

FDA

CONSUMER

November 1980



A Food
Poisoning
Whodunit

NORLESTRIN® 28 1/50

(Norethindrone Acetate and Ethinyl Estradiol Tablets, USP)

Caution—Federal law prohibits dispensing without prescription.

Directions For Use

Oral Contraceptives (Birth Control Pills)

Do Not Take This Drug Without Your Doctor's Continued Supervision.

The oral contraceptives are powerful and effective drugs which can cause side effects in some users and should not be used at all by some women. The most serious known side effect is abnormal blood clotting which can be fatal.

Safe use of this drug requires a careful discussion with your doctor. To assist him in providing you with the necessary information, Parke-Davis has prepared a booklet written in a style understandable to you as the drug user. This provides information on the effectiveness and known hazards of the drug including warnings, side effects and who should not use it. Your doctor will give you this booklet if you ask for it and he can answer any questions you may have about the use of this drug.

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CAUTION: Oral contraceptives are of no value in the prevention or treatment of venereal disease.

Petipac® Tablet Dispenser

Each contains 21 yellow tablets and 7 white inert tablets.

Each yellow tablet contains norethindrone acetate, 1 mg; ethinyl estradiol, 50 mcg.

Your Petipac tablet dispenser consists of the attractive outer case and a replaceable refill containing 28 tablets arranged in four rows of seven. The first three rows of yellow tablets are Norlestrin. The seven white tablets in the last row are inert. Their purpose is to make your tablet schedule convenient and easy to remember.

Directions

1. The first day of your period is Day 1. On the fifth day (Day 5), start taking one *yellow* tablet daily, beginning with the tablet in the upper left corner of the Petipac. In the space provided, write the day you start. Take all the tablets in the top row first, followed by the second row, and so on. To remove a tablet, press down on it with your thumb or finger. The tablet will drop through a hole in the bottom of the Petipac. Do not press on the tablet with your thumbnail or fingernail, or any other sharp object.

If your period begins on:	Start taking tablets on:
Sunday	Thursday
Monday	Friday
Tuesday	Saturday
Wednesday	Sunday
Thursday	Monday
Friday	Tuesday
Saturday	Wednesday

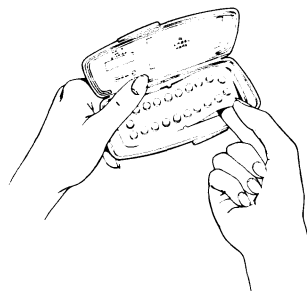
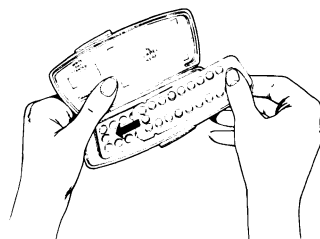
2. On the day after taking the last *yellow* tablet, begin taking one *white* tablet daily until all the tablets have been taken.

3. When the last tablet has been taken, put a new refill in your Petipac and, without interruption, begin a new course of tablets by taking the *yellow* tablets first, followed by the *white* tablets. There should never be a day when you are not taking a tablet.

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Insert new refill into Petipac by sliding under center tabs as shown. Slide refill as far left as possible.



With thumb and index finger lift right end of refill as shown and tuck under right edge.

4. After seven days, during which you take no tablets, put a new refill in your Petipac and begin a new course of tablets, taking one tablet daily for 21 days. You will always start each new course of 21 tablets on the same day of the week. Likewise, the interval of no tablets will always start on the same day of the week.

5. If spotting should occur at an unexpected time, continue to take your tablets as directed. Spotting is usually temporary and without significance. However, if bleeding should occur at an unexpected time, consult your physician. Call your physician regarding any problem or change in your general health that may concern you.

6. If you forget to take a tablet, take it as soon as you remember, even if it is the next day. Then take the next scheduled tablet at the usual time. If you miss two consecutive tablets, take two tablets daily for the next two days. Then resume the regular schedule. While there is little likelihood of pregnancy occurring if you miss only one or two tablets, the possibility of pregnancy increases with each successive day that tablets are missed. If you miss three consecutive tablets, discard any tablets remaining, and begin a new course of tablets, starting seven days after the last tablet was taken, even if you are still menstruating. You should use an alternate means of contraception, other than oral tablets, until the start of your next menstrual period.

7. If you have taken your tablets according to directions and menstruation does not occur, start another course of 21 tablets as directed. If, at the end of this course of tablets, menstruation again fails to occur, you should promptly call your physician, since the possibility of pregnancy must be ruled out before continuing medication. A supplementary method of contraception should be employed during this time.

8. If you *have not* adhered to the prescribed schedule and you miss a menstrual period, you should promptly call your physician since the possibility of pregnancy must be ruled out before continuing medication. A supplementary method of contraception should be employed at this time.

9. Refills for your Petipac may be purchased in accordance with your physician's prescription. Show the pharmacist your prescription number which is on the label inside your Petipac. Be sure to have your prescription refilled in time so that you can continue taking medication according to directions.

Keep this and all drugs out of the reach of children.

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FDA CONSUMER was previously known as **FDA PAPERS**.
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: Michael David Brown

FDA CONSUMER

A Food Poisoning Whodunit

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The culprit in this case, in which two English people died, was identified, but never tracked down. The article relates what lengths were taken to find how a can of salmon was tainted.

Making 'Clean Is Keen' a Warehouse Motto

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Warehouse sanitation is taught to the people who move the boxes and drive the forklifts in special programs. The aim is to cut down on sanitation violations, and the reactions have been positive.

Estrogens: Another Riddle for Middle Age

12

Estrogens can be used to ease the passage through the change of life, but they also can pose some problems. The pros and cons of using the drugs in middle age are discussed.

How Consumers Get Activated

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One woman in Missouri and another in New York were touched by separate, sensitive issues. Each soon found herself "fighting city hall" like any other modern-day consumer advocate.

For the Elderly, Cool Can Be Too Cold

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Hypothermia—lowered body temperatures—can be extremely dangerous for the elderly. Often it happens accidentally. Precautions that can be taken include avoiding certain drugs.

Rx With a Dose of Info

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FDA embarks on a 3-year pilot program of providing information leaflets along with 10 drugs. Patients will be given comprehensive material about those drugs. Covered will be one out of every six new prescriptions filled in a year's time.

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Inside Front Cover: *Reproduced here is an existing patient package insert (PPI) for an oral contraceptive. PPI's similar in form to this one will be provided for 10 drugs under a 3-year pilot program that FDA will begin in 1981. Details of the pilot program are covered in the article Rx With a Dose of Info.*

Fewer Tranquilizers Prescribed

The most popular drug for "coping" has been Valium. How it came on the market and what it's been doing since then was described in Overcoming with Valium, in the December 1979-January 1980 FDA CONSUMER. Here's an update.

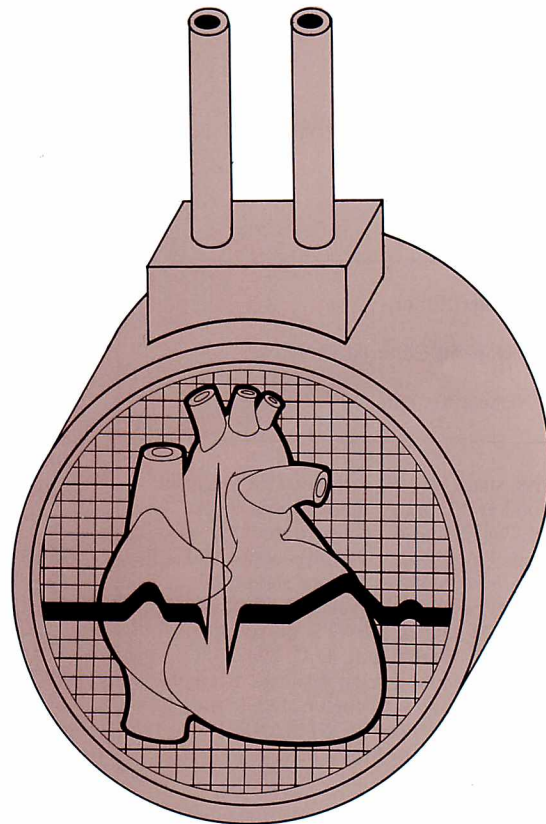
American physicians are cutting back on the number of so-called minor tranquilizers they prescribe. Legally filled prescriptions for benzodiazepines dropped from 88.3 million in 1975 to 62.3 million in 1979. The biggest drop was in prescriptions for Valium, which slipped by a third to about 38 million a year since 1975, according to statistics from the National Prescription Audit, a private survey performed as a marketing tool for drug companies, by IMS America Ltd., Ambler, Pa.

Prescriptions for sedatives, or sleeping pills, also dropped from 46 million to 32.5 million since 1975. One type of sedative, barbiturates, fell from 22.8 million to 12.8 million prescriptions after the Federal Government imposed tighter controls in 1975. Painkillers also are among the drugs being prescribed less frequently, dropping from 120 million to 104 million since 1975. The biggest drop for painkillers was in prescriptions for propoxyphene (Darvon) which went from 39.2 million in 1975 to 24.9 million last year.

Along with the decrease in the number of prescriptions for these drugs was a corresponding decrease in admissions to hospital emergency rooms as a result of their abuse. Figures compiled by the Federal Government's Drug Abuse Warning Network (DAWN) have shown that the number of incidents of Valium abuse treated in emergency rooms has been dropping steadily in recent years as the number of legal prescriptions dispensed has gone down. Much the same pattern has occurred with Darvon.

Fast Track for Medical Devices

OSMA, the Office of Small Manufacturers Assistance, is FDA's answer to the national problem of helping small businessmen understand and comply with the requirements for marketing medical devices. How OSMA does it was discussed in FDA Makes Elbow Room for Small Business, in the September 1979 FDA CONSUMER. Now the Agency has developed an alternative system for approving new devices that will particularly help these small firms. It's explained in this update.



Under an alternative system for approving new medical devices, manufacturers can ask FDA to review and approve in advance a product development protocol—a plan for testing a new device to see if it is safe and effective. This approval would help ensure that the manufacturer's laboratory and animal testing will later be acceptable to the Agency without having to be re-done.

The new system is intended to foster innovation in the medical device field and should particularly help small manufacturers, although it can be used by any device firm.

It is also designed to help reduce the costs of developing devices that are of significant medical benefit to only a small number of patients and thus have limited profit potential. Without the new system, manufacturers might be less willing to invest money in limited-use products.

Under present procedures, FDA does not evaluate new devices until the manufacturers are ready to start studies on people to see if the devices are safe and effective. Under the new alternative system, FDA will assist manufacturers by reviewing research plans before the devices are even tested in laboratories or on animals.

A similar system is in use to speed the review of promising new drugs. Products that might be suitable for development under the new procedures include new types of artificial heart valves and heart pacemakers and implantable insulin pumps for diabetics.

FDA Commissioner Dr. Jere E. Goyan said he expected the new system to particularly benefit small companies, which are generally in greatest need of FDA's early technical review in planning suitable studies and evaluating the results.

The new procedures are explained in a guideline available from FDA's Bureau of Medical Devices. Availability of the guideline was announced in the FEDERAL REGISTER of September 19.

Cyclamate Ban Remains

Cyclamate, once the most popular artificial sweetener on America's tables, was banned by FDA in 1970. Its status was reviewed in Saccharin: Where Do We Go From Here? in the April 1978 FDA CONSUMER, and various News Highlights in subsequent issues. Here's an update.

FDA has denied a petition by Abbott Laboratories, North Chicago, Ill., to remarket the artificial sweetener cyclamate. Announcement of the action was made September 4.

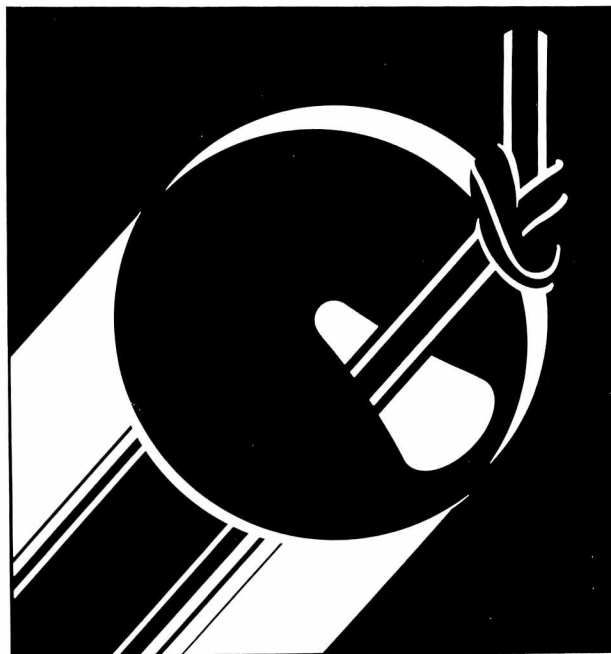
During the 1950's and 1960's cyclamate was the most popular artificial sweetener, but it was banned in 1970 after a study implicated it as a possible carcinogen. It originally had been approved by FDA in 1951.

After reviewing all the data submitted by Abbott, FDA Commissioner Dr. Jere E. Goyan said that the Agency has concluded cyclamate was not shown safe. Specifically, he said the studies failed to prove that cyclamate does not cause cancer or inheritable genetic damage.

Goyan said the evidence he reviewed included scientific studies in mice and rats that found increased numbers of lung, liver, bladder, and lymph system tumors in these animals given cyclamate.

Animal studies found that cyclamate could cause adverse effects on chromosomes, which suggest that the sweetener could cause inheritable genetic damage that can lead to diseases, such as Down's syndrome, mental retardation, and alterations in metabolism.

Goyan pointed out that the law requires FDA to deny approval of a food additive if the data fail to



establish its safety. "Safety" in this context means a reasonable certainty of no harm. The law places the burden for proving safety on the company seeking to market the additive; the law does not require FDA to prove lack of safety, Goyan explained.

Abbott's petition to remarket cyclamate was submitted in November 1973. Dr. Alexander M. Schmidt, then Commissioner of FDA, denied the petition in October 1976. Abbott objected, and asked for a formal hearing. It began in April 1977, before FDA Administrative Law Judge Daniel J. Davidson. In August 1978, he ruled that cyclamate had not been shown to be safe.

However, then Commissioner Donald Kennedy, after reviewing the hearing record, remanded the case to Davidson to develop further evidence on a number of safety issues. The hearing was reopened in September 1979, and on February 4, 1980, Davidson concluded, "It is apparent that the reevaluation of the evidence presented on further hearing tends to increase the likelihood that cyclamate is a carcinogen."

Goyan's decision is based on a review of the entire hearing record including Davidson's recommendation.

A Food Poisoning

WHODUNIT

There was no disputing the fact that a can of contaminated salmon caused the botulism that led to the deaths of two people in England, in July 1978. But how did the contamination happen, and why? The search for the answer led to one of the most exhaustive international investigations in the annals of public health.

by Emil Corwin

At about 5 o'clock on the evening of July 30, 1978, two retired brothers, Jesse and Leonard Farmer, and their wives sat down to a light Sunday dinner at the Jesse Farmers' modest flat at Shard End on the outskirts of Birmingham—England's second largest city—about 100 miles north of London.

The Farmer couples lived about 2 miles apart and visited frequently. On this Sunday they began their meal with fresh fruit and fruit juice, followed by a salad consisting of tomatoes, lettuce, cucumbers, and canned salmon. They also had bread and butter, and tea with canned milk. Their meal finished, the couples sat around chatting until it was time for the Leonard Farmers to leave for their home in nearby South Yardley.

At 2 o'clock the following morning Jesse Farmer, 64, and his wife Bessie, 66, awoke feeling sick. They vomited, later complained of dryness in their mouths, blurred vision, and difficulty in swallowing and speaking. At about 6 a.m. they were taken by ambulance to the East Birmingham General Hospital. In South Yardley, police summoned to the home of Leonard Farmer, 79, and his wife Clara, 72, found both of them seriously ill. They also were taken by ambulance to the hospital, arriving an hour after the Jesse Farmers.

The four patients were placed in intensive care for respiratory assistance when paralysis of the chest muscles threatened asphyxiation.

To Dr. A. P. Ball, the examining physician, the symptoms suggested botulism, a rare and dreaded type of food poisoning. The disease affects the nervous system and is often fatal. No case of botulism had been reported in England for 20 years. Botulism results from eating food contaminated by botulinal toxin, a poison that infrequently occurs in preserved foods in which spores of the microorganism *Clostridium botulinum* have survived the processing. It is the failure to inactivate these spores that produces the deadly poison, which is really a byproduct of growth. Even after adequate processing, contamination can occur if spores of the bacterium enter the can.

The search for the poisoned food began early on Mon-

day, July 31, soon after the Farmer couples were hospitalized. Although finding the cause of the food contamination proved to be a fruitless, needle-in-the-haystack search, it created an international crisis and touched off one of the most far-reaching investigations in the annals of public health. Such consequences didn't seem likely at the time to Roger Beery, a food specialist at the Birmingham Environmental Health Department, who went with a policeman to the Farmer home to collect food remnants for laboratory analysis. He found a neat home, but noticed there was no refrigerator. He picked up the remains of a pudding, some cooked chicken left over from an earlier meal, and an empty salmon can. The "evidence" was brought to Dr. James Hutchinson, director of the Midland Laboratory Services in Birmingham, for microbiological examination.

The chicken and pudding were ruled out as a source of the botulinal toxin since they showed no pathogenic or unusual microorganisms. So Dr. Hutchinson focused his attention on the can of salmon. He noticed it had a slightly strong odor, however one not objectionable enough, as he said, "to put me off" from eating the contents. (An insidious aspect of botulinal contamination is that the toxin sometimes can develop in a food without producing spoilage odors or other signs of deterioration.) But this time Dr. Hutchinson's preliminary laboratory tests of salmon particles suggested that the salmon was the source of the botulism episode. For confirmation he sent his findings and the suspect can to the Food Hygiene Laboratory in London, a unit of the Department of Health and Social Security. By this time, the patients' symptoms, plus the early laboratory results from testing the salmon residue, had made the outcome of the London tests practically certain.

A botulism alert, it has been said, is "as dramatic and highly prioritized as a hurricane warning." Within hours of the incident in Birmingham, the appropriate scientific and investigative resources of Great Britain and the United States were mobilized to track down the cause of the salmon contamination.

When word reached the Food and Drug Administration in Washington, the suspected salmon had been traced to an Alaska cannery. The Agency's Emergency Command Center, a unit of the Epidemiology and Environmental Health branch, which is on alert day and night to deal with such emergency problems, sprang into action. Richard Swanson immediately telephoned Dr. Richard Gilbert, director of the London Food Hygiene Laboratory:

SWANSON: Did you check the can seam?

GILBERT: Mercy, no. We have our hands full confirming the clinical diagnosis.

SWANSON: Why did they suspect only salmon?

GILBERT: Because we observed gram positive sporulating rods in the can in large numbers and further, we injected mice and the mice died with characteristic botulism symptoms—wheezing and extended hind legs.

Because Dr. Hutchinson, in Birmingham, and Dr. Gilbert, in London, were looking at the patients and food under suspicion, they failed to notice that the salmon can itself had a rusty, abraded area on the bottom seam through which botulinum spores might have entered to eventually cause all the trouble. Botulinum spores are normally harmless, but when not destroyed by heat, and when in the kind of environment suitable for growth, the spores will begin reproduction or sporulation and produce the lethal toxin. Botulinal microorganisms are classified as anaerobes, that is, their spores grow only in an oxygenless environment (anaerobic growth). This growth may occur in sealed cans, jars, plastic bags, or in any place where the organism is shut off from the air and other conditions such as temperatures and acidity of food are favorable for growth. If spores of this ubiquitous microorganism enter or are drawn through a hole in a can, it is hypothesized that the gaseous condition produced by food spoilage microorganisms can cause the hole to be clogged with food and seal live spores in the oxygenless environment necessary for them to sporulate and begin producing their deadly toxin.

In a botulism poisoning incident, there's no waiting for confirmation of laboratory tests to move to prevent further incidents, and there was no waiting this time in London or in Washington to do what was required to prevent other possibly contaminated stock from reaching consumers and to determine the cause for the contamination of the can of salmon.

On the same day that the Farmers were confined to the Birmingham hospital, the British Department of Health and Social Security issued warnings to the public not to buy American or Canadian salmon and not to open their old stock if they had any doubts about the product. The department also sent a cautiously worded telegram to the British Embassy in Washington, the British Commissioner in Ottawa and Canada's Department of Health and Welfare that read as follows:

Advising that four elderly people were admitted to hospital in Birmingham suffering from what appears botulism. The source of the disease seems to have been a 7 ½ ounce can of John West salmon from North America. You will wish to take such action as you consider necessary to ensure that this warning is effective.

John West Foods, Ltd., the British importers, issued a press release announcing they would take back any of the 400,000 cans they had distributed bearing the same code number as the suspected "index" can. This release went on to say:

The suspect salmon was purchased from a highly reputable canner in the U.S. The canned salmon is subject to many checks before it is sold . . . It has been sold for over 100 years and in great quantities

in the United States and throughout the world . . . 100 million cans per year were sold . . . No previous case of botulism has been proved in canned salmon. Full efforts are being made by the company to locate cans bearing the suspect code. It is too early at this stage to say when clearance for the resumption for sale will be given.

This importer's reference to "many checks" being made to assure the safety of salmon is something of an understatement. Salmon canning is one of the most thoroughly inspected food processing preparations in the United States. This industry has a voluntary Salmon Control Plan which since the 1930's has been most effective in minimizing the processing of an unsafe product. In addition, FDA's food processing inspection program, known as the Hazard Analysis Critical Control Point (HACCP), begun several years ago, is designed to spot potential hazards at critical points in the canning process. FDA's Good Manufacturing Practice (GMP) regulation for thermally processed low-acid canned foods is the most extensive and detailed of all FDA GMP's. It covers more than 40 pages in the CODE OF FEDERAL REGULATIONS, including diagrams of complete and proper thermal processing machinery.

