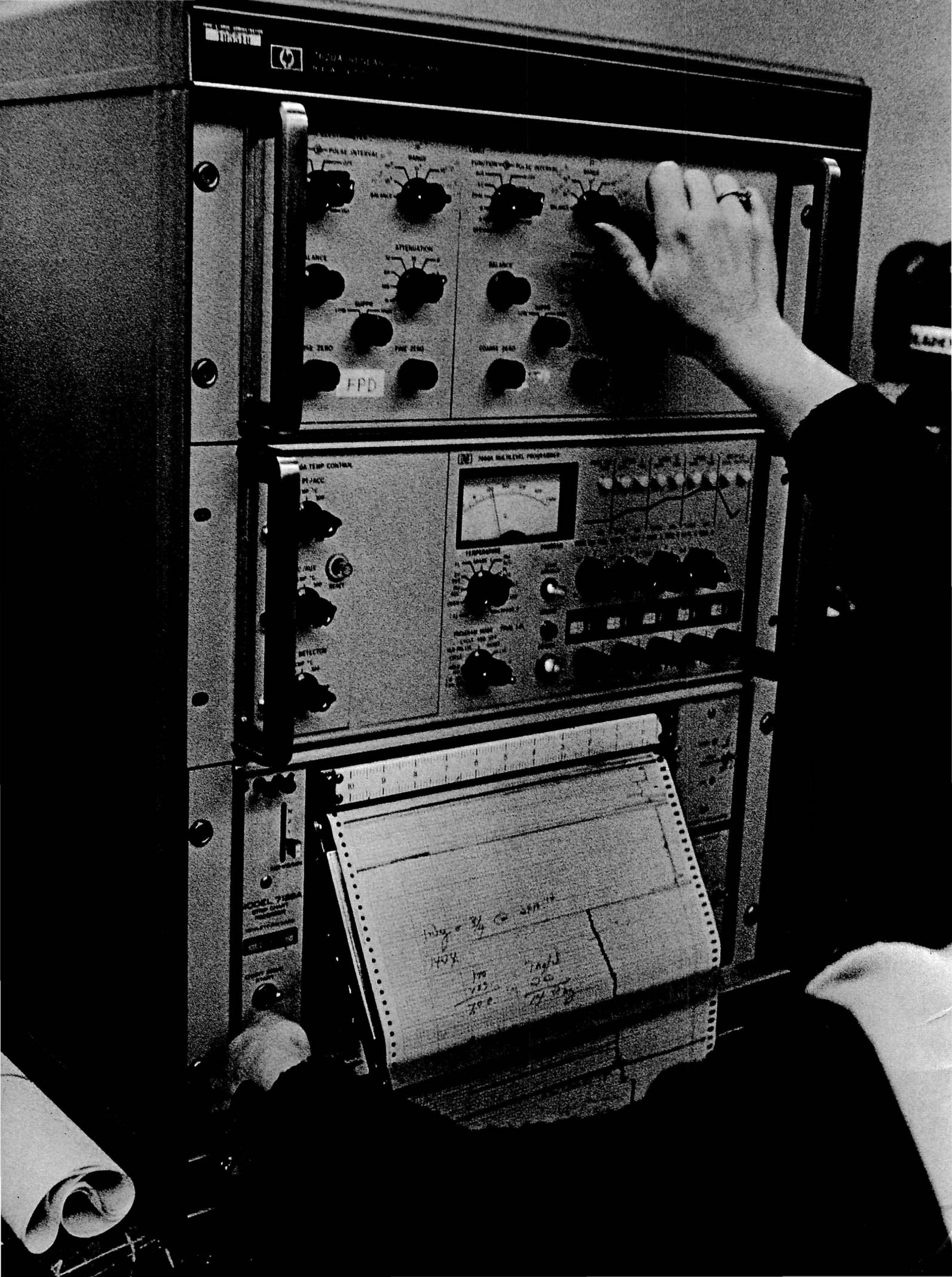
FDA
CONSUMER
FEBRUARY 1977

The Gadget Quacks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This Month

Whenever an article is written about a Government agency that is involved in scientific issues the key on the typewriter that produces capital letters is likely to get quite a workout. Between them, bureaucracy and modern science have produced an ocean of alphabet soup. People concerned about the purity and elegance of our language might be aghast at the growing tendency to substitute a string of capital letters for real words, but there is little likelihood that acronyms will disappear from our Nation's newspapers any time soon. DES simply fits into a one-column headline much more comfortably than diethylstilbestrol.

One acronym that has cropped up in the news often in recent months is PBB's. It stands for polybrominated biphenyls, and in Michigan it spells trouble. The trouble began when bags containing PBB's were mistaken for packages of another chemical that is used in cattle feed. There's a report on the mixup and the problems it produced under the title *PBB's: One State's Tragedy.*

When acronyms appear in the list of ingredients on food labels there is a good possibility that they refer to additives. The proper use of additives in food is just one subject discussed in a wide-ranging interview with nutritionist Joan Dye Gussow. Her views on what we are eating and how it might affect our health are presented in *A Nutritionist Looks at Food and the Marketplace.*

Acronyms are a form of shorthand, a way of shortening the time or space it takes to say a long word or phrase. Initials aren't the only means to that end, of course. The shorthand for oral contraceptives, for example, is "The Pill." Whatever oral contraceptives are called, FDA believes that women who take them should be fully informed about the benefits and risks of using this popular method of birth control. The most recent steps taken by FDA to assure that this belief is translated into action are described beginning on page 12.

Down through the years, acronyms haven't been especially popular with the promoters of medical gadgetry. The inventors and sellers of cure-all devices have shown a preference for words that give their wares an aura of scientific validity or hint at the presence of some mysterious healing force. *The Gadget Quacks* is a short tour through the often wacky world of lights, boxes, and ball bearings that have been offered to the unwary as cures for everything from hives to heart disease.

Completing this month's lineup is an article on a much more creditable group of medical devices known as gonad shields. How and why they are used is the subject of *Reducing Genetic Risk From X Rays.*

Inside Front Cover Photo: *An analytical device known as a gas chromatograph played a key role in identifying polybrominated biphenyls—PBB's—as the chemical that triggered an epidemic of mysterious maladies among livestock on Michigan farms in 1973. An article on how PBB's became an agricultural contaminant and what was done to control the situation once the mystery was solved begins on page 22.*

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

(a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of charge and the disposition thereof.
(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

Cover Design: Michael David Brown

Update

Fats and Oils Labeling Rule Revised

Early last year FDA ruled that fats and oils present in food should be listed on labels by their common or usual name, such as lard, or coconut oil, or beef fat and soybean oil shortening blend, instead of more generalized names such as animal fat, vegetable oil, or shortening. FDA also ruled that when hydrogen is added to a fat or oil the term "saturated" or "partially saturated" should be used as part of the name in the ingredient list. These new rules—scheduled to go into effect January 1, 1978—were explained in an article entitled Getting Specific About Fats and Oils *in the March 1976* FDA CONSUMER. *Here's an update.*

FDA has proposed a change in the rule covering the labeling of fats and oils that have been treated with hydrogen. The Agency has now proposed that such products be labeled as "hydrogenated" or "partially hydrogenated" rather than "saturated" or "partially saturated."

Hydrogen is added to some fats and oils during processing to convert them from a liquid to a solid form. (Hydrogenated products sometimes are referred to as "hardened.") Adding hydrogen to a fat or oil increases the amount of saturated fatty acids in the product. That is why FDA ruled last year that hydrogenated fats and oils should be labeled as "saturated" and "partially saturated."

However, even after hydrogen has been added to them, certain oils may still have less saturated fat than do animal fats, palm oil, and coconut oil that contain no added hydrogen. It is therefore possible for a hydrogenated product to contain less saturated fat than a product which has not been hydrogenated. Because of this FDA decided it would be misleading to substitute the word saturated for hydrogenated.

Under FDA's proposed new regulation, which was published in the November 30, 1976 FEDERAL REGISTER, the term "hydrogenated" will be used in an ingredient name when a fat or oil has been completely hydrogenated or hardened—meaning that it contains no unsaturated fat. Consumers are unlikely to see this term very often because few fats or oils are hardened to the point where they contain no unsaturated fat. The term "partially hydrogenated" will be used for ingredients that have been partially hardened.

Consumer Forum

Elusive Pain

As Mr. Larkin has pointed out in the opening statement of his article entitled, *To Serve Well And Not To Please: An FDA Dilemma,* October 1976 issue of FDA CONSUMER, *much* has changed since 1591 when the English scholar, John Florio, listed the ten pains of death.

We are all aware of the "new math" that has come into vogue, but the dilemma I have is that using either the old or the new math, I can only calculate nine, not ten, pains of death as the poem is written in Mr. Larkin's article.

Knowing the pains the FDA takes to be accurate and its interpretive nature, maybe the tenth pain should be, "to read that which is not printed". We could then use Mr. Larkin's suggested "eleventh pain of death—to mistrust the guard you hired to watch."

