall. In April, 16 people in Coamo, P.R., reported getting sick from eating grouper. In June more than 30 people became ill with ciguatoxic symptoms; two died.

Since the fish were locally caught and sold, FDA's San Juan district had no authority to act but provided assistance and the results of the lab tests to the department of natural re-

sources. In June the department banned the sale and purchase of three types of fish: barracuda, amberjack and blackjack. The department did not ban the sale of grouper or snapper, holding that the three species banned are those historically known to cause ciguatera poisoning. Red snapper and grouper are both commercially valuable fish in Puerto Rico, sales of fresh fish had already dropped dramatically because of the warnings, and Puerto Rico fishermen were feeling the pinch.

The ban appears to have been effective. Since June there have been no reports of ciguatera poisoning. Now health officials can only wait and hope that a test for ciguatoxin is developed before the troubling dinoflagellate becomes active again.

—Carol Ballentine

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

Fish Smugglers Caught

According to U.S. Customs officials, some boat owners along the New England coast have been making trips to Canada to buy swordfish from fishing boats there for smuggling into the United States. These shuttle runs have cut into the market for swordfish caught by the legitimate New England fishing industry. No duty is paid on the smuggled fish. In addition, the smuggled fish is not normally sampled by FDA and may contain undetected levels of the heavy metal mercury.

Customs agents broke up one swordfish smuggling ring near Boston earlier this year, seizing three trucks, a 65-foot fishing boat and 50,000 pounds of fish worth \$200,000. The agents asked FDA's **Boston District** laboratory to analyze the swordfish for mercury. The lab found 1.44 parts per million (ppm) in one sample and 1.52 ppm in another, both well above the legal tolerance of 1 ppm.

Swordfish is considered a choice (and expensive) seafood delicacy that must be watched for mercury levels. The problem is that swordfish eat smaller fish that often have been feeding in coastal waters near industrial sites that have a high content of organic mercury compounds and other toxic wastes. The mercury is absorbed into the tissues of the smaller fish and then accumulates in the larger, long-living swordfish in amounts that exceed the tolerance considered safe for humans.

Since swordfish often contains levels of mercury above the FDA tolerance, the agency routinely samples swordfish lots offered for import. The seized fish, had they been imported through the usual channels,

would likely have been tested by FDA and turned back for being over the mercury tolerance.

Customs officials prosecuted the case (as smuggling) in the U.S. District Court for the District of Massachusetts. The three defendants were given prison terms of three, six and nine months each, and were placed on two years probation. The smuggled swordfish was destroyed, and the seized trucks and boat, since they were used in an illegal operation, were forfeited and became the property of the U.S. government.

Time Runs Out

An importer recently found out the hard way that he who procrastinates is lost. The importer's 250-bag lot of dried lemon peel from Spain was seized and destroyed after the importer waited too long to return the items to Spain.

The lot, offered for import through the port of Seattle, was denied admission to the United States after an analysis by FDA's **Seattle District** laboratory of samples taken at the time of entry revealed that the product was contaminated with rodent hairs, feather barbs and insect fragments.

Goods refused entry into the United States are permitted to be re-exported within 90 days. When the period for export expires, the goods lose privilege for export and are subject to seizure like any other goods in interstate commerce.

The lot had been stored at Western Herb Farms Inc., in Seattle. While the lot was in storage, an inspection by the Washington state Department of Agriculture found extensive rodent infestation in the warehouse and noted rodent excreta pellets on the bags of lemon peel.

FDA's Seattle District officials were notified and a joint follow-up inspection by the two agencies confirmed rodent activity in the facility. Numerous rodent excreta pellets were found on the bags, and laboratory analysis of a sample confirmed rodent excreta and urine on the bags, and penetration of urine into the lemon peel.

Since the 90-day period allowed for exportation had expired, the lot was placed under the state's embargo until seizure and the lot, valued at \$13,629, was destroyed.

Deadly Dolomite

Dolomite is a form of limestone rich in magnesium and calcium carbonate and is widely found throughout the world. A company named Essentials 4 U found a ready supply in a lead mine near Galena, Ill., and combined it with other ingredients to make agricultural products. These included a soil conditioner, silage preservative, manure odor controller and animal feed additive. The firm's home office is in Webb City, Mo.; its manufacturing plant in Corwith, Iowa; and it shipped the finished products to farmers and farm dealers in the central United States.

But because the dolomite came from a lead mine, it contained dangerously toxic levels of lead, one of the most hazardous of the heavy metals. When ingested, lead will accumulate in human and animal bones, organs and tissue, and remain there for a very long time. Absorbed lead can cause lethargy, mental disorders and, in extreme cases, death. Once lead enters the food chain, as it might in beef and dairy cattle, it can be transmitted to humans who consume the meat or milk. Farmers working with and exposed to the dolomite products could also be affected by the lead.

The **Iowa Department of Agriculture** had found high lead levels when it routinely sampled the silage preservative with the dolomite additive, and asked FDA's **Kansas City District** laboratory to confirm this. Both findings ranged up to 2,700 parts per million (ppm), far above the level considered safe for most animal species. Cattle that ate this feed would suffer lead poisoning, and the milk and meat products from these animals could be unsafe for humans.

When Essentials 4 U was told by FDA of the extremely high levels and the potential health hazards, the firm decided to recall and discontinue the products. Some 500 tons of the

products had been manufactured since January 1981. Much of that was recovered from dealers.

Sun Lamps Defective

FDA began taking a closer look at sunlamps about two years ago, when the tanning booth craze was getting under way. The lamps are ultraviolet radiation devices, and their manufacture is regulated by the Bureau of Radiological Health. The bureau set standards effective May 6, 1980—for design, construction and output to protect users from burn injuries and hazards. The standards apply to sunlamps manufactured in the United States and imported.

One importer, Dynex International of New York City, unaware of the new standards, failed to inform FDA

that it was bringing in sunlamps from West Germany. One shipment, Solarium 6040A, made by Original Hanau, cleared U.S. Customs and was being distributed by Dynex outlets before the matter came to FDA's attention.

The agency's **New York District** office tested the Solarium unit and found it defective in several ways. The timer, intended to turn off the lamp after 10 minutes, was not accurate. The unit was promoted for use by two persons at a time, yet only one pair of protective goggles was provided. Finally, the label did not carry the required warnings on ultraviolet radiation and maximum exposure times, or proper instructions for use.

Because the units failed to meet these and other standards, FDA in-

voked a seldom-used regulation that places imported products back in import status, even though distribution in the United States has already taken place. This allows the importer to recall and return the articles to the country of origin, and shifts the burden of correction from importer to manufacturer. U.S. Customs must agree to the procedure, the importer must have had no reason to know the products were in violation, and whatever made the products violative (labeling, etc.) must have occurred before the products entered the United States.

Dynex has retrieved the faulty sunlamps for return to Germany, and FDA is considering corrections that may be needed on other sunlamps imported by Dynex.

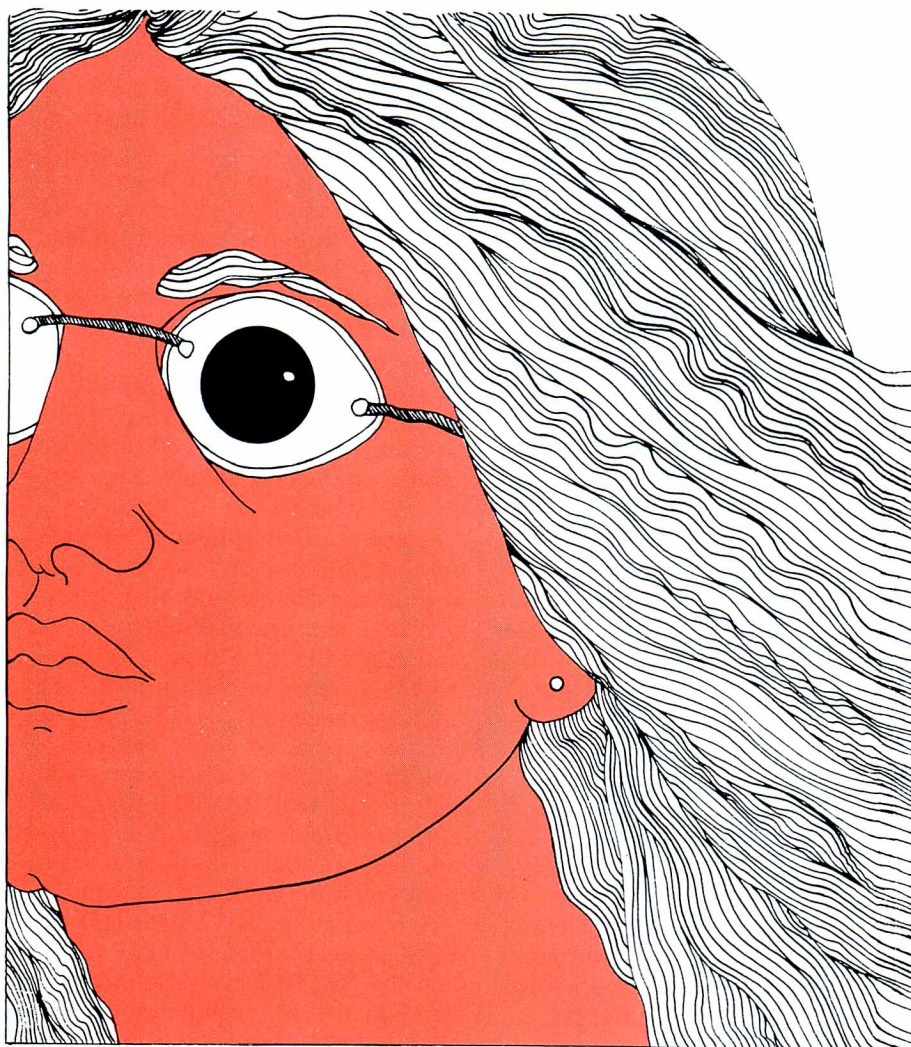
At the Last Minute

In 1977, FDA inspected Larson Laboratories, a drug manufacturer in Erie, Pa., and found numerous violations of good manufacturing practice regulations. These included failure to test finished products for identity and strength of ingredients, failure to determine the stability of finished drug products, and failure to assure that products met the required specifications before distributing them.

Based on these findings, FDA's **Philadelphia District** office obtained an order from the U.S. District Court for the Western District of Pennsylvania, and made a mass seizure at the plant of all raw materials and finished drugs, valued at \$8,400.