With such safeguards as the industry and Government-administered Salmon Control Plan, the GMP regulations for thermal food processing, and the intensive inspection program, how could anything go wrong? How did it happen? On the United Kingdom side, John West looked for some answers. John West sent the retrieved cans to the laboratories of Unilever, its parent company, for a series of microbiological tests. The suspect can itself was studied for possible defects, first by canning experts at the London can manufacturing firm of Metal Box, Ltd., and then at the laboratory of the Government Chemist.

Official confirmation of botulinal contamination awaited the outcome of tests conducted at London's Food Hygiene Laboratory under the supervision of Dr. R. H. G. Charles, chief medical officer in charge of the investigation in England. In one test, minute particles of salmon rinsed from the original can with a saline solution revealed the "shadow" of botulinal spores. In another test, a few drops of the washing from the can cultured in agar showed anaerobic growth. In a third test, a solution from the suspect can injected into a mouse killed it in 80 minutes. The evidence clearly pointed to the patients being victims of botulinal poisoning. The clincher came on August 4 when serum from the blood of the four patients, still in intensive care, was injected into four mice. Botulism symptoms appeared in 2 ½ hours and within 4 hours all 4 mice were dead.

FDA was informed that the botulism verdict was official. By this time the U.S. agency was already 3 days into the investigation and the searchlight had shifted from London to two focal points in the Pacific Northwest—False Pass, Alaska, where the suspect salmon was canned, and Seattle, the headquarters of the cannery owner, Peter Pan Seafoods, Inc., and location of the company's salmon storage facilities.

Peter Pan stopped distribution. Importers in foreign locales which had received Peter Pan salmon under the John West label—in Canada, Australia, South Africa, Singapore, and Hong Kong—were requested to return or

to hold all of the 1977 pack. There were no returns, but Australia sent to FDA (via diplomatic pouch to the State Department), 48 cans of the salmon for testing before releasing the rest of its 1977 consignment. The FDA tests were negative and marketing of the salmon was resumed in that country.

Notwithstanding this evidence of safety of the 1977 pack, FDA instructed its Seattle District Office to collect all of the cannery processing and inspection records for Peter Pan's 1977 and 1978 packs, and also to send investigators to the Alaska cannery in False Pass.

The cannery visit was not the easiest assignment that Norman Wong and Dan Schneringer had ever undertaken. Briefcases stuffed with Peter Pan Seafood's overseas shipment records of the suspect code, plus data on processing and seam records, the investigators flew from Seattle to Cold Bay, Alaska, the location of a U.S. military base during World War II. There they boarded a single engine plane, with a "bush" pilot at the controls, for what proved to be a hazardous 2-hour flight to False Pass on bleak, wind-swept Unimak Island, in the Aleutians. The aircraft, buffeted by strong winds and a heavy rain, landed precariously on an airstrip that had been cut by a flooding stream. Since the cannery was the only building at False Pass, and there was no room for visitors in the plywood shanties where employees lived, the FDA men passed the next two nights in their sleeping bags on the cannery floor. Their assignment was to determine whether the salmon contamination was attributable to inadequate thermal (heat) processing done to render the contents sterile or to a leak in the can resulting from faulty closure or handling.

FDA meanwhile dispatched a second team of investigators—Dr. Thomas Mulvaney and Frank Barnes—to England to review the botulinal tests and to trace the movement of the implicated can of salmon. In Birmingham they reviewed a health department report about the Farmer couples and then visited the supermarket where the salmon was purchased to look for any evidence that there had been can damage in handling. In Liverpool, they inspected the John West warehouse, where labels were put on the cans to see if, in that process, botulinal spores in the labeling paste or in environmental dust might have entered the can through a leak. Samples of the paste and swabs from the surface of the equipment cultured in meat broth proved negative, confirming similar tests performed at Unilever. In London, Mulvaney and Barnes studied the problem can with Dr. Charles and noted an apparently damaged part of the bottom seam that could have allowed escape of the large amount of gas that *C. botulinum* normally produces. They felt this might explain why the can was not swelled when opened by the Farmers.

Dr. Charles hypothesized the trouble began at the cannery, with a defect in seam formation. Other experts thought the seam damage occurred after the can was formed.

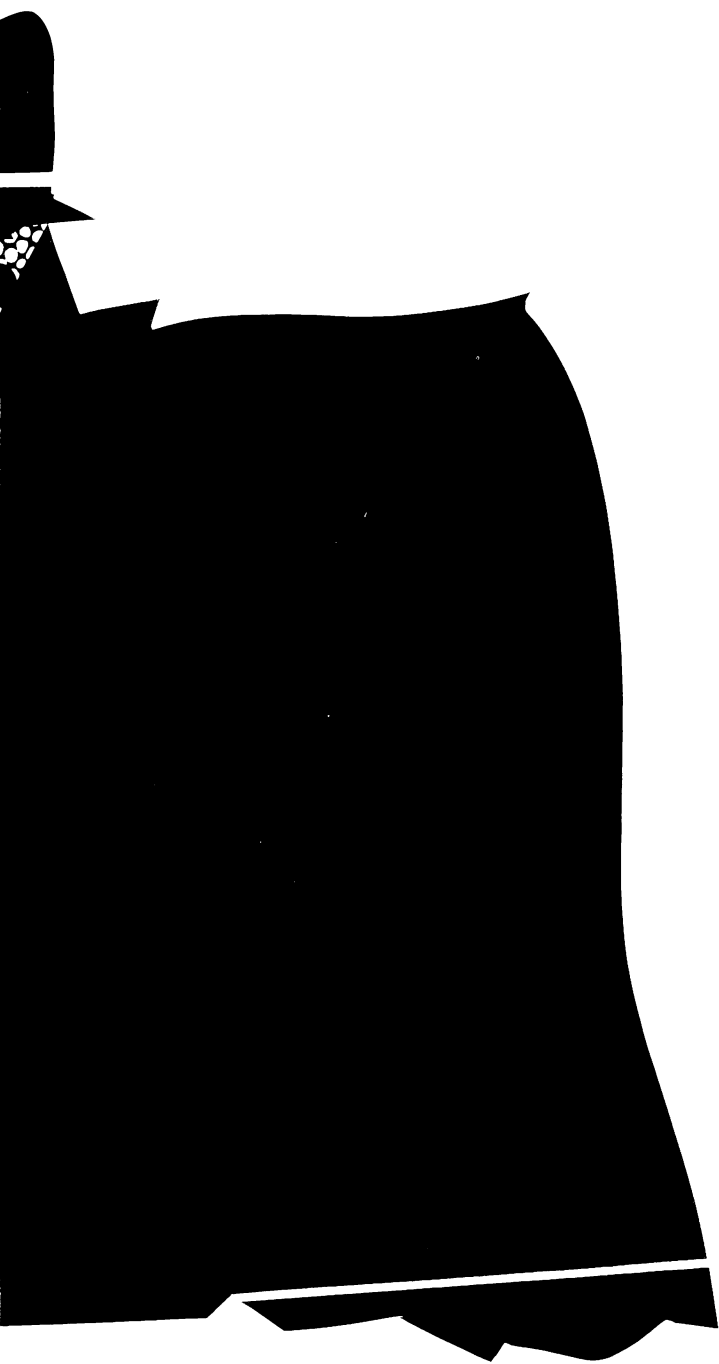
To help cannery investigators test these and other theories, British authorities were asked to send detailed information on the index can, including electron microscope pictures of swabs from the surface of the can and a spectograph analysis that could show any foreign metal left at the abrasion site on the can's double seam that might have come from malfunctioning can handling equipment.



Accordingly, the implicated salmon can in London was measured, weighed, and photographed from all angles. An artist's sketch, a movie, and color slides were made for good measure. An abrasion was noticed that had caused a microleak at the can's double seam. The investigators reported that the can seam appeared to have been worn flat for approximately 2 inches on one side of the bottom seam; the worn area had a microleak requiring 6 pounds of air pressure per square inch to produce leakage bubbles; the worn area consisted of two areas.

This description, together with the visuals of the damaged can, were sent in a diplomatic courier's pouch to FDA in Washington, transmitted by wire to Seattle and then to False Pass. The information enabled Wong and Schneringer to compare results they had obtained by experiments at the cannery with actual damage to the can, to strengthen their hypothesis about the cause of the original external damage, and how it resulted in a leaking can.

The FDA team studied each step of the cannery operation—unloading salmon caught in the Bering Sea off fish-



ing boats, depositing them in a tank to be circulated in chilled seawater, and conveying them to the fish house where the heads and fins were mechanically lopped off, the eggs removed, and the belly cavity brushed clean. The critical final stages were studied with special care as sections of the fish were placed in a can with a salt tablet, the can was seamed and moved to the retort for thermal processing, and afterward moved to the cooler trays to complete the processing. Everything checked out; there was no undercooking, no seam defects or leaks similar to that of the implicated can. Could the seam damage be caused by one can hitting the other as the filled cans slid down the metal chute into the metal retort basket? This too was tested, but there was no can damage.

The only faulty practice noted at False Pass was that workers from the slaughtering area were placing their wet gloves and aprons to dry on the retort baskets loaded with hot retorted cans. It was conjectured that if there was a leak in any of the hot cans, the suction created by cooling could draw in botulinum spores from the work-

ers' clothes. However, some botulinum spores could be expected on cans handled in an environment of this kind, even in the absence of these faulty practices. The critical safety factors are container integrity, retorting room processes, and can handling equipment sanitation.

Several other theories were considered and tested. In England, for example, 1,500 cans of salmon were deliberately damaged at Unilever and then challenged with spores in a variety of ways so the investigators could more fully understand the routes by which the botulinal strain may have entered the can. The cans were examined for botulinal toxin and the open cans were photographed at intervals.

On the theory that the hole on the bottom of the can may have been caused by a conveyor belt "burn," the FDA investigators ran experiments at the cannery to find the possible effects of several hours of continuous abrasion on 7½-ounce cans. None of the cans wore through.

No clue, however remote, was overlooked. Thus, when it was reported that someone with a handsaw might have cut the index can while sawing a piece of wood on a case of salmon cans, tests were held to determine whether wood fibers carrying botulism spores could enter an opening in a "damaged" can and infect the contents. A number of cans were subjected to this sawing action and sent to England for examination. Photomicrographs and other examinations revealed no evidence of saw-type damage.

In early September 1978, FDA sent Donald Kautter, of its Microbiology Division, and Dr. Mulvaney to England to meet with British health authorities, and representatives of Unilever, Metal Box, Ltd., and the U.S. National Food Processors Association to review the various theories and all the biological and mechanical test results received up to that time.

When all tests and examinations had failed to show any definite sign of canning error, or any likelihood of further contamination, the British Department of Health and Social Security withdrew its warning advising the public not to eat canned salmon from the United States. On September 19, 1978, the department announced that the investigations had not revealed with certainty the cause of the damage to the can or how it came to be contaminated. "It is very unlikely that any other cans from the cannery have been similarly contaminated, but the possibility cannot be ruled out," the department said.

Lifting of the warning against buying U.S. salmon came 1 month after Jesse Farmer died of botulism. He died on August 16, 1978, 17 days after being admitted to the hospital. His wife died of the same disease a week later, on August 24; both were victims of an accidental food contamination of still undetermined cause. As the LONDON TIMES put it, the couple had obtained one faulty tin in thousands or millions. The older Farmer couple, the Leonard Farmers, recovered and were discharged from the hospital.

Such is a public health detective story. The "criminal" may prove elusive but the search continues.

Emil Corwin in a member of FDA's public affairs staff.





Making 'Clean Is Keen' A Warehouse Motto

FDA's message to operators of food storage warehouses is a simple one: Ignorance of the law is no excuse when it comes to good sanitation practices. Some FDA regional and district offices are using educational workshops to stress the point that informed warehouse operators and their employees are the real solution to any food contamination problem.

by Chris Lecos

The one-story warehouse stands on a 5-acre site in a rural area about 25 miles northwest of Boston. Built 8 years ago, it has an enclosed rail siding and truck shipping docks. About \$200 million worth of food flows in and out of the modern facility each year—stored there until it is shipped to retail food outlets in Massachusetts and New Hampshire.

The first indication of insanitary conditions in this warehouse occurred about 3 years ago when two investigators for the Food and Drug Administration went there to check on a consumer's allegation of glass in a can of tuna fish. Their mission took on added dimensions after they observed signs of rodent infestation—pellets, nesting material, gnawed paper goods, and a strong odor of urine around a shipment of canned fruit juices warehouse employees were cleaning up and which, they admitted to the inspectors, had become contaminated after the shipment had been received.

A week later, a team of FDA investigators went through the warehouse making visual observations, taking notes and pictures, making tests, and collecting samples for later laboratory analysis and verification of the widespread, unchecked, rodent infestation they had found. Their examination of 80 lots of food revealed rodent filth "in, on or around" the wide variety of products. The investigation resulted in a State-imposed embargo to prevent any foods from going out of the warehouse, and a

U.S. district court approved seizure of \$4 to \$5 million worth of products.

The 80 lots of food that FDA built its case on represented only 2 percent of what was stored in the huge complex. But this was enough to tie up most of the food kept there and to persuade the court to dispatch Federal marshals to seize the products. Was all the food seized actually contaminated? The answer is no, but the fact that it was being stored under conditions whereby it might have become contaminated gave FDA the power to act under the provisions of the Federal Food, Drug, and Cosmetic Act.

According to FDA officials, this distinction in the law—whether contamination is actual or potential—is often misunderstood by many of the approximately 25,000 food storage warehouses in the United States. Lamar H. Furr, a compliance officer for FDA's district office in Atlanta, explained it this way to a group of warehousemen in Macon, Ga.: A large number of sanitation and other violations in warehouses are committed through ignorance of the law, but "you (warehouse operators) are still bound by the law whether or not you know its requirements." The law's provisions and its definitions of adulteration and other illegalities were then explained to the warehousemen.

The law, he said, further defines an adulterated food as one which had been "prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or may have become injurious to health." The emphasis is on what "may" happen.

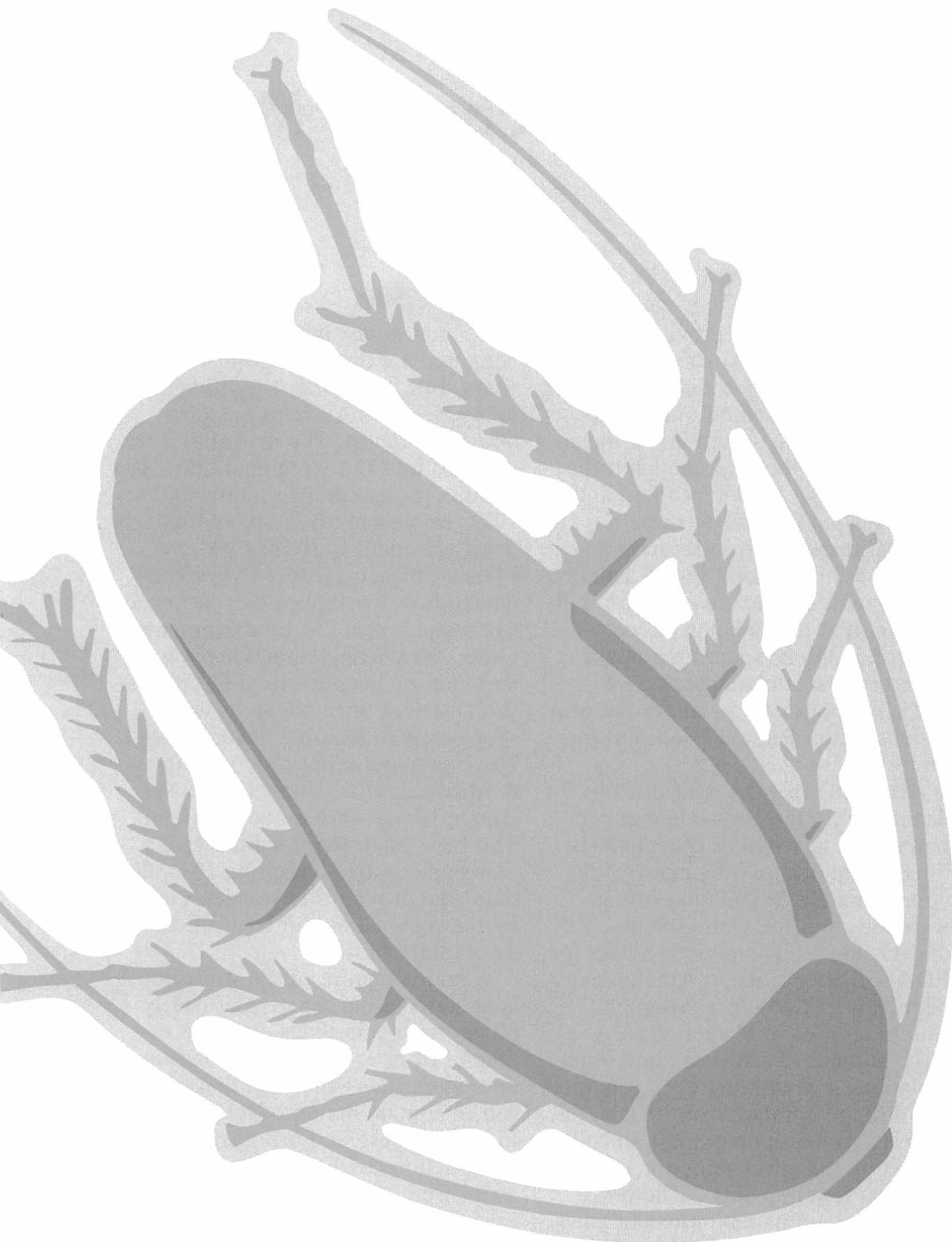
Furr continued: "This section of the law is saying simply that when food products are prepared, packed or held (as in your warehouse) under insanitary conditions, the food products are legally considered adulterated. These foods are subject to action under the law—whether or not they are actually adulterated. FDA must prove only that conditions exist that could lead to their adulteration."

It is not a new message. FDA has been making the same point for years. But it is being stressed again in a series of workshops on warehouse sanitation. The first ones were initiated by FDA's regional office in Atlanta in the closing months of 1979. Representatives of 349 food firms attended. Early this year, FDA's Chicago District Office conducted four workshops that attracted 512 people from 251 establishments. Others had been planned but were curtailed by budget cuts. FDA's Boston District Office began its workshop series in October 1980. Warehousemen and other food operators in Massachusetts, Connecticut, and Rhode Island were asked to attend. The New York Regional Office is planning sessions for spring 1981. To date, the programs have been put on by the regional and district offices on a voluntary basis.

A major feature of the workshop is an audiovisual segment of nearly 90 photographic slides of actual examples of poor warehouse conditions and operations—the kind that can result in contamination of foods stored in a warehouse and bring enforcement actions by FDA. The slides and script were prepared by FDA's Bureau of Foods Industry Programs Branch. The slide presentation was prepared so that warehouse owners and other food establishment operators can present it to employees. Maurice D. Kinslow, FDA's Atlanta regional director, said the package is a vital part of the sanitation workshops FDA officials are conducting on the local level.

"We needed something that could be directed not to owners, managers and supervisors, but to the guy who drives a forklift, sweeps up food spilled on a floor, or who unloads a boxcar," Kinslow said. "FDA and industry trade organizations have useful materials but their content has often been above the understanding of average warehouse workers," he said.

Kinslow considered the seven At-



audiovisual presentation they could borrow from us and use with their own employees to acquaint them with the facts of life of food sanitation in a warehouse.” Kinslow said he decided to undertake a warehouse sanitation program because of a number of “outrageously severe” insanitary conditions in warehouses in his region.

“It was just a perception of mine . . . that we were having an excessively high number of prosecutions, injunctions, and mass seizures against warehouse operators. It did not matter how many we were prosecuting or closing up, they still continued to come across my desk. So, we decided to have a series of workshops aimed at smaller, independent operators because some of these firms were being prosecuted for the second or third time.”

Kinslow launched the first workshop session by reminding a large audience of warehouse operators at Jackson, Miss., of the problems FDA ran into 10 years ago with the industry. Citing a random survey made by FDA in 1971 of 300 dry storage warehouses, Kinslow said the Agency had expected to find about 30 percent out of compliance; instead, its investigations showed some 60 percent were in violation of the law’s sanitation requirements. In the same year, he said, the General Accounting Office (GAO) audited 97 food manufacturing plants in 21 FDA districts and found 40 percent operating under insanitary conditions. Its findings prompted GAO to conclude that a serious sanitation problem existed in the food manufacturing industry throughout the country, leading to more money and manpower being pumped into food sanitation inspections.

“I think there has been considerable improvement over the conditions that existed 10 years ago,” Kinslow said, “but I still have too many examples of filthy, rotten conditions to be complacent about it. Very frankly, the very nature of this particular kind of violation is one that fluctuates according to the amount of

lanta Region workshops held over 2 months to be time and money well spent “because we had some unbelievably good evaluations of the workshops (from the warehouse operators).” The four workshops held by the Chicago District Office, in different Illinois cities in early 1980, were attended by more than 500 people.

“They were hungry for this kind of information,” said Philip Sheeler, district director of compliance, “and there was a lot of good give and take. They want to avoid compliance action against them. They don’t want complaints from their customers. They don’t want to get involved in recalls, seizures and injunctions. And

they don’t want any of the attendant publicity that might be generated by any legal action.”

Kinslow said he tried to encourage participation by mailing a personal letter to industry representatives in his region: “I sort of put it on the line to them that we have a lot of problems in this area, that we are taking legal actions left and right, that we are putting together these workshops, and that we would like them to attend. Sure, there was a subtle warning there, but I think it was effective in generating the kind of interest that we had.

“We felt that once we got them there we could show them something they had not been offered before, an

pressure you put on these folks. If left alone, it is so easy to slip and let little things occur that can create serious problems. Unless pressure is kept on them, they are going to regress.”