Robert E. Moore
Glen Ridge, New Jersey

Mr. Larkin's initial source for Florio's poem was a book by Gavin Maxwell on Sicily. Maxwell's book, like our article, lists but nine pains of death. Fortunately, the Rare Book Room of the Library of Congress had the answer. There, in Florio's book SECOND FRUITES, *reposes the tenth pain of death: "To hire a servant who disobeys."*

In his preface to FIRST FRUITES, *published in 1578, Florio addressed a plea to "the friendly, courteous and indifferent reader." He wrote: "Gentle Reader, for such faultes which have escaped the Authours naughty pen, the Compositors wavering hand, the Correctors dazeling eye, and the Printers presse, we desire thee courteously to amend. . . ."*

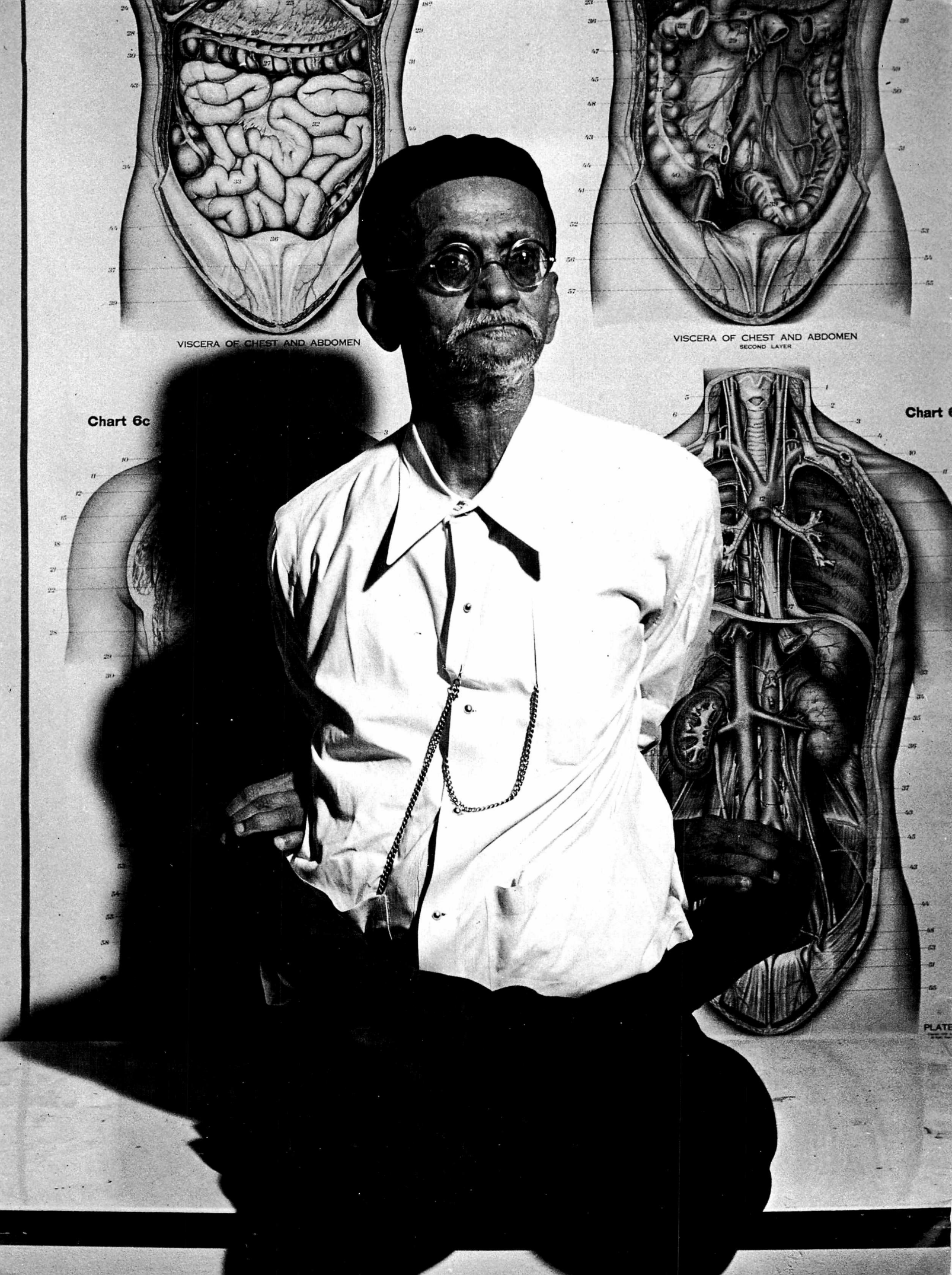
We thank Mr. Moore for his amendment, his courtesy, his friendliness and, above all, his lack of indifference.

Spray Paint Propellants

I noted in your November 1976 issue in a story on the fluorocarbon/ozone controversy that spray paints were included among a group of products which purportedly contain fluorocarbon propellants.

You and your readers will want to know that 97 percent of the aerosol spray paints on the consumer market today contain hydrocarbon propellants (propane, isobutane or combinations) which are not suspected of harming the upper atmospheric ozone layer.

Jerry L. Colness
Director, Communications Division
National Paint and Coatings Association
Washington, D.C.


VISCERA OF CHEST AND ABDOMEN
VISCERA OF CHEST AND ABDOMEN
SECOND LAYER
Chart 6c
Chart

The Gadget Quacks

Their devices may differ but down through the years the promoters of medical gadgets have relied on the same pitch: quick, painless cures of virtually all ailments and diseases. A new law gives FDA greater authority to control the promotion of useless medical devices, but an informed, skeptical public still is an important element in the consumer protection picture.

by Wallace F. Janssen

There was dead silence in the courtroom.

The tense little man in the witness chair leaned forward and shook his finger at the jury.

"I had fits all my life till Dr. Ghadiali cured me!" he shouted. "His Spectrochrome stopped my fits and now I feel grand!"

Suddenly the witness paled, stiffened in his chair and frothed at the mouth. As he began to convulse, a Government physician and courtroom attendants stepped forward, placed something in his mouth, and carried him away.

This shocking moment was but one of the dramatic episodes which marked the trial of Dinshah P. Ghadiali, "seventh son of a seventh son," and organizer of a nationwide healing cult which became a religion to his followers.

Ghadiali was a "gadget quack," inventor of the "Spectrochrome," a machine which resembled a theatrical spotlight. Spectrochrome, he claimed, would cure all diseases by projection of colored light. Not ordinary light, of course, but rays from a 1,000-watt bulb passed through a glass tank of water and focused by a crude lens through colored glass slides. Spectrochrome promised something special—"No diagnosis, no drugs, no manipulation, no surgery"—simply "attuned color waves." The light boxes bore labels stating they were "for the measurement and restoration of the human radioactive and radio-emanative equilibrium."

Directions for the treatment were spelled out in Ghadiali's textbook, SPECTROCHROMETRY. Combinations of light colors were specific for body areas and diseases being treated. Time of treatment was determined by the phases of the moon and the dictates of astrology. Latitude and longitude of the place of treatment were determined according to "solar, lunar and terrestrial gravitation." The patient had to be nude, with his body facing north.

Followers of the cult were organized in local congregations called "planets." Each planet was headed by a "Normalator" who gave treatments and instructed the faithful. Spectrochrome was more than colored light seances—it was a way of life to its followers! They must eat no meat and use no alcohol, tea, coffee, or tobacco. Honey and eggs were likewise taboo. Membership cost $90. Most amazing was the growth of the cult. At the time of the trial, Ghadiali had some 9,000 followers who paid dues and many others who took "treatments."

Spectrochrome promoter Dinshah P. Ghadiali was proud of his ability to assume the posture of a Hindu holy man.

Pathos and tragedy marked the trial in Federal court at Camden, New Jersey. The saddest testimony concerned people who had abandoned rational medical treatment and then succumbed to their diseases while depending on Spectrochrome. The Government presented facts on five of these cases in court and proved that the allegedly successful results were false. Three of the victims had died from the conditions Ghadiali claimed to have cured—two from tuberculosis, and a third from complications following severe burns. In the third case, Ghadiali's literature contained photographs purporting to show the stages in the healing of burns that covered a little girl's body. The mother testified that scars and open sores had continued until the girl died.

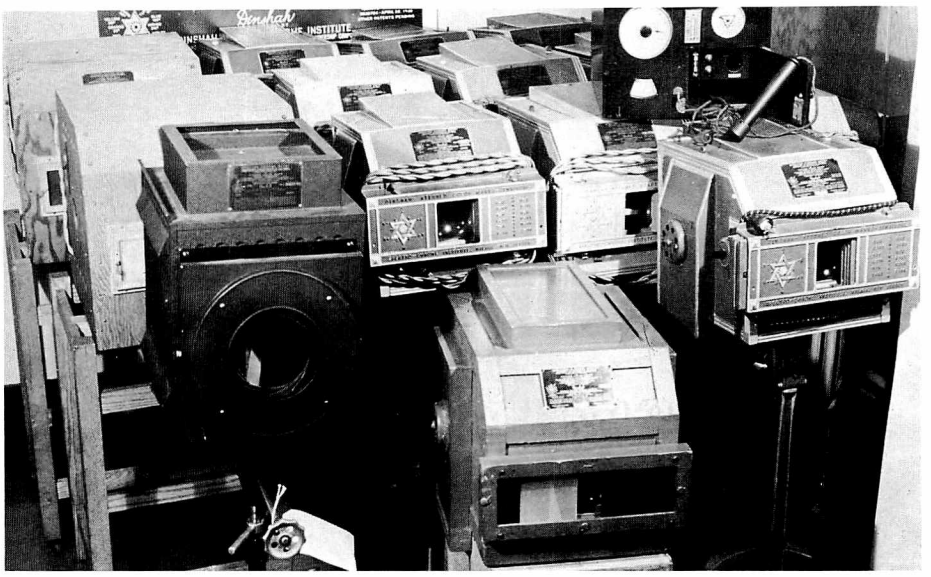
The fourth case was that of a girl whose sight Ghadiali claimed to have "restored," but who in fact was still totally blind. The fifth victim, a spastic girl completely paralyzed from the waist down, was carried to the witness chair. She had been photographed standing alone and the claim made that she could walk unaided. She testified that she had been supported by others except at the moment the picture was snapped.

The 42-day trial was the longest one involving FDA in its history up to that time. Ghadiali had 112 witnesses who testified they had used Spectrochrome successfully, making a total of 216 persons whose cases figured in the trial. Government witnesses included experts on cancer, diabetes, tuberculosis, heart disease, blood pressure, and nervous and mental disorders. The Government had to prove beyond a reasonable doubt that Spectrochrome was a fraud and Ghadiali its perpetrator.