Larson's president sought a temporary restraining order against the seizure, but it was denied. Instead the court set a cash bond of \$2,000, to be lifted whenever Larson achieved compliance with FDA regulations.

FDA returned to the plant when the firm reported that it was in compliance, and discovered that Larson was continuing to use the seized raw materials while under a court order. The court promptly found the firm in contempt, revoked the \$2,000 bond, and ordered that the remaining drug products and materials be destroyed. The court also directed the firm to



pay \$2,427.50 for the cost of litigation and for time spent by FDA staff supervising the reconditioning of Larson products.

For three years, Larson ignored the bill owed FDA until threatened with additional charges of contempt of court. A hearing on the new charges was set for Monday, June 22, 1981, in federal court. Moments before it was to begin, Larson's delivered a check for the unpaid amount to the U.S. attorney's office in Erie, Pa.

The bottom line? Larson was out \$2,000 on the revoked bond, \$2,427.50 on the last-minute payment, and up to \$8,000 on the seized drugs that had been destroyed under the 1977 court order.

Tilt

Equipment used in medical diagnostic laboratories has become increasingly automated, and some equipment now includes computers that print out the laboratory findings.

One such device is a blood chemistry analyzer made by the Photovolt Corp. of New York City. The analyzer measures and prints out the levels of potassium, sodium, bicarbonate and chloride in a sample of the patient's blood. The results are the serum electrolyte levels, an important indicator to the physician of the patient's condition and the treatment that may be needed.

Besides giving the four electrolyte levels, the analyzer also computes a total of the four, a composite figure called the "electrolyte balance," which normally ranges from +8 to +19.

But in rare instances, where one or more of the electrolyte levels is significantly negative, the total will be negative. That is, it should print out as a negative number. But Photovolt had not programmed its computer to do this. Instead, when confronted with negative levels, the analyzer would print a random positive number as a total. A physician looking only at the total and not at the four levels could be misled. Photovolt claimed that a physician would not

rely on the total figure alone, and that therefore the quirk in the computer was acceptable.

A hospital in Butler, Pa., did not agree with this when its analyzer printed a large positive number for a patient whose electrolyte balance was less than zero. The hospital reported it as a medical device defect, and FDA's **New York District** office investigated the complaint.

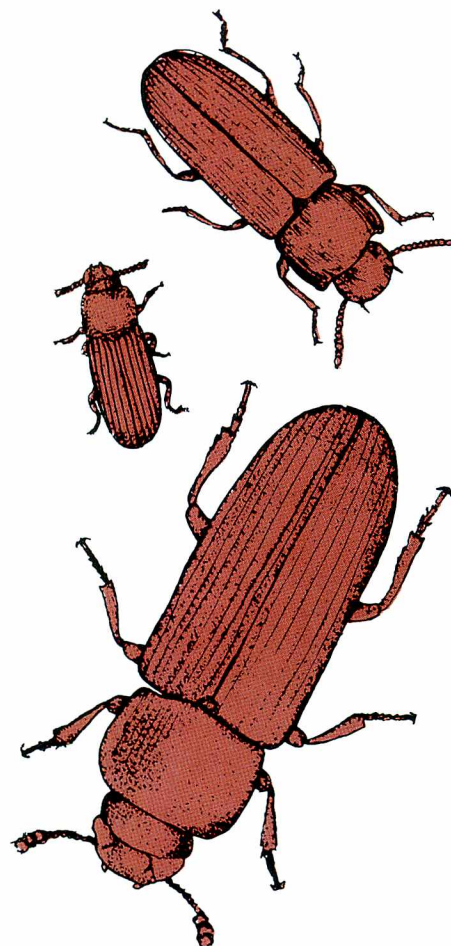
Photovolt admitted that its machine would not handle negative balances, and offered to include in the operator manual instructions for calculating a negative total. But FDA saw this as only an interim correction, and instead required the company to reprogram the analyzer. The new program, allowing for negative balances, is to be in all newly manufactured units, and must also be fitted to units already in use by the end of the year.

Food Watch

Contaminants that can get into food are many and varied, and no one knows this better than investigators from FDA, as the following incidents illustrate.

At the Schwebel Baking Co., Youngstown, Ohio, the problem was flour beetles. **Cincinnati District** investigators made two inspections and found beetles, dead and alive, in the equipment and storage and processing areas. On both occasions the bakery closed down for a thorough cleaning and destroyed a total of \$12,000 worth of possibly contaminated raw dough, bread, flour and finished rolls.

Mold and yeast were the culprits in the case of the Ohio Pure Foods Co. in Akron. Investigators from Cincinnati District checked the firm after receiving complaints about the cleanliness of the company's bottled water. The inspection found several violations of good manufacturing practice regulations (GMPs) and pinpointed the source of the contamination: a water hose that had not been properly cleaned between the processing of apple cider and the bottled water. The firm recalled approxi-



mately 144,000 eight-ounce bottles of water, valued at \$12,000. Investigators reported after a second inspection that the violations had been corrected.

Investigators from the **Springfield (Ill.) and Jackson (Miss.) resident posts** encountered a less common problem: fertilizer residues on a shipment of corn. A merchant in Jackson noticed a white powdery substance on the grain and called the Jackson resident post. The investigator learned that the shipment originated near Springfield and contacted the resident post there. The problem, the two learned, was that the corn had been shipped in a railcar that had previously carried ammonium nitrate, a fertilizer, and had not been adequately cleaned afterward. The U.S. marshal in Jackson seized 185,000 pounds of corn. The Illinois shipper has filed a claim to recondition the product.

Fatal Errors

A rancher in northwest Nebraska, thinking he had a bag of feed supplement, mistakenly poured insecticide into a feedbox in one of his pastures, and within days had lost 70 head of cattle from poisoning by the substance.

Laboratory tests showed that the cattle died so quickly that the organic phosphate (turfefos) did not get past the animals' stomachs and ruminative tracts into meat and tissue. However, the cattle could not be sold as beef, so the carcass parts were converted into pet food or processed (rendered) into tallow and bonemeal.

The incident was investigated by the **Nebraska Department of Agriculture** and by FDA's **Kansas City District** office. Until it was found to be the rancher's error, FDA was concerned that there might be poisoned or contaminated cattle feed in use in that area.

Much the same thing happened this past spring in central New York, but involved dairy cattle. A part-time worker on a dairy farm poured 50 pounds of a toxic soil insecticide into a feed hopper, thinking he was putting a protein supplement on the silage. The farm lost 40 cows, was required to dump hundreds of gallons of milk, and had a large veterinary bill for treating the animals that survived.

Here, too, the carcasses of the dead cattle were converted into pet food, some before the cause of death (poisoning) had been established. The **New York Department of Agriculture** had to locate and test the pet food after it had been distributed in several northeast states, to be certain it contained no toxic residues. Again, the poison worked so quickly that it did not reach the animals' tissues. It took two weeks, however, for milk from surviving cattle to test negative for pesticide so that the farm could ship again.

The New York incident involved the state's Division of Milk Control, Division of Food Inspection Services, Division of Animal Industry, Cornell University Veterinary College, and

FDA's **New York District** office and laboratory.

Mixed Up Labels

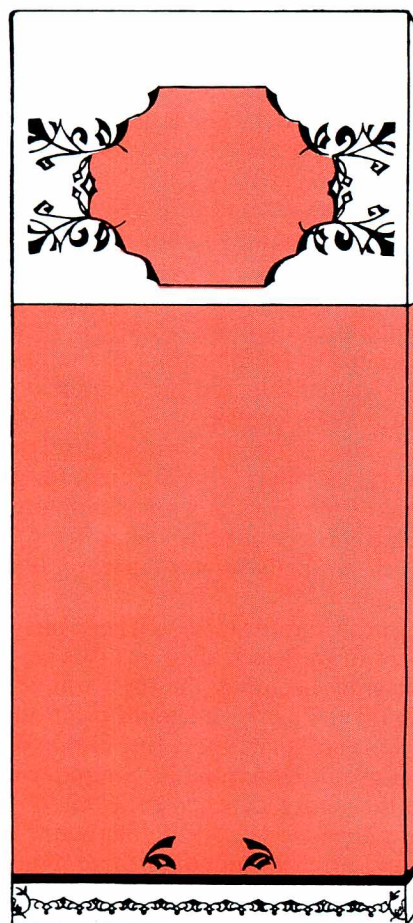
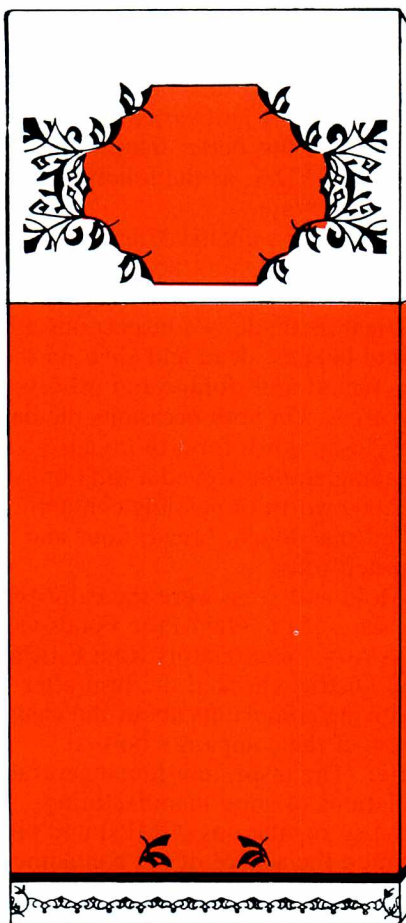
Pavalon is a muscle relaxant drug, and Regonol is a muscle stimulant. When injected into patients they produce exactly opposite effects. It could be dangerous if the relaxant were used where the stimulant was intended, or vice versa. Both are made by Organon, Inc., a West Orange, N.J., pharmaceutical firm.

Last February the company changed its packaging. The designs it chose for the two drugs were similar in color and format. In April the staff at DePaul Hospital in Norfolk, Va., discovered ampules of Regonol in a box labeled Pavalon. The hospital notified the U.S. Pharmacopeia (U.S.P.), the drug information and

standards organization in Rockville, Md. The U.S.P. in turn notified FDA and the manufacturer, following a prearranged system.