A wide variety of food products that are processed, packed, labeled, and stored in the United States come under FDA's jurisdiction. Most FDA inspections, especially those involving multiple food storage warehouses, are conducted under what is known as the Food Safety Program that was put into effect by the Agency's Bureau of Foods in the mid-1970's. Data supplied by the Bureau show a steadily increasing level of compliance under the program.

For example, during the 1975 fiscal year, a total of 11,124 inspections were made of food manufacturing, packing, labeling, and storage establishments for possible sanitation, chemical, and food and color additives violations under the Bureau's program. Of that total, 83.4 percent were found to be in compliance with the law. The total included 3,108 inspections of warehouses, of which nearly 84 percent were found to be in compliance.

At present, only about 5 percent of the inspections being made under the Food Safety Program are revealing violations of the law, requiring Agency enforcement action, although the noncompliance level for warehouses alone is around 10 percent. During the first 10 months of the 1980 fiscal year (through last July 31), less than 4 percent of the 13,000 inspections made were out of compliance with the law. The total includes 2,322 inspections of warehouses, of which slightly less than 10 percent were found to be in violation.

Sanitation problems are the predominant violations found. These are those caused primarily by rodents, insects, and birds, and, according to an earlier 1976 study by FDA, generally are responsible for almost 70 percent of the domestically produced food that has to be destroyed or diverted to nonhuman food uses because of FDA enforcement actions.

(See October issue of FDA CONSUMER.)

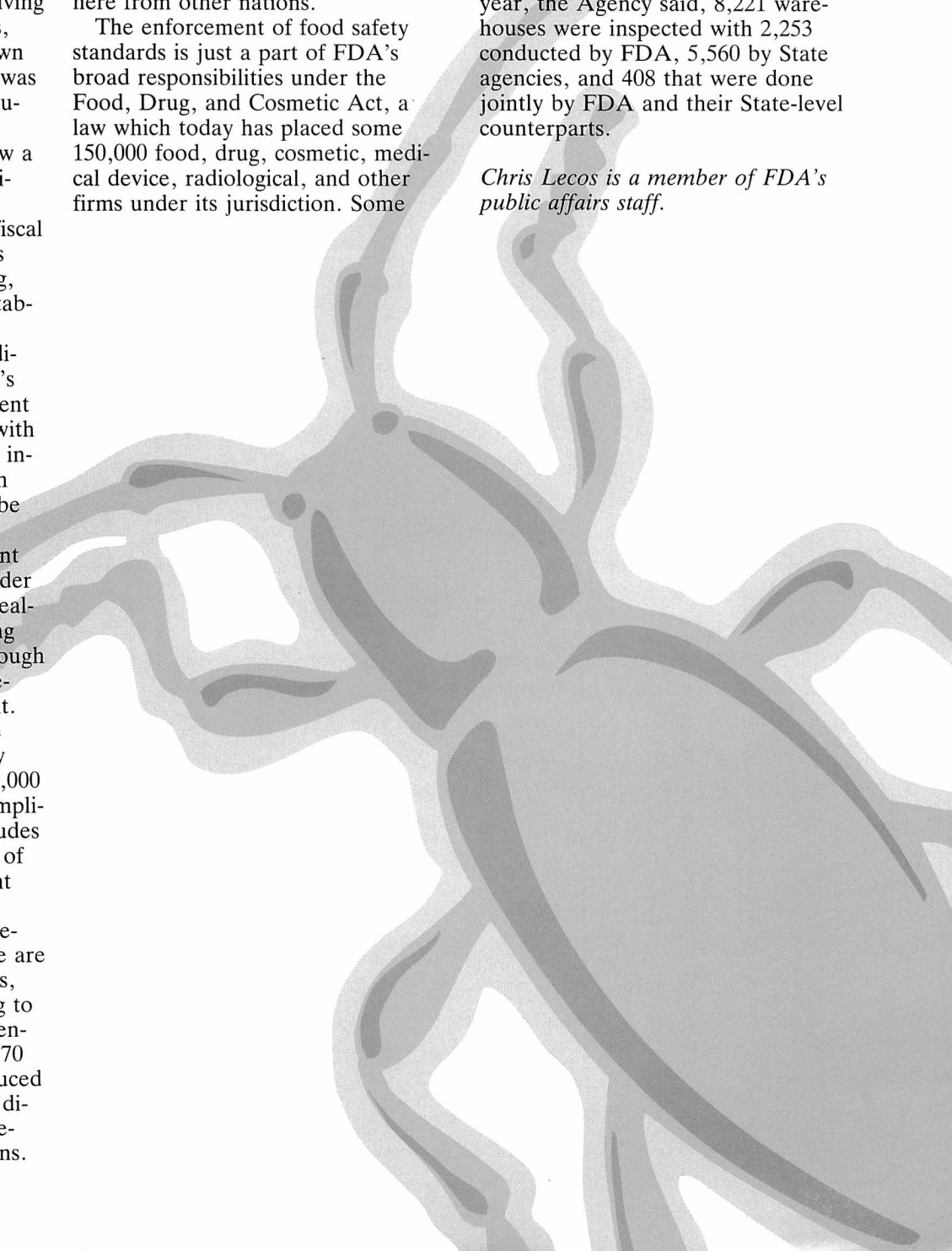
FDA officials readily admit that this effort barely scratches the surface of the total amount of food involved and that the Agency is faced with an almost impossible task of trying to monitor the safety of all foods, both that which is produced in this country as well as that imported here from other nations.

The enforcement of food safety standards is just a part of FDA's broad responsibilities under the Food, Drug, and Cosmetic Act, a law which today has placed some 150,000 food, drug, cosmetic, medical device, radiological, and other firms under its jurisdiction. Some

79,000 of these are food establishments which manufacture, process, ship, pack, relabel, and store (warehouses) food.

Currently, say FDA officials, FDA inspects food storage warehouses on the average of once every 7 years. However, FDA at present has contract arrangements for inspections with 34 States. During the 1979 fiscal year, the Agency said, 8,221 warehouses were inspected with 2,253 conducted by FDA, 5,560 by State agencies, and 408 that were done jointly by FDA and their State-level counterparts.

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





Estrogens: Another Riddle For Middle Age

Estrogens—once widely publicized as the way to remain feminine forever—can help some women through the common discomforts associated with menopause. There are risks, however, and women should learn all the facts before they ask their physicians to prescribe these drugs.

“Should I be taking estrogens?” Middle-aged women, hoping to avoid the discomforts of menopause or to hold on to a youthful appearance, often ask themselves and their physicians this question.

Unfortunately it's a question with no easy answers. Because so many factors are involved, it is not possible to make general recommendations about estrogens that will apply to all women. The decision whether to use them is up to the woman herself after she carefully considers both the benefits and the risks.

An immediate benefit is relief of the “hot flashes” or “hot flushes” (feelings of warmth in the face, neck, and chest or sudden intense episodes of heat and sweating) that many women suffer during “the change.” Estrogens also relieve vaginal changes that can cause dryness, burning, itching, and pain during intercourse in middle and later life.

On the minus side, there is the possibility that the woman taking estrogens for long periods will develop cancer of the uterus.

Risks and benefits aside, there is one thing estrogens will not do, and that is stop the process of aging or give a woman eternal youth.

Estrogen, a hormone produced largely in a woman's body, plays a key role in creating femaleness. It helps give women the appearance that makes them women, and is important to the menstrual cycle. As a woman approaches menopause, usually sometime between 40 and 55 years of age, the amount of estrogen produced by her body falls off. How quickly this happens varies from woman to woman, and so do the symptoms that go along with this change of life.

For the past 40 years or so estrogens have been available in the form of prescription drugs. Some of these preparations contain natural estrogens obtained from animal sources—such as the urine of pregnant mares. Others contain synthetic or manmade substances. Uses that medical science has found for these estrogens include contraception and the treatment of problems of menstruation, of breast cancer in women and prostate cancer in men, and of acne in young women. During the

1950's and 1960's one of the synthetic estrogens, diethylstilbestrol (DES), was widely prescribed to prevent miscarriage, with tragic results. DES not only was ineffective for this use, but increased the risk of vaginal problems for the daughters of the women who had taken it. FDA now requires that information on estrogens provided to physicians include a statement against their use by pregnant women.

While drugs containing estrogens have long been used to treat the more severe symptoms of menopause, the real boom in the use of estrogens came in the mid-1960's when millions of women were encouraged to take these drugs by the promise they would remain healthy, youthful, and sensual the rest of their lives. This tantalizing prospect was the theme of FEMININE FOREVER, a book by Dr. Robert Wilson that played a large part in the estrogen boom. Menopause could not only be cured, but prevented if treatment was started before menopause began, Wilson said. And what woman wouldn't seek this miracle treatment if she could keep her youth and avoid the horrors of age Wilson described?

Promotion of estrogens was not limited to the women of the country. Physicians also were exposed to a barrage of ads in their professional journals encouraging them to prescribe these products indefinitely. The results were predictable. Dollar sales of estrogens for noncontraceptive use quadrupled between 1962 and 1973.

Then came the bad news. In 1975 information came to light that made the medical community, FDA, and the public take a new look at estrogens. Scientific papers published in the NEW ENGLAND JOURNAL OF MEDICINE confirmed what had been suspected for years: Women treated with estrogens for more than 1 year ran an increased risk of developing endometrial cancer—a cancer of the lining of the uterus.

FDA called a meeting of its Obstetrics and Gynecology Advisory Committee in December of 1975, and after a review of these reports, the group recommended that the information about estrogens provided to health professionals (called physician labeling) be revised to underscore the risk of endometrial cancer; it also recommended that a special brochure be developed to explain to patients the risks as well as the benefits of using estrogens.

Shortly thereafter, in February 1976, FDA sent a DRUG BULLETIN to all physicians in the United States calling attention to these findings and recommending that



estrogens be used in the lowest effective dose for the shortest possible time.

The new physician labeling became effective at the end of November 1976. The patient brochure was scheduled to be distributed in September of the year following but was delayed a month by a challenge from a number of organizations, including the Pharmaceutical Manufacturers Association and the American College of Obstetricians and Gynecologists. These groups contended that FDA didn't have authority to require the brochure for patients and that this requirement interfered with the practice of medicine. These efforts to stop distribution of the brochure failed, however.

On another occasion estrogens became the center of controversy. In late 1978 two researchers writing in the *NEW ENGLAND JOURNAL OF MEDICINE* contended that the methods used in previous studies were biased and that the association between estrogens and uterine cancer had not been proved. A major study, published January 4, 1979, in the same medical journal, rebutted the charges that there were problems associated with the initial studies and reaffirmed the link between estrogen use and uterine cancer.

"Women now taking or considering taking these drugs

should read carefully the information provided with them and discuss the drugs with their doctors," Donald Kennedy, Commissioner of Food and Drugs at the time, said when the January article was published. "The drugs can be valuable in treating, for a short time, some of the most severe symptoms of menopause. But there is no evidence they are effective for many of the purposes for which they have been used. They always should be taken in the lowest effective dose for the shortest possible time."

This also was the opinion of the approximately 250 physicians, researchers, and consumers who participated in a Consensus Development Conference on Estrogen Use and Postmenopausal Women, held in September 1979 at the National Institutes of Health under the sponsorship of the National Institute on Aging. What the group concluded about the current state of knowledge concerning estrogens is summarized:

- Research confirms that estrogens are effective in relieving hot flashes and sweating, however the decision whether to start taking these hormones should depend on the severity of the symptoms and how the woman feels about her need for this relief. The occurrence of hot flashes naturally declines over a period of time and treatment should not be prolonged unnecessarily.

- Estrogens also are effective in relieving the burning, itching, and pain that can come with vaginal changes. Sometimes these symptoms have been treated with local applications of creams that contain estrogen in the hope that use of this form of the drug will avoid the risk to the rest of the body from estrogens that are taken orally. There is evidence that estrogens in these creams may be absorbed rapidly into the bloodstream. The effects of these creams required further study.

- After menopause, a woman's bones become thinner and more brittle, sometimes resulting in a condition called osteoporosis. As a result, tens of thousands of women suffer broken hips each year and many others sustain fractures of the back and arms. Several studies show that if taken for several years around the time of menopause, estrogens can slow down thinning of the bones. Studies not yet published at the time of the meeting reported a link between the use of estrogens and a decrease in osteoporosis-related fractures. However, more data are needed before it can be determined for certain whether estrogens will reduce the occurrence of fractures in older women.

- More research is needed as well on the effects of estrogens on the heart and blood vessels. There is no convincing evidence that estrogens in the usual doses increase the risk of heart attacks, stroke, or blood clots; nor has it been demonstrated that they will prevent heart disease in aging women, a once-hoped-for side effect.

Because estrogens can improve the levels of certain fatty substances in the blood, some scientists think that some day it may be shown that they help prevent heart attacks.

- At one time estrogens were viewed as a way to handle the emotional problems sometimes associated with menopause. Surveys discussed at the consensus conference have shown no connection between this stage of life and altered sleep patterns, mental performance, mood, or psychological state. There is no evidence to justify using estrogens to treat primary psychological problems. Nevertheless, estrogens may sometimes improve emotional well-being indirectly. For example, relief of severe hot flashes or vaginal discomfort can improve a woman's outlook on life. In addition, preliminary studies suggest that estrogens might help some women sleep better.

- Use of estrogens increases a woman's likelihood of developing endometrial cancer. Each year, on the average, a woman who has passed the menopause and is not taking estrogens faces a chance of about one in a thousand of developing this type of cancer. (Of course, if a woman has had a hysterectomy, she cannot develop this condition.) The risk for a woman who has been taking estrogens a number of years is several times higher than that for nonusers. Most studies suggest that after 2 to 4 years of use her yearly chance of developing endometrial cancer ranges from about 4 to 8 in 1,000. The longer she takes estrogens, the greater the risk. Once a woman stops taking estrogens, the risk falls—perhaps eventually as low as that for women who have never taken estrogens. Fortunately, most cases of endometrial cancer can be treated successfully.

- Some studies have suggested that taking other female hormones known as progestins along with estrogens might reduce the risk of endometrial cancer. However, little is known about the possible side effects of giving progestins to middle-aged women. Before this combination treatment is considered for wide use it should be studied more fully.

- Most studies do not indicate that use of estrogens increases the risk of developing breast cancer. Nevertheless, the suspicion remains, for estrogens can cause breast cancer in animals. Because this disease is the leading cause of cancer death in women, any possible association with using estrogens is of concern. Major studies in this area are under way.

- The consensus of the conference was that, as far as the individual woman is concerned, there is no pat formula for estrogen treatment. Each woman must decide for herself whether this is what she wants.

For the woman who is asking herself and her physician, "Should I take estrogens?" here are some guidelines:

Get as much information as possible. Keep alert for re-

ports of new findings. Ask your pharmacist to show you the patient brochure for estrogens.

Talk it over with your doctor. The decision to use estrogens should not be an isolated event. Rather, it should be part of a complete plan to help a woman grow older in the best possible health. You should discuss your needs with a doctor who knows you and your medical history.

Women who have had breast cancer or endometrial cancer should not take estrogens for menopausal symptoms. Nor should those who have had heart attacks, blood clots, or related conditions. It also has been suggested that women avoid estrogens if they took diethylstilbestrol (DES) to prevent miscarriage or if they were exposed to DES before birth.

Ask about alternatives to estrogen use. Other medications can help to relieve hot flashes, and vaginal lubricants can alleviate dryness and discomfort. A balanced diet rich in calcium may help to maintain strong bones. Good eating habits, plenty of exercise, and avoiding overexposure to sunlight can contribute to a youthful appearance—something estrogens cannot do. And knowing what to expect during and after the menopause can aid you in coping with this stage of life.

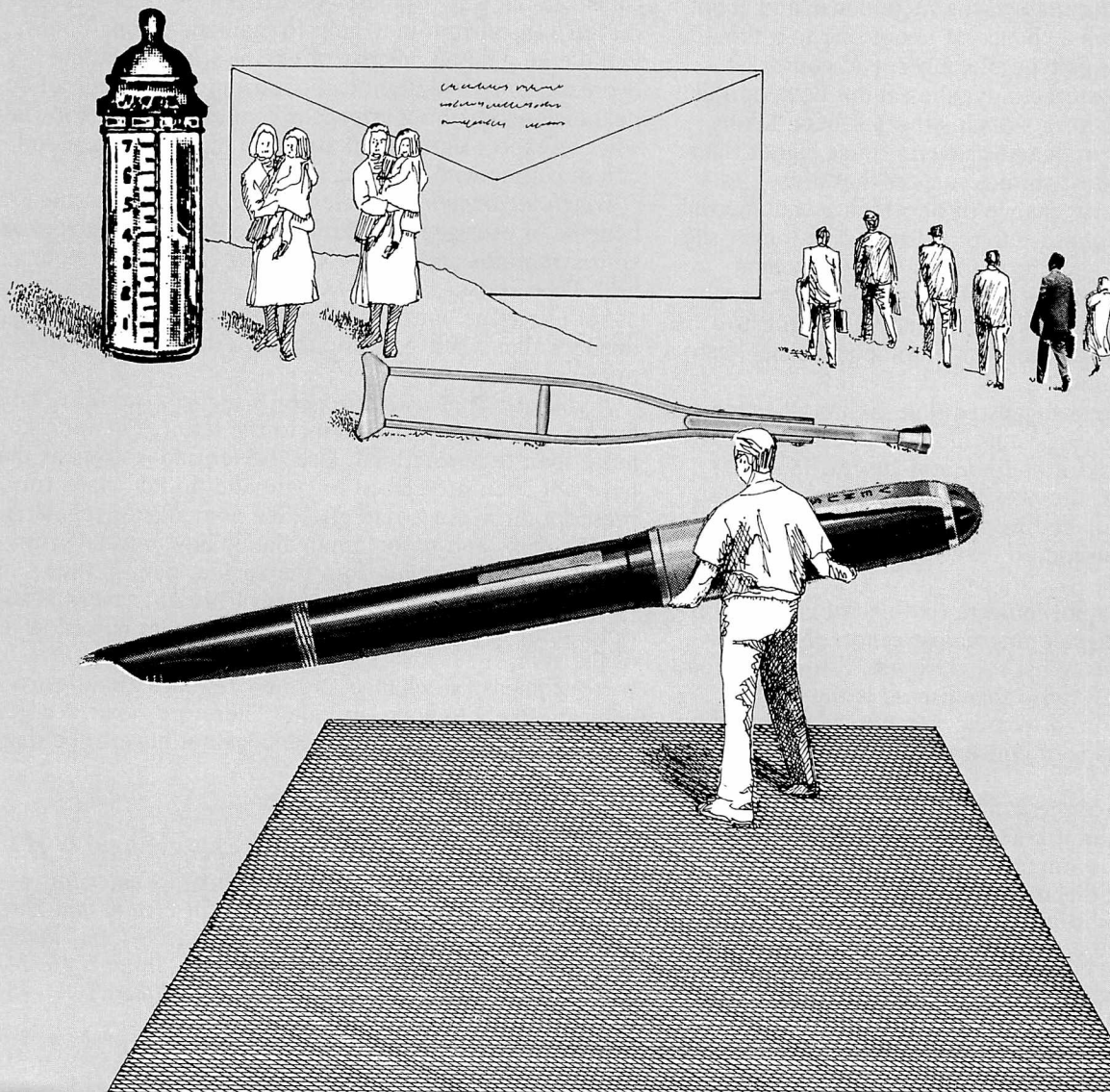
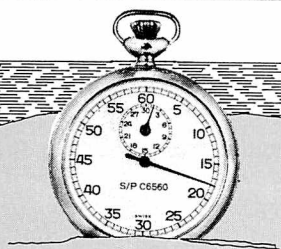
Weigh the benefits and the risks. Consider what the benefits of estrogens would mean to you. How severe are your symptoms and how would their relief affect your life? Then consider the risks. How concerned are you about estrogens' known and possible side effects? Remember that when you stop taking estrogens the symptoms may return.

If you decide to take estrogens, use them carefully. Follow your doctor's instructions to the letter. Do not take more than the prescribed dose. Never take estrogens that have not been prescribed for you and do not share your prescription with anyone else. See your doctor regularly for checkups and report immediately any unusual symptoms, such as bleeding from the vagina, pain in the calves or chest, sudden shortness of breath, severe headache, lumps in the breast, or jaundice—that is, yellowing of the skin.

Your needs can change and new findings about estrogens are likely to come to light. Therefore, your decision about whether to use estrogens does not have to be final.

★ ★ ★ ★

(Contributing to this article were Barbara Gastel, M.D., Special Assistant to the Director, National Center for Health Care Technology, Department of Health and Human Services (formerly Special Assistant, Office of the Director, National Institute on Aging), and Annabel Hecht, staff writer with FDA's Office of Public Affairs.)



How Consumers Get Activated

It takes dedication, perseverance, and an awful lot of time, but if you have something you want to say, it is possible to "fight city hall." This was the lesson two mothers learned when they decided to speak out on issues close to their hearts.

Who said "you can't fight city hall?"

This is about two women who found that if you have the time, the energy, and the dedication you can make yourself heard, even without the backing of a large or well-heeled organization. Something that happened to their children caused both to become consumer activists; both decided to speak out when they became concerned about products regulated by FDA. They are among a small but growing number of consumers who have proved that you can fight city hall.

Barbara Snyder, a suburban housewife of Kansas City, became involved because her son was affected by Neo-Mull-Soy, an infant formula that was deficient in chloride. Carol Buchholz, of East Rockaway, New York, became involved because she feared that a screening test to detect defects in unborn children would be put on the market without adequate controls, or consumer and professional education.

For Barbara Snyder, the story began when her baby, Andy, was about 2 months old. That was in February 1979. Breast fed up to that time, Andy developed a congestion his doctor thought might be related to something in his mother's milk. He was put on Neo-Mull-Soy. After a few months, Mrs. Snyder noticed a change in Andy. Instead of growing normally, he was losing weight. When hospitalized in July he was extremely pale, lethargic, and constipated.