On January 7, 1947, the jury brought in a verdict of guilty on all 12 counts in the case. The sentence, by Federal Judge Philip Forman, was carefully designed to avoid making a martyr of Ghadiali and to put a stop to his gigantic swindle. This was accomplished through a $20,000 total fine, probation for five years, and a three-year prison term to be served if the defendant resumed his illegal activities.

On the day his probation ended, Ghadiali announced his

A variety of models of Spectrochrome projectors were seized by U.S. marshals because of their false claims to cure disease by colored light.



intention to found a new "Institute." Changing the name slightly, he built more machines and resumed leadership of the local branches, renamed "studios." New literature was issued bearing substantially the same unwarranted claims as before. FDA requested an injunction which became permanent in July 1958, finally ending the operations of this "colorful" cult.

The Spectrochrome was but one of hundreds of contraptions and gadgets which FDA has dealt with since it first obtained legal powers over "therapeutic devices" in 1938. They range from seemingly complex electronic instruments to disarmingly simple articles of everyday use. In the mid-1950's, FDA seized a device called "Babylon's Zone Therapy Roller." This was simply a single large ball bearing mounted on a block of wood—resembling a furniture caster. The general idea was that massaging the feet on the ball would be beneficial for many different conditions. After all, are not the feet connected to the rest of the body, and do they not affect the way you feel? So why not treat the whole body through the soles of the feet?

A seemingly harmless device can be inherently dangerous. Consider the " Relaxacisor ," an electrical contraption for the overweight—designed to provoke muscle spasms through mild electrical shocks. This was promoted as "passive exercise," a pleasant and effortless way to reduce. It took years of investigation and a five-month court battle to put this profitable gizmo out of business. Forty witnesses testified about the injuries they had received from using it. Medical experts explained the hazards of treatment with such a machine. Federal Judge William P. Gray summed up the evidence by saying the Relaxacisor would be hazardous in a wide range of conditions including gastrointestinal, orthopedic, muscular, neurological, vascular, skin, kidney, and female disorders. He found it could cause miscarriages and could aggravate such pre-existing conditions as epilepsy, hernia, ulcers, and varicose veins.

More than 400,000 Americans fell for this major health hoax of the late 1960's. Obviously, to round up all these machines from all their users would have been practically impossible. Accordingly, FDA issued a public warning and arranged for public notices to be displayed in U.S. post offices throughout the country.

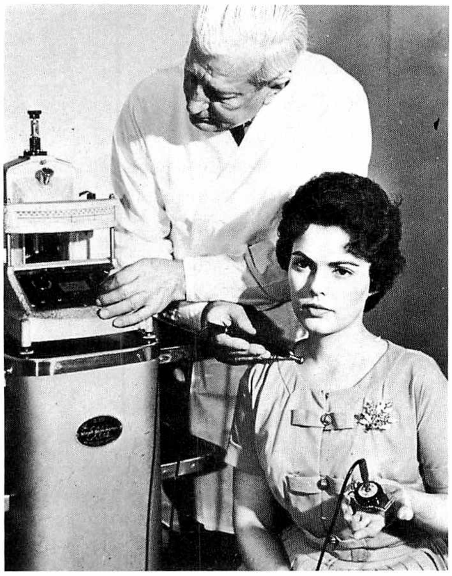
Much gadget quackery has been designed for use by health practitioners. During the 1950's and early 1960's, more than 5,000 "Micro-Dynameters" were sold. Chiropractors purchased many of them at prices up to $875. This machine was represented as capable of diagnosing and treating virtually all diseases (a sure sign of quackery). It consisted of a highly sensitive galvanometer fitted with various electrodes which were applied to different areas of the patient's body. Actually, the only condition it could detect was perspiration! Because of its uselessness, the court of appeals found the device unsafe even in the hands of a licensed practitioner.

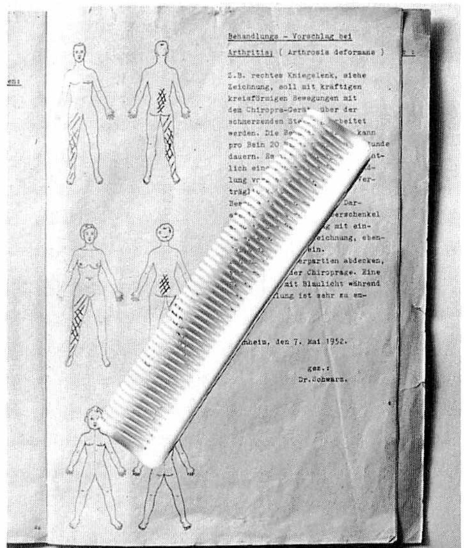
Since so much gadget quackery is absurd, why do people fall for it?

Gadget quackery had its beginnings thousands of years ago when man first invented charms and fetishes to ward off evil spirits and cure disease. Belief in magic is still a major factor in the success of health fads and cults. At the same time, the seeming miracles of science have made it easy to believe in science fiction.

When Benjamin Franklin published his discoveries on electricity he also helped open the door to a rash of medical frauds that probably has yet to run its course. The idea that electricity might have medical applications quickly became widely popular. Franklin himself worked with a physician who attempted to use electric shock in treating a woman for convulsions.

A few years after Franklin's death Elisha Perkins, a mule trader turned physician, secured a patent for "Perkins Tractors." The tractors, two pointed rods about three inches long, one gold-colored, the other silver, were simply drawn downward across the afflicted part of the anatomy, in a sort of scratching motion. This, it was theorized, would draw off the "noxious fluid" (electricity) which was alleged to cause disease. For a time, the Perkins treatment enjoyed amazing popularity. Ministers, college professors and Congressmen gave enthusiastic endorsement. The Chief Justice of the Supreme Court bought a pair and President Washington himself is supposed to have been a customer. The medical profession was initially impressed; but in 1796 the Connecticut Medical Society condemned the treatment as "gleaned from the miserable remains of animal magnetism," a quack theory that a few years before

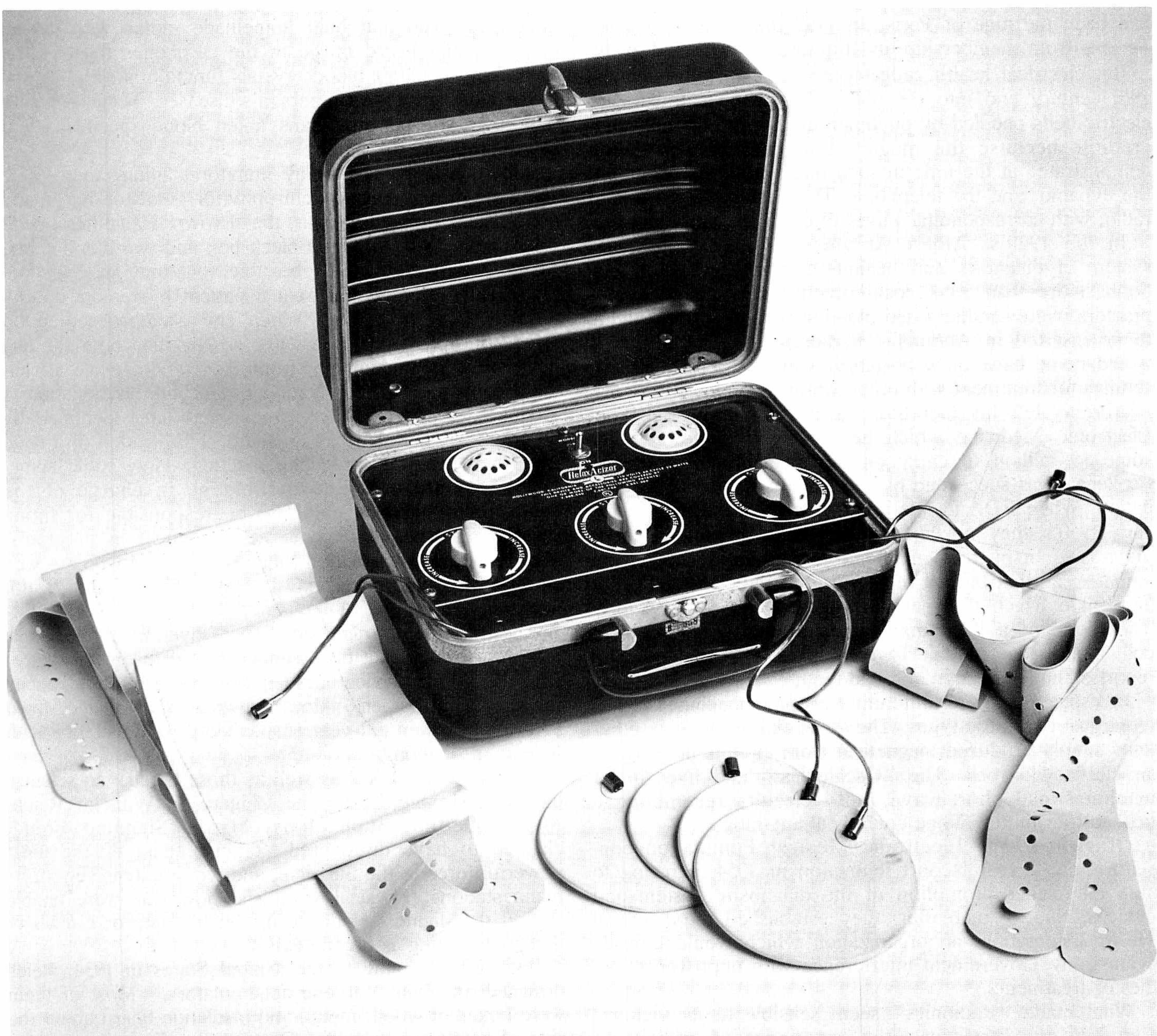




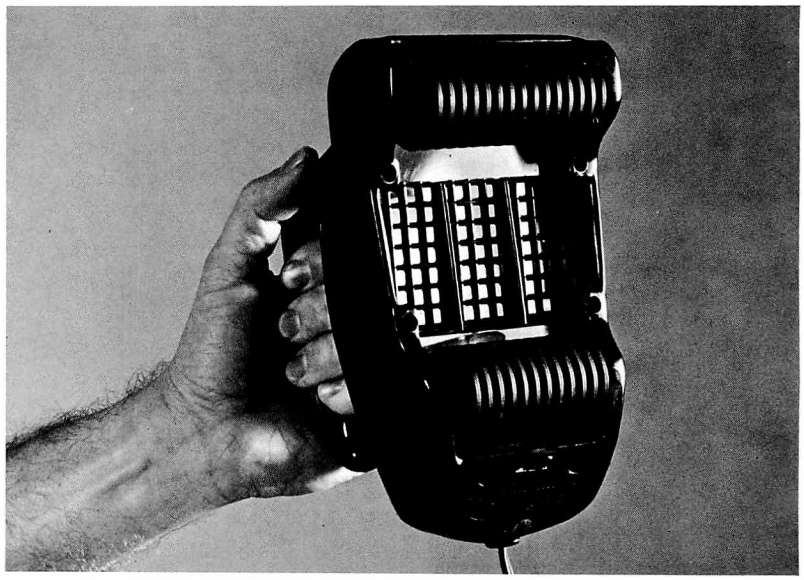
Micro-Dynameters were designed to impress patients with their scientific appearance, but the only condition they could diagnose was the amount of perspiration on the skin.