Organon distributes through warehouses at West Orange and Oak Forest, Ill. The company stopped further shipments from these warehouses and recalled the Pavalon and Regonol already distributed. The drugs were re-inspected and repacked, the Regonol going into a relabeled box that could not easily be confused with Pavalon.

FDA's **Newark District** office monitored the recall, which affected 77 hospitals, 12 wholesalers and six veterans hospitals. Company records showed that distribution was limited mostly to the Eastern Seaboard and the Great Lakes area, one shipment being sent to Texas. No injuries or ill effects were reported.



Postal Service Cases

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)

- January 5, 1981: **B & M**, 1706 S. State, Lockport, Illinois. Advertising and sale through the mail of the product "Esoteric Wisdom," representing the ability to regulate the menstrual cycle.
- January 7, 1981: **Hair Ender**, 1350 Avenue of the Americas, New York, New York. Advertising and sale through the mail of the product "Hair Ender." The published advertisement for the product states, "Hair Ender stops the growth of unwanted hair by gently penetrating hair follicles and inhibiting regrowth at the roots. You may never shave, wax or pluck again! Clinical tests in France and Germany prove that with daily use, Hair Ender can stop hair growth in as little as 30 days."
- January 13, 1981: **That Special Look Inc.**, P.O. Box 1490, Pompano Beach, Florida. Advertising and sale through the mail of the product "Slim-X Capsules," representing the ability to "lose weight overnight. Works up to 5 times faster than dieting or exercise alone."
- January 13, 1981: **Diet Sales Group Inc.**, 20 Jerusalem Avenue, Hicksville, New York. Advertising and sale through the mail of the product "Complete Contentment Pill." The published advertisement for the product states "burn away fat up to 2 times faster than diet or up to 5 even 7 times faster than exercise. You are about to become immune to fat for the rest of your life! If you want to see pounds and inches vanish from sight and stay vanished forever, faster than you'd every dream possible. . . ."
- January 14, 1981: **Hanover House**, 340 Poplar, Hanover, Pennsylvania. Advertising and sale through the mail of the product "Bio-Gro," representing "an incredible formula that actually restores hair, fights 'male-patterned' baldness."
- January 16, 1981: **Mail Away For Value Inc.**, 2015 Lakeland Avenue, Ronkonkoma, New York. Advertising and sale through the mail of the product "Waist Trimmer and Reducing Shorts," representing the ability to "use natural body heat to lose 4-6 inches the very first day . . . the waist trimmer actually melts away excess fat and water retention so fast, your waist will measure up to 4, 5 even 6 inches slimmer the very first day."
- January 19, 1981: **Speculum Press**, P.O. Box 1063, Hollywood, California. Advertising and sale through the mail of the product *When Birth Control Fails*. The published advertisement for the literature states in part, "How to abort ourselves safely. . . . it includes specific directions on how to construct and use early abortion equipment safely and cheaply . . . as a tool for groups, *When Birth Control Fails* is a creative, stimulating overview of the kinds of background, networking and learning that will be needed if women are ever going to be able to provide safe, early, supportive abortions for one another."
- January 22, 1981: **Weight Loss Center**, 2000 Rockwell Blvd., Canton, Ohio. Advertising and sale through the mail of the product "Dyna-Slim WL Tablets," representing the ability to cause weight loss with the "ultimate diet pill, it's as powerful as dynamite, yet as safe as aspirin . . . years of fat build-up are quickly flushed from your system."
- January 22, 1981: **National Pharmacals**, 2100 National Blvd., Canton, Ohio. Advertising and sale through the mail of the product "Dietrim 24 Tablets." The published advertisement for the product states in part, "burns more fat in one day than 6 hours of brutal exercise . . . Dietrim 24 plan burns off up to 1800 calories a day . . . 6 pounds weight loss in the first 48 hours alone . . . 10 pounds in first 7 days!"
- January 22, 1981: **Richelieu Pharmacals**, 1 Richelieu Plaza, Canton, Ohio. Advertising and sale through the mail of the products "Maxi-Slim 1000 Capsules" and "Slim-N-Trim Pill," representing the ability to cause weight loss with the "ultimate weapon against fat."
- January 22, 1981: **Health-Wealth**, 2066 N. Humboldt Blvd., Canton, Ohio. Advertising and sale through the mail of the product "The Bates Method Eye Exercise Program." The published advertisement for the product states in part, "there is an alternative to passively accepting eye deterioration as being normal and inevitable. It is a method of eye relaxation and training that was developed by Dr. William H. Bates, a famed New York ophthalmologist. This method corrects the impairment of the eye and brings it back to normal instead of covering the weakness up with harmful eyeglasses."
- January 27, 1981: **McKenzie-Roberts**, P.O. Box 510028, Miami, Florida. Advertising and sale through the mail of the product "Nilamine," representing the ability to cause weight loss. "Similar to—yet safer—than amphetamines. No prescription needed . . . diet drug does help people lose weight . . . lose up to 60 pounds in 12 short weeks!!! The Nilamine program does not let you starve yourself."
- January 29, 1981: **21st Century Labs**, P.O. Box 2541, New York, New York. Advertising and sale through the mail of the product "Nymphomaniac Drops," representing the ability to excite sexual desires. "Just a few luscious drops where she needs it most will turn her into a raging inferno."
- January 30, 1981: **Balsam 2000**, 507 5th Avenue, New York, New York. Advertising and sale through the mail of the product "Balsam 2000," representing the ability to "make wrinkles, skin blemishes, acne and pimple marks disappear."
- January 30, 1981: **Natures Harvest Inc.** 95 M South Hoffman Lane, Central Islip, New York. Advertising and sale through the mail of the product "RNA + Plus." The published advertisement for the product states in part, "the foundation of the 'no aging' diet concept is nucleic acid . . . our bodies already have nucleic acid, but some doctors feel that we need more to stay healthy than our bodies can manufacture."
- January 30, 1981: **Nature Life Products Inc.**, 95 M South Hoffman, Central Islip, New York. Advertising and sale through the mail of the product "RNA + 13 No Aging Diet," representing the ability to "combat many skin disorders including acne, psoriasis, brown spots! Improve heart functions . . . the program that takes years off your appearance."
- February 11, 1981: **L. W. Estes Co. Inc.**, Alma, Georgia. Advertising and sale through the mail of the product "Herbal Slim Down," representing the ability to cause weight loss. "Why stay overweight 1 day longer? Herbal Slim Down is sciences' amazing new all-vegetable weight control capsule that helps you lose weight naturally."
- February 20, 1981: **Magnolia Lab**, Box 1306, Pascagoula, Mississippi. Advertising and sale through the mail of the product "Stale Food vs Fresh Food," representing the ability to "cleanse arteries without surgery, but diet alone."
- February 20, 1981: **H-E-L-P**, 2310 Central Avenue, Memphis, Tennessee. Advertising and sale through the mail of the product "Potency Plus," representing the ability to have "a positive effect on such troubles as bad eyesight, hearing problems, constipation, male problems, nerve ailments, headaches, hayfever, arthritis, skin problems, and sexual inadequacies."
- February 25, 1981: **Athena Products Ltd.**, P.O. Box 81112, Chamblee, Georgia. Advertising and sale through the mail of various well-being and weight reducing products, "The Youth Factor, RNA, Eu Zinc-D, Power Tabs, Chromill GTF, Natural Calm, Food for Thought, Rx for Aging, META-E, Ex-Sel, and Cellulite TR3." The published advertisements state in part, "stay healthy, alert, energetic and young;

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

- helps slow the aging process; make your sexual relationship more exciting and satisfying than ever; increases your natural energy production; helps stabilize your blood sugar level; helps solve the problem of sleeplessness and nervousness; lets you improve your memory; help prevent and reverse the damage age does to skin; and cause weight loss."
- February 25, 1981: **Athena Products Ltd.**, 3545 Broad Street, Chamblee, Georgia. Advertising and sale through the mail of the product "Athena Stay Young Program," representing the ability to "slow down the aging processes. With regular use, the Athena Stay Young Program should result in skin that is moist and soft, higher energy levels, and a memory that will remain sharp."
- February 25, 1981: **Athena Products Ltd.**, P.O. Box 48392, Doraville, Georgia. Advertising and sale through the mail of the product "Athena Nutrition for Women," representing the ability "to protect against the nutritional deficiencies that age women more quickly."
- February 25, 1981: **Athena Products Ltd.**, P.O. Box 80783, Atlanta, Georgia. Advertising and sale through the mail of the product "Cellulite P.M.," representing the ability to "break up cellulite even while you keep your elimination processes working as productively at night as they do during the day."
- February 25, 1981: **Athena Products**, 3176 Marjan Drive, Atlanta, Georgia. Advertising and sale through the mail of the product "Control," representing the ability to "curb appetites and promote fast weight loss."
- March 2, 1981: **Auer Laboratories**, 721 Sheridan Avenue, Cody, Wyoming. Advertising and sale through the mail of the product "Mykon 83 Plus." The published advertisement states in part, "lifetime freedom from pain with doctor's amazing 'Mykon' program . . . temporary relief from nagging aches and pain caused by arthritis, rheumatism, bursitis."
- March 5, 1981: **M. George Research**, Box 216, Fredonia, Wisconsin. Advertising and sale through the mail of the product "MG 218-Tablets," representing the ability to "heal psoriasis from the inside."
- March 6, 1981: **G.H.P. Laboratories**, 1551 Dunwoody Village Parkway, Atlanta, Georgia. Advertising and sale through the mail of the product "Gerovital HP Capsules and Cream," representing the ability to keep you young.
- March 9, 1981: **Klar Company Inc.**, P.O. Box 4634, Manchester, New Hampshire. Advertising and sale through the mail of the product "Bio-Re-Store and Pre-Form 10," representing the ability to "cleanse your hair and supply your hair and scalp with the ingredients that have been reported to help stop hair loss and in cases grow new hair and Pre-Form 10 is reported to be a powerful stimulant for prolonged sexual desire."
- March 9, 1981: **Hair & Scalp Product Specialists**, P.O. Box 173, Hooksett, New Hampshire. Advertising and sale through the mail of the products "Jo-Jo-Ba" and "Bio3Plus Gel," representing the ability to stop hair loss and dandruff.
- March 9, 1981: **Merit Products Co.**, 3200 Lawson Blvd., Oceanside, New York. Advertising and sale through the mail of the product "Sauna Suit," representing the ability to "lose pounds and inches in your very own sauna suit . . . you'll feel younger, healthier, slimmer in no time when you wear this exclusive miracle sauna suit!"
- March 11, 1981: **Squaligan-2**, 516 Fifth Avenue, New York, New York. Advertising and sale through the mail of the product "Squaligan-2," representing the ability to "enjoy beautiful skin all day long—rid yourself of fine lines, wrinkles, crows feet, saginess[sic], pouches, crinkled areas and other complexion problems."
- March 11, 1981: **Quick Slims**, 234 Fifth Avenue, New York, New York. Advertising and sale through the mail of the product "Quick Slims," representing the ability to "melt off those unwanted inches and pounds! Be slender for life—without dieting."