Fortunately, Andy's pediatrician sent him to a physician who correctly diagnosed a problem which by this time had been observed in many infants across the country. A lack of chloride in the formula had caused a condition known as metabolic alka-

losis. Potassium chloride added to Andy's diet got his system back on the right track. Still undetermined is whether the child suffered any long-term effects because of the lack of an essential nutrient during crucial months of his growth.

"It's a hard thing to live with," Barbara Snyder says. At the time that Andy was at his worst she felt she was at the mercy of big business, big government, and big medicine. Still, she decided that as a consumer she had to speak out and demand that something be done to prevent such a tragedy from happening again. She called Congressman Thomas Coleman's office and was put in touch with FDA's Kansas City District Office. Here she learned that FDA was planning to hold two public hearings on infant formulas in February and March 1980. What was even better, she was told that if she wanted to testify, her expenses might be paid under a new pilot program to reimburse consumers, public interest groups, or small businesses for participating in public hearings. As it turned out, she became the second person to receive these funds, which paid for the second of two trips she made to Washington to testify at the infant formula hearings. Both times she urged that FDA set nutrient levels for these products to ensure the safety of the formulas. Such changes in FDA regulations would "revive the sagging confidence in the FDA" felt by parents of affected children, she told the assembled Government and industry representatives in March.

On the trips to Washington, Mrs. Snyder was a one-woman lobby, conferring with FDA officials, visiting Congressmen, talking to their aides, and always leaving behind innumerable copies of her statement. One of her main desires was that any proposed legislation include a requirement that every lot of infant formula be tested before going on the market.

Barbara Snyder's activist efforts did not end with her trips to Washington. She felt there were other parents in her part of the country who

had similar experiences with the infant formula and would want to know what was happening. The problem of how to get the word out was solved when she learned from two other mothers who had become infant formula activists that a Rhode Island woman reached some 200 people just by writing a letter to a consumer exchange column in a local newspaper.

Back home in Missouri, Mrs. Snyder tried the same approach. Her ad in a Kansas City paper brought a response that matched that reported from Rhode Island. The whole thing "just snowballed," she recalls. TV and newspaper stories, sparked by the ad, gave a big boost to her efforts to reach affected families. She lost count of the total number of parents and physicians who called, but now has a card file of some 240 parents who want to be kept informed about the formulas.

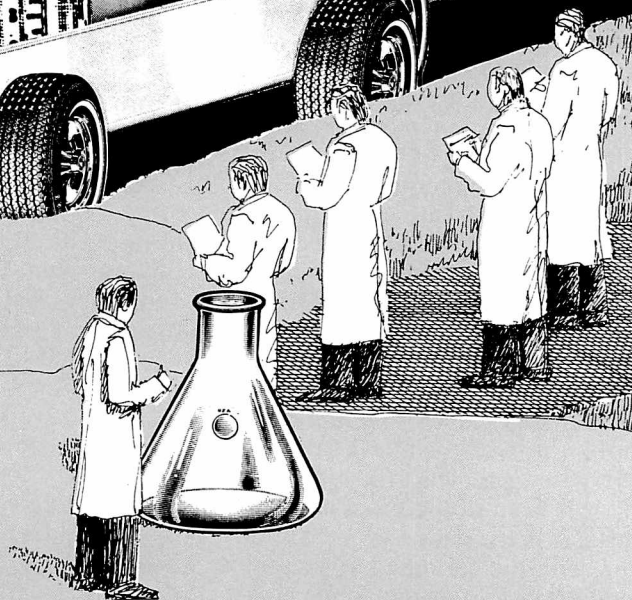
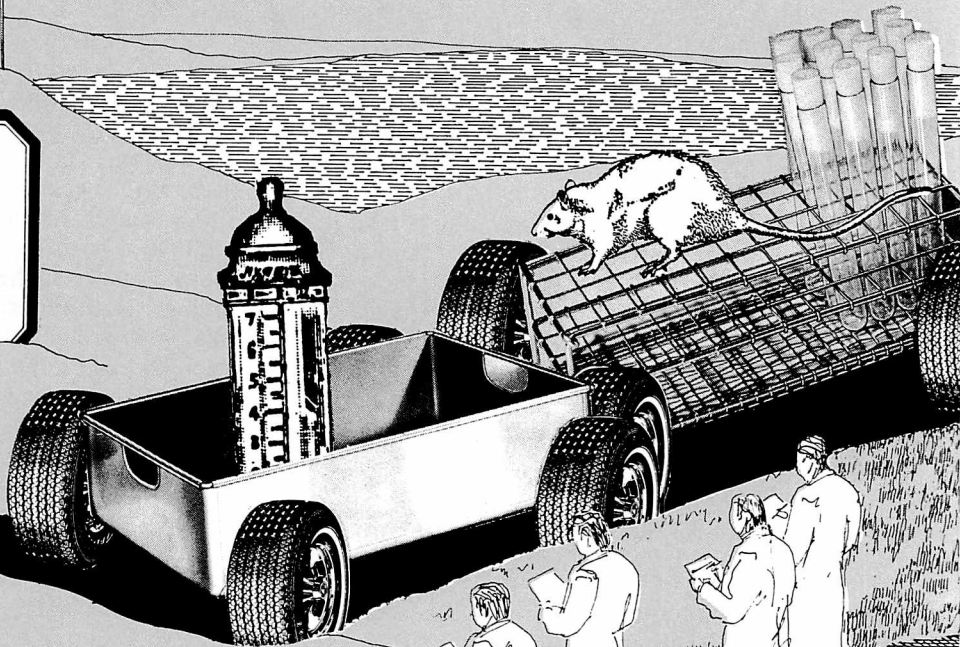
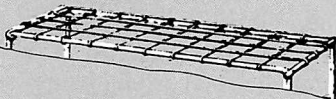
With the help of two other families, the Snyders organized a meeting of parents in late March, issuing a personal telephone invitation to all who had expressed an interest in the formula problem. According to newspaper accounts, 200 parents overran a small motel meeting room to learn more about what had happened since the chloride deficiency problem was pinpointed. A newsletter sent out by the Snyders brought about 100 people to a second meeting in May. Among the speakers were representatives of three Congressmen, and Dr. Shane Roy, a Memphis pediatrician who was one of the first to link the formula with metabolic alkalosis. Also on the program from FDA's Bureau of Foods was Dr. Allan Forbes, who outlined what the Agency was doing to regulate infant formulas.

Although some parents in other areas are suing the manufacturer of the defective formula, legal action was not the purpose of the Kansas City meetings. As Barbara Snyder explains, the parents are not organized in a formal way, but have come together as a sort of emotional support group "to keep their fears in check."



PERIODIC CHART OF THE ATOMS
The Atoms Grouped According to the Number of Outer (Valence) Electrons
in the completed outer shell

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92
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Andy Snyder is now one of 50 youngsters being examined at the National Institutes of Health to find out if the chloride deficiency will have any long-term effects on their growth and development.

At about the same time the Snyders were noticing the effects of the chloride-deficient formula, another mother was making her voice heard on a very different problem. Carol Buchholz, housewife and mother from East Rockaway, New York, was addressing a meeting of FDA's Immunology and Obstetrics and Gynecology Advisory Committees about alpha-fetoprotein (AFP) reagent, a preliminary screening test that can be used to detect certain defects in an unborn baby.

Proper use of the AFP test is of particular concern to Carol Buchholz because her first child, Karin, was born with spina bifida, an incomplete closure of the spinal column, which the AFP test can help to detect in the fetus. Since Karin's birth in December 1963, Mrs. Buchholz has taken an active role in local and national Spina Bifida Associations. She didn't take on FDA until 1978.

As a result of her many years of work with spina bifida, Mrs. Buchholz learned early on about the AFP test and its potential as a screening tool in the detection of such birth defects. "Watching quietly from the sidelines," as she says, she gathered as much information as she could on AFP and became so knowledgeable about it that she was asked to present papers before national and international conferences. In November 1978 she was named chairperson of an AFP Task Force for the Spina Bifida Association of America.

What concerned Mrs. Buchholz was that the AFP test kits might be put on the market without any restrictions on their use, sale, or distribution or without any quality controls in the laboratories running the tests. The test is a simple blood drawing procedure. It is a measurement of the level in the mother's blood of a protein produced by the developing fetus. The catch is that the test must be made at a very specific time during pregnancy and if the result is positive, must be followed by several other clinical tests to confirm the possibility of a neural tube defect. Uninformed interpretation of

the AFP test results or unavailability of follow-up tests could lead many parents to a tragic decision regarding the fate of their unborn child, perhaps even aborting fetuses that are, in fact, normal.

In the fall of 1978, when it appeared that AFP test kits would be up for approval by FDA, Carol Buchholz began her campaign to insure that the sale, use, and distribution of these test kits would be subject to appropriate restrictions that were possible under the Medical Device Amendments.

First she wrote to every physician she was able to determine had women patients who had a high risk of bearing children with spina bifida. She told the doctors that the kits might soon be on the market and asked whether they had heard of them and if not, whether they would like more information. Of the 190 or so physicians contacted, about half wrote back, a response that would warm the heart of any polltaker. The majority admitted they did not know what the AFP test was; many wondered why the non-risk woman would want to undergo such a test. Clearly, more professional education was needed.

Carol Buchholz also learned that FDA was not taking a position at that time on the use of AFP kits for large-scale screening programs, because the Agency did not feel it had jurisdiction over the extent of use of the test once it was approved. Kits would be released on a product-by-product basis under premarket approval provisions of the Medical Device Amendments to the food and drug laws, she was told. A public hearing was imperative, Mrs. Buchholz felt. Use of the AFP test without adequate controls could lead to a medical, social, and legal nightmare.

That's when Carol Buchholz learned the power of the pen. She wrote to every chapter of the Spina Bifida Association of America urging members to ask FDA for a hearing on AFP test kits. At the time, she didn't realize what a paper avalanche she had loosed, but she—and FDA—were soon to find out. Just before Christmas in 1978 she received a call from FDA's Bureau of Medical Devices asking that she stop her letter-writing campaign. The hearing would be held in February 1979.

For the next 2 months, Mrs. Buchholz worked full time on AFP. She spent 45 hours a week preparing her testimony, writing to major medical centers for support and researching whether FDA could indeed restrict the use of AFP kits. On February 26, accompanied by another official of the Spina Bifida Association, Carol Buchholz went to Washington to present the case for AFP restrictions.

Her association favors prenatal detection of neural tube defects, Mrs. Buchholz told FDA's Immunology and Obstetrics and Gynecology Advisory Committees. But the group was concerned about the quality of the test and of the information that would be provided to physicians and patients. "Informed consent and fetal rights, as well as parental freedom of choice, are based on the availability of objective and accurate information to the attending physician and consequently to the patient," she said. She also urged that FDA and CDC work together to ensure the safety of the diagnostic tool.

Mrs. Buchholz brought to the advisory committees 53 questions she had developed relating to quality control in laboratories and interpretation of test data. She urged that only those labs that can answer these questions satisfactorily be authorized by the Department of Health and Human Services and FDA to do AFP testing. That this had never been done before was no argument, she said; it was time to address the issue now.

Nearly 2 years after "her" hearing, Carol Buchholz is waiting to see what will happen to FDA's proposed regulations governing AFP test kits. As she understands, the Agency is calling for certain restrictions on the use of the test kit as a condition of marketing approval. She is pleased, too, that several agencies within the Department of Health and Human Services, including CDC and the National Center for Health Care Technology, have joined FDA in its efforts to make certain these kits are properly regulated.

Admitting that her family and friends thought she was "nuts" to tackle the AFP test kit problem, she is glad for the experience. After precipitating the February 1979 hearings Carol Buchholz is now confident of her ability to speak out as a consumer.



For The Elderly, Cool Can Be Too Cold

Winter poses many health hazards, particularly to the elderly. One of the most serious side effects of cold weather is accidental hypothermia—a sometimes fatal drop in deep body temperature. Some drugs make older people more vulnerable to the condition, which can occur even in mildly cool temperatures.

When wintry winds doth blow, poor Robin of nursery rhyme fame is not the only one to suffer. Cold weather, snow, and ice can hold dangers for anyone, but the combination is particularly hazardous for the elderly. Broken bones from falls on icy streets, heart attacks brought on by shoveling snow, and frostbite from the cold are among the dangers faced by our senior citizens during the winter months.

One of the most serious yet least known side effects of cold weather is accidental hypothermia—a drop in deep body temperature that can be fatal if it is not recognized and treated promptly.

Hypothermia

It is a well established fact that accidental hypothermia is the leading environmental cause of death among outdoor sports enthusiasts. What is not so well known is that even mildly cool temperatures of 60° to 65° Fahrenheit (15.5° to 18.3° Celsius) can bring on accidental hypothermia in the elderly. Diseases of the veins and arteries and treatment with certain drugs can make a person more susceptible to this condition, according to the National Institute on Aging (NIA), one of the research units of the Department of Health and Human Services.

Chlorpromazine and other phenothiazines given for various psychiatric disorders, nausea, and sedation have been identified by NIA as drugs that may increase an elderly person's vulnerability to accidental hypothermia. These drugs apparently depress the temperature controlling mechanism of the hypothalamus—that part of the brain responsible for the body's metabolic functions. Chlorpromazine also affects a person's ability to shiver.

Tricyclic antidepressants, benzodiazepines, reserpine, and morphine can also depress the body's temperature controls even in therapeutic doses, according to other authorities. In an article, *Accidental Hypothermia: The Body's Energy Crisis* (GERIATRICS, December 1979), Dr.

Richard W. Besdine names these drugs as culprits and adds that many other drugs taken in excessive doses or combined with alcohol can have the same effect. Barbiturates are the most common offenders, he says, but any tranquilizer or sedative-hypnotic drug has the same potential.

It is only recently that accidental hypothermia has been recognized as a threat to the aged. Credit for identifying it as a geriatric problem goes largely to research done in Great Britain in the past 25 years. It is difficult to estimate how extensive this problem is in the United States since no studies have been done on its frequency. One difficulty in making estimates is that the symptoms of the condition are like those of many other illnesses.

The elderly probably account for nearly half of all victims of accidental hypothermia, the National Institute on Aging estimates. Infants under 1 also are susceptible, as well as some adults between 35 and 64 years of age. Immature temperature control is blamed for the occurrence of accidental hypothermia in infants. Why middle-aged people are susceptible is not known.

Among the elderly, the most likely victims of accidental hypothermia, according to NIA, are the very old, the poor who are unable to afford adequate heating, and those whose bodies do not respond to cold normally. The greatest risk is to those whose temperature regulation is defective. They do not shiver and cannot conserve body heat when they need it most.

Based on British estimates that 10 percent of the aged in the United Kingdom are susceptible to accidental hypothermia, NIA projects that at least 2.3 million elderly in the United States could be vulnerable. According to material assembled by the Carolina Wilderness Institute, Greensboro, N.C., Dr. Besdine estimated that 25,000 people over the age of 65 died of accidental hypothermia in 1975.

While accidental hypothermia in the elderly may be confused with a stroke, diabetic coma, or heart condition, there are some clues to the correct diagnosis of this chilling condition. The victim's face may be bloated and the skin color pale at times, or oddly pink at other times. There may be trembling on one side of the body or in one arm or leg. But the shivering and pallor usually associated with the body's normal response to cold are strikingly absent. (Shivering is protective; the movement warms the body.)

Other signs of accidental hypothermia include: irregular and slowed heartbeat, low blood pressure, slurred speech, and shallow, very slow breathing. Victims feel cold to the touch and may appear to be in an acute state of confusion. At low body temperatures—90° F. (32.2° C.) or below, the victim will probably be unconscious.

Hypothermia can best be diagnosed by taking a person's temperature using a special low-reading clinical thermometer, one with a scale that goes below the normal 94° F. (34° C.). Unfortunately, NIA points out, such

thermometers are not usually available in drugstores and other retail outlets. A less reliable method is to feel the person's abdomen to determine if it is noticeably cold.

A person whose body temperature has dropped below 90° F. (32.2° C.) should be considered a medical emergency and should be treated in a hospital. It is important to remember two things about hypothermia: The condition is persistent, so a victim will stay chilled unless rewarmed; and whatever the apparent severity of the condition, the victim must be seen by a physician.

Rewarming must be done slowly, NIA says, no more than 1 degree per hour. Blood pressure must be held steady. Rapid rewarming may dilate the blood vessels in the skin, further lowering blood pressure, and also may force relatively cold blood from the skin into the body's core, making the deep hypothermia even worse.

The chances for recovery from accidental hypothermia depend on the severity of the cold and how long the person was exposed, as well as on general health before the incident. If the body temperature did not go below 90° F. (32.2° C.) chances for a normal recovery are good. If the body temperature fell to between 80° F. (26.6° C.) and 90° F. (32.2° C.) most victims will recover but may experience some lasting health damage. Most victims, especially the very old, will not survive a fall in body temperature below 80° F. (26.6° C.).

A bout with accidental hypothermia can worsen pre-existing conditions, such as heart disease and diabetes, and lead to problems with the kidneys, liver, and pancreas. Permanent brain damage also can result. The most severe complication of hypothermia is a form of irregular heartbeat called ventricular fibrillation, that leads quickly to death if it is not treated.

Elderly people, especially those over 75, can protect themselves against accidental hypothermia by following these suggestions of the National Institute on Aging:

- Consider keeping rooms at temperatures of at least 70° F. (21° C.).
- Avoid any prolonged exposure to cold.
- Wear adequate clothing, including sweaters, robes, a cap or hat, and thick socks.
- Have enough blankets for the bed.
- Try not to be alone for very long, or ask friends or neighbors to look in once or twice a day—particularly after a cold night.
- Those who are taking medication to treat anxiety, depression, nervousness, or nausea should check with their physician to determine if the drug is a phenothiazine.

* * * *

Material for this article was provided by the National Institute on Aging, National Institutes of Health, Department of Health and Human Services, through its publication *A Winter Hazard for the Old; Accidental Hypothermia*. DHEW Publication No. (NIH) 78-1464.

Rx With A Dose Of Info

Information similar to that provided to physicians will be available to patients who get new prescriptions for 10 drugs, as part of a 3-year pilot program of the Food and Drug Administration. The information, in leaflet form, is to be handed out to the customer at the time the prescription is filled. Included will be possible side effects, proper uses for the drug, and any precautions in taking the particular medicine.

by Roger W. Miller

Six people enter a pharmacy to get a prescription filled for the first time. Five of them leave with their medicine and any information that they may have been given about their new drug from their doctor or the pharmacist.

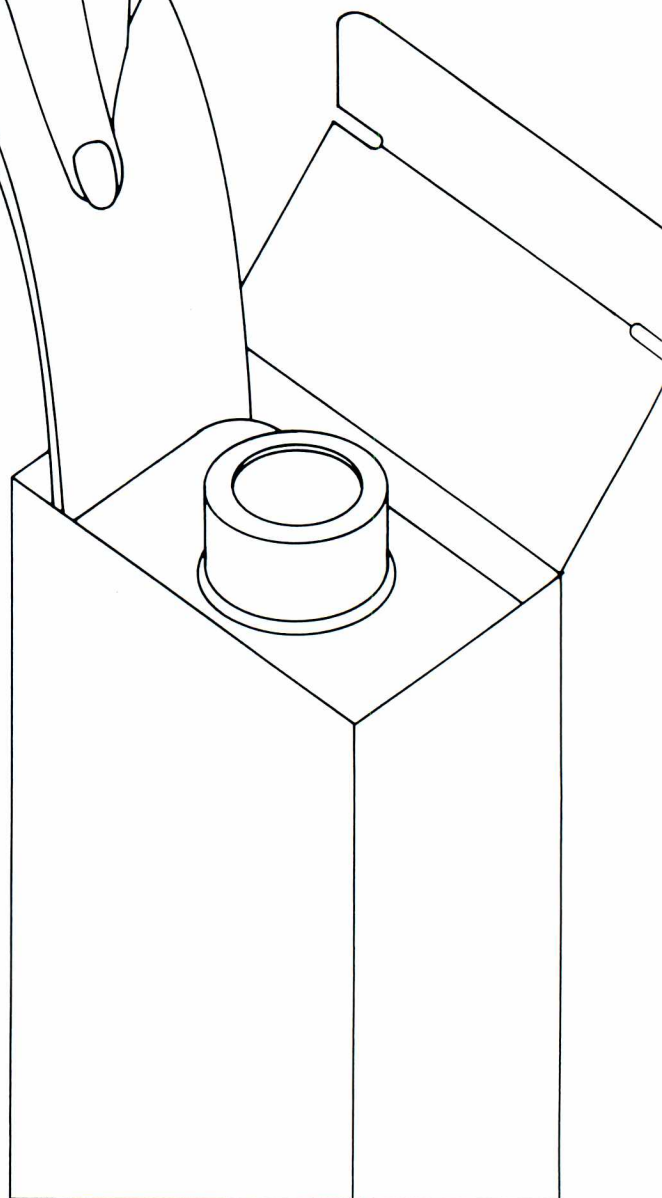
The sixth leaves with the medicine plus a leaflet giving—

- A summary of information about the drug
- Proper uses for it
- The circumstances under which it should be taken
- Any possible adverse reactions or side effects
- Any precautions the user should take

The first five people to get their prescriptions filled are quite typical patients. The information they have about their medicines may range from vague and sketchy to quite detailed, depending upon the people who prescribed and dispensed it. The patients may know little more than when to take the drug. They may not even know the name of it, or how to pronounce it.

Many will not care to know much more than how and when to take the medicine and how soon it will make them well. However, some people will want to know more.

The sixth person has the opportunity—or will have the opportunity—to get educated about his or her drug. For, that person will receive the information leaflet as a result of a 3-year pilot program by the Food and Drug Administration to tell patients more about the drugs they are taking. The program will provide leaflets, called patient package inserts (PPI's), for 10 drugs or classes of drugs that account for over 100 million new prescriptions a year—or slightly better than one out of every six new Rx drugs. The sixth person's prescription happens to be for one of these drugs.