The Chiropra Therapeutic Comb, an import from Germany, was banned for false claims that scratching with it was effective treatment for many diseases. The 34-page brochure sold with the comb recommended body areas to be scratched for specific ailments.

The Relaxacisor was claimed to produce the benefits of exercise by means of electric shocks to stimulate muscle contractions.



The Roll-a-Ray, typical of a host of fake devices for reducing, was claimed to be effective for removing unsightly bumps and bulges. An ordinary electric light bulb was mounted behind two rubber rollers in a plastic case resembling an iron. Instructions were hardly necessary—just iron your fat to make it melt away.



had been the rage of Paris. In 1797 the Society expelled Perkins from membership and tractoration withered away.

But electrical health gadgetry marched on—through the 19th century and into the 20th. The medical efficacy of electric belts peddled by pitchmen at county fairs appeared credible because the magic of magnetism was being demonstrated at the time in such marvels as the telegraph, the dynamo, and the telephone. Then came the x ray and radio, with corresponding waves of electronic quackery.

In the 1920's, Albert Abrams, M.D., invented the system of diagnosis and healing he called "Radionics." Soon, more than 3,000 local practitioners, mainly chiropractors, were sending dried blood specimens from patients to be inserted in Abrams' "Radioscope." The diagnosis would come back on a postcard, with recommended dial settings for treatment with other Abrams machines.

Abrams left his lucrative business to the College of Electronic Medicine which he reportedly endowed with some $3 million to carry on his medical theories. The "college" was succeeded by the Electronic Medical Foundation. When FDA agents investigated this business in the early 1950's, they looked first into the blood spot system of diagnosis. Inspectors arranged to send blood from an amputee and got back a report of arthritis in the right foot and ankle which the man had lost several years before. The blood of a dead man brought back a diagnosis of colitis, and that of an 11-week-old rooster resulted in a report of sinus infection and bad teeth.

Investigating the 13 different treatment machines, FDA found just two basic types. The "Depolaray" and six other units simply produced magnetism from circuits like that of an electric doorbell. The "Oscilloclast" and five similar machines had short-wave radio circuits resembling a taxicab transmitter. None could heal anything.

Officials of the Electronic Medical Foundation consented to a Federal court injunction in 1954, agreeing to stop all further promotion of the diagnostic system and devices. Shortly thereafter, they established the National Health Federation, an organization which would crusade against any Government interference with unproven remedies or treatments.

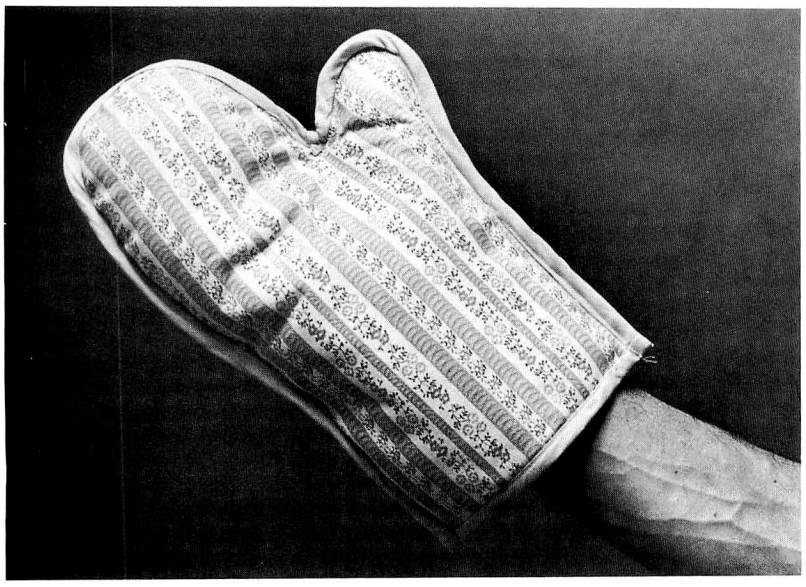
What made "Radionics" seem sensible to its victims? Certainly one factor was the experience of millions of Americans who had built homemade radios with crystal detectors and heard music in the earphones for the first time. Why couldn't blood crystals function like the crystal in the radio and reveal a person's diseases? Besides, hadn't their own trusted physicians taken blood specimens and sent them away for analyses?

Albert Abrams had many imitators, among them Ruth Drown, a Los Angeles chiropractor. One of her many nonsensical inventions was the Drown Radiotherapeutic Instrument. With this little black box and two blood spots, Mrs. Drown claimed to be able to "tune in" specific organs of the body and treat a patient by remote control anywhere in the world. When she was prosecuted by FDA, one of the defense witnesses testified how she had been cured of pneumonia, from Hollywood, while attending a convention of the National Education Association in Atlantic City. When this witness was later identified by reporters as chairman of the Board of Education of a large city, there was an immediate reaction. How could someone so uninformed and gullible be in charge of the education of 400,000 children, be responsible for hiring science teachers, organizing health education programs, and the like? A resignation followed. Persons who are well educated in some areas may be extremely naive in health matters.

The trial had its tragic side. The Government's principal case history was that of a woman treated for breast cancer with the Drown device until her case became too advanced for successful surgery. Mrs. Drown was convicted, fined $1,000, and given a 1-year suspended prison sentence with 5 years' probation.

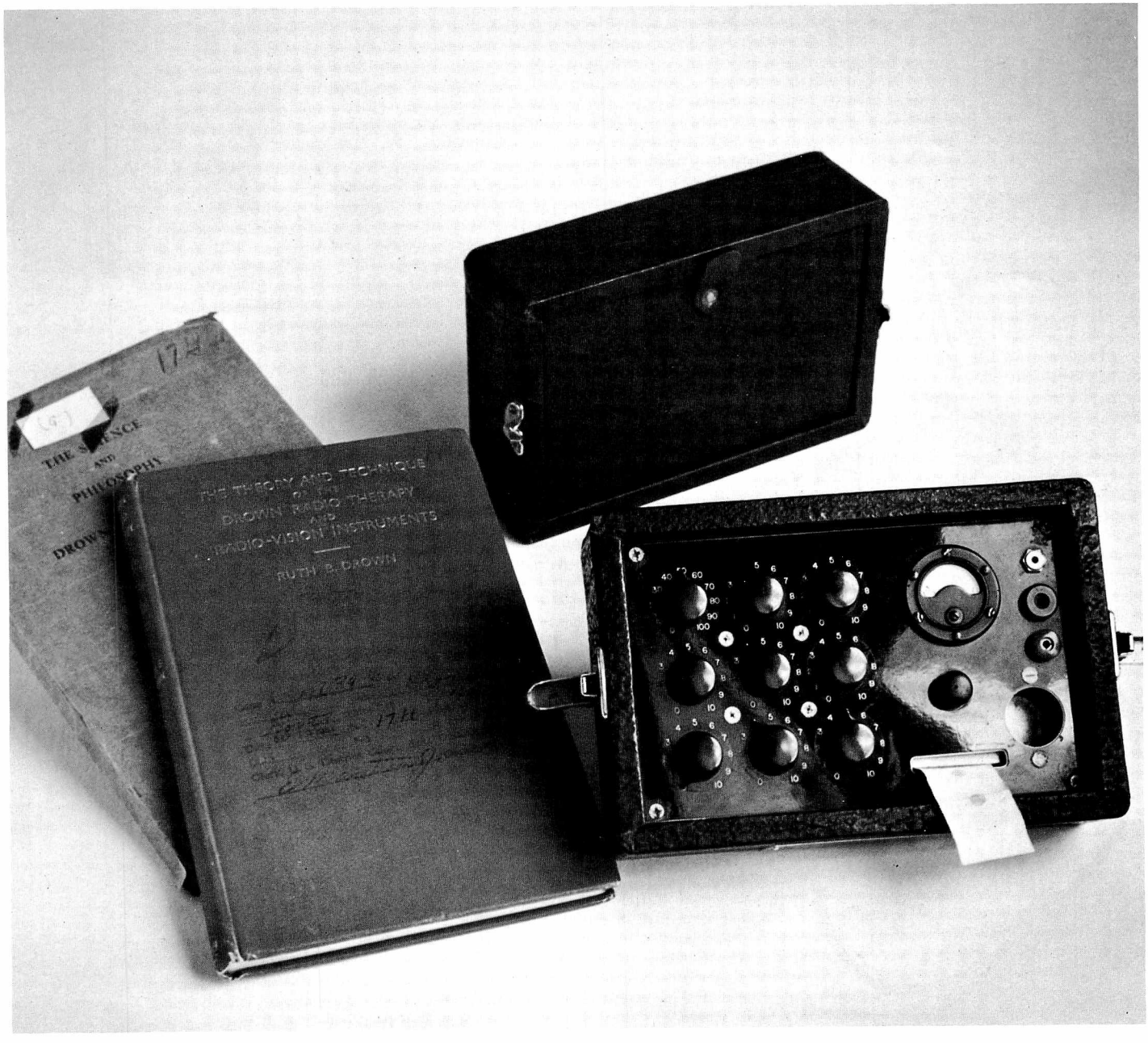
"Unknown forces," as well as those familiar to science, have been exploited by the gadgeteers. Wilhelm Reich, M.D., one-time pupil of psychiatrist Sigmund Freud, claimed to have discovered "orgone energy," the most powerful force in the universe, and wrote extensively of its manifestations. Physical scientists, however, were unable to find the slightest evidence in Reich's data or elsewhere that such a thing as orgone exists.