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

- January 30, 1981: Against **Nail Builder**, P.O. Box 9669, Atlanta, Georgia. Satisfactory evidence was presented to the Postal Service that Nail Builder and their representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising "Liquid Protein for the Nails," representing the ability to make the "nails stronger and adding the needed protein that stops cracking and splitting."
- February 2, 1981: Against **Vibrant Sales**, P.O. Box 1964, Grand Central Station, New York, New York. Satisfactory evidence was presented to the Postal Service that Vibrant Sales and their agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product "Waist Away Belt." The ad states in part, "You will lose 4-6 inches the first day! Imagine how delighted you will be to find yourself inches slimmer in the waist and hips the very next day!"
- February 3, 1981: Against **B & M**, 1706 S. State, Lockport, Illinois. Satisfactory evidence was presented to the Postal Service that B & M and their representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising "Esoteric Wisdom," representing the ability to regulate the menstrual cycle.
- February 12, 1981: Against **Diet Sales Group Inc.**, 20 Jerusalem Ave., Hicksville, New York. Satisfactory evidence was presented to the Postal Service that Diet Sales Group Inc. and their agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product "Complete Contentment Pill." The ad states in part, "burns away fat up to 2 times faster than diet or up to 5 even 7 times faster than exercise. You are about to become immune to fat for the rest of your life!"
- February 18, 1981: Against **Health-Wealth**, 2066 N. Humboldt Blvd., Chicago, Illinois. Satisfactory evidence was presented to the Postal Service that Health-Wealth and their representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product "The Bates Method Eye Exercise Program." The ad states in part, "this method corrects the impairment of the eye and brings it back to normal instead of covering the weakness up with harmful eyeglasses."
- March 12, 1981: Against **Great Life Laboratories**, 500 Dorian Road, Westfield, New Jersey. Satisfactory evidence was presented to the Postal Service that Great Life Laboratories and their agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising "Ribomins," representing the ability to "fight against the effects of aging."

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Apricot kernels, at Knoxville, E. Dist. Tenn.

Charged 5-12-77: while held for sale, after being repackaged at Greenville, Tenn., and labeled in part "Natural Apricot Kernels . . . Millet, Pit and Seed Company, Inc., Gatlinburg, Tennessee," the article contained the poisonous and deleterious substance hydrocyanic acid (hydrogen cyanide) in such quantity as might render it injurious to health and was unfit for food due to the hydrocyanic acid—402(a)(1), 402(a)(3); and, as a drug, the article's labeling lacked adequate directions for use and was not exempt due to its new drug status and due to lack of adequate information for use by licensed practitioners—502(f)(1).

Millet, Pit and Seed Co., Inc., Sevier County, Tenn., claimed the article, denied the charges, and moved for summary judgment. The court denied the motion for summary judgment because there were material facts in dispute. However, after a hearing in which the court ruled upon the merits on this and a related action (see N.J. No. 35 of this issue of FDA CONSUMER), the court found for the claimant saying:

"We have for consideration two suits, the first of which is styled *Millet, Pit and Seed Company, Inc. v. United States of America, et al.*, Civ. 3-77-172. In that case the State of Tennessee embargoed or tagged a number of cases of apricot kernels belonging to plaintiff, Millet, Pit and Seed Company, and valued at approximately \$164,000.00. Douglas Heinsohn, who is the principal owner of the seed company, filed a complaint on May 6, 1977 against the United States, the Secretary of Health, Education and Welfare Califano, and other agents of the United States, and Robert Reeves and Roy G. Stipe, who are both agents of the State of Tennessee, and the State of Tennessee.

"It is alleged that on April 15, 1977, the defendants, acting under color of state statutes and regulations and participating in a conspiracy, embargoed and seized a quantity of apricot kernels owned by Douglas L. Heinsohn (the complaint was later amended to name Millet, Pit and Seed Company as the plaintiff), without legal justification and in violation of the Fourth, Fifth and Fourteenth Amendments to the Federal Constitution, the Federal Food, Drug and Cosmetic Act, and in violation of Title 42 U.S.C. § 1983.

"More specifically, it is alleged that on the above mentioned date, Norman Miller, an investigator for the Federal Food and Drug Administration, and Roy G. Stipe, an agent for the Department of Agriculture, Food and Drug Division of the State of Tennessee, acting in concert with the defendants Reeves, Jancarek, and certain other defendants who are federal employees, visited the Munford Refrigerated Warehouse and embargoed and detained 6,701 cartons of apricot kernels owned by the plaintiff and stored in the warehouse.

"It is further alleged that the defendant Stipe, pursuant to the authority and direction of Reeves, and without complying with the provisions of the Tennessee Food, Drug and Cosmetic Act, turned the further enforcement action over to defendant Miller, acting pursuant to the authority and direction of Jancarek, all of which enforcement action was under color of state law, namely, T.C.A. § 52-101 *et seq.*, and more particularly, T.C.A. § 52-106.

"It is the plaintiff's theory that all of the actions of the defendants were under color of state law and the rules and regulations of the Department of Agriculture, Food and Drug Division, State of Tennessee, and were part of a conspiracy and subterfuge by the defendants to circumvent and evade applicable federal law, to-wit, the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* It is alleged

that such actions were unlawful because the apricot kernels were seized and detained in the absence of a finding of or having probable cause to believe that the kernels were adulterated, as required by T.C.A. § 52-106. Plaintiff claims he has sustained serious and extensive damages on account of the seizure, and seeks damages in the sum of \$1,000,000.00.

"Plaintiff sought a hearing in the matter as expeditiously as possible requiring the defendants to show cause why they should not release plaintiff's property, and following the hearing, the issuance of an injunction requiring the defendants to release to plaintiff the apricot kernels.

"The Federal Government has moved to dismiss the complaint because, after this suit was instituted, the Federal Government seized the kernels pursuant to a libel proceeding filed on May 12, 1977 under the Federal Food, Drug and Cosmetic Act. Thus, the United States argues that any challenge to the Federal Government's seizure must be litigated in the pending libel proceedings and that equitable relief is not appropriate due to the pendency of such proceedings.

"The State of Tennessee, Reeves and Stipe have likewise moved to dismiss on the ground that the Court lacks jurisdiction because plaintiff has not availed itself of the method of review provided in T.C.A. § 27-901 *et seq.* They further assert that the relief sought by the plaintiff concerning the return of the kernels is a moot issue since the kernels are currently under seizure of the federal marshals. Finally, the State of Tennessee correctly asserts that it is not a person under 42 U.S.C. § 1983.

"The second suit is that of the *United States v. An Article of Food and Drug, etc.*, Civ. 3-77-180, in which the aforementioned apricot kernels were seized, on May 12, 1977, by the federal marshals under authority of an arrest warrant signed by the Clerk of this Court, issued pursuant to a libel for forfeiture under the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 301 *et seq.*, filed by the United States Attorney for this District. Millet, Pit and Seed Company, Inc. has intervened in this proceeding and filed a claim to said kernels.

"A motion for summary judgment has been made by the claimant, Millet, Pit and Seed Company, based upon the theory that: (1) claimant sold the kernels as a food and not a drug, therefore the drug provisions of the Act are not applicable; (2) the kernels are not poisonous within the meaning of the Act; and (3) the kernels are not unfit for food. It is ORDERED that the motion for summary judgment be, and the same hereby is, denied, because obviously there are material facts in dispute. We now consider each case on its merits.

I. Condemnation Case (3-77-180)

A. Government's Claim That Kernels Are an Adulterated Food

"The United States first alleges that the seized apricot kernels are subject to condemnation because they constitute an 'adulterated food' within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* The charge that the kernels are an adulterated food is based on two separate provisions of the Act. Section 342 contains many definitions of adulterated food, including the two provisions [402(a)(1) and 402(a)(3)] at issue here. . . .

"As to the first provision, the Court finds that the potentially poisonous substance (amygdalin) found in these apricot kernels is not an 'added substance' within the meaning of the Act.

"The test for determining whether a substance is an added substance is whether it occurs naturally in the food. See *United States v. An Article of Food, Etc.*, 395 F. Supp. 1184 (S.D. N.Y. 1975). It is obvious from the evidence presented to the Court that the potentially poisonous substance in apricot kernels (amygdalin) occurs naturally in the kernels. Therefore, the United States must prove that the kernels



contain a quantity of the poisonous substance sufficient to render them injurious to health under *ordinary* conditions and usage.

"Based on the testimony of expert witnesses presented by both the Government and the claimant, the Court is of the opinion that apricot kernels do not contain sufficient amounts of poisonous substance that might render them ordinarily injurious to health. The evidence demonstrates that ordinary use of these kernels as a food would not be injurious to the health of the consumer.

"The Supreme Court, in an opinion rendered in 1914, quoted one of the Congressional sponsors of the original Food and Drugs Act of 1906, a predecessor of the Act involved here, as follows: 'As to the use of the term "poisonous", let me state that everything which contains poison is not poison. It depends on the quantity and combination. A very large majority of the things consumed by the human family contain, under analysis, some kind of poison, but it depends upon the combination, the chemical relation which it bears to the body in which it exists as to whether or not it is dangerous to take into the human system.' *United States v. Lexington Mill Co.*, 232 U.S. 399, 412 (1914).

"We have such a substance here. Amygdalin occurs naturally in approximately twelve-hundred different fruits, vegetables, grains and seeds, including strawberries, lima beans, barley, rye, apple seeds, peach kernels and cherry pits. So far as the Court has been advised, none of these substances has been condemned by the FDA as being adulterated solely by reason of its amygdalin content.