The 10 drugs for which PPI's are being drawn up are: Ampicillin—a penicillin-type antibiotic; 23.6 million new prescriptions were written for it in 1979.

Benzodiazepines—a class of minor tranquilizers that includes Valium, Librium, and Tranxene; 29.7 million prescriptions in 1979.

Cimetidine—used for treatment of ulcers; a relatively new drug generally known by the trade name Tagamet; 4.8 million prescriptions in 1979.

Clofibrate—used to treat patients who have problems with high cholesterol and triglycerides (blood fats); 700,000 prescriptions in 1979; trade name, Atromid-S.

Digoxin—for use in treating heart problems; 7.3 million in 1979.

Methoxsalen—used in treatment of skin pigmentation problems and, investigational, in psoriasis; also known by the trade name Oxsoralen Capsules; 20,000 R_x's in 1979.

Phenytoin—used to control epileptic seizures; 2.5 million prescriptions filled in 1979.

Propoxyphene—more commonly known by the leading brand Darvon, this painkiller resulted in 13.9 million prescriptions in 1979.

Thiazides—a class of diuretic drugs commonly used in the treatment of high blood pressure; 20.5 million in 1979.

Warfarin—an anticoagulant, or blood thinner, used in the prevention of blood clots; 1.1 million 1979 prescriptions.

(All prescription figures are from the NATIONAL PRESCRIPTION SERVICE, published by IMS America, Ltd., Ambler, Pa.)

The 3-year program calls for the PPI's to be in pharmacies in late spring or summer 1981. Printing and distribution of the PPI's will be the responsibility of the manufacturer or distributor. The information in the PPI's will be based largely on the professional (physician) labeling—information that manufacturers are required to provide physicians about their drugs. The physician labeling is the drug information provided in the PHYSICIANS' DESK REFERENCE (PDR). The leaflet information being developed for the 10 drugs in the pilot program will be carried in full in the PDR along with the physician labeling for those drug firms that advertise in this text.

The new leaflets will not be required under the following circumstances: (1) If the prescription is refilled or if the physician directs that the PPI be withheld from the patient (but the PPI must be given to the patient if he or she asks for it), and (2) if the drug is being given during emergency treatment. Special requirements apply to drugs given out in health care institutions.

The leaflets will also be available in Spanish for pharmacists who serve Spanish-speaking communities if the pharmacists or physicians request them.

FDA already requires patient package inserts for a few drugs, such as birth control pills and estrogens that are used by menopausal women. In addition, some pharmaceutical manufacturers have voluntarily provided the information leaflets for some drugs, including Darvon and Atromid-S, as well as Valium, on a test basis. These drugs will now become part of the mandatory PPI program.

During the 3-year period of the PPI test program, FDA will study not only the costs of the operation but also the benefits associated with the use of PPI's and the best methods of PPI distribution before deciding whether to extend, revise, or defer the patient labeling requirement to additional drugs. The Agency will also try to ascertain what effects patient exposure to drug information has on the patient-health professional relationship. In addition, the Agency is encouraging alternative distribution systems that might include a book containing PPI infor-

mation that would be available for consumers to read at pharmacies.

FDA anticipates that the cost of patient labeling will be passed on to the consumer but it is still difficult to calculate what the actual cost will be. The costs include printing, distribution, pharmacist's storage and dispensing, etc.

The benefits of PPI use are expected to be both of a direct and indirect nature. Tangible benefits may be seen in the form of better informed medicine users and thereby, hopefully, in cost savings. The indirect effects may include better use of medicine, avoidance of known food-drug interactions, more careful adherence to dosage instructions, better ability to deal with side effects, etc. All of these things will be taken into consideration when the program is evaluated.

PPI's have not been without controversy. The pharmaceutical industry, physician groups, and pharmacist organizations have generally disagreed with the idea of dispensing leaflets with medicine. Several groups brought suit against FDA over the earlier leaflets that were required for estrogen drug products. However, FDA's authority to require the patient labeling for estrogens was upheld in court.

The arguments against PPI's involve costs, philosophy, and effects. Pharmacist groups contest FDA's cost figures, saying the whole program will run several times Government estimates. Health professionals argue that PPI's amount to the bureaucracy practicing medicine and that the leaflets can cause more harm than good.

Backing the patient information program are consumer groups, many of whom testified at a hearing held in 1978 and 1979 on the proposal. At those hearings and in written comments to the Agency, consumers overwhelmingly favored the leaflets, contrary to health community and industry groups.

Experience thus far with PPI's has been good and bad, depending on who you talk to or what you read. Some doctors maintain that patients have been frightened after reading the side effects and possible adverse reactions from oral contraceptive and estrogen-containing products. FDA, however, contends that in many cases this was important especially for those patients who should not be taking these drugs in the first place. On the other hand, FDA cites two studies on the return of drugs that had PPI's. In one study, no drugs were returned among 400 prescriptions filled, and in the other there were only three returns out of 1,600 prescriptions dispensed.

Obviously, conflicting philosophies are being forced into the PPI issue. The consumer groups believe in protecting against an attitude of "caveat emptor" (let the buyer beware), while others subscribe to Alexander Pope's advice that "a little knowledge is a dangerous thing."

The 3-year experiment aims to find out if the buyer can swallow a spoonful of education along with the medicine.

Roger W. Miller is editor of FDA CONSUMER.

The Notebook

■ Food marketers in Belgium will not be permitted to put into their ads such words as "natural," "pure," "low-calorie," "medical," and "organic," under a new law to **prevent advertisers from misleading consumers** by claiming their products have "medical properties or effects." ADVERTISING AGE reports in its August 25 issue that the new directive was passed by the Belgian Parliament after token opposition from advertising groups which apparently knew that legislation now being considered by the European Economic Community (EEC) will probably cover many of the same points.

The law also forbids the representation on food labels of body organs; blood, circulatory, or nervous systems; the use of people, clothing, or equipment evoking the medical, dental, pharmaceutical, or nursing professions; and the use of infants in such advertising or packaging. The decree also declares it unlawful to induce consumers to believe that the product or brand possesses particular qualities when, in fact, all similar food products have the same qualities.

* * * *

■ There are **shortages of pharmacists** in 128 counties in 28 States, according to the Health Resources Administration of the Public Health Service. The most up-to-date list of health manpower shortage areas reveals that 45 percent of these counties were designated "Group I," meaning that they are areas of the highest degree of shortage. Missouri had the most counties in need of pharmacists (19), followed by West Virginia with 16, and Pennsylvania and Virginia, each with 14 areas of need.

In addition, seven districts in the Trust Territory of the Pacific and one service district covering three islands of the Commonwealth of North Mariana Islands are short of pharmacists. The list of Health Manpower Shortage Areas, updated as of April 30, 1980, was

published in the August 26 FEDERAL REGISTER.

* * * *

■ There are **Communist Quacks**, too. Cancer researchers in the Soviet Union face problems similar to those of U.S. researchers. They are convinced cancer is curable but say their work is being hindered by quacks pushing fake remedies. The newspaper PRAVDA recently carried an interview with three cancer specialists who said they have controlled the incidence of the disease in men and reduced the rate in women. "Recent years have witnessed a rapid development of immunotherapy, which is a combination of techniques designed to increase cancer resistance in the human body," they said.

* * * *

■ In the first 4 years after enactment of the Medical Device Amendments of the Food, Drug, and Cosmetic Act, 10,541 **premarket notifications** were made to FDA's Bureau of Medical Devices (BMD). Under the amendments, which became effective in May 1976, any manufacturer who develops a device has to give FDA 90 days notice before the product can be put on the market. During that time the Agency decides how the device should be classified. If premarket approval is required (Class III), the manufacturer will have to provide evidence that the product is safe and effective.

In the first 2 years, FDA issued 83 denials of the manufacturer's claim that his product is the same as one on the market before the amendments were passed. In the second 2 years, the Agency issued 90 denials. This represents less than 2 percent of all pre-market notices.

The number of applications for premarket approval of new devices is on the rise. Ten applications were submitted in the first 2 years, another 80 have come in

subsequently, and 48 are now undergoing BMD review. There are relatively few significantly "new" devices created annually. Most so-called new products are improvements or modifications or copies of old products.

* * * *

■ When FDA published medical device regulations classifying scented menstrual pads and scented menstrual tampons the word "deodorized" was deleted. Manufacturers of these products objected, pointing out that dropping the word "deodorized" from the device name would imply that products represented to be deodorized would be misbranded unless they were treated with an antimicrobial agent. FDA agreed, and in the August 1 FEDERAL REGISTER amended the regulations classifying menstrual pads and tampons. Products that have scent added for an aesthetic effect are identified as scented pads or scented tampons. Those that have scent added as a masking agent to achieve a deodorizing effect are called scented deodorized pads or tampons. Menstrual pads or tampons treated with an antimicrobial agent or other drug would be regulated as drug products.

* * * *

■ By December 8, 1980, at the latest, the labeling for neuroleptic drugs, except for rauwolfia alkaloids, must include a statement that these drugs elevate serum prolactin levels and may pose a potential risk to patients. Prolactin is a hormone that stimulates breast milk production. FDA called for the new statement in the Precautions section because studies have shown that human breast cancer cells depend on prolactin to grow in the laboratory and that testing has indicated an increase in mammary tumors in rodents which are exposed to prolactins for long periods. These factors

are important if neuroleptic drugs are to be prescribed for patients who have had breast cancer.

Examples of neuroleptic drugs include: acetophenazine, butaperazine, chlorpromazine, haloperidol, promazine, thiopropazate, and thioridazine. Combination products containing neuroleptic drugs are also covered by the regulation that was published in the August 8 FEDERAL REGISTER.

* * * *

■ FDA has proposed to amend its blood and blood components regulations to cut down on the number of error and accident reports manufacturers have to make. At present, licensed establishments are required to notify the director of FDA's Bureau of Biologics about errors and accidents that may affect the safety, purity, or potency of blood products. FDA feels much of this information is unnecessary because the errors are corrected before the blood is used for transfusions. Under the proposed changes, error reports will be limited to those related to hepatitis-reactive blood and blood components and the accidental infusion of the wrong red blood cells to a donor during plasmapheresis. The proposal was published in the August 8 FEDERAL REGISTER.

* * * *

■ The Justice Department's Drug Enforcement Agency has issued a final rule permitting the partial filling of prescriptions for **Schedule II controlled substances** in Long Term Care Facilities. In addition, the period during which the prescription is valid has been extended from 72 hours to 60 days. According to the FEDERAL REGISTER notice of August 15, the new rule should reduce health care costs to patients in nursing homes and retirement care or mental care institutions by limiting the amounts of controlled substances permitted to be held in such facilities.

Investigators' Reports

A Drug By Any Other Name

In the early months of 1979 Pharmadyne Laboratories, Inc., took FDA to court; a year later FDA returned the favor in an attempt to resolve a piece of the generic drug controversy. The piece of the controversy, which courts in New York and New Jersey seem to have settled, is: Are copies of approved drugs therapeutically the same as the original drug and do the copies need premarket approval by FDA?

Pharmadyne, a drug manufacturer in Hackensack, New Jersey, was marketing a diuretic drug called furosemide; FDA, in the fall of 1978, told Pharmadyne that furosemide was a new drug and that the firm needed an approved NDA (New Drug Application) or ANDA (Abbreviated New Drug Application) for it to obtain premarket clearance. Pharmadyne said that furosemide was not a new drug because it was a generic version of an approved brand name drug (Lasix—manufactured by Hoechst-Roussel Pharmaceuticals, Inc.) and its safety and effectiveness had already been established. When FDA began having the drug seized all over the country, Pharmadyne filed a request for injunction in a U.S. District Court in New Jersey in an attempt to have the Agency legally prevented from taking regulatory action against furosemide.

The furosemide incident was only part of a very large and very confusing controversy over generic and “me-too” drugs. When a drug is first developed, it is assigned a generic name (also called the “nonproprietary” or “official” name) which is generally descriptive of the chemical composition or class of the drug. The drug is usually patented and is sold exclusively under a single brand name, which is the name devised to help advertise the drug. Such original drugs are often referred to as “brand name” drugs. When the patent

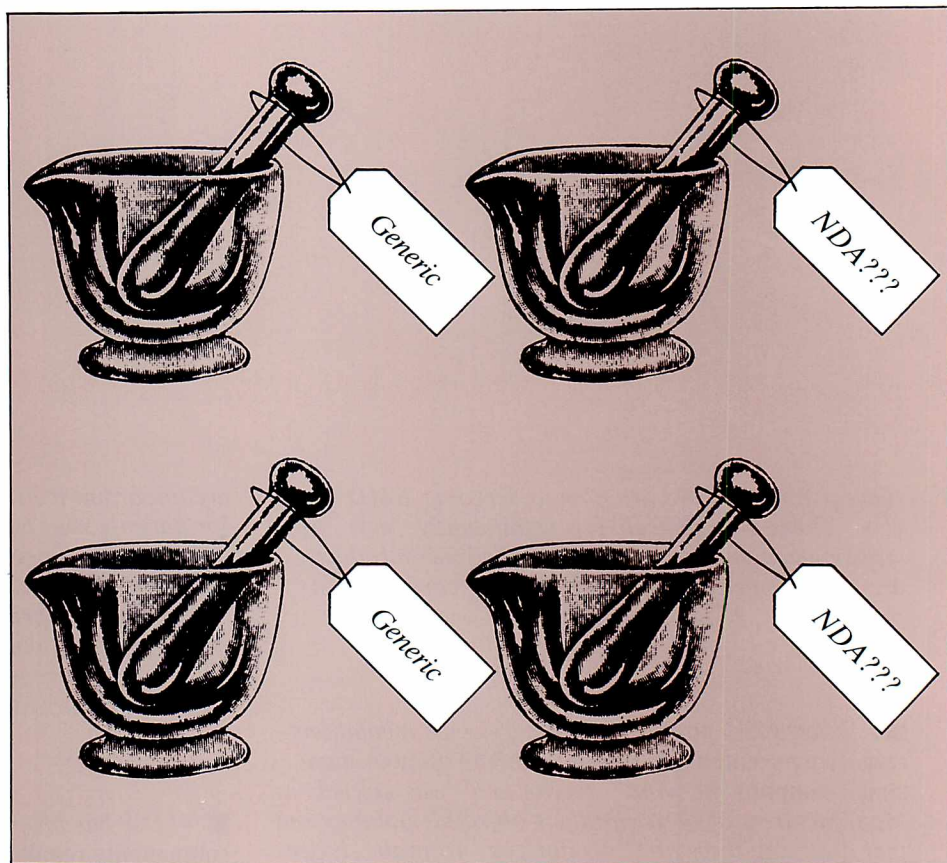
expires (drug patents run for 17 years), or if there is no patent, other firms may begin to manufacture and sell their own versions of the drug, either under a different brand name or under the drug's generic name. These copies of the original drugs are called generic or “me-too” drugs.

The controversy hinges on whether generic versions of already approved drugs are “new” drugs, as defined by the Food, Drug, and Cosmetic Act. According to the Act, a drug that has been generally recognized by qualified experts as safe and effective for its intended purpose is not a new drug and does not need premarket approval. A new drug, by contrast, must be approved by FDA as being safe and effective for its intended purpose before it can be marketed.

Furosemide was the generic name of a diuretic developed and marketed by Hoechst under the brand name Lasix. Hoechst had an approved New Drug Application (NDA) for Lasix, had demonstrated to FDA that the drug was

safe and effective as a diuretic. When Pharmadyne began marketing its version of furosemide (under the drug's generic name) the firm did not get an NDA and argued that the drug was the same as Lasix, which was approved, and was therefore recognized by experts as safe and effective and did not require an NDA. If the difference was purely semantic (brand name as opposed to generic name), the firm argued, why should the one version be any different therapeutically from the other?

Pharmadyne believed that its position was legally supported by a 1978 court ruling in the historic Lannett case. Lannett, a Philadelphia generic drug manufacturer, had contested in court FDA's contention that 12 of its products were new drugs without NDA's and thus were illegal. On August 14, 1978, the Third Circuit Court of Appeals in Philadelphia ruled against FDA. In doing so, the court made statements that were widely interpreted as stating that generic duplicates possessing the same active ingredient as approved products do not



require FDA approval. The court stated the opinion that manufacturing methods, bioavailability, and bioequivalence are not criteria of new drug status.

The Lannett ruling became a cornerstone in the generics controversy, the decision relied upon by Pharmadyne and another big generics manufacturer in South Hackensack, New Jersey—Premo Pharmaceutical Laboratories, Inc. Premo also was in the process of suing FDA, had begun suit in November 1978 seeking to enjoin the Agency from taking regulatory action (such as initiating seizures) against its “me-too” drug *Insulase*. (*Insulase* was a copy of Pfizer’s approved drug, *Diabinese*.)

The legal dance seemed to be turning upon the crucial question of when a drug is the same (a faithful and reliable copy) as another drug. The Lannett decision focused on the active ingredient. In the case of *furosemide*, obviously Pharmadyne’s drug and Hoechst’s *Lasix* contained *furosemide* as its active ingredient. Equally obviously, there were problems with Pharmadyne’s product not found with Hoechst’s. FDA had confirmed four reports of patients who became ill because Pharmadyne’s version of the drug was not effective in removing fluid, which would affect their heart conditions; three of the patients had to be hospitalized and the fourth, already in the hospital, became seriously ill while taking the Pharmadyne drug. When switched back to *Lasix*, the problems ceased. FDA hypothesized the unapproved version of the drug was not the same in terms of bioavailability, that is, was not absorbed the same way in the body, and therefore could not accomplish the intended therapeutic effect. In a news release, FDA warned consumers taking *furosemide* to make sure the name Hoechst was on the tablets.

Pharmadyne’s attempt to have FDA enjoined failed in both the U.S. District Court and Court of Appeals for the Third Circuit. New Jersey District Judge H. Curtis Meanor ruled that generic products—even with the same active ingredients as drugs previously approved and marketed—still were subject to the New Drug provisions of the FDC Act. In his Opinion, Judge

Meanor said that because Pharmadyne may have used different inactive ingredients and may have manufactured the drugs by different processes, these differences could significantly affect the rate and extent to which the active ingredients of a drug product are absorbed after ingestion. (The Court of Appeals upheld his decision on a different, procedural ground.) In March 1979 Pharmadyne officially recalled all distributed *furosemide* and filed ANDA’s for it and 14 other generic drugs.

But the generics battle was far from over. FDA was still in litigation with Premo; and as fall chilled the 1979 air, complaints by other drug manufacturers reached FDA that both Pharmadyne and Premo were continuing to market a large number of generic drugs that had not been approved.

FDA issued an import alert to its field offices and to customs officials on the eastern seaboard, seeking detention of bulk raw ingredients from overseas destined for use in manufacture of the unapproved products. Newark District investigators wearied of trudging to and from Premo and Pharmadyne gathering evidence for seizure after seizure of the unapproved drugs. In less than a year four seizures were made at Premo, the last of \$150,000 worth of drugs.

In early 1980, FDA issued a news release, reminiscent of the one about *furosemide*, warning that the drug *Triamthiazide*, Premo’s generic version of the approved prescription diuretic *Dyazide* (marketed by Smith Kline & French), could cause elevated potassium levels if, as appeared possible, the Premo version was absorbed more readily by the body. This could lead to heart irregularities, FDA said.

In early May, FDA went to court in an attempt to stop Pharmadyne from distributing unapproved generics. And 8 days in July brought two legal victories for the Agency that might prove to be the beginning-of-the-end of at least one part of the generics controversy.

On July 21 in the Newark U.S. District Court, Pharmadyne signed a consent decree of permanent injunction in which the firm agreed to stop marketing 15 disputed generics then on the market

and agreed to the condemnation of those already seized. One of the drugs was, of course, *furosemide*. The firm also agreed to give FDA 45 days advance notice of intent to market any unapproved drug. If the Agency and Pharmadyne disagree whether the product is a new drug, the dispute will be settled by the court and Pharmadyne cannot market the product until the court makes its decision.

Eight days later, Premo lost its suit against FDA when the U.S. Court of Appeals for the Second Circuit reversed an earlier District Court ruling—and disagreed strongly with the spirit of the Third Circuit’s Lannett decision—and said that Premo’s *Insulase* was not exempt from premarket clearance. The court said, “Later developed ‘me-too’ products such as *Insulase* are required to apply for FDA approval for the undisputed reason that a difference in inactive ingredients, as exists here, when combined with the active ingredient, can affect the safety and effectiveness of the drug product.”

The Premo ruling left a potential loophole by sidestepping the issue of premarket clearance in cases where the “me-too” drug is exactly identical to the original drug. The court said, however, that the law “is not intended to permit a pharmaceutical manufacturer to substitute its opinion regarding the safety or effectiveness of a drug for that of FDA.” Congress gave that job to FDA, the court said.

Since the Lannett decision, FDA compiled a “winning record” in subsequent litigation on the issue of preclearance for “me-too” drugs. The litigation is not over. In the U.S. District Court in New Jersey, FDA is currently seeking a preliminary injunction preventing Premo from marketing unapproved “me-too” drugs; and both the U.S. District Court in Florida and the Fifth Circuit Court of Appeals are considering different aspects of a suit seeking to enjoin Generix Drug Co. from distributing unapproved generic drugs. The issue may eventually reach the Supreme Court, which would have to reconcile the Lannett decision with subsequent court rulings.

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.