Soon after coming to the United States in 1934, Reich designed and built "orgone accumulators." Most of them were boxes of wood, metal, and insulation board about the size of a telephone booth. Disease, he claimed, could be

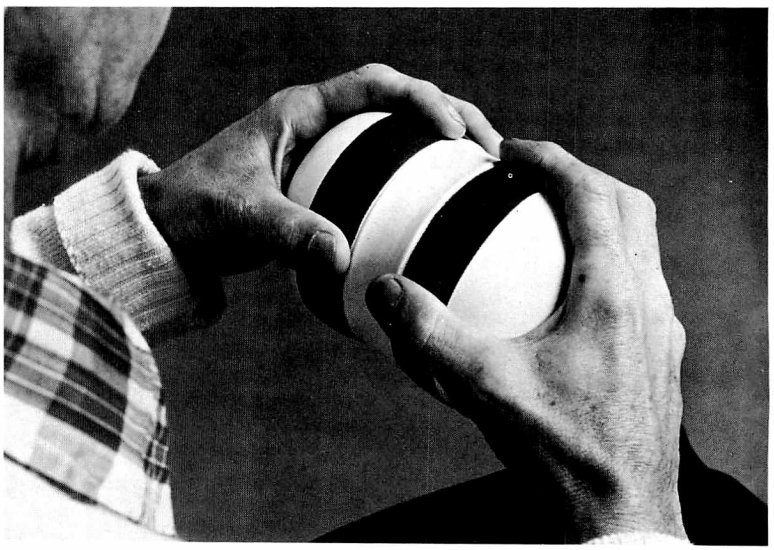


The Uranium Wonderglove, for painful arthritic hands, was one of many fake promotions based on alleged therapeutic radiation from uranium ore.

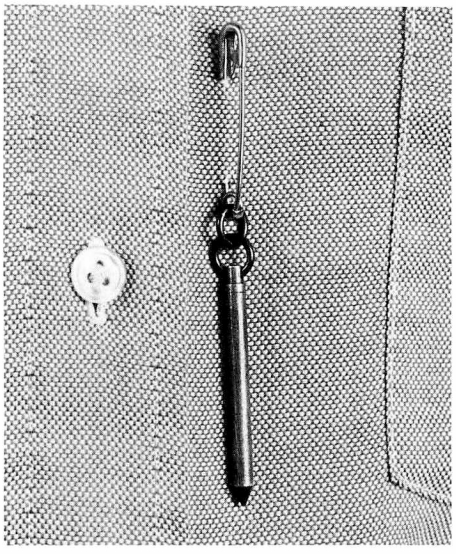
Ruth Drown claimed that with her Radio Therapeutic Instrument, using a single drop of the patient's blood as a "detector," she could "tune-in" on diseased organs of the body and restore them to health. With a two-drop specimen she claimed to be able to treat a patient by remote control, anywhere in the world. Thousands of Californians patronized her establishment, including many notables. Prosecuted by the State for grand larceny, she died awaiting trial.



The Zerret Applicator exploited popular interest in medical uses of atomic energy following World War II. Inside were tubes of "Zerret Water," claimed to produce the "Z-Ray, a force unknown to science." This was said to "expand the atoms of the body," thereby curing all diseases. Users were directed to hold one end of the device in each hand but not to cross the legs, which would cause a "short circuit." More than 5,000 were sold at $50 each. Prosecuted by FDA, the promoter was sentenced to two years in Federal prison.



Bust developers—hardy perennials in the garden of quackery—have been around going on a century. The Princess Bust Developer advertised in the 1897 Sears Roebuck catalogue is shown with a variety of similar gadgets seized by the FDA during the 1960's.



The Vrilium Tube, which came with a safety pin so it could be attached to the patient's clothing, contained a fraction of one cent's worth of barium chloride, a chemical used in developing photographs. Offered as a therapeutic source of radiation, thousands were sold for $306 each. The leading witness against the two promoters of the device was the father of a young male diabetic who was persuaded to use the "magic spike" instead of insulin, and died in a diabetic coma. Both promoters received one-year prison terms.

cured simply by sitting inside the box and absorbing the orgone. Hundreds of the boxes were sold or leased to practitioners and laymen for treatment of all kinds of diseases, including cancer. Rentals were around $250 per month. When FDA sued in 1954 for an injunction to stop the hoax, Reich told the judge that neither the court nor FDA were capable of understanding his orgone science and therefore he would not offer a defense. The injunction was then issued on the basis of the Government's evidence. When Reich continued to promote the box for treating the sick, he was prosecuted for contempt of court. Found guilty, he was sent to prison where he died in 1956.

From the outset of his difficulties with the Government, Reich attempted to pose as a martyr and to make his case a cause celebre. His family and followers have continued this effort. Destruction (by court order) of seized labeling material on the accumulator devices has produced accusations of "book burning." Actually, Reich's books have continued to be available. There has been no destruction of any of his publications other than those which accompanied the seized devices.

For many years, the only Federal control over device quackery was under the laws against mail fraud, with FDA acting as a scientific and medical adviser to the Post Office Department. This cooperative activity continues today.

In 1938, the new Federal Food, Drug, and Cosmetic Act made it illegal to sell therapeutic devices which are dangerous or marketed with false claims. Unfortunately, the need to establish that devices are safe and effective *before* they are marketed was not appreciated in 1938. Manufacturers continued to offer health devices—genuine or fake—with little or no effect to determine their safety or usefulness. To remove a device from the market, the Government first had to learn about it, then be able to prove in court that it was dangerous or misrepresented. Unless a device was clearly dangerous it could usually continue to be sold until all court proceedings were ended. And the more profitable the business, the more likely were its promoters to stretch out the litigation.

The 1938 law was designed primarily to control "quack" devices—generally those whose claims greatly exceeded their performance. Devices for legitimate medical uses which might be defective were left largely unregulated. Since the Government could stop sale of a device only by proving actual harm or deception, a manufacturer could in effect test his device on the public and wait for FDA to take action.

Last year a new law (the Medical Device Amendments of 1976) was enacted, substantially strengthening FDA's authority to require premarket approval of certain medical devices and to remove defective or fraudulent devices from the market. This new law will improve consumer protection, but there are still some guidelines consumers should follow to avoid being cheated by the gadgeteers and their gadgets.

First and foremost, don't believe anyone who tells you that one kind of diagnosis or one kind of treatment is effective for a wide range of diseases. The ancient Greeks had a word for this kind of oversimplification—"panacea"—good for curing everything. All panaceas are quackery.

Beware of all gadgetry promoted to aid in weight reducing. All "passive" or "effortless" exercise machines are fakes. The same is true of massagers which are represented as capable of "spot reducing." There are no devices which can "reproportion" one's figure without dieting and proper exercise. That includes all so-called "body wraps" and other sweat-inducing garments, girdles, belts, etc.

Beware of any treatment used by faith healers or promoted by crusading groups of laymen.

Don't fall for "science fiction." The real accomplishments of legitimate medicine are much more wonderful and deserving of confidence.

If you suspect a device is misrepresented, don't hesitate to contact the nearest Food and Drug Administration office.

Last, do not assume that because an article is on the market, is advertised, is prescribed, or is sent through the mail, it must be legitimate. Even under the new medical devices law, premarketing approval is not required for all new medical devices as is the case for all new drugs. And no matter how stringently and efficiently it is enforced, no law of this kind can provide total protection for consumers.

Wallace Janssen is FDA's historian. This article is taken from a chapter he wrote for THE HEALTH ROBBERS, *published by George F. Stickley Co., Philadelphia, Pa.*

A Nutritionist Looks At Food And The Marketplace

Few subjects generate greater interest and diversity of opinion than food. Such issues as how food is processed, the additives that go into it, the labels that go on it, and its impact on our health are matters of continuing concern to consumers. Joan Dye Gussow, chairman of the Program in Nutrition, Teachers College, Columbia University, discusses these and other issues in this interview with FDA CONSUMER *staff writer Annabel Hecht.*

Q. *How do you rate the nutritional status of the average American?*

A. I think we have to go by the only kind of data we have—which are morbidity and mortality (disease and death) rates. The increasing rates of cancer, heart disease, and diabetes are all suggestive of a complex of problems that seem to be related to diet factors. The whole complex of diseases we're talking about apparently would be less of a threat to our health if we ate a diet which had less meat, less saturated fat, less sugar, less salt, and probably less cholesterol in it, and more complex carbohydrates in the form of beans, grains, fruits, and vegetables. This would bring more fiber into our diet too. That appears now to be the appropriate dietary response for all of these diseases.

Perhaps for me the most distressing thing is that despite a tremendously complex and expensive medical treatment system which involves things like coronary by-pass operations and kidney transplants and dialysis machines and pacemakers we haven't significantly increased life expectancy for adults in twenty years. What this suggests is that we're sicker longer. If we're not living any longer, and we've got more things to keep us alive when we're sick, then the suggestion is that we have a shorter *healthy* life span. Something has been undercutting what should be steady progress toward health. And I don't think you can escape the conclusion that improper diet is a major contributing factor.