"Most substances, if consumed in excessive quantities, will produce some adverse effects in some individuals. One highly qualified government witness testified that excessive quantities of common table salt can produce consequences harmful to the ordinary person. The Government has produced evidence which tends to establish that the ingestion of excessive quantities of apricot kernels may produce headaches and nausea in some individuals, particularly those who are weakened by disease. Claimant has introduced persuasive evidence to the contrary, including the testimony of a medical doctor who, in an experiment, ingested one-half pound (approximately 400) of the unpleasant tasting kernels in one day without suffering adverse effects.

"Be that as it may, we are concerned here with ordinary usage under ordinary conditions. Having considered the evidence of record, the Court finds that the amygdalin content of apricot kernels is not sufficiently great to render the kernels injurious to health under ordinary conditions and usage. Accordingly, the kernels cannot be condemned as an adulterated food on the alleged ground that they may be injurious and poisonous within the meaning of the Act.

"As to the Government's second ground for condemning the kernels as an adulterated food, the Government has produced little evidence which would tend to establish that these kernels are 'unfit for food.' This provision is a separate and independent basis for a finding that a food is adulterated. See *United States v. 484 Bags, etc.*, 423 F.2d 839 (5th Cir. 1970). A finding of unfitness for food must be based on proof that, although the food item did not meet the other definitions of an adulterated food, it was 'otherwise unfit for food.' Such a finding can be made only when the proof demonstrates that the article of food was inedible for the average person under ordinary conditions. See *United States v. 24 Cases, etc.*, 87 F.Supp. 826 (D. Me. 1949). The Government has failed to prove that the kernels are unfit for food as contemplated by the Act.

"The Court finds that the seized kernels are not an adulterated food within the meaning of the Act and cannot be condemned on that ground. However, this does not end our inquiry, as the United States also charges in the libel of information that the kernels are 'drugs' as that term is defined in the Act, and that the kernels fail to meet the

labeling requirements imposed on drugs under the Act.

B. Are the Kernels Drugs?

"The term 'drug' is defined in 21 U.S.C. § 321 (g)(1) as including: '[A]rticles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals. . . .

"The courts have held that it is the *intended use* which determines whether or not an article is a drug. . . . The Sixth Circuit Court of Appeals has held that ordinary honey must be classified as a drug when it is sold for therapeutic purposes. *United States v. 250 Jars, etc.*, 344 F.2d 288 (1965).

"In determining the intended use of a given article, the Court must seek to ascertain the intent of the claimant by looking to all the facts and circumstances shown at trial. The cases emphasize that, in determining the intent of a claimant engaged in the distribution of the article, the Court should consider not only the claimant's own assertions, but also the 'label, accompanying label, advertising, and any other relevant source. . . .' Statements made by a claimant through virtually any medium are relevant to this inquiry. . . .

"Only one claimant has intervened in these proceedings, Millet, Pit and Seed Company. The proof shows that it is a corporation managed and owned solely by Heinsohn. Accordingly, the Court considers the intent manifested by Heinsohn to be highly relevant to these proceedings. Heinsohn testified that he sold the apricot kernels solely as a food supplement. His testimony was positive and unequivocal on the issue of the intended use of the articles. He swore that he made no representations to his customers regarding the efficacy of apricot kernels as a treatment or cure for cancer or any other disease. He sold the kernels in bags labeled: 'Millet, Pit & Seed Co. Natural* APRICOT KERNELS. NOT LESS THAN ONE POUND AT TIME OF PACKAGING. HOT AIR DRIED TO REMOVE EXCESS MOISTURE. . . . *NO ADDITIVES.

"The Court has considered the documentary evidence introduced by the Government to establish that the claimant, in fact, intended that the apricot kernels be used for the prevention and treatment of a disease and is thus a drug. The first document is a letter from Heinsohn dated December 2, 1974 and printed on Millet, Pit and Seed Company stationery. It contains the salutary greeting 'Dear Friend.' Almost the entire letter refers to peach kernels, and only one sentence mentions apricot kernels. The letter states, in substance, that one scientist believes that the ingestion of eight to twelve peach kernels per day can prevent malignancies from becoming clinical and that peach kernels could be purchased from the claimant. The letter does not state that the claimant had apricot kernels for sale or would ever have any for sale.

"The second document is a letter dated January 5, 1975 and addressed to Heinsohn and the Millet, Pit and Seed Company. The letter was sent by the scientist referred to above, who in this letter evaluated the amygdalin content of the peach kernels being sold by the claimant. Only one remark in the letter contains any mention of apricot kernels; the apricot kernels were referred to solely as a reference point for evaluating the amygdalin content of peach kernels.

"The third document is a leaflet dated June 6, 1975 and printed on Millet, Pit and Seed Company stationery. The leaflet deals primarily with peach kernels and their alleged value in the prevention of cancer, and repeats the references made in the first two documents to apricot kernels. One additional comment is made to the effect that the FDA has banned the retail sale of apricot kernels but has not banned the retail sale of peach kernels.

"Each of the above documents focuses upon peach kernels, which contain approximately the same amount of amygdalin as apricot ker-



nels. Although the Government seeks to equate peach kernels with apricot kernels, there is no evidence that the FDA has ever made any attempt to condemn peach kernels sold by Heinsohn or anyone else. The proof shows that agents of the FDA inspected the premises of Millet, Pit and Seed Company over two years ago, and Heinsohn was most cooperative in showing them his stock of peach kernels and some of the above documents. He asked the agents if there was anything wrong with the sale of peach kernels, and the agents replied that they did not believe so, but would advise him should they change their minds. With the exception of several unknowing encounters with FDA undercover agents, Heinsohn had no further contact with the FDA until the apricot kernels at issue were seized.

"The above documents fail even to intimate that Heinsohn had apricot kernels for sale. They were written approximately two years before he began to sell apricot kernels. This circumstantial evidence on the issue of intended use does not outweigh the positive sworn testimony of Heinsohn and the other evidence of record that he did not hold the apricot kernels out as a substance to be used in the prevention and treatment of cancer. An additional factor in support of this holding is the wholly natural state of the seized articles and the appearance of their packaging. The articles are not in pill, capsule or liquid form, nor are they packaged or labeled in a manner suggesting that they are a drug. They were sold with no representations or warranties.

"The Government further contends that Heinsohn intended that apricot kernels be used for the prevention and treatment of disease because he is an advocate of the use of a highly controversial substance known as 'Laetrile' for the prevention and treatment of cancer. It cannot be doubted that Heinsohn has advocated the use of Laetrile as a supplement to conventional therapy for the treatment of cancer. Laetrile, which is derived from apricot kernels, contains a highly concentrated dosage of amygdalin, the same substance that occurs naturally in apricot kernels, and is generally administered intravenously or in tablet form to cancer patients who believe in its efficacy. See *Rutherford v. United States*, *supra*. The Government seeks to equate Laetrile with apricot kernels so as to link all statements made by Heinsohn about Laetrile to the apricot kernels.

"This is not a Laetrile case. We are concerned here only with apricot kernels. Although Heinsohn admitted that he has purchased Laetrile in liquid and tablet form for use by his wife, the Government does not seek to condemn Heinsohn's supply of Laetrile. It seeks to condemn apricot kernels, the likes of which may be found in most supermarkets throughout the country and in many of the so-called health food stores. He sold the kernels without making any representations or warranties about their efficacy to anyone who wished to buy them for whatever purpose. Under these circumstances we cannot agree with the Government that Heinsohn's statements about Laetrile must be translated into statements about apricot kernels.

"Having considered all the evidence of record, the Court is of the opinion, and finds, that the apricot kernels at issue were not intended by the claimant to be used for the prevention and treatment of a disease. Accordingly, they are not a drug as that term is defined in the Act.

"For the foregoing reasons, it is ordered that the seized articles be returned, forthwith, to the claimant, Millet, Pit and Seed Company, because they are not in violation of any provision of the Act, and therefore are not subject to condemnation. The Court has been advised by the Marshal that the Government has agreed to pay the storage costs of the articles for the period of time during which they were under seizure by the United States.

"Having reached this decision, the Court emphasizes that we have dealt here only with apricot kernels sold in their natural state as a food supplement. We hold only that under the particular facts and circumstances shown at trial that the apricot kernels at issue were neither adulterated nor sold for the prevention and treatment of a disease. We further emphasize that this decision should not be construed as placing this Court's imprimatur on the use of apricot kernels, Laetrile or any other substance for the prevention and treatment of cancer. . . ."

The government moved for a stay pending an appeal. The court denied the motion. However, the government pursued its appeal, based as follows: upon the curtailment of discovery by requiring a trial on the merits one week after the seized articles were claimed and an answer to the complaint was filed; and upon the court's refusal to permit the government to call expert witnesses at a hearing on the merits by ruling that the government had used all the expert witnesses that it was entitled to use at a preliminary hearing held to determine probable cause. The court of appeals vacated the judgment of the district court and remanded the case for a full hearing on the merits, saying:

"Finding from the record that the government made a reasonable request to conduct discovery for a brief period and to present at the hearing which was conducted certain additional witnesses; and

"Further finding on this whole record that the denial of these requests was an abuse of discretion which may have prejudiced the result in an important case.

"Now, therefore, the judgment of the District Court is hereby vacated and the case is remanded for a full hearing on the merits."

Ultimately, after all but one case of the seized articles had been returned to the claimant under the district court's earlier order, the parties stipulated that the action be dismissed without prejudice, and the one remaining case of the article was destroyed. (F.D.C. No. 61210; S. No. 77-67-723; N.J. No. 1)

FOOD/Contamination, Spoilage, Insanitary Handling

Beans, kidney, dried, at Nashville, M. Dist. Tenn.

Charged 9-18-80: while held for sale in two truck trailers, the article contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). The article was claimed by Tarke Warehouse Inc., Meridian, Calif. Consent decree authorized release to the claimant for salvaging. (F.D.C. No. 63199; S. Nos. 80-229-518/9; N.J. No. 2)

Flour, regular and other foodstocks, at Pickens, Dist. S.C.

Charged 5-18-81: while held by Morris and Co. Inc., Pickens, S.C., the articles had been held under insanitary conditions, and the flour contained rodent filth; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 63448; S. No. 81-288-202; N.J. No. 3)

Flours, rye, first-clear, and high gluten, at Atlanta, N. Dist. Ga.

Charged 1-23-81: while held by Manhattan Bakery, Atlanta, Ga., the clear and white rye flour contained rodent filth, and all of the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 63307; S. No. 81-164-292 et al.; N.J. No. 4)

Mustard seed, paprika, melba toast, ground mustard, malto-dextrin and citric acid granules, at Miami, S. Dist. Fla.