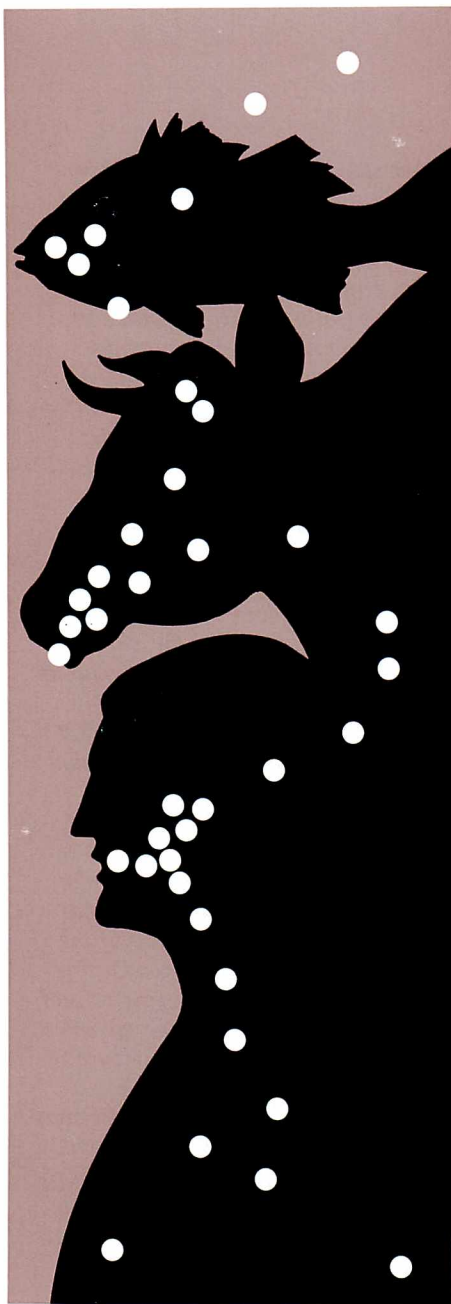
Not Fit for Man Nor Beast

In March 1980, FDA's **Minneapolis District** found polychlorinated biphenyls (PCB's) in fish oil at a Minneapolis feed mill. The oil was intended as an ingredient in livestock feed, which could have been harmful both to the animals and people who later consumed the meat.

PCB's are a group of related chemicals, originally heralded as ideal for use in insulating fluid, but later discovered to be toxic. Their manufacture, processing, and marketing was banned by Congress in 1976, but about 750 million pounds had already been used in electrical transformers, capacitors, and heat transfer systems. PCB's, which are virtually indestructible, have been detected in many foods, such as eggs and bakery items and in breast milk and even garden soil, but where they have turned up most frequently is in animal feeds and food.

Minneapolis District requested seizure of the oil. The District also investigated to find out where the oil came from. An examination of the feed mill's shipping records revealed the source: Scandinavian Oil Co., a New York-based firm that stored the oil at the Hudson Tank Terminal in Weehawken, New Jersey.

FDA's **New York and Newark Districts** continued the investigation and determined that of all the oil stored at the terminal only two tanks (Nos. 40 and 43) contained violative levels of PCB's. Shipments from those tanks were traced. Oil from tank No. 43 had gone to a manufacturer in Aiken, South Carolina, for use as horse hoof dressing, and to a firm in Shenandoah, Iowa, for use in the manufacture of drugs for small animals, such as dogs and cats. (Analysis of samples of these drugs revealed only trace amounts of PCB's.) The Minneapolis feed mill had received



oil from tank No. 40; and one other shipment from that tank had evidently ended up as a component of laundry detergent.

Although FDA's primary concern is to keep PCB's out of foods intended for human consumption, PCB's are not permitted in food for animals either, including "nonedible" animals such as dogs and cats. In studies of PCB toxicity in animals (designed, of course, to measure effects on humans) they have suffered liver tumors and other liver damage, reproductive problems, acne, eye inflammations, hair and weight loss, and behavioral and learning disabili-

ties. The tolerance set by FDA for PCB's in feed ingredients is 2.0 ppm (parts per million); for finished animal feed and food the tolerance is 0.2 ppm.

To prevent further distribution of the violative oil, Newark District recommended seizure of oil in tanks No. 40 and 43. Seizure was approved by the Bureau of Veterinary Medicine and carried out by a U.S. marshal.

Beyond Salvage

An anonymous tip about a cargo of corn in moldy, swelling bags led investigators from the **Houston Station** to a leaking barge docked at the Port of Houston.

The barge began leaking during a trip from Freeport, Texas, and all 8,172 of the 100-pound bags of corn had become submerged in water. The cargo was the property of the U.S. Department of Agriculture but was claimed by the carrier, Waterman Steamship Co., which had hopes of reconditioning it.

Upon finding the corn moldy, FDA informed the **Texas State Health Department**. While samples were being collected by investigators for aflatoxin analysis, the State placed an embargo on the cargo to prevent movement pending the analysis results.

When the **Dallas District** laboratory informed the company that the corn contained 53 parts per million aflatoxin, a contamination in excess of the 20 parts per million allowable by FDA, the company decided to destroy the lot, valued at \$82,000, in a landfill in Houston.

Drug Theft?

Possible criminal tampering with a distributor's stock of a potent narcotic antagonist analgesic dating back as much as 2 years was reported to FDA's **New York District** by Park Surgical Co., Inc., Brooklyn, New York.

Park Surgical discovered the safety seals were broken on 70 10-milliliter vials of Stadol (butorphanol tartrate), a drug recommended for relief of moderate to severe pain, after a physician complained that the product "looked turbid," or cloudy, and that

the seal was open. The firm, which is the drug distributor, checked its remaining inventory of Stadol and found all the seals were broken.

The firm returned the shipment to the Syracuse (New York) manufacturer, who analyzed the contents of a random sample. Lab analysis showed the vials contained only trace amounts of the drug, which evidently had been replaced with nonsterile water. The water was contaminated with microscopic amounts of bacteria, plant materials, yeast, and algae. The rubber stoppers had been punctured, and officials at the firm suggested that the stocks at Park Surgical had been deliberately broken into.

Park Surgical reported to FDA that it was recalling all Stadol distributed since December 1978—the date the firm began marketing the drug—since it had no way of determining how many shipments had been tampered with. The recall, monitored by the New York District, was categorized as Class I (the most serious type of recall), since Stadol is administered intramuscularly and intravenously and the injection of nonsterile water into either a muscle or a vein could be extremely dangerous.

The Price of Mice

Mice can be costly. Just ask Walter F. Eberle, Jr., of the C. Eberle Sons Co., a food distributor in Cincinnati, Ohio. On June 30, 1980, the U.S. District Court for the Southern District of Ohio fined Mr. Eberle \$1,000 on each of two misdemeanors and the firm a total of \$10,000 on three felony charges.

This is the second time Mr. Eberle and the company have had to pay for having mice reside in the company warehouse, which houses foods for distribution to institutions, such as nursing homes. In 1974 a routine inspection by FDA's Cincinnati District found that the facility was rodent infested and the food contaminated. In the resultant criminal case the firm was found guilty and fined a total of \$2,000. Mr. Eberle was fined \$1,000.

During 1977, Cincinnati District investigators found traces of minor rodent infestation. The firm destroyed contaminated foods and promised to make changes in their sanitation pro-

gram to maintain a rodent-free facility.

But reinspection in 1978 revealed that mice had moved back into the Eberle warehouse. Investigators reported extensive rodent infestation and rodent-defiled foods, and added that the firm did not have an adequate inspection program to prevent contaminated foods from being shipped out of the warehouse.

Eberle agreed to shut down the operation until the mice were evicted, necessary repairs were made to the warehouse, and a sanitation program was instituted that would keep out the mice.

About \$20,000 worth of food was destroyed, and it cost the firm another \$80,000 to \$100,000 to recondition the facility so that the warehouse would meet FDA standards. When the company attorney complained that it would cost C. Eberle Sons Co. \$20,000 a year to maintain the new sanitation program, the district judge replied that this was the cost of doing business and that the firm should do the things necessary to stay out of the doghouse with FDA and the court.

In addition to the fines, Eberle was placed on probation for 4 years.

Epidemic Sleuthing

A mysterious outbreak of infections at three hospitals in Ohio presented a problem that was solved by the **Ohio State Health Department** and the **Cincinnati District**.

The hospitals, one at the University of Cleveland and two operated by the Veterans Administration, called the department after receiving complaints about infections from both patients and staff personnel. Fearing an epidemic, the department assigned an epidemiologist to determine the cause.

After a series of tests on the affected victims, the epidemiologist discovered that all the infections were caused by *Pseudomonas aeruginosa* and *P. klebsiella*, bacteria that are usually found in cosmetics and lotion preparations. With one part of the mystery solved, the epidemiologist asked help from the Cincinnati District in identifying the source of the infections.

District investigators visited each

of the hospitals to pick up the test results, to collect samples for analysis, and to ask which type of lotion each hospital used. When all three hospitals said they used MacAlister Hospital Body Lotion, the District alerted the distributor, Schumann Laboratories of Northfield, Ohio.

The District's laboratory analysis confirmed the bacteria contamination and notified the manufacturer, Bowman Pharmaceuticals, Inc., Canton, Ohio. Subsequently, Schumann initiated a recall and Bowman buried 200 gallons of the lotion in a landfill at Glenwillow, Ohio.

Allen on a Rampage

Hurricane Allen pummeled the Gulf Coast area of Texas in early August. But there was early warning of the storm, and a quarter million residents took heed.

After the storm's passage, health officials went to work. **Houston Station** chief Anthony Whitehead coordinated FDA's part of the cleanup operation. The **Brownsville Resident Post** investigators, aided by volunteer investigators from **Dallas District** and the rest of Houston Station, began checking on establishments dealing in FDA-regulated products, including food storage warehouses, grain elevators, drugstores, restaurants, and retail food stores. The investigators made their way over a 300-mile coastline and almost 20,000 square miles in a 20-county area. Under supervision by FDA and State officials, several thousand pounds of spoiled seafood (mostly shrimp) was destroyed by seafood processors and packers whose facilities had been flooded. In Brownsville, another 41,000 pounds of waterlogged foods were destroyed. The storm had ripped the roof off the Brownsville Elevator, and some 5,000 bushels of cottonseed meal received damaging exposure. In Brownsville and Corpus Christi \$56,000 worth of food, \$10,000 worth of drugs, and \$6,000 worth of liquor were destroyed.

Allen was a vicious hurricane, Whitehead said. It caused a lot of damage and some loss of life. It could have been worse, he added, but wasn't—mainly because everyone took it seriously and showed the respect that hurricanes deserve.

A Cleanup in Time

An injunction to Dunford Industries would have meant no more dough. To FDA it would have meant forcing the Salt Lake City bakery to comply with sanitation requirements or lose its business with food caterers to the airlines and other customers.

Early in 1980, following an inspection of the company by an investigator from FDA's **Salt Lake City Resident Post**, the Denver District Office proposed to seek an injunction from the courts. The inspection revealed the firm's premises were heavily infested with rodents and insects. There was evidence of contamination in the manufacturing and storage areas, equipment, raw materials, and finished products.

The company supplies its baked goods to stores and restaurants, but since it also provides these products to airline caterers, FDA classified it as "not approved" for this purpose. Under FDA's Interstate Travel Sanitation program the airlines were instructed by FDA to stop using the firm's products.

The proposal of an injunction proved to be the best recipe because, before the U.S. district attorney was asked to file the injunction, the firm entered into a voluntary compliance agreement with FDA. Investigators reinspected the plant after cleanup and found that all the necessary corrections had been made. FDA then reclassified the firm as "approved."

A Recall, Day by Day

Thursday, May 29 (1980). FDA's **Baltimore District Microbiological Laboratory** found preformed *Clostridium botulinum* toxin (type B) in three cans (No. 10 size) of mushrooms manufactured by Emil Lerch, Inc., Hatfield, Pennsylvania. The sample—later determined to be from a batch of mushrooms packed April 4 of that year—had been collected by the **Milwaukee Resident Post** in response to an anonymous complaint of "abnormal shaped" cans. Botulinal poisoning can cause severe illness or death; however, no illness or injury had been reported.

Friday, May 30. FDA's **Philadelphia District** collected samples of No. 10 cans at the manufacturer's Hat-

field warehouse and began checking out the firm's customers in Pennsylvania. With the aid of the State departments of agriculture and environmental resources, and the Alleghany County Health Department, over 2,800 customers were contacted, either by phone or in person.

Saturday, May 31. FDA, in a news release, announced that Emil Lerch was recalling over 3,500 cans of mushrooms (pieces and stems in 4-pound, 4-ounce cans, No. 10 size), which had been processed on April 4, 1980. The mushrooms, sold under the brand names Even Tide and Railton's Natural, had been distributed to wholesale grocers in Illinois, Wisconsin, and New York.

Sunday, June 1. Baltimore microbiologists found what was apparently botulinum toxin in the samples collected by Philadelphia District—which were from a batch canned on March 14, 1980—and began further testing to confirm this.

Tuesday, June 3. The analysis was confirmed, and a second FDA news release announced expansion of the recall to include all mushrooms in No. 10 cans produced since February 1977—about 75,000 cases (with 6 cans to a case). This was the date the company began using a new canning process for its mushrooms, and the change was linked to the subsequent problems with No. 10-size cans. The mushrooms had been distributed under 12 brand names (the best known being Chef's Finest and Even Tide) in 19 States: Connecticut, Delaware, Florida, Georgia, Illinois, Kentucky, Maryland, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, Tennessee, Virginia, West Virginia, and Wisconsin. No injuries or illnesses have been reported.

Wednesday, June 4. After testing samples of 16-ounce and 8-ounce containers of the firm's mushrooms, Baltimore microbiologists reported no new findings of toxic materials.

PB&J, Hold the Peanut Butter

Deep South Products, Inc., a peanut butter manufacturer in Forest City, Florida, destroyed over 1,000 cases of peanut butter because that frequent companion to grape jelly

was contaminated with aflatoxins, a carcinogen produced by naturally occurring molds.

The molds that produce aflatoxins grow on a variety of crops, including peanuts, corn, wheat, rice, cottonseed, and tree nuts. Although scientists once thought these molds would grow only when the products were stored improperly—if they were inadequately dried or allowed to become moist—it has since been learned that aflatoxin-producing molds can grow on crops still in the field, particularly on plants which have been attacked by insects or which are under stress. FDA has set a tolerance for the toxin in susceptible foods. The tolerance for marketed peanuts is 20 ppb (parts per billion)—a guideline set in 1969 when improved analytical techniques allowed the Agency to detect the chemical at that low level.

FDA routinely checks products for aflatoxins. In addition, the U.S. Department of Agriculture (USDA) inspects batches of raw shelled peanuts (and other nuts) and certifies them if they contain less than 22 ppb; this level, set by agreement between FDA and USDA, is higher than the FDA tolerance because the Agency expects these levels to be reduced during subsequent processing. FDA also expects that manufacturers will do further sampling and analysis to make sure their products comply with the law.

This, however, is what Deep South Products did not do. The peanuts used had been certified by USDA, but certification had been made 7 to 10 months previously, and by the time they ended up in the peanut butter, the aflatoxin levels had apparently increased.

FDA's **Orlando District** discovered the problem during routine surveillance for aflatoxin contamination. Lab analysis showed that a number of jars from Deep South Products contained aflatoxin in excess of 20 parts per billion. The manufacturer recalled and destroyed the peanut butter from the contaminated lots, about \$16,500 worth. In addition, local grocers checked their shelves for peanut butter from Deep South Products that had come from those lots—which were identified by the code on the jars—and destroyed another 800 cases.

Seizures and Postal Service Cases

FILED SEIZURE ACTIONS

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

A total of 32 actions to remove from the consumer market products charged to be violative was reported in September. These actions included 13 of foods: 3 involved charges of poisonous and deleterious substances, 7 of contamination, and 3 of economic and labeling violations. Others included 16 of drugs, 2 of veterinary/medicated feed, and 1 of a medical device.

PRODUCT, DISTRICT & DATE FILED	FIRM & PLACE OF BUSINESS	CHARGES
FOOD/Poisonous and Deleterious Substances		
Cheese, sliced, Austrian/U.S. District Court for the Southern District of Texas 5/21/80	N. Dorman & Co., Inc./Syosset, N.Y.	Contains the poisonous or deleterious substance histamine.
Peanuts, shelled/U.S. District Court for the District of Utah 5/28/80	Birdsong Peanuts, Div. of Birdsong Corp./Gorman, Tex.	Contains the added poisonous or deleterious substance aflatoxin.
St. Johnswort, and St. Johnswort capsules/U.S. District Court for the Eastern District of Washington 6/4/80	J & P Industries, Inc., d/b/a Red Apple Herbs/Wenatchee, Wash.	Contains the poisonous and deleterious substance St. Johnswort (<i>Hypericum perforatum</i> L.), in such quantity as ordinarily renders it injurious to health; and contains the nonconforming food additive St. Johnswort, since not in hypericin-free alcohol distillate form and not limited to alcoholic beverages.
FOOD/Contamination, Spoilage, Insanitary Handling		
Bakery base, and powdered sugar/U.S. District Court for the District of Puerto Rico 6/2/80	Mendez Martinez & Co., Inc./Guaynabo, P.R.	Held under insanitary conditions; rodent gnawed and contain insects.
Cheese, cheddar/U.S. District Court for the Central District of California 6/11/80	Timber Lake Cheese Co./Timber Lake, S.Dak.	Prepared and packed under insanitary conditions.
Cornstarch, flour, rice, and other foods/U.S. District Court for the Middle District of Louisiana 5/19/80	Imperial Food Supply (Michael Di-Vincenti, Sr.)/Baton Rouge, La.	Held under insanitary conditions; some articles contain rodent filth.
Flour/U.S. District Court for the Northern District of California 4/7/80	Shipped from Spokane, Wash.	Held under insanitary conditions in a railcar; rodent contaminated.
Garbanzo beans, lentils, and other dried peas and beans/U.S. District Court for the Southern District of Texas 6/19/80	Atlantic Steamers Supply of Pennsylvania, Inc./Houston, Tex.	Held under insanitary conditions.
Peanuts/U.S. District Court for the Western District of Washington 5/29/80	Rogers Candy Co./Seattle, Wash.	Held under insanitary conditions.
Pumpkin seeds, raw, and roasted/U.S. District Court for the Eastern District of California 4/15/80	Nature's Goodies, Inc./Woodland, Calif.	Roasted seeds had been prepared and packed under insanitary conditions; raw seeds were insect contaminated.
FOOD/Economic and Labeling Violations		
"Honey"/U.S. District Court for the Southern District of Texas 4/21/80	Oliver Anthony/Philadelphia, Miss.	Corn sirup substituted for honey. Violation of Fair Packaging and Labeling Act, since quantity of contents statement lacked a dual declaration of net quantity of contents.

PRODUCT, DISTRICT & DATE FILED	FIRM & PLACE OF BUSINESS	CHARGES
"Maple" sirup and "honey"/U.S. District Court for the Western District of Kentucky 7/3/80	Anthony's Syrup Co./Philadelphia, Miss.	Substances other than maple sirup and honey had been substituted for the products. Labeling is false and misleading since neither product is what its label claims it to be; the "maple" sirup fails to meet standard of identity for maple sirup. Label statement of weight of the "honey" is not in ounces followed in parentheses by pounds.
FOOD ADDITIVE		
Egg noodles, enriched/U.S. District Court for the Western District of Michigan 4/23/80	House of Noodles, Inc./Chicago, Ill.	Contains the nonconforming food additives lindane, methoxychlor, and Diazinon; prepared and packed under insanitary conditions.
DRUGS/Human Use		
Allopurinol tablets/U.S. District Court for the Central District of California 6/13/80	Pharmadyne Laboratories, Inc./Elmwood Park, N.J.	New drug without an effective approved New Drug Application.
AN-57 acid neutralizing powder/U.S. District Court for the District of Kansas 5/23/80	Dean of Vitamins/Newton, Kans.	Circumstances of manufacture not in conformity with current good manufacturing practice. Misleading labeling, since lacks general pharmacological category statement "antacid"; labeling lacks adequate directions for use or adequate warnings against unsafe use.
Betamethasone valerate cream/U.S. District Court for the Southern District of Florida 5/1/80	Clay Park Laboratories/Bronx, N.Y.	New drug without an effective approved New Drug Application.
Chlorthalidone tablets/U.S. District Court for the Central District of California 6/13/80	Pharmadyne Laboratories, Inc./Elmwood Park, N.J.	New drug without an effective approved New Drug Application.
Chlorthalidone, and other specified drugs/U.S. District Court for the Southern District of Florida 6/17/80	Pharmadyne Laboratories, Inc./Elmwood Park, N.J.	New drugs without effective approved New Drug Applications.
Diethylpropion hydrochloride T.D. tablets/U.S. District Court for the Central District of California 6/13/80	Pharmadyne Laboratories, Inc./Elmwood Park, N.J.	New drug without an effective approved New Drug Application.
Diocetyl sodium sulfosuccinate tablets/U.S. District Court for the Eastern District of Pennsylvania 6/27/80	Pharmacaps, Inc./Elizabeth, N.J.	Manufacture, processing, and holding not in conformity with current good manufacturing practice.
Doxine tablets, and other specified drugs/U.S. District Court for the District of Connecticut 5/12/80	Premo Pharmaceutical Laboratories, Inc./South Hackensack, N.J.	New drugs without effective approved New Drug Applications.
Doxylamine succinate combination tablets/U.S. District Court for the Central District of California 6/13/80	Pharmadyne Laboratories, Inc./Elmwood Park, N.J.	New drug without an effective approved New Drug Application.
Furosemide tablets/U.S. District Court for the Southern District of Florida 5/1/80	Superpharm Corp./Central Islip, N.Y.; Generix Drug Corp./Hollywood, Fla.	New drug without an effective approved New Drug Application.
Furosemide tablets/U.S. District Court for the Central District of California 6/13/80	Pharmadyne Laboratories, Inc./Elmwood Park, N.J.	New drug without an effective approved New Drug Application.
Furosemide tablets/U.S. District Court for the Central District of California 6/25/80	Superpharm Corp./Central Islip, N.Y.	New drug without an effective approved New Drug Application.
Hydroxyzine hydrochloride tablets/U.S. District Court for the Central District of California 6/13/80	Pharmadyne Laboratories, Inc./Elmwood Park, N.J.	New drug without an effective approved New Drug Application.
Hydroxyzine pamoate capsules/U.S. District Court for the Central District of California 6/16/80	Pharmadyne Laboratories, Inc./Elmwood Park, N.J.	New drug without an effective approved New Drug Application.
Prednisone tablets/U.S. District Court for the District of Connecticut 5/23/80	Zenith Laboratories/Northvale, N.J.	New drug without an effective approved New Drug Application.
Prochlorperazine capsules/U.S. District Court for the Central District of California 6/13/80	Pharmadyne Laboratories, Inc./Elmwood Park, N.J.	New drug without an effective approved New Drug Application.