Q. *How can we change the lifestyle and eating habits of the Nation?*

A. As a nutrition educator, I'm supposed to have an answer to that, aren't I? Well, the first thing we have to do is recognize that education is considerably more than schooling. Most people say nutrition education has failed. I'll begin by saying we haven't really tried. We don't have nutrition education in schools; physicians are not trained to think of nutrition as an important factor in the cause and treatment of disease.

A great deal of what has passed for nutrition education in the past 10 or 15 years has been done by advertising, most powerfully by advertising on television. It has sold a whole set of attitudes and values about consumption in general, about newness and the value of newness, about making things easy.

I guess my answer to your question of how you change what the American people eat is that you must take a much broader view of what nutrition is and what the implications of diets are. If you look at the people who've changed their diets in the last five years they are people who have come to recognize that how you eat is a reflection of a kind of moral stance. For instance, if you eat less meat and more food that is lower on the food chain and requires less energy to produce, that is a responsible thing to do. It also happens to be better for your health.

I've been interested in the relationship between energy and food for many years. It's only in the last few years that people have begun to look at the American food supply in terms of its energy costs. We've been living in a fool's paradise for the past couple of years in terms of petroleum. We're not going to have petroleum in 40 or 50 years. We're going to have a very hard time finding a portable energy source which is going to allow us to do things like grow vegetables and fruits in California and ship them East or do the elaborate processing of food that we're presently doing.

Q. *What constitutes a good, well-balanced diet?*

A. A good dinner might be a relatively small portion of meat with the rest of your plate filled with vegetables and potatoes and maybe a green salad. In this country we've probably always had an overabundance of meat protein, animal protein in general, including eggs and cheese. We eat it because we can afford it, because we're rich, and it's a rich man's diet. I think a diet considerably higher in beans and grains, fruits and vegetables, is good. I don't necessarily say only fresh fruits and vegetables. Obviously people in certain parts of the country have difficulty getting fresh vegetables all year around.

Q. *What do you consider to be junk food?*

A. I once tried to help a student of mine define nutritious food, which I would define as the opposite of junk food. We came up with a

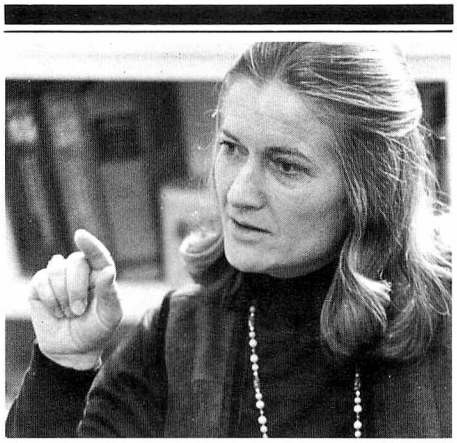
definition that a nutritious food is a food which contains a reasonable quantity of nutrients. That is protein, vitamins, and minerals, without being debased by excessive amounts of added salt, sugar, or fat. I don't like the term junk food. It's kind of a rag bag that saves thinking.

Do I think it's terrible if someone has a potato chip with a glass of wine before dinner? Not as long as the rest of the diet is okay. The foods I most object to are the really high sugar, high fat, snack foods that are sold to children. Most people are not aware of the degree to which many of these things are high in both sugar and fat. I once looked at the composition of some of those big snack-type cookies and several of them actually got 50 percent of their calories from fat. I don't believe most mothers know that. They're busy putting their husbands on low fat diets and giving their kids skim milk. They think of these cookies as loaded with sugar, not with fat. They're loaded with both!

Those are some of the worst things and the trouble is there really are kids in this country living off the stuff. I *do* blame the manufacturers. I don't think we have to keep doing studies to prove that advertising sells products. I am quite aware that if people ate the way I think they ought to eat, about half of the food industry would go out of business. The economics of food processing is such that the foods most likely to be heavily advertised are those which have been most processed to make them profitable over and above the cost of their raw ingredients.

Q. *Apparently you don't like a great deal of what you see in modern food markets. But can't you still get an adequate and well-balanced diet in the food market today?*

A. Most of what you need is available, but there are some difficulties. I wish there were more really good whole grain products. And there are things that are available in one store—maybe something like Jerusalem artichokes—that you can't get in another. I don't believe people have to do all their shopping in health food stores. In fact, I believe all markets should be health food stores. An awful lot of what you find in health food stores is a rip-off. It isn't necessarily healthful and it's often overpriced. I don't understand why, if



"An awful lot of what you find in health food stores is a rip-off. It isn't necessarily healthful and it's often overpriced."

the *food* is so healthful, they have to have all those vitamin and mineral supplements on the other wall.

Q. *Would you favor a total ban on food additives?*

A. No, I wouldn't. Some additives serve a really useful purpose. Many do not, however, especially those used for cosmetic purposes only, and I doubt that they should be permitted.

All additives certainly should be listed specifically on labels because consumers have a right to know. Additives pose a lot of problems. For example, a series of recent studies shows that such additives as phosphates and EDTA interfere with iron absorption by the body. We haven't got science to the point where we can be sure what we're doing. The only kinds of diets we have any long-term experience with are diets composed mainly of unprocessed foods. It isn't a question of proof of harm. It's simply that with the limitations of our science at the moment I think it's wise to eat food that is as close to the state in which it comes from the ground as is feasible.

There was a time when we could bring food into the house and tell by taste and smell and color and so forth whether it was fit to eat. But with all the preservatives and flavors and colors being put in food now you can't do that anymore. And so in a sense what we've done—as one author put it—is we've made FDA into a mother surrogate. We say to FDA, "Reassure us that this is okay to eat." And FDA really can't. There is no way FDA can adequately monitor our present food supply.

People have the notion that if it's there on the shelf somebody's assuring them that it's okay to eat it—that it's safe bacteriologically, that the chemicals in it are safe, even that it is nutritious. Our measures are too primitive for that to be possible.

One of the things that most disturbs me about food additives is that the GRAS list (additives that are classified by FDA as generally recognized as safe) grew from something like 180 items in 1959 when the list was published to almost 700 now. Things appear to get on that list by somebody calling up somebody and saying, "We're going to use this substance as GRAS." Then a couple of people get together and say, "Yes, it is safe," and it gets on the list. I am worried about the limitations on our ability to test for safety, and I am worried about interactions between different chemicals and how they react in the body—things we don't really test for at all.

I worry about the fact that in 1968 we were eating three pounds of additives per capita and by 1973 we were eating five pounds per capita. Given the limitations on our ability to judge whether something is healthy or not, it's very troubling to see this tremendous surge of novel chemicals into the food supply.

One encouraging development was the way FDA handled the decision on Red No. 2. It seems to me that it marked a turning point in the way FDA has enforced the law on when an additive should be permitted in food. The law says an additive shall not be allowed in food unless it's been shown to be safe. But to a large extent FDA has enforced the law by saying, "Prove that an additive is unsafe and we'll take it out of food." FDA said Red 2 hadn't been proved unsafe, but the Agency wasn't convinced that it was safe either, so it had to go. That was a very courageous decision because Red 2 was a major food coloring and I know the kind of pressure that must have been put on.

Q. *A new law forbids FDA to regulate vitamin and mineral supplements solely on the grounds that the dosages are greater than the*

body can use. Are consumers wasting their money when they buy vitamins and minerals in dosages three or four times greater than the U.S. Recommended Daily Allowance?

A. That's a really tough one. As I understand it, the new law is a reaction to an earlier effort by FDA to restrict vitamin and mineral supplements. The new law may go too far in restricting what FDA can do to protect consumers, just as FDA's earlier proposal may have gone too far in trying to regulate vitamin and mineral sales. FDA wanted to put fairly rigid limits not only on the dosages of vitamin and mineral food supplements, but on the combinations of vitamins and minerals that could be sold as well. I opposed that because I don't believe FDA or anyone else can say with any great degree of precision what the human needs are for all vitamins and minerals. The recommended daily allowance for ascorbic acid was set at 60 milligrams in 1968 and then lowered to 45 in 1974. I think that shows that FDA can't speak with certainty on this subject so we have to be careful how we regulate vitamins and minerals.

I do feel strongly that we should have absolutely clear-cut labeling. I have no objection at all to regulating vitamins like A and D, fat soluble vitamins which can be stored and for which there is evidence of harm from overdoses. But I don't agree that the best way to regulate them is to require prescriptions for high dosages. That just raises the price. People who want to take them are going to take them anyway. Perhaps they could be prominently labeled, with a skull and crossbones if you like, saying in very large letters that overdoses may be seriously toxic, and so forth.

Q. *Do people who eat a good diet need vitamin and mineral or protein supplements?*

A. On protein supplements, I must say that the Federal Trade Commission (FTC) did a marvelous job in developing the background for its proposed labeling requirements. I had very mixed feelings when I first heard that FTC wanted to require that the labels on protein supplements state that they are not needed by most Americans. That's a very broad statement to make about a whole population—that they get enough protein in their regular diet and don't need supplements. But FTC has the data to support its position.

"I only recommend that people take vitamin supplements if they're willing to learn enough about nutrition to figure what they personally might need based on the evidence."

I was shocked when I found out the price being charged for some of these protein supplements and the kinds of products that are being sold. Some of these products are not appropriate for old people with kidney problems and many aren't appropriate for young people. There ought to be warning labels on these products. I wish there was some way to require that the price per gram of protein in these supplements be revealed, because it is outrageous.

When you come to vitamins I have a lot of trouble. I mean personally I take a B complex supplement because there is no way, given my lifestyle, that I can eat solely unrefined grain products. I may be wasting my money and I don't go around recommending it to everybody. I only recommend that people take vitamin supplements if they're willing to learn enough about nutrition to figure what they personally might need based on the evidence. For instance, many city people, people who smoke, people who are under stress probably need extra ascorbic acid.