Charged 9-19-80: while held by Purity Condiments Inc., Miami, Fla., all of the articles except the malto-dextrin contained insect and/or rodent filth, and all of the articles had been held under insanitary



conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 63171; S. No. 80-166-956 et al.; N.J. No. 5)

Pecans, shelled, at Seattle, W. Dist. Wash.

Charged 10-29-80: while held for sale, the article contained moldy pecans and had been prepared, packed or held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 63222; S. No. 80-235-164; N.J. No. 6)

Rice, enriched (2 lots), at Phoenix, Dist. Ariz.

Charged 2-19-81: while held by Eastern Enterprise, Phoenix, Ariz., one lot of the article contained rodent filth, and both lots had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 63329; S. No. 81-257-650; N.J. No. 7)

Soybeans (seasoned), pinto beans, pastry mix, wheat flour, milk sugar, and arrowroot flour, at Richmond, N. Dist. Calif.

Charged 3-2-81: while held by Hirschfelder Corp., Richmond, Calif., the milk sugar, arrowroot flour and poppyseed contained rodent filth, and all of the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 63336; S. Nos. 81-253-131/6; N.J. No. 8)

Seasoning for popcorn, at Dallas, N. Dist. Texas

Charged 5-11-81: while held for sale, the article had been held under insanitary conditions; 402(a)(4). Consent decree authorized release to the dealer, Modern Sales & Service, Dallas, Texas, for salvaging. (F.D.C. No. 63441; S. No. 81-266-705; N.J. No. 9)

Textured vegetable protein, at San Juan, Dist. P.R.

Charged 3-16-81: while held for sale, the article contained insect and rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 63393; S. No. 81-274-859; N.J. No. 10)

FOOD/Economic and Labeling Violations

Syrups for table use, "honey," at Stillwater, W. Dist. Okla.

Charged 2-20-81: when shipped from Dekalb, Miss., the article labeled in part "H.W. Pilgrim Clover Honey . . . Packed by H.W. . . . Dekalb, Miss.," had had corn syrup substituted for honey, and while held for sale, the article, labeled in part "Clover Honey . . . A.E. Harris . . . Quinton, Oklahoma," had had corn syrup substituted for honey—402(b)(2); the articles' labeling was false and misleading in representing that the articles were pure honey and consisted wholly of honey—403(a)(1); and the articles were also in violation of the Fair Packaging and Labeling Act, because the net content statements were not expressed as prescribed (i.e., in fluid ounces followed in parentheses by a declaration of the largest whole unit of net content with any remainder in terms of fluid ounces or fraction of the pint or quart—15 U.S.C. 1453(a)(3)(A)(i)). Default decree authorized donation to a charitable institution. (F.D.C. No. 63331; S. Nos. 81-265-468/70; N.J. No. 11)

Syrups for table use, "honey" and "maple," at Evansville, S. Dist. Ind.

Charged 4-20-81: when shipped from Dekalb, Miss., the article which had been labeled in part "Big Mountain Brand Clover Honey . . . Big Mountains . . . Dekalb, Miss." and which had been shipped by H.W. Pilgrim, Dekalb, Miss., and the article which had been labeled in part "Made in Vermont, bottled in Miss. Maple Syrup sold by Larry Miles . . . Dekalb" and which had been shipped by Larry Miles, Dekalb, Miss., had had corn syrup substituted in the articles—402(b)(2); the labeling of the articles was false and misleading in representing that the articles consisted, respectively, wholly of honey and wholly

of maple syrup when both of the articles contained corn syrup—403(a)(1); the "maple" syrup failed to conform to the definition and standard of identity for maple syrup because the article was made with syrup derived from a source other than the maple tree—403(g)(1); the articles were also in violation of the Fair Packaging and Labeling Act, because the quantity of contents statement for the "maple" syrup was expressed in terms of weight which was not an accurate reference with respect to this food which was in liquid form—15 U.S.C. 1453(a)(2); and because the quantity of contents declarations of the articles were not followed in parentheses by a declaration of the largest whole unit of appropriate measure with any remainder in terms of the specified smaller units or common or decimal fractions—15 U.S.C. 1453(a)(3)(A)(i). Default decree ordered destruction (F.D.C. No. 63443; S. No. 81-183-031 et al.; N.J. No. 12)

Syrups for table use, "maple" and "sorghum," at Bixby, N. Dist. Okla.

Charged 7-1-81: when shipped by Elmer Eakes, Philadelphia, Miss., the articles, labeled in part "Pure New Frontier Maple Syrup packed for Elmer Eakes . . . Philadelphia, Mississippi," and "Country Sorghum Made By Elmer Eakes . . . Philadelphia, Mississippi," had had glucose syrup substituted for the articles—402(b)(2); the labels were false and misleading in representing that the articles consisted, respectively, wholly of maple syrup and wholly of sorghum—403(a)(1); and the articles failed to conform to the definitions and standards of identity for maple syrup and sorghum, since the respective articles had been made with syrup derived from sources other than the maple tree and sorghum cane—403(g)(1). Default decree ordered destruction. (F.D.C. No. 63411; S. Nos. 81-266-144/6; N.J. No. 13)

DRUGS/Human Use

Allopurinol tablets, chlorthalidone tablets, furosemide tablets, and trimethoprim with sulfamethoxazole tablets, at Glasgow, W. Dist. Ky.

Charged 1-28-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). Consent decree ordered destruction. (F.D.C. No. 62750; S. No. 80-229-529 et al.; N.J. No. 14)

Chlorthalidone tablets, hydroxyzine HCl tablets, diethylpropion HCl tablets, furosemide tablets, prochlorperazine capsules, hydroxyzine pamoate capsules, spironolactone tablets, spironolactone with hydrochlorothiazide tablets, and trimethoprim with sulfamethoxazole tablets, at Lexington, W. Dist. Tenn.

Charged 3-11-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The shipper claimed the articles, and pursuant to stipulation, the case was consolidated for trial with a similar case in the District of New Jersey. Ultimately, a consent decree ordered the articles destroyed. (F.D.C. No. 62800; S. No. 80-208-564 et al.; N.J. No. 15)

Dipyridamole tablets, and other specified drugs, at City of Industry, C. Dist. Calif.

Charged 7-24-79: when shipped by Pharmadyne Laboratories Inc., Hackensack, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Pursuant to stipulation by the parties, the action was transferred to the Eastern District of New York for consolidation for trial with a similar action. Subsequently, a consent decree ordered destruction. (F.D.C. No. 62384; S. No. 79-153-757 et al.; N.J. No. 16)

Guaiacol combination injection, at Caparro, Dist. P.R.



Charged 1-29-81: when shipped by Carter-Glogau Laboratories Inc., Glendale, Ariz., the article, labeled in part "Dirocon (Expectorant Formula). . . Injection . . . Distributed by International Ethical Laboratories, San Juan, Puerto Rico," was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 63298; S. No. 81-274-504; N.J. No. 17)

Guaiacol combination injection, at Rio Piedras, Dist. P.R.

Charged 1-29-81: when shipped by Carter-Glogau Laboratories Inc., Glendale, Ariz., the article labeled in part "Injection . . . Tosevite (Expectorant Formula). . . manufactured for Quiver Pharmacal Co. Inc., Puerto Rico," was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 63297; S. No. 81-274-503; N.J. No. 18)

Hydroxyzine HCl tablets, and other specified drugs, at Chicago, N. Dist. Ill.

Charged 7-24-79: when shipped by Pharmadyne Laboratories Inc., Hackensack, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Pursuant to stipulation, the action was transferred to the Eastern District of New York for consolidation for trial with a similar action. Subsequently, a consent decree ordered destruction. (F.D.C. No. 62385; S. No. 79-150-872 et al.; N.J. No. 19)

Hydroxyzine HCl tablets, furosemide tablets, hydroxyzine pamoate capsules, spironolactone with hydrochlorothiazide tablets, and trimethoprim with sulfamethoxazole tablets, at San Diego, S. Dist. Calif.

Charged 5-9-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). Default decree ordered destruction. (F.D.C. No. 62981; S. No. 80-244-862 et al.; N.J. No. 20)

Hydroxyzine HCl tablets, hydroxyzine pamoate capsules, and other specified drugs, at Hollywood, S. Dist. Fla.

Charged 4-1-81: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; and the labeling of the articles lacked adequate directions for use and the articles were not exempted due to their new drug status; 505(a), 502(f)(1). Default decree ordered destruction. (F.D.C. No. 63412; S. No. 81-239-827 et al.; N.J. No. 21)

Mint Glo cream, JC-6 Podiatry Pretape aerosol spray, Adhesive Balm Pink cream, JC-4 Pretape dressing solution, and drug components, at Erie, W. Dist. Pa.

Charged 3-24-77: while held by Larson Laboratories Inc., Erie, Pa., who was manufacturing the named drugs using the interstate drug components, the circumstances of the articles' manufacturing, processing and packing failed to conform with current good manufacturing practice; 501(a)(2)(B).

Consent decree authorized release to the manufacturer for reconditioning. The parties litigated the reconditioning of the articles. Meanwhile, the government filed a petition to show cause in criminal contempt (see N.J. No. 27 of this issue of FDA CONSUMER). After a hearing on whether the drugs had been reconditioned or whether the drugs should be destroyed, the court found for the government and ordered the articles destroyed, saying in part:

Findings of Fact

* * *

"7. On May 18, 1977, Larson's President Arthur Berenstein filed a bond with this Court and was given, pursuant to the terms of the

Consent Decree, 60 days from the filing of the bond, that is, until July 19, 1977, to bring the condemned drugs into compliance with the Federal Food, Drug, and Cosmetic Act (Act).

"8. The Consent Decree allowed Larson to recondition the condemned drugs only on the following conditions: (a) Larson must retain intact all of the drugs for inspection by the United States Food and Drug Administration (FDA) (paragraph 2, p.3); (b) The reconditioning process must be under the supervision of the (FDA) (paragraph 5, pp.3-4); (c) Larson must abide by the decisions of the FDA, which decisions shall be final (paragraph 6, p.4); (d) Larson cannot sell or dispose of the drugs without the written release of the FDA (paragraph 4, p.3); and (e) Larson cannot sell or dispose of the drugs contrary to the Act (paragraph 7, p.4).