PRODUCT, DISTRICT & DATE FILED	FIRM & PLACE OF BUSINESS	CHARGES
Veterinary/Medicated Feed		
Cattle feed containing DES premix/U.S. District Court for the District of Minnesota 5/30/80	Mixed in Minnesota prior to DES ban.	The animal feed contains the new animal drug DES, and no New Animal Drug Application is in effect with respect to its use or intended use.
Feed supplement for horses, Sho 'n Pro Gain or Sustain/U.S. District Court for the Southern District of Mississippi 6/19/80	Reyncon, Inc./Columbus, Ohio	New animal drug and no New Animal Drug Application is in effect with respect to its use or intended use.
MEDICAL DEVICE		
Oxygen generator kits for emergency use/U.S. District Court for the Southern District of Florida 5/22/80	Green Cross Solid State Oxygen, Inc./Dania, Fla.	Quality falls below its represented quality since it delivers less than the amount of oxygen stated on its label. Labeling fails to bear adequate directions for use since adequate directions for use cannot be written for the purpose for which it is intended. Product is dangerous to health when used in the manner suggested in its labeling.

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)

- June 9, 1980: **Biotex**, P.O. Box 644, Laurel, Maryland. Advertising and sale through the mail of the product "Herpes Genitalis," pamphlet entitled "A Method of Treating Herpes Genitalis Symptoms," representing guaranteed treatment for *herpes genitalis*.
- June 10, 1980: **Rush, Inc.**, 300 Park Avenue, S, New York, New York. Advertising and sale through the mail of the product "Sauna Slim Shorts." The ad states in part, "you can feel the action of sauna slim shorts working to rid you of unwanted inches. Amazing sauna shorts works like a sauna . . . locks in body heat as you shrink inches off."
- June 11, 1980: **Hanover House**, 340 Poplar Street, Hanover, Pennsylvania. Advertising and sale through the mail of the product "Streamliner Body Sauna." The ad states in part, "exciting new way to melt off pounds 'n inches without diet or exhausting exercise. Now it's easy to conquer flab, fat, cellulite with our scientifically designed fat-away garments. No special diets, exercise, or massage needed . . . promotes fluid loss and helps tone up flabby muscles."

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

- March 24, 1980: Against **American Health Products**, P.O. Box 9669, Atlanta, Georgia. Satisfactory evidence was presented to the Postal Service that American Health Products and their agents are engaged in conducting a scheme or device to obtain money by means of false representation. This firm was advertising the product "FORMULA 12." The advertisement states in part, "the cellulite eliminator . . . get rid of these ugly lumps, bumps, and bulges of cellulite with remarkable, new medical discovery . . . FORMULA 12 is a 100% natural way to help you REMOVE cellulite bulges and keep them away. Working with the body's natural functions FORMULA 12 is much more effective than creams and much simpler than strenuous exercise . . . now there is a way to defeat cellulite."
- March 26, 1980: Against **L. S. King, Mr. Bold Co.**, P.O. Box 233, Manuta, New Jersey. Satisfactory evidence was presented to the Postal Service that L. S. King, Mr. Bold Co., and their representatives are engaged in conducting a scheme or device to obtain money by means of false representation with respect to the sale of Alpha I, representing the ability to cure impotency.
- April 4, 1980: Against **Standard Research Labs**, P.O. Box 9547, Fort Lauderdale, Florida. Satisfactory evidence was presented to the Postal Service that Standard Research Labs and their agents are engaged in conducting a scheme or device to obtain money through the mails by means of false representation. The firm was advertising the product "Biotin Hair Restoration Gel." The ad states in part, "in the intensive research done with Biotin, in addition to proving Biotin able to catalyze hair growth in dormant scalps, Biotin brought excessive hair loss under control in 9 out of 10 cases."
- April 10, 1980: Against **Rush Industries**, 300 Park Avenue, New York, New York. Satisfactory evidence was presented to the Postal Service that Rush Industries and their representatives are engaged in conducting a scheme or device to obtain money through the mails by means of false representation with respect to the sale of Hair-Plus. The advertisement states in part, "Hair-Plus contains ingredients to promote healthy, beautiful hair, even though your hair problem may be hereditary, you may have only inherited dietary deficiencies that each Hair-Plus tablet will help correct."

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Mung beans, peeled, and whole mung beans, at South San Francisco, N. Dist. Calif.

Charged 3-2-78: when shipped by Kong Peng, Bangkok, Thailand, the article contained the added pesticide chemical endrin and no tolerance or exemption for such pesticide chemical in or on mung beans had been prescribed; 402(a)(2)(B). Consent decree authorized release to Eastimpex, San Francisco, Calif., for salvaging of the whole mung beans and for export to the original foreign supplier of the peeled mung beans. (F.D.C. No. 61604; S. No. 78-144-980 et al.; N.J. No. 1)

Soybeans, at Loxley, S. Dist. Ala.

Charged 1-19-79: when shipped by Lapeyrouse Grain Corp. of Mississippi, Inc., Okolona, Miss., the article (commingled food soybeans and pink-colored, fungicide-treated seed soybeans) contained the pesticide chemical captan and the pink-colored soybeans exceeded the 2 ppm tolerance for captan (105 to 302 ppm); 402(a)(2)(B). Consent decree authorized release to Lapeyrouse Grain Corp., Loxley, Ala., for salvaging. (F.D.C. No. 61978; S. Nos. 79-100-806/8; N.J. No. 2)

FOOD/Contamination, Spoilage, Insanitary Handling

Beans, kidney, at Dallas, N. Dist. Tex.

Charged 12-4-79: when shipped by Blount Agriculture Co. (Agri Sales, Inc.), Elwell, Mich., the article contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the shipper for salvaging. (F.D.C. No. 62701; S. No. 80-210-231; N.J. No. 3)

Beans, pinto, canned, at Ponce, Dist. P.R.

Charged 11-20-79: while held for sale, the article was contained in swollen cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 62675; S. No. 79-173-372; N.J. No. 4)

Flour, at Richmond, N. Dist. Calif.

Charged 4-7-80: while in transit in a railcar, the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Southern Pacific Transportation Co., San Francisco, Calif., for salvaging. (F.D.C. No. 62922; S. No. 80-219-325; N.J. No. 5)

Flour, rolled oats, and macaroni, at Shreveport, W. Dist. La.

Charged 1-21-80: while held by Shreveport Warehouse Services, Inc., Shreveport, La., the articles contained insect and/or rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decrees authorized release of the macaroni to the dealer for salvaging and release of the flour and oats to Benhard Grain, Inc., Palmetto, La., for salvaging. (F.D.C. No. 62756; S. Nos. 80-221-321/4; N.J. No. 6)

Milk, nonfat, dry, at Jacksonville, M. Dist. Fla.

Charged 3-19-79: while held by Jefferies Foods Co., Inc., Jacksonville, Fla., the article had been held under insanitary conditions; 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 62151; S. No. 79-172-625; N.J. No. 7)

Peanuts, shelled, at Albany, N. Dist. N.Y.

Charged 4-17-80: while held by Empire State Nut Co., Inc., Albany, N.Y., the article had been held under insanitary conditions; 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 62926; S. No. 80-175-393; N.J. No. 8)

Pumpkin seeds, roasted, and unroasted pumpkin seeds, at Woodland, E. Dist. Calif.

Charged 4-15-80: while held by Nature's Goodies, Inc., Woodland, Calif., the articles contained insect filth, and roasted pumpkin seeds had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 62872; S. No. 80-219-421; N.J. No. 9)

Rice, and dog food chunks, at Metter, S. Dist. Ga.

Charged 4-30-80: while held by Greene Grocery Co., Metter, Ga., two lots of the rice and the dog food chunks contained rodent filth—402(a)(3); all of the articles had been held under insanitary conditions whereby the articles may have become contaminated with filth, and the dog food chunks had been held under insanitary conditions whereby they might have been rendered injurious to health—402(a)(4). Consent decree ordered destruction. (F.D.C. No. 62876; S. No. 80-197-881 et al.; N.J. No. 10)

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

Charged 9-25-79 and amended 11-2-79: when shipped by Kenai Packers, Inc., Kenai, Alaska, the article contained decomposed salmon; 402(a)(3). The shipper claimed the article and denied the charge. Subsequently, a consent decree of condemnation authorized release to the claimant for salvaging. (F.D.C. Nos. 62476, 62621; S. Nos. 79-212-573 et al., 79-212-807 et al.; N.J. No. 11)

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

Charged 9-17-79: while held for sale, the article contained decomposed fish; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 62445; S. No. 79-212-035; N.J. No. 12)

Sticks of mint cream candy, at Miami, S. Dist. Fla.

Charged 7-3-78: when shipped by J. G. McDonald's Chocolate Co., Salt Lake City, Utah, the article was unfit for food; 402(a)(3). B & A Sales Inc., Miami, Fla., claimed the article, denied the charge, and filed a request for the production of documents. The claimant also served written interrogatories. Consent decree ordered destruction. (F.D.C. No. 61803; S. No. 78-172-443; N.J. No. 13)

Whiskey, wine, beer, nonalcoholic beverages, grapefruit juice, preserved cherries, and other foods, 4 seizure actions, at Nome, Dist. Alaska.

Charged 3-27-75: while held for sale in four retail establishments, the articles had been held under insanitary conditions whereby they might have been contaminated with filth and whereby they might have been rendered injurious to health (the articles were inundated by flood waters); 402(a)(4). The articles were claimed by K & L Distributors, Inc., Bellevue, Wash. The parties served written interrogatories on each other. Postseizure sampling was undertaken upon motion of the claimant; and a U.S. marshal was authorized to approximate the quantities of goods seized without requiring a precise accounting until the time the goods were removed for destruction or returned to the owners. Consent decrees ordered the destruction of all beer products and all nonalcoholic articles. Subsequently, consent decrees of condemnation authorized release of the remaining alcoholic beverages to the claimant for salvaging. The parties litigated the method of salvaging in each of the actions. The court ruled for the Government, saying:

"This cause comes before the court on Claimants' Motion to Permit Reconditioning of Articles After Decree of Condemnation.

"These articles, consisting of bottles and cans of various types, were damaged in a flood in Nome, Alaska, in 1974. Upon a Complaint for Forfeiture by the United States a Consent Decree of Condemnation was entered by the Court on June 9, 1976. The Decree declared the items to be adulterated while held for sale after shipment in interstate commerce within the meaning of 21 U.S.C. §342(a)(4). The Decree also allowed the Claimants to recondition the articles pursuant to 21 U.S.C. §304(d) under the supervision of the Food and Drug Administration.

"The F.D.A. has notified Claimants that it will certify the goods as acceptable only upon complete reprocessing of the product. Claimants desire to reprocess by using a combination of external cleansing and visual inspection. In the Claimants' view the position of the F.D.A. is arbitrary and capricious and will result in significant financial harm.

"In *United States v. 1322 Cans, Etc.*, 68 F. Supp. 881 (N. D. Ohio 1946) the Court stated that in such matters the F.D.A. is to determine the proper method for reconditioning. It is also worthy to note that the Consent Decree specifically authorized the F.D.A. to supervise and approve the reconditioning. The F.D.A. has submitted an extensive affidavit of an expert in support of its position that it cannot be said that its action is arbitrary and capricious nor an abuse of discretion.

"Claimants wish to distinguish *United States v. 1322 Cans, Etc.*, 68 F. Supp. 881 (N. D. Ohio 1946) on the ground that in that case there was actual adulteration of the goods and that here there is only external contamination. Alternatively, Claimants maintain that the F.D.A. does not need to test all of the bottles but only a representative sample. See e.g., *United States v. 43 1/2 Gross 'Xcello's Prophylactics'*, 65 F. Supp. 543 (D. Minn. 1946), *Aff'd sub nom. Gellman v. United States*, 159 F.2d 881 (1947). These points are not well taken.

"The thrust of the F.D.A.'s affidavits is that the reconditioning plan proposed by Claimants may in fact result in actual adulteration once the bottles and cans are opened. In addition, the Consent Decree deems the articles adulterated in violation of 21 U.S.C. §342(a)(4).

"As to the sampling procedure proposed by Claimants, the case relied upon is not on point. In *United States v. 43 1/2 Gross 'Xcello's Prophylactics'*, supra, the court specifically noted that there was no issue as to the samples being representative. 65 F. Supp. at 536. In the present case the affidavits submitted by the government show that there is serious question in this case as to the representative status of any sample. The affidavit of Mr. Davis shows that each can or bottle is subject to differing degrees of contamination and, therefore, it is impossible to obtain a representative sampling.

"As to the financial loss that will befall Claimants, the court in *United States v. 1322 Cans, Etc.*, 68 F. Supp. 881, 882 (N. D. Ohio 1946) noted that such consideration is immaterial."

The claimant requested the court to reconsider its decision on the grounds that the court had failed to consider: that danger to health and safety was not an issue; that the remaining articles were "lots" of liquor in a variety of conditions, not all meriting the same disposition; and that the reconditioning plan should be feasible, incorporating the doctrine of a *de minimus*. In denying the claimant's motion to reconsider, the court said:

"The issues raised in the Motion to Reconsider were considered by the Court prior to its August 13 decision. The [claimant's] plan for a pilot reconditioning is based on the premise that a representative sample can be obtained. This question was previously dealt with. The fact that the approved reconditioning plan may be economically unfeasible was also specifically considered."

Ultimately, when the claimant failed to bring the remaining articles into compliance, the court ordered them destroyed. (F.D.C. Nos. 60241, 60243/4, 60246; S. Nos. 19-599 H, 19-601 H, 19-602 H, 19-604 H; N.J. No. 14)

FOOD ADDITIVES

Candy suckers, at Willow Springs, W. Dist. Mo.

Charged 2-29-80: when shipped by Lecas Candy Mfg. Co. (Palmer Candy Mfg. Co.), Pana, Ill., the article contained the nonconforming color additives amaranth (the former FD&C Red No. 2) and Violet

No. 1; 402(c). Default decree ordered destruction. (F.D.C. No. 62846; S. No. 79-164-867; N.J. No. 15)

DRUGS/Human Use

Amygdalin powder, at Wilmington, Dist. Del.

Charged 12-1-78: when shipped by Chemisches Labor Heinrich Kaden, W. Germany, the article, labeled in part "Chemisches Labor Heinrich Kaden . . . 5 kg. Vitamin B17 - Raw - Chemicals" was a new drug without an effective approved New Drug Application, and was not exempt pursuant to the order in *Rutherford v. United States*, since the article was not solely for the personal use and benefit of any individual having the required affidavit—505(a); the article's label lacked the prescription legend—503(b)(4); and the article's labeling lacked adequate directions for use and was not exempted since the label lacked adequate information for use by licensed practitioners—502(f)(1). The article was claimed by Metabolics Products, Inc., Wilmington, Del., which denied the charges. Subsequently, a consent decree ordered the article destroyed. (F.D.C. No. 61965; S. No. 78-143-621; N.J. No. 16)

Aromatic crystals, silver nitrate solution, pyrogallol acid ointments, undecylenic acid combination ointment, and other human and veterinary finished drugs, in-process drugs, and drug components, at Upper Darby, E. Dist. Pa.

Charged 5-5-77: while held by Gordon Laboratories (Bernice Gordon), Upper Darby, Pa., who was manufacturing finished human and veterinary drugs using interstate components, the circumstances used for the articles' manufacture, processing, packing, and holding failed to conform with current good manufacturing practice—501(a)(2)(B); a number of specified veterinary drugs were new animal drugs and no approval of a New Animal Drug Application was in effect with respect to the use or intended use of such drugs—501(a)(5); and the silver nitrate solution lacked adequate directions for use—502(f)(1). The manufacturer claimed the articles. Consent decree ordered destruction of the specified new animal drugs and authorized release to the manufacturer of the other drugs for bringing into compliance. (F.D.C. No. 61145; S. No. 77-47-932 et al.; N.J. No. 17)

Bitter Food amygdalin, lactose & cellulose tablets, at E. Orange, Dist. N.J.

Charged 1-28-76: while held by Spectro Foods Corp., Metamail Food Corp., and Ernst O. & Jeanene Moenckmeier, E. Orange, N.J., after manufacture from interstate components, the article contained the nonconforming food additive amygdalin, and the article's labeling lacked adequate directions for its intended use, since the labeling did not state the purpose and condition for which the article was intended, i.e., the treatment and prevention of cancer; 402(a)(2)(C), 502(f)(1). The dealers of the article appeared and moved to dismiss the complaint on a number of grounds, including that the complaint was not verified, that the complaint did not describe the property with reasonable particularity, and that other proceedings against amygdalin had been commenced contrary to law. Subsequently, the article was destroyed pursuant to a consent decree. (F.D.C. No. 60634; S. No. 76-35-136; N.J. No. 18)

Chlorthalidone tablets, allopurinol tablets, and furosemide tablets, at Pulaski, W. Dist. Va.

Charged 2-20-80: when shipped by Pharmadyne Laboratories, Inc., Hackensack, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). Default decree ordered destruction. (F.D.C. No. 62815; S. No. 80-208-580; N.J. No. 19)

Chlorthalidone tablets, hydroxyzine HCl tablets, allopurinol tablets, furosemide tablets, hydroxyzine pamoate capsules, and trimethoprim with sulfamethoxazole tablets, at Richmond, E. Dist. Va.

Charged 2-7-80: when shipped by Pharmadyne Laboratories, Inc., Hackensack, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). Default decree ordered destruction. (F.D.C. No. 62785; S. No. 80-208-547; N.J. No. 20)

Chorionic gonadotropin for injection with combination diluent, at Memphis, W. Dist. Tenn.

Charged 11-29-79 and amended 1-28-80: when shipped by Carter-Glogau Laboratories Division, Melrose Park, Ill., the article, labeled in part (carton) "Multiple Dose Vial 10 ml. (When Mixed) GLUKOR When Mixed, each ml contains Chorionic Gonadotropin . . . Thiamine Hydrochloride . . . Procaine Hydrochloride . . . Manufactured For . . . Hyrex Pharmaceuticals . . . Memphis, Tennessee," was a new drug without an effective approved New Drug Application—505(a); the circumstances used for the article's processing, packing, and holding failed to conform with current good manufacturing practice—501(a)(2)(B); the quality and purity of the article fell below the U.S.P. standard for chorionic gonadotropin for injection, since the U.S.P. product only allowed suitable diluents, buffers, and an antimicrobial agent in the preparation, while the article's diluent contained thiamine and procaine hydrochlorides (not permitted in the official product), without stating in its labeling that the product differed from the official one and how it differed—501(b); the labeling of the article failed to bear adequate directions for use and was not exempted due to the article's new drug status—502(f)(1); and the labeling was false and misleading as to the expiration date, since the manufacturer had inadequate stability data to support such date—502(a).

The article was claimed by B-G Corp., Inc., Memphis, Tenn., which denied the charges. Subsequently, a consent decree ordered destruction. (F.D.C. No. 62387; S. No. 79-132-244; N.J. No. 21)

Diuril chlorothiazide tablets, at West Point, E. Dist. Pa.

Charged 4-1-80: while held by Merck, Sharpe & Dohme (Div. Merck & Co., Inc.), West Point, Pa., who manufactured the article using interstate chlorothiazide, the quality of the article fell below the U.S.P. standards for chlorothiazide tablets, since the article did not meet the standard for weight variation; 501(b). Default decree ordered destruction. (F.D.C. No. 62901; S. No. 79-203-224; N.J. No. 22)

Procaine hydrochloride combination capsules, 2 seizure actions, at El Paso, W. Dist. Tex.

Charged 3-14-80 and 3-14-80: when the capsules manufactured at Cork, Ireland, were imported by Ayoub Exports, Inc., El Paso, Tex., and when the capsules manufactured at Cologne, Germany, were imported by International Bonded Warehouses, Inc., El Paso, Tex., the articles, labeled in part "K.H.3 Geriatricum - Schwarzhaupt . . . Procaine HCl B.P. . . Hematoporphyrine base . . . capsules . . . Schwarzhaupt Ltd., Cork . . . Ireland" and "K.H. 3 Schwarzhaupt . . . Procaine HCl . . . Hematoporphyrine . . . Kapseln . . . Schwarzhaupt Koln," were new drugs without effective approved New Drug Applications; 505(a).

After more than a month, the clerk entered default in the actions. Subsequently, Ayoub Exports, Inc., filed a motion for a new trial as to the article manufactured in Ireland, as did International Bonded Warehouses as to the article manufactured in Germany. The Government opposed such motions. On the court's own motion, the actions were consolidated and both actions proceeded under the action number of the seizure of the German-made article. The court refused to grant a new trial and ordered the articles destroyed. In so acting, the court said:

"Claimant has filed a Motion for New Trial which the Court will

treat as a motion to set aside default under the terms of Rule 55, F.R. Civ. P. Even considering the more liberal provisions of Rule 55, however, the Court does not find that Claimant has shown good cause to set aside the default.