But vitamins don't make up for a poor diet and I'd much prefer people to get their nutrients from a good diet.

Q. *Do you think that nutrition labeling is a useful and effective way of getting people to eat a proper diet?*

A. I have two problems with it. One is it's so complicated that I don't think people can really use it. I can't really use it and I'm a nutritionist. I've gone to the store and stood in front of a can of beans for the longest time trying to figure out what I was paying per gram of protein. If I want to make comparisons between things it becomes absolutely horrendous.

The other problem is that nutrition labeling may actually be debasing true nutritional values. Nutrition labeling can make products that are devoid of real nutritional value look better simply because it's awfully cheap and easy to throw in 100 percent or 50 percent of the recommended daily allowance of a nutrient. How will a person looking at an orange drink made out of sugar and water and maybe 10 percent orange juice, and fortified with vitamin C, distinguish between that and an orange? The orange isn't labeled.

The nutrition label itself influences people. They know what the food value of the labeled product is and they don't know what the food value of the orange is. Are they going to be more inclined to say the processed product has a better value?

Q. *Under our system of food marketing very few foods are required to meet minimum nutritional standards or requirements. Do you think the Government ought to establish minimum nutrition requirements for processed food?*

A. I find that a hard question simply because it's so broad. Requiring all food to meet a nutrient standard won't guarantee good nutrition unless there are restrictions on how the standard is met. If you are going to guarantee or require a certain level of nutrient density or nutritional value in food you have to also do something about how the nutrients get there. I would like to see regulations which encourage processing in such a way as to retain nutrients that occur naturally in food.

Q. *Is there a difference between natural and artificial nutrients?*

A. I know of no evidence that there is any chemical difference. But when you eat food that contains natural rather than artificial nutrients you know that the food hasn't been processed in a way that destroys the naturally occurring nutrients. I think that is important. There is a lot we don't know about

how the body uses nutrients. One of my favorite pieces of information, for instance, is that the chromium in beer is effective in the body, but the chromium in lettuce is not.

Clearly, you can cure a disease caused by the lack of a vitamin with a synthetic form of that vitamin as well as with a food source. But I am not a strong believer in vitamin supplements. I believe in getting vitamins in the context in which they occur in nature in as unprocessed a form as possible.

Q. *FDA has just proposed that baby and junior food labels indicate the percentage of each ingredient in the product. Is this a good thing?*

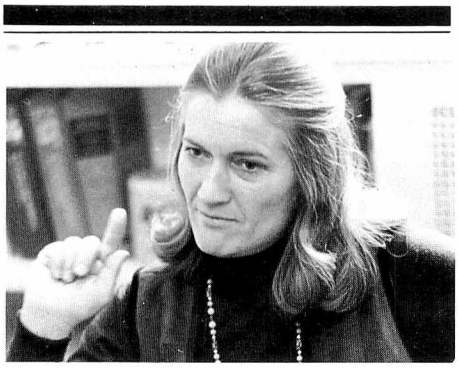
A. I am absolutely in favor of ingredient labeling. I think I could teach nutrition better with really good ingredient labeling than I can with nutrient labeling. I doubt that I'm ever going to be able to interest the majority of the people in the United States in learning about 40 nutrients. I do think I can teach them something about food composition.

To the extent that we can let people know exactly what's in food, and how much of it, that is a tremendous leap forward. Certainly labels are not now fully informative. For instance, the whole thing about the source of the fat in those coffee lighteners, or the source of "vegetable shortening" in a lot of products. Many times people are taking coconut oil and not even realizing that it's worse for their serum cholesterol than butter fat. And they're busy buying these things trying to cut down on their saturated fat and they're being fooled.

Q. *Some nutrition and health professionals say overuse of sugar is a serious health problem and that little or no sugar should be added to food. Do you think there is any place in our diet for sugar?*

A. Sure. I don't think it would hurt anyone to use sugar as a condiment the way people used to.

The problem is we've gotten to be real sugar addicts in this country. We've raised a generation that is addicted to an intense level of sweetness, and the type of food that is available in the marketplace reflects that addiction, or perhaps it would be more accurate to say that the processed food sold has caused it.



"The world is full of wonderful tasting things and we're running the risk of bringing up a race of robots who can eat only one kind of taste."

Q. *FDA recently refused to permit the remarketing of cyclamates. Saccharin is the only artificial sweetener on the market and there are questions about that too. Do you think it is important to have artificial sweeteners for dietary reasons?*

A. From what I've read there's no evidence at all that cyclamates really help people lose weight or keep weight off. In fact, there was an interesting study which showed that rats had an increased appetite when they were fed cyclamates. I don't know what kind of evidence has been accumulated on saccharin.

If people finally force themselves to stop for a month, let's say, putting sugar in their coffee, putting sugar in their cereal, they find that they lose their taste for it. I don't think we can postpone forever coming to terms with that problem. I simply don't think we can just keep finding substitutes for our substitutes. When any substance is consumed to excess it becomes a questionable thing. I would agree with people who complained about cyclamates being banned and said that if sugar was subjected to the same testing it would have to be banned too.

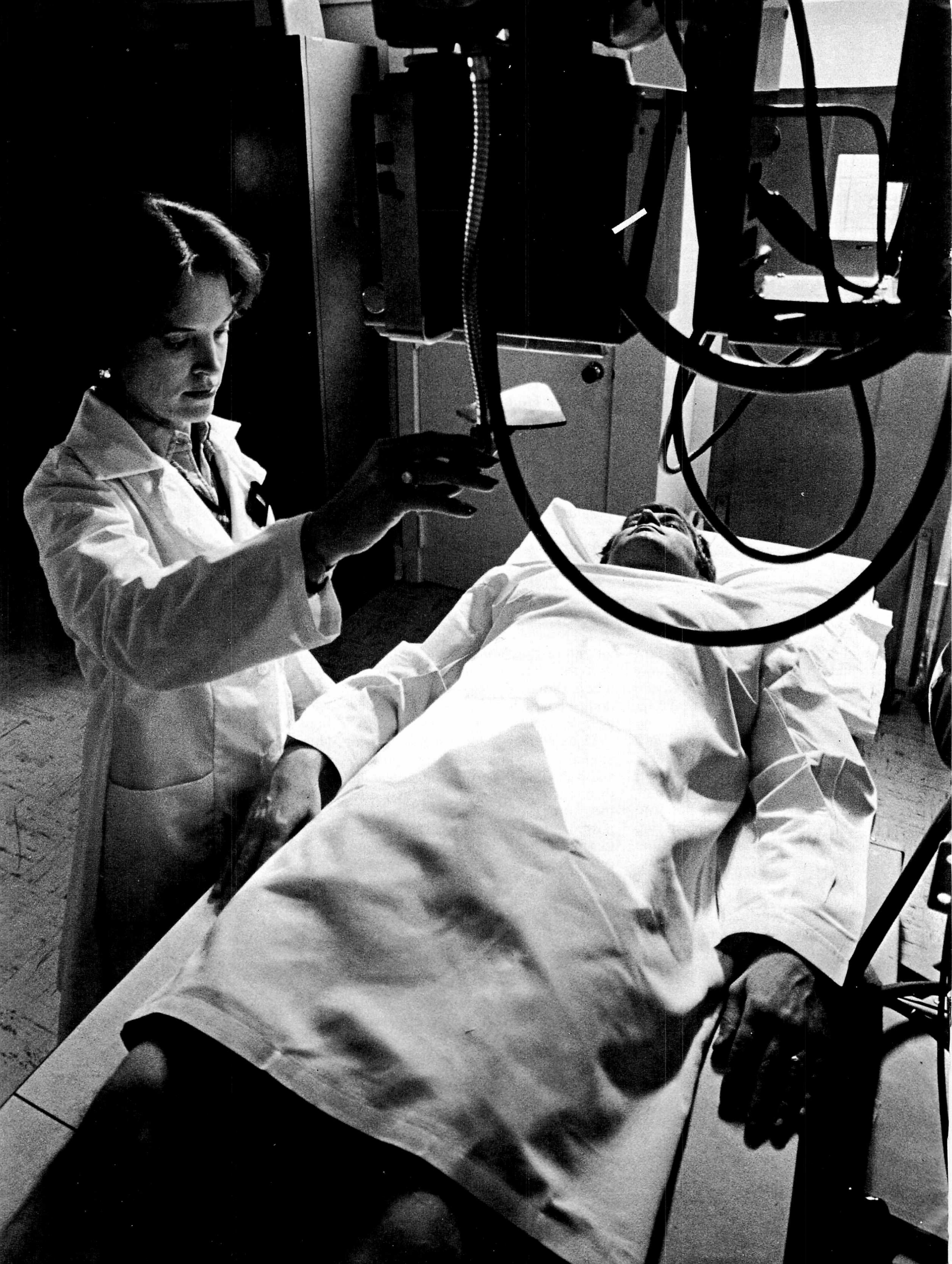
Sugar is clearly a substance which, when consumed to excess, represents a hazard. But we can't solve the problem by substituting artificial sweeteners for sugar. The problem is sweetness addiction. We are producing children who have no taste for anything except something that tastes sweet. Several years ago, some scientist at Rutgers was talking about impregnating spinach with sugar so you could get kids to eat it. The world is full of wonderful tasting things and we're running the risk of bringing up a race of robots who can eat only one kind of taste.

Q. *The food industry has responded to criticism about eating habits by promoting low cholesterol products, polyunsaturated fats, and now there is bread with wood fiber in it. Is this a healthy trend or is it a kind of faddism with a profit motive?*

A. This is food faddism at its worst. Real food faddism is buying the latest thing that comes on the market. I consider this a typical American fix. About four or five years ago the American Medical Association Council on Food and Nutrition had a symposium on nutrition and food processing and there was some comment that if we had to have fiber in food we could always put it in. I got hysterical with laughter. I thought, oh my God, we're going to supplement with *fiber*! And, of course, now we are. I think it's dangerous. The current evidence seems to be that it is not even useful. Cellulose and dietary fiber are not the same things. Real dietary fiber includes a lot of complex sugars which we can't digest, like those in beans. The populations which seem to have the fewest problems with cancer of the colon are populations which have starchy tubers as a large part of their diet. They are not crude fiber at all; they are complex starches. Adding crude fiber to food is a non-solution. It's a technological fix as a way of selling a product and it doesn't solve anything.