"9. The Consent Decree further provided that if Larson breached any of its conditions or any other subsequent Orders of this Court, Larson would be required to return the condemned drugs immediately to the United States Marshal, at Larson's expense, for destruction or other disposition pursuant to an Order of this Court (paragraph 6, p.4).

"10. After the Consent Decree had been entered into and at Larson's request, in June and July, 1977, FDA inspected the drugs and reviewed Larson's manufacturing and laboratory testing methods to determine if the drugs had been reconditioned.

"11. On the basis of these inspections and scientific analyses, the FDA found that the manufacturing still failed to conform to good manufacturing practices, the testing procedures employed by Larson remained faulty, and the drugs did not meet Larson's own specifications. The FDA refused to release the drugs because they had not been reconditioned.

"12. The FDA inspections of June and July, 1977, revealed that Larson had used the condemned active ingredients to manufacture new lots of finished drugs and shipped these drugs in interstate commerce without prior FDA approval as required by the Consent Decree. On May 25, 1978, in proceedings before this Court, Larson's President Arthur Berenstein was found in contempt of Court and his bond was revoked.

"13. By letter of May 25, 1978, Larson's President Arthur Berenstein asked the FDA to conduct an inspection to determine whether the drugs were reconditioned and therefore could be released.

"14. Pursuant to Larson's request, on June 5-7, 1978, FDA conducted an inspection of the condemned drugs. This inspection revealed that the drugs had not been reconditioned. By letter dated August 24, 1978, the FDA informed Larson's President Arthur Berenstein of the reasons why the drugs had not been reconditioned and informed Larson of the materials that needed to be submitted to FDA as a prerequisite to the release of the seized materials.

"15. Since Larson had failed to avail itself of the opportunity to recondition the condemned drugs in accordance with the terms of the Consent Decree, on November 21, 1978, FDA filed a Petition For Order To Show Cause why the drugs should not be destroyed. On January 30, 1979, Larson filed an Answer to this Petition.

"16. A hearing on this Petition was held on February 6, 1979, at which time Larson maintained that its testing procedures were valid and that the drugs were in compliance with the Act. The FDA maintained that the drugs had not been reconditioned because Larson did not use good manufacturing practices and had failed to establish that it used proper testing methodology and testing procedures.

"17. On February 6, 1979, this Court ordered the FDA to inspect Larson and to collect samples of the condemned drugs to determine whether Larson's testing methodology and testing procedures were proper.



"18. Subsequently, FDA inspected Larson in February and March, 1979, collected samples of the condemned drugs, and reviewed Larson's testing methodology and testing procedures.

"19. By letter of April 12, 1979, Larson's President Arthur Berenstein asked the FDA to give Larson the actual test procedures, test results and pertinent calculations of all tests run on our products by the Food and Drug Administration. By letter of June 14, 1979, the FDA provided Larson with copies of all analytical worksheets in possession of the FDA relating to the condemned drugs.

"20. On June 11, 1979, FDA filed, in accordance with this Court's Order of April 10, 1979, a Statement in Support of An Order For Destruction in which the FDA stated that it found the drugs were not reconditioned and stated the reasons therefore.

"21. Larson failed to file a response to the FDA's Statement in Support of An Order For Destruction by July 11, 1979, the date ordered by this Court in its Order of April 10, 1979.

"22. On October 2, 1979, this Court set a hearing on Larson's failure to timely file its response. On October 19, 1979, Larson filed its response and on October 22, 1979, a hearing was held on this matter. At this hearing, this Court ordered that an evidentiary hearing be held to resolve the FDA's pending Petition For Order To Show Cause why the drugs condemned in this matter should not be returned to the United States Marshal and destroyed.

"23. On November 1, 1979, Larson filed a Pre-Trial Narrative and the United States filed a Motion For Reconsideration of this Court's Order of October 22, 1979.

"24. A hearing was held on November 13, 1979, at which time Larson presented testimony designed to show that the condemned drugs had been reconditioned; such testimony did not establish, *prima facie*, that the drugs are now in compliance with law.

"25. Accordingly Larson has failed to carry its burden of showing that the seized and condemned drugs have been reconditioned as required by the Consent Decree.

Conclusions of Law

* * *

"7. Larson has failed to establish that it has reconditioned the condemned drugs and the Food and Drug Administration has not acted arbitrarily or capriciously in refusing to release the condemned drugs.

"8. Larson violated the terms of the Consent Decree when it sold condemned drugs prior to their release by the FDA and when it failed to timely file a submission as ordered by this Court on April 10, 1979.

"9. The condemned drugs shall be disposed of pursuant to 21 U.S.C. 334(d) and the terms of the Consent Decree. . . .

"Ordered, adjudged, and decreed that the condemned drugs shall be forthwith returned to the United States Marshal and destroyed, and due return made to this Court, pursuant to 21 U.S.C. 334(d); and it is further Ordered, adjudged, and decreed that Larson Laboratories, Inc., promptly compensate the FDA for all costs of supervision and the full cost of this litigation in the amount of \$2427.50, pursuant to 21 U.S.C. 334(e) and the terms of the Consent Decree."

A second petition to show cause in criminal contempt was filed because the claimant failed to pay all costs of supervision and the full cost of litigation in the amount of \$2,427.50. The court issued a show cause order. However, the claimant subsequently paid the \$2,427.50, thereby obviating the need for the second contempt hearing. (F.D.C. No. 61478; S. No. 77-04-331 et al.; N.J. No. 22)

DRUGS/Veterinary

Canine parvovirus vaccine, at Kingman, Dist. Ariz.

Charged 4-14-81: while held for sale, the article, labeled in part

"Vaccine . . . inactivated canine parvovirus . . . intramuscularly . . . For Sale To Licensed Veterinarians in the State of Iowa," was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to its use or intended use; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 63388; S. No. 80-244-180; N.J. No. 23)

Diethylstilbestrol implants, at Wheeler, N. Dist. Texas

Charged 6-16-80: while held for sale, the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to its use or intended use; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 62993; S. No. 80-221-374; N.J. No. 24)

Hemo-Tol vitamin mineral solution, Stress-Eze oral electrolytes, trace-elements combination salts, and Electrobol electrolyte supplement boluses, at Aiken, Dist. S.C.

Charged 11-27-79: while held by Vet-Aid Laboratories, Inc., Aiken, S.C., who had manufactured the Hemo-Tol solution and repacked the Stress-Eze salts using interstate components, all of the articles were new animal drugs and no New Animal Drug Applications were in effect with respect to their uses and intended uses—501(a)(5); and the Hemo-Tol solution and Stress-Eze salts had been processed in an unregistered establishment—502(o); the article was claimed by the dealer-processor who denied the charges. The government served written interrogatories on the claimant. After a hearing before the court, the court accepted the claimant's request to withdraw its claim. The government moved for entry of a default decree. Ultimately, a default decree ordered the articles destroyed. (F.D.C. No. 62669; S. No. 79-163-825 et al.; N.J. No. 25)

MEDICAL DEVICE

Muscle stimulator, electrical, Vitatone 2000E, at New York, S. Dist. N.Y.

Charged 1-21-81: the article, which was held by Tone n' Trim Centers Inc., New York, N.Y., and which was accompanied by labeling, such as booklets entitled "Congratulations . . . Lose Inches Without Special Fads, Foods, Diets, or Exercise . . . Tone N' Trim Centers, Inc." and "Vitatone International Limited . . . Training and Sales Manual," had in its accompanying labeling false and misleading claims for losing inches without dieting, pills, hypnosis or exercise; trimming the user's body to perfect shape; slimming; putting curves in the right places; eliminating flab; working off cellulite; being an effortless way to lose inches without special fads, food, diet or exercise; melting inches off exactly where you want, in specific areas—legs, thighs, hips, waist, abdomen, buttocks and upper arms; and being equivalent to 1,500 sit-ups when used for 36 minutes—502(a); the article's labeling lacked adequate directions for use—502(f)(1); and the labeling lacked adequate warnings against unsafe uses, such as use in conditions of pregnancy, varicose veins, cardiac conditions and conditions requiring a pacemaker—502(f)(2). Default decree ordered destruction. (F.D.C. No. 63105; S. No. 80-200-209; N.J. No. 26)

NOTICE OF JUDGMENT on Forfeiture and Contempt Action

Larson Laboratories Inc., and Arthur Z. Berenstein, president, Erie, W. Dist. Pa.

Charged 3-6-78 in a petition to revoke and forfeit a bond and in a petition for an order to show cause in criminal contempt: that the defendants violated a consent decree of condemnation in a seizure action (see N.J. No. 22 of this issue of FDA CONSUMER) as follows: by the failure to retain intact the entire lot of seized goods until released by FDA, since some of the seized drug components (e.g., parachlorometaxyleneol, 1,1,1 trichloroethane, and zephiran chloride)



had been used in the production of lot 22 of JC-6, lot 24 of JC-5, a lot of an industrial product, and lots 34, 35 and 36 of Mint Glo; by the shipping and selling of parts of the products containing portions of the seized articles (e.g., lot 22 of JC-6 and lot 23 of JC-5 offered for sale and shipped to Buffalo, N.Y., and lots 35 and 36 of Mint Glo offered for sale and shipped to Pueblo, Colo.), and by the sale and disposal of parts of the seized articles in a manner contrary to law, in that each of the drugs manufactured from the seized articles and shipped by the defendants had been manufactured, processed and packed under circumstances that failed to conform with current good manufacturing practice. After a hearing by the court, the court decreed that the provision of the consent decree concerning retaining the articles intact had been violated, that the bond was therefore revoked, and that the \$2,000 portion of the bond which had been deposited was forfeited to the government. However, the court modified the consent decree to permit the defendants to tender a 90-day unsecured note in lieu of full payment of costs, fees, storage and other expenses required to be made before the seized goods are released.

The court also found the individual defendant guilty of contempt of court, but suspended imposition of sentence and imposed no fine or costs. (F.D.C. No. 61478; S. No. 77-04-334 et al.; N.J. No. 27)

NOTICE OF JUDGMENT on Criminal Action

Van Brunt Stores, Inc., and Wallace B. Shapiro, vice president, Brooklyn, E. Dist. N.Y.

Charged 9-28-79: cocoa press cake, flour, turmeric and cocoa beans were held in a building under insanitary conditions and were exposed to contamination by rodents; 402(a)(4). Guilty plea to counts involving cocoa press cake and turmeric by individual; \$1,000 fine. Guilty plea to counts involving flour and cocoa beans by corporation; \$1,000 fine. (F.D.C. No. 61931; S. No. 76-40-868 et al.; N.J. No. 28)

NOTICES OF JUDGMENT on Injunction Actions

Lawrence Gross, president of Van Brunt Stores Inc., Brooklyn, E. Dist. N.Y.