"Claimant received the Summons on March 17, 1980. Nothing was filed with this Court until May 2, 1980. In Claimant's motion, Claimant asserts that at the time it received the Summons, Claimant did not realize that it had a potentially meritorious defense to the claim. The affidavit attached to Claimant's motion indicates that Claimant relies on the defense of equitable estoppel due to Claimant's lack of notice that the drug K.H.3 could not be imported. Claimant first relies on two Customs Service circulars that Claimant argues created a right on Claimant's part to be notified about the status of K.H.3 prior to seizure of the drug. A reading of those circulars reveals no confusion on the part of the Customs Service regarding the drug K.H.3; a reading of the circulars shows that the only notice required in those Customs Service memos was notice to claimants after a drug was detained. Claimant received such notice in this case.

"Claimant also seeks to establish lack of notice, or detrimental reliance, by pointing out that Claimant imported the drug K.H.3 for several years prior to 1980 without comment from the Customs Service. Prior importation of the drug without trouble from the Customs Service was a fact known to Claimant even before the Summons was served on Claimant in this case; Claimant was not entitled to delay filing an answer and verified claim on this ground.

"Furthermore, the affidavit attached to Claimant's Motion for New Trial is vague as to the time Claimant learned all the facts Claimant argues were not within its knowledge at the time it received the Summons. More than six weeks passed between the time Claimant received the Summons and filed the Motion for New Trial; over five weeks went by between the time Claimant received the Summons and the Clerk entered the Default.

"The Court also notes that Plaintiff filed an affidavit stating that the manufacturers of the drug never registered with the Food and Drug Administration so as to entitle the manufacturers to notice of the status of K.H.3, and that there is no approved New Drug Application or Notice of Claimed Investigational Exemption on file for the drug K.H.3. Claimant has not controverted Plaintiff's affidavit.

"Finally, although Claimant submitted an Answer and Verified Claim with its Motion for New Trial, Claimant has not pled equitable estoppel as an affirmative defense in its answer." (F.D.C. Nos. 62888, 62889; S. Nos. 80-211-186, 80-211-187; N.J. No. 23)

DRUGS/Veterinary

Aminoplex boluses, D-Panthenol injectable, Kalflex calf scours treatment, Methiodol cat & dog tablets, vitamin K, Pecto-Mycin diarrhea treatment, and amino acid boluses, at Elwood, Dist. Kans.

Charged 2-24-77: while held by Medico Industries, Inc. (t/a Med-Tech, Inc.), Elwood, Kans., who manufactured the articles using interstate components, the articles were new animal drugs and no approval of New Animal Drug Applications were in effect with respect to their use or intended use; 501(a)(5). Consent decree ordered destruction of the Pecto-Mycin diarrhea treatment and authorized release to the manufacturer for salvaging of the other articles. (F.D.C. No. 62062; S. No. 77-85-446 et al.; N.J. No. 24)

Sulfa combination medicated premix, at Dayton, Dist. Oreg.

Charged 1-24-80: when shipped by Quality Plus Products Co., Inc., Fort Dodge, Iowa, the article, labeled in part "Special Mix . . . Sodium Sulfamethazine . . . Sodium Sulfamerazine . . . Sodium Sulfathiazole . . . Sodium Sulfaquinoxaline . . . Vitamin A . . . Manu-

factured For Northwest Territories Gresham, Oregon," 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. 62757; S. No. 80-176-134; N.J. No. 25)

MEDICAL DEVICES

Urinometer tester for glucose in the urine, at North Logan, Dist. Utah.

Charged 11-8-79: the article, which had been manufactured by Brothers Scientific Products, Inc., Chicago, Ill., bore a label and an accompanying insert which contained false and misleading claims for testing sugar levels in the urine of diabetics, for being accepted by FDA, and for being approved by the medical profession—502(a); the device's labeling lacked adequate directions for use and such could not be written for the intended use of testing sugar levels in the urine of diabetics—502(f)(1); and the article was dangerous to health when used as directed—502(j). Default decree ordered destruction. (F.D.C. No. 62464; S. No. 79-118-763; N.J. No. 26)

X-ray system, Traceray III, at Bryan, N. Dist. Ohio.

Charged 10-18-79: the article, which had been manufactured by Western States Supply, Ltd., Pueblo, Colo., was dangerous to health when used as directed because the device would emit radiation beyond the pre-set exposure time—502(j); and the article's quality fell below its purported quality because the x-ray control component failed to comply with the required performance standard—501(c). Consent decree authorized release to the possessor for reconditioning. (F.D.C. No. 62496; S. No. 79-186-425; N.J. No. 27)

X-ray systems, Traceray III, 6 seizure actions, at Colby, Dist. Kans.; Cedar Falls, N. Dist. Iowa; Brent, N. Dist. Ala.; Austintown, N. Dist. Ohio; Boardman, N. Dist. Ohio; and Fredericksburg, N. Dist. Ohio. Charged 10-5-79, 10-5-79, 10-16-79, 10-2-79, 10-9-79, and 10-2-79: the articles, which had been manufactured by Western States Supply, Ltd., Pueblo, Colo., were dangerous to health when used as directed, because the articles would emit radiation beyond the pre-set exposure time—501(j); the accompanying labeling was false and misleading in claiming compliance with the regulations' standards, and in claiming that the devices would deliver the radiation exposure stated in the instruction manual—502(a); and the articles' quality fell below their purported quality—501(c). Consent decree authorized release to possessors for reconditioning. (F.D.C. Nos. 62477, 62478, 62491, 62497, 62498, 62499; S. Nos. 79-164-647, 79-164-648, 79-158-594, 79-186-733, 79-112-669, 79-186-056; N.J. No. 28)

NOTICES OF JUDGMENT on Criminal Actions

Richard E. Goldhamer, consultant and animal laboratory director for a drug investigation laboratory, Englewood Cliffs, Dist. N.J.

Charged 7-12-79: that the defendant knowingly and willfully conspired with an Englewood Cliffs' drug investigation laboratory, its officers, and others to make, use, and caused to be made and used false writings and documents knowing them to contain false, fictitious, fraudulent statements and entries in matters within the jurisdiction of FDA (including the creation of reports which allegedly reflected the results of laboratory preclinical investigations, but which investigations had not been performed as represented; that, as part of the conspiracy, the conspirators would and did provide reports to pharmaceutical companies sponsoring the drug, which reports were maintained and submitted to FDA as part of their obligations to provide FDA with information about laboratory preclinical investigations, including animal studies, and which led the sponsor to conclude that the drug was reasonably safe to initiate clinical investigations; that,

as part of the conspiracy and to deceive FDA and the sponsors into believing that the reports were based on actually completed laboratory preclinical investigations, the conspirators created a number of specified fraudulent documents and materials (e.g., animal feeding data sheets, animal blood chemistry data sheets, slides purporting to show animal organ sections, and reports of histological examinations of organs, tissues, and slides); and that in furtherance of the conspiracy a number of specified overt acts were committed; 18 U.S.C. 1001; 18 U.S.C. 371. Guilty plea; 3 years imprisonment, 2 ½ years suspended (provided 6 months served in a minimum security prison), and probation for 3 years. (F.D.C. No. 61868; C.F. No. 20850; N.J. No. 29)

Gardner Brooklyn Warehouse, Inc., John M. Gardner, vice president, and **Max Reiner**, warehouse manager, Brooklyn, E. Dist. N.Y.

Charged 11-30-77: anise seeds were held under insanitary conditions in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; \$500 fine. Guilty pleas by individuals; \$250 fines each. (F.D.C. No. 60906; S. No. 76-42-082 et al.; N.J. No. 30)

T.L. Jeffrey Distributing Co., Inc., and **Thomas L. Jeffrey**, president, at Dallas, N. Dist. Tex.

Charged 4-16-80: strawberry gelatin mix, cornstarch, cherry gelatin mix, black cherry gelatin mix, and vanilla pudding mix were held under insanitary conditions in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Corporation pleaded guilty; \$500 fine. Individual pleaded guilty; \$500 fine. (F.D.C. No. 61517; S. No. 76-15-142 et al.; N.J. No. 31)

Schepps Grocer Supply, Inc., and **Gary N. Schepps**, vice president & general manager, Dallas, N. Dist. Tex.

Charged 11-13-78: buttermilk pancake mix (count 1), regular cornmeal (count 2), cornmeal mix (count 3), and enriched degerminated cornmeal (count 4) were held under insanitary conditions in a building accessible to insects and were contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty plea to count 1 by individual (not charged in other counts); \$800 fine. Guilty plea to all counts by corporation; \$3,200 fine. (F.D.C. No. 61705; S. No. 77-114-862 et al.; N.J. No. 32)

Shaw-Perdue Corp., t/a Seven-Up Bottling Co., Richard L. Shaw, president, and **Robert L. Kimmich**, plant manager, North Kansas City, W. Dist. Mo.

Charged 3-16-78: when shipped to Olathe, Kans., 7-Up beverage had been prepared and packed under insanitary conditions, and contained mold, yeast, and foreign particles—402(a)(3), 402(a)(4); and 7-Up beverage (contains interstate liquid sugar) was prepared, packed, and held at North Kansas City, Mo., so as to result in the beverage containing mold and foreign particles—402(a)(3). Nolo contendere plea by corporations; \$2,000 fine. Nolo contendere plea by president; \$2,000 fine, imposition of imprisonment sentence suspended, and probation for 1 year. Nolo contendere plea by plant manager; \$1,000 fine, imposition of imprisonment sentence suspended, and probation for 1 year. (F.D.C. No. 61317; S. No. 77-24-690 et al.; N.J. No. 33)

NOTICES OF JUDGMENT on Injunction Actions

Barry-Martin Pharmaceuticals, Inc., and **Barry I. Russinof**, president, Miami, S. Dist. Fla.

Charged 4-11-78: that the defendants were engaged at their plant in Miami, Fla., in manufacturing, processing, packing or repacking, labeling, holding, and distributing in interstate commerce various drugs, a number of which were held for sale after shipment of their interstate components; that the circumstances used in the drugs' manufacture, processing, packing, and holding failed to conform with current good

manufacturing practice; that the quality of several lots of digitoxin tablets fell below the U.S.P. standard, since the tablets failed to meet the dissolution standard; that the defendants' digoxin tablets failed to bear adequate warnings against unsafe use; that FDA inspections revealed a number of specified significant deviations from current good manufacturing practice; and that the defendants were well aware that their activities were in violation of the law; 501(a)(2)(B), 501(b), 502(f)(1), 502(f)(2).

A consent decree of permanent injunction enjoined the complained of violations and enjoined further operations involving interstate drugs unless and until a number of specified conditions had been met. (Inj. No. 846; S. No. 78-140-806 et al.; N.J. No. 34)

Crystal Cream & Butter Co., Kenneth W. Hansen, president, and Robert J. Beard, production manager, Sacramento, E. Dist. Calif.

Charged 5-21-75: that the defendants had been engaged in manufacturing, processing, packing, labeling, holding for sale, shipping in interstate commerce, and shipping locally (for use in products shipped in interstate commerce) nonfat dry milk; that such food contained the new animal drug penicillin in excess of the prescribed zero tolerance; that USDA analyses of eight sublots of nonfat dry milk indicated penicillin contamination at levels of from 0.08 units per gram to 0.10 units per gram; and that the defendants were well aware that their activities were in violation of the law; 402(a)(2)(D).

A consent decree of permanent injunction enjoined the complained of violations and enjoined the distribution of any milk product of the defendants which was for introduction into interstate commerce or which was for use in a product for introduction into interstate commerce, unless and until a number of specified conditions were met. Subsequently, the defendants moved to dissolve the decree of permanent injunction for the following reasons: the firm had been in compliance for 5 years; the firm would continue to use a sensitive detection system approved by FDA; the firm's facilities would continue to be open for normal inspection by HEW; and the decree was unique among dairy processors in California and was no longer necessary. Thereafter, pursuant to stipulation of the parties, the decree of permanent injunction was dissolved and dismissed. (Inj. No. 701; S. No. 30-012 H et al.; N.J. No. 35)

Irma Hernandez, Inc., Edwin Hernandez, president, and Carlos R. Hernandez, secretary, Aguada, Dist. P.R.

Charged 4-4-78: that the defendants were engaged at their warehouse in Aguada, P.R., in holding interstate foods, such as salted codfish, flour, pink beans, and rice; that such salted codfish, flour, and pink beans contained rodent filth and had been held under insanitary conditions; that FDA's inspections disclosed a number of insanitary conditions and practices; and that the defendants had been repeatedly warned of the insanitary conditions and practices in their warehouse; 402(a)(3), 402(a)(4).

The court issued a temporary restraining order temporarily restraining and enjoining the defendants from placing in their warehouses and distributing therefrom any interstate foods. Subsequently, a consent decree of permanent injunction was entered permanently enjoining the defendants from the complained of violations. (Inj. No. 848; S. No. 78-147-236 et al.; N.J. No. 36)

NOTICE OF JUDGMENT on Miscellaneous Action

X-Otag Plus tablets and new drug status thereof, Broomfield, Dist. Colo.
Charged 2-24-77 (and amended 3-14-77) by Tutag Pharmaceuticals, Inc., against the United States of America, HEW Secretary Joseph A. Califano, Jr., Acting FDA Commissioner Sherwin Gardner, and

the Food and Drug Administration, in a complaint for injunction and declaratory judgment: that the plaintiff had been a manufacturer and distributor of X-Otag Plus since September 1975; that, previously, the drug had been in use for many years in the United Kingdom; that individual ingredients making up the combination drug had been in use for many years; that the combination of ingredients was generally recognized as safe and effective by substantial evidence and by qualified experts; that plaintiff, on the basis of such widely held and documented evidence, had concluded that its combination of ingredients could not be classified as a new drug and hence began to market the product (without an NDA); that, subsequently, the plaintiff received an FDA letter stating that the drug would be subject to regulatory action by FDA since there was no approved NDA for the drug; that such letter and a further FDA letter constituted the only Government evidences known to the plaintiff that X-Otag Plus was a new drug; that to avoid Government seizure and/or injunction action, the plaintiff submitted an Abbreviated New Drug Application (ANDA) for X-Otag Plus tablets; that X-Otag Plus was related to a pre-1962 drug, a drug covered by a DESI (Drug Efficacy Study Implementation Group of the National Academy of Sciences/National Research Council) announcement (e.g., Norflex orphenadrine citrate tablets and injectable, and Norgescic orphenadrine citrate, aspirin, phenacetin and caffeine); that nevertheless FDA refused to process plaintiff's ANDA for X-Otag Plus tablets; that FDA's assertions that X-Otag Plus was a new drug and was not a drug related to a pre-1962 DESI drug placed the plaintiff in an untenable position where plaintiff must either concede the issues, discontinue marketing, file a complete NDA and await NDA approval, or force imminent regulatory action; that irreparable harm could have been prevented by FDA if FDA had not arbitrarily and capriciously refused to find X-Otag Plus "related" to a pre-1962 drug.

The Government moved to dismiss the complaint. The plaintiff moved for a preliminary injunction. After a thorough examination of all the pleadings and exhibits in the case, and a study of the relevant cases, the court granted the Government's motion, saying:

"This case involves the restraint of enforcement proceedings by the Food and Drug Administration (FDA) against the manufacture for sale of X-Otag Plus by Plaintiff.

I.

"This matter arises on Defendants' Motion to Dismiss, filed on March 7, 1977, and on Plaintiff's Motion for a Preliminary Injunction, filed on March 9, 1977. We have thoroughly examined all the pleadings and exhibits in this file, and have studied the relevant cases. We grant Defendants' Motion to Dismiss.

"The Complaint for declaratory and injunctive relief in this case was filed on February 24, 1977. New drugs are subject to the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301, *et seq.*, which requires the filing of an approved New Drug Application (NDA) prior to marketing the drug. New drugs marketed without an NDA are subject to immediate regulatory action. Plaintiff seeks to enjoin Defendants from taking any threatened enforcement action. Plaintiff wants this Court to declare that Defendants' determination that X-Otag Plus is a new drug is arbitrary and capricious. Alternatively, Plaintiff seeks to enjoin any enforcement action until the FDA has made a final determination on the Abbreviated NDA submitted by Plaintiff on October 26, 1976. Further, Plaintiff wants this Court to declare that Defendants' refusal to approve its Abbreviated NDA was arbitrary and capricious.

"Plaintiff admits that it has not exhausted its administrative remedies. However, Plaintiff argues that Defendants' decision should be

considered final, because of the threat of imminent enforcement action. Indeed, the Government has instituted a suit in this Court for Forfeiture on March 7, 1977, Civil Action No. 77-F-248. Moreover, the Government has seized quantities of X-Otag Plus on March 8, 1977. Plaintiff alleges that this drug is generally recognized as safe and effective, and is sufficiently related to other drugs that have been reviewed for their safety and efficacy, so that a[n] NDA is not required. See 21 C.F.R. §310.6. Therefore, Plaintiff argues that the public interest would not be harmed by enjoining the Government. On the other hand, Plaintiff claims that it is being irreparably harmed by Defendants' actions.

II.

"We lack jurisdiction to issue the injunctive relief prayed for in this case. *Ewing v. Mytinger & Casselberry*, 339 U.S. 594 (1950) held that a Court lacks jurisdiction to enjoin enforcement proceedings under the Federal Food, Drug, and Cosmetic Act, even where there is no claim of a danger to public health, and where the seizure of drugs would cause irreparable harm to Plaintiff's business. *Id.* at 599. The manufacturer cannot collaterally attack the Government's decision to seize the drugs. Such an attack must be made directly, in the enforcement proceedings themselves. *Id.* at 598.

"Plaintiff argues that *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967) undermined the rationale of *Ewing*. On the contrary, *Abbott* reinforced the applicability of *Ewing* to the facts of the instant litigation. *Abbott* involved a challenge by drug manufacturers of regulations issued by the Commissioner of Food and Drugs. The Supreme Court held that pre-enforcement judicial review of these regulations is permissible. However, it sharply distinguished the challenge of regulations issued by the Commissioner from the challenge of an administrative finding with respect to a particular drug. . . . The instant case involves a determination by the FDA with regard to a particular drug. Moreover, this factual finding is not a 'final agency action.'

"Plaintiff relies on *Parke, Davis & Co. v. Matthews*, Civ. Action No. 6-72464 (E.D. Mich., Jan. 10, 1977) . . . to support our authority to issue injunctive relief. Because of the similarity of the relief requested in both cases, we must examine the fact situation and holdings in *Parke, Davis* at some length. The latter case is clearly distinguishable on its facts from the instant litigation. In 1948, Parke, Davis obtained an approved NDA permitting the marketing of Benylin as a prescription drug. In 1974, an advisory panel of experts tentatively approved Plaintiff's proposed over-the-counter (OTC) labelling for Benylin. In the same year, Plaintiff applied for supplemental NDA's for Benylin OTC. The FDA deferred action on these NDA's until the OTC drug review was completed by the panel. In March 1975, the FDA assured Plaintiff that there would be no legal proceedings against Plaintiff if it were to sell Benylin OTC, because it had been marketed for so many years in the past. In September 1975, Plaintiff commenced marketing Benylin OTC. In 1976, the FDA announced a new policy that OTC sale is permitted after final approval of the advisory panel, unless the Commissioner disagrees. In September 1976, the advisory panel approved Benylin OTC. The Commissioner postponed his decision until decision on the supplemental NDA's that had been filed by Plaintiff. In November 1976, these NDA's were denied, and the Commissioner dissented from the opinion of the advisory panel. This did not constitute the final decision of the FDA with regard to Benylin OTC, but Defendants threatened immediate enforcement.

"Parke, Davis sought a declaratory judgment that Benylin is not a new drug, and that it is not limited to distribution by prescription. Alternatively, Plaintiff asked that Defendants be enjoined from taking enforcement action against OTC sale of Benylin until a final agency

determination of the status of this drug. The Court held that it could not consider issues currently under consideration by the FDA, and dismissed Plaintiff's action for a declaratory judgment. However, the Court enjoined Defendants' threatened enforcement action. *Parke, Davis* represents a limited exception to *Ewing*, based on a theory of estoppel against the Government. . . .

"The instant case involves a drug that has not been marketed in the United States, either OTC or by prescription. Most significantly, the FDA has never assured Plaintiff that the sale of X-Otag Plus would be permitted. On the contrary, letters from the Government, attached as Exhibits to Plaintiff's Complaint, reveal that from the beginning of this controversy, the Government has disapproved of Plaintiff's actions, and has clearly set forth the procedures that Plaintiff must follow in order to market its drug. Moreover, unlike Parke, Davis, Plaintiff has not even attempted to file a[n] NDA. Indeed, Plaintiff has brought this action in an effort to circumvent this requirement. Because the *Ewing* rationale applies in this case, we lack jurisdiction to issue the injunctive relief prayed for by Plaintiff.

III.

"We also lack jurisdiction to issue the declaratory relief prayed for in the Complaint. Plaintiff would have us determine that X-Otag Plus is not a new drug, and that Defendants acted arbitrarily in making their initial decision that X-Otag Plus is a new drug. Defendants do not dispute Plaintiff's right to judicial review of a final agency determination that X-Otag Plus is not a new drug. However, even *Parke, Davis* emphatically held that such determinations cannot be made by the Court until the FDA has rendered a final decision. *Id.* at 8 and 11. A Court lacks the jurisdiction, as well as the expertise, to decide issues involving determinations of scientific facts, in the absence of a final decision by the FDA. The final, reviewable decision of the FDA on these issues should contain full findings of fact. We cannot usurp the intended function of this administrative agency. . . .

"Plaintiff cannot avoid the prescribed regulatory procedures by marketing its product and then asking this Court to make administrative determinations, while we enjoin the Government from taking action upon its own non-final determinations. Therefore, we lack jurisdiction to issue any of the declaratory or injunctive relief prayed for in Plaintiff's Complaint. Accordingly, it is hereby ordered that Defendants' Motion to Dismiss is granted. Plaintiff's Motion for a Preliminary Injunction is denied. The Complaint and cause of action herein are dismissed." [See also N.J. Nos. 36 & 40 of FDA CONSUMER for September 1980.](Misc. No. 406; N.J. No. 37)

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.

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Jere E. Goyan, *Commissioner of Food and Drugs*
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