Charged 2-24-81 in a complaint for injunction: that the defendant had engaged in storing foods, including cocoa and coffee beans, raisins, turmeric, cocoa press cake and flour, after shipment in interstate commerce; and that holding such food for sale in an unsanitary warehouse resulted in the food being adulterated; 402(a)(3), 402(a)(4).

The defendant consented, without acknowledging the truth of the allegations of the complaint, to a decree of permanent injunction which permanently enjoined the complained of violations and which enjoined him for five years from directly or indirectly doing or causing the storage of any food for profit or sale anywhere in the Eastern District of New York other than food held at that time under U.S. Customs Service general order storage, and providing 30 days to remove certain foods held at the Van Brunt Street warehouse. (F.D.C. No. 61931; S. No. 76-40-868 et al.; N.J. No. 29)

Billy D. Hicks, t/a Hicks & Associates, at McGehee, E. Dist. Ark.

Charged 11-20-75 in a complaint for injunction: that the defendant was in the business of marketing, holding for sale, and distributing in interstate commerce salvage grains and other ingredients for animal feed use (including cottonseed meal, cottonseed oil and cottonseed hulls) that FDA investigation showed an agreement with a Tunica, Miss., oil mill to receive and process poison-treated cottonseed and to deliver to the defendant or his agent the resulting cottonseed oil, cottonseed meal and cottonseed hulls; that the invoices prepared by the oil mill bore the disclaimer "Fertilizer, chemical and industrial use only," and the shipping records bore the disclaimer "Fertilizer use only"; that such meal and oil were delivered and/or sold to sup-

pliers of feed ingredients in more than 30 specified railcars of animal foods (including railcar lots of finished feed made with such feed ingredients); that such animal foods had been found to be contaminated with pesticides, fungicides and other poisonous or deleterious substances; that while held for sale after interstate shipment or when distributed in interstate commerce, such animal foods were violative in one or more of the following respects: the article contained a non-conforming food additive (e.g., pentachloronitrobenzene, Disyston and chloroneb) since the use and intended use of the food additive was not in conformity with a regulation or exemption, and the article contained the added poisonous and deleterious substance mercury; that labeling (i.e., the invoices and some bills of lading) which accompanied the sale and delivery of such articles to the defendant in care of the railroad agent at Tunica, Miss., or in care of others elsewhere, bore fertilizer-use-only disclaimers, but the defendant failed to inform his customers, either verbally or in writing, that such articles were not suitable for feed use; that the defendant violated the law by causing the shipment in interstate commerce of such articles, by receiving in interstate commerce such articles and causing their delivery for pay or otherwise, and by failing to reveal, either verbally or in writing, that the cottonseed meal was not suitable for food use thereby causing the resale and reshipment on invoices without the statement that the article was not suitable for food use; 402(a)(1), 402(a)(2)(c), 403(a).

The court issued a temporary restraining order. Subsequently, a consent decree of permanent injunction enjoined the complained of violations, and enjoined specified commerce in interstate cottonseed meal oil and hulls, unless and until: all contaminated food controlled by defendant had been destroyed or diverted to non-food use; appropriate sampling and analytical procedures and controls were established; and a coding system was established for each shipment in order to make proper identification of such shipments. (Inj. No. 715; S. No. 76-32-058; N.J. No. 30)

Ingman Laboratories, Inc., Ralph H. Durr, president, **Robert C. Ingman**, secretary-treasurer, and **Glenn H. Kyle**, chief chemist, Minneapolis, Dist. Minn.

Charged 4-30-79 in a complaint for injunction: that the defendants were engaged, at their Minneapolis, Minn., laboratories, in the analysis of drugs which were shipped in interstate commerce or would be shipped in interstate commerce after analyses; that the circumstances used for the analyses of such drugs failed to conform with current good manufacturing practice; that FDA inspections revealed a number of specified violations of the current good manufacturing practice regulations; and that the defendants had been informed that they were analyzing finished pharmaceuticals and medicated feed in a manner violative of good manufacturing practice regulations; 501(a)(2)(B).

A consent decree of permanent injunction enjoined the complained of violations. (Inj. No. 866; S. No. 79-129-911; N.J. No. 31)

Pacific-Oriental Terminal Co., Werner Lewald, president, **Ashley A. Rucker**, terminal superintendent, and **William B. Farrelly**, asst. terminal superintendent, San Francisco, N. Dist. Calif.

Charged 11-5-76 in a complaint for injunction: that the defendants, at their San Francisco, Calif., warehouse, held for sale after interstate shipment various foods, including cinnamon quills, coffee beans, chili peppers, black pepper and lentils; that the coffee beans, cinnamon quills, lentils and chili peppers contained bird filth, and the foods had been held under insanitary conditions; that FDA inspections disclosed a number of specified insanitary conditions; that FDA laboratory analysis confirmed the bird excreta; and that the defendants had been repeatedly warned of insanitary conditions and practices in their warehouses; 402(a)(3), 402(a)(4).



The court issued a temporary restraining order restraining the complained of violations. The court also issued a complaint for forfeiture against one lot of chili peppers which contained bird excreta. Subsequent FDA inspection did not reveal any new contamination from either pigeons or rodents, and the government's motion for a preliminary injunction was withdrawn from the court's calendar. Subsequently, the parties stipulated that the action might be dismissed with each party to bear its own costs. (Inj. 749; S. No. 77-73-910 et al.; N.J. No. 32)

Tarke Warehouse Inc., Louis Tarke, president, **Gordon L. Rohleder**, secretary, Meridian, E. Dist. Calif.

Charged 12-4-78 in a complaint for injunction: that the defendants, at their Meridian, Calif., mill and warehouses, were cleaning, polishing, storing and distributing in interstate commerce various types of dried beans; that, when distributed, the beans contained insects and insect filth and had been held under insanitary conditions; that FDA inspection disclosed a number of specified insanitary conditions and practices; that FDA laboratory analyses identified a number of specified insects and insect filth and identified specified rodent filth; and that the defendants knew of the insect/rodent problem in their plant; 402(a)(3), 402(a)(4).

The parties consented to a temporary restraining order enjoining the complained of violations. Subsequently, a consent decree of permanent injunction was entered. (Inj. 879; S. No. 78-114-972; N.J. No. 33)

Van Brunt Stores, Inc., and Wallace B. Shapiro, vice president, Brooklyn, E. Dist. N.Y.

Charged 3-9-81 in a complaint for injunction: that the defendants had engaged in storing various foods, including cocoa and coffee beans, raisins, turmeric, cocoa press cake and flour, after shipment in interstate commerce, and that holding such foods for sale in an unsanitary warehouse resulted in the foods being adulterated; 402(a)(3), 402(a)(4).

The defendants consented to a decree of permanent injunction which permanently enjoined the complained of violations and which enjoined the defendants for five years from directly or indirectly doing or causing the storage of any food for profit or sale anywhere in the Eastern District of New York other than food held at that time under U.S. Customs Service general order storage and providing 30 days to remove certain foods held at the Van Brunt Street warehouse. (F.D.C. No. 61931; S. No. 76-40-868 et al.; N.J. No. 34)

NOTICE OF JUDGMENT on Miscellaneous Action

Apricot kernels, and the state embargo and detention of 6,700 cartons of such kernels, Knoxville, E. Dist. Tenn.

Charged 5-6-77 by Douglas L. Heinsohn (Millet, Pit and Seed Company, Inc.), Knoxville, Tenn., against the United States of America. Health, Education, and Welfare Secretary Joseph A. Califano. FDA Commissioner Donald Kennedy, FDA Officers Miller and Jancarek, and state agents Reeves and Stipe in a complaint for injunction and damages: that Douglas L. Heinsohn had engaged in the purchase and sale of apricot kernels to food stores and other individuals and companies as a wholesale distributor; that, acting under color of state statutes and regulations, while participating in a conspiracy, the defendants, illegally, embargoed and detained Heinsohn's apricot kernels; that such action was done to circumvent and evade applicable federal law, and thereby deprived Heinsohn of due process in violation of the Fourth, Fifth and Fourteenth Amendments to the U.S. Constitution; that there was no probable cause to believe that the apricot kernels were adulterated; that the apricot kernels did not bear or

contain any poisonous or deleterious substance which rendered them injurious to health and did not contain any quantity of any substance which would ordinarily render them injurious to health; and that the court was requested to find that the defendants' actions were illegal, to issue an injunction requiring the release of the apricot kernels, and to award extensive damages.

The court issued an order to show cause why the apricot kernels should not be released. After the federal government seized the article on May 12, 1977 (see N.J. No. 1 of this issue of FDA CONSUMER), the state of Tennessee and its agents moved that they be dismissed from the action since the relief sought was moot as to them because release of the article must be adjudicated on the merits under federal statutes, since plaintiff had not sought the remedy prescribed by state law, and since the state of Tennessee had not consented to be sued in federal court.

The federal government moved to dismiss primarily on the ground that an injunction was not an appropriate remedy against the seizure and that the seized article might not be released prior to adjudication on the merits of the federal government's Complaint for Forfeiture. Meanwhile, upon motion of Douglas L. Heinsohn (sole owner and president of Millett, Pit and Seed Co., Inc.), the Millett, Pit and Seed Co. Inc., was substituted as plaintiff and owner of the apricot kernels, and the individual was deleted.

After a hearing, the court dismissed the various defendants and ordered the action dismissed, saying:

"The State of Tennessee and the United States Government are both dismissed as improper defendants in Millet, Pit and Seed Company's civil rights action under 42 U.S.C. § 1983.

"The individual federal officials are also dismissed as they were not acting under color of State law at the times in question. The Court further finds plaintiff's conspiracy theory to be without merit.

"As to the remaining two defendants, Stipe and Reeves, the Court finds no basis upon which the plaintiff could establish an intentional violation of its constitutional rights. Plaintiff admitted that these defendants acted in good faith. Therefore, it is Ordered that plaintiff's action be, and the same hereby is, dismissed." (Misc. No. 426; N.J. No. 35)

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

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

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

Arthur Hull Hayes Jr., M.D., *Commissioner of Food and Drugs*
Washington, D.C., November 1, 1981

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