Q. *Do you see a significant change in people's attitudes toward food and nutrition?*

A. Yes, I believe people are beginning to find out more about what's in the food they buy and are expressing their misgivings. The food companies are becoming aware of it and I think they are getting a little nervous about it. There's really a very large movement afoot, which is quite spontaneous, of people going back to eating very simple foods and growing a lot of their own and trying to find ways of being more self-sufficient. I believe that the kind of hyperinflation of the food industry we have seen in this country and the proliferation of these endless novel products is going to end.



Reducing Genetic Risk From X Rays

by James Morrison and Mark Barnett

Gonad shields can help protect the reproductive organs from unnecessary radiation during diagnostic x rays. FDA has launched a campaign to educate the public and the medical profession to the importance of using these simple, inexpensive devices.

It wasn't too many years ago that shoe stores kept x-ray devices handy so customers could satisfy curiosity by examining the bones in their feet. And it's been quite recently that mobile x-ray units screened the general population for tuberculosis by offering a free chest x ray on the spot to anybody who walked by, a practice now generally discontinued as needlessly exposing large numbers of people to x rays for the relatively few tuberculosis cases that are detected by this random screening practice.

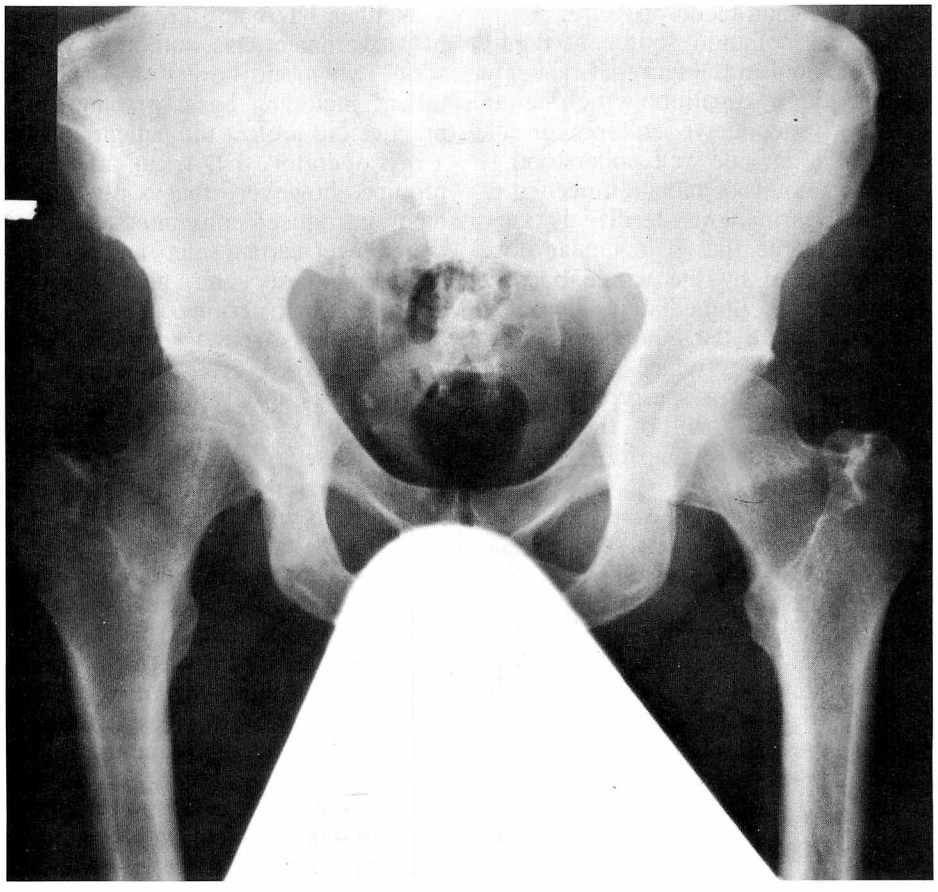
But people are becoming more knowledgeable about the proper use of x rays, a trend FDA is seeking to encourage and accelerate. One of FDA's newest and most important efforts is a program to educate the public and the medical profession about the importance of shielding the reproductive organs from unintended and unnecessary exposure to x rays.

The program is intended to facilitate and encourage the use of shielding devices during diagnostic x raying of parts of the body near the male testes and the female ovaries to protect these organs, known by the general term gonads.

FDA's concern is with the possibility that exposure of reproductive cells (sperm cells in the male and egg cells in the female) to x rays can cause changes to the genetic material in the cells. These changes are called genetic mutations, and they can be caused by other chemical and physical agents as well as by x radiation. If the damaged sperm or egg cells are later used in conception, the damage is passed on to all the child's cells, including those which will later become sperm or egg cells. Thus, the original damage can be transmitted through many generations. Some genetic changes in the reproductive cells of parents may be seen in the first generation of their offspring, while others may be passed on undetected for several generations before producing any apparent effects.

Genetic changes or mutations occur in all living organisms, and they can occur spontaneously or as the result of exposure to chemical or physical agents. Mutations can be beneficial to humans if the changes help them to survive or adapt to the conditions they face in life at any given time. But practically all mutations are known to be harmful or otherwise detrimental to existence.

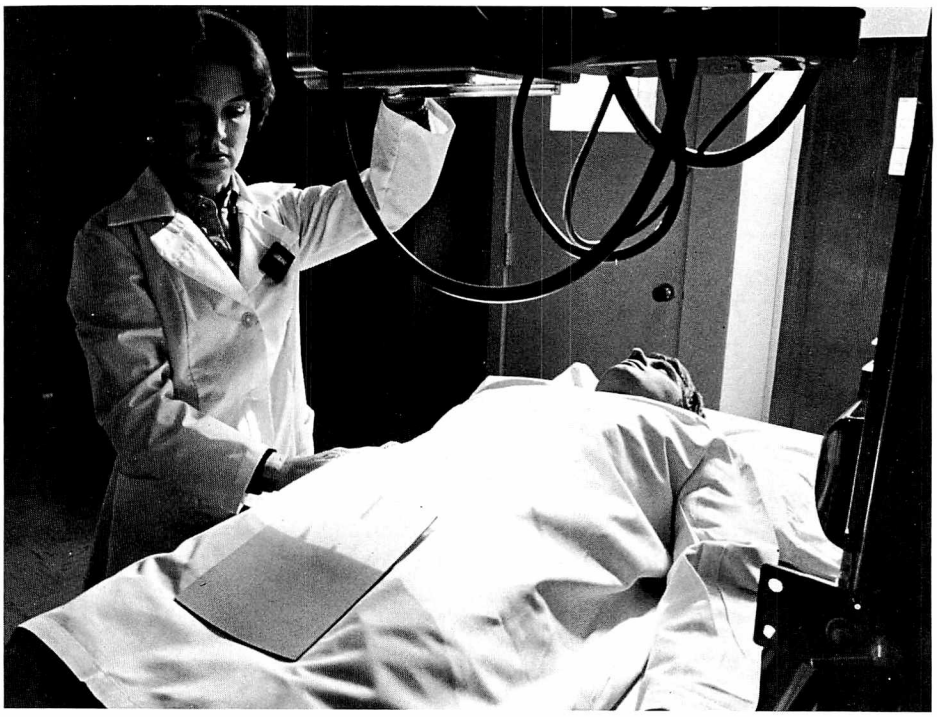
A popular misconception about mu-



The shadow shield is attached to the x-ray machine and is suspended in part of the path of the x-ray beam. It absorbs most of the radiation in the field it is protecting. This x ray (right) was made using a shadow shield. The cone-shaped white area at the bottom of the x ray shows where the shield prevented much of the radiation from reaching the patient.

Flat contact shields usually are strips of lead-impregnated material.

Shaped shields—lead impregnated cuplike devices (opposite page) sometimes held in place by special undershorts or athletic supporters —are for male patients only. They provide protection in front-to-back and lateral x rays.



tations is that they commonly cause dramatic abnormalities, such as gross birth defects or extra fingers and toes. Actually, the effects of the vast majority of mutations are subtle and would be hard to identify at birth. For example, they can lead to an increased susceptibility to certain chronic diseases later in life, like diabetes or high blood pressure.

Another common source of confusion is related to the fact that radiation can produce sterility, which is an inability to conceive children at all. What is often not well understood is that the amount of radiation needed to produce permanent sterility is very large—so large that if a similar dose were received by the whole body it might well be immediately fatal. On the other hand, the amount of radiation required to produce a single genetic mutation in a sperm or egg cell is low, certainly within the dosage received in many diagnostic x-ray examinations.

It should be emphasized that the potential benefits from most diagnostic x rays far outweigh the risks involved, and the probability of any individual suffering genetic damage from a diagnostic x ray is very small. But because millions of people are exposed to this small risk each year—and because genetic damage eventually can be passed on to succeeding generations—a considerable number of people could be subject to the effects of genetic injury.

If used properly, gonad shields can substantially reduce unnecessary exposure of the reproductive organs to x rays without changing diagnostic procedures or reducing the diagnostic information available to the physician. Unfortunately, gonad shields are not often used, and increasing their use is not an easy task.

Neither FDA nor any other agency of Government has authority to prescribe when and how x rays shall be taken, including basic precautionary practices to protect the patient and the x-ray operator. FDA can and does require, however, that x-ray equipment introduced into interstate commerce meet certain safety and performance standards and bear adequate operating instructions. The Agency also has programs to keep the public and the medical professions informed of the risks involved in the use of diagnostic x rays and of ways to reduce these risks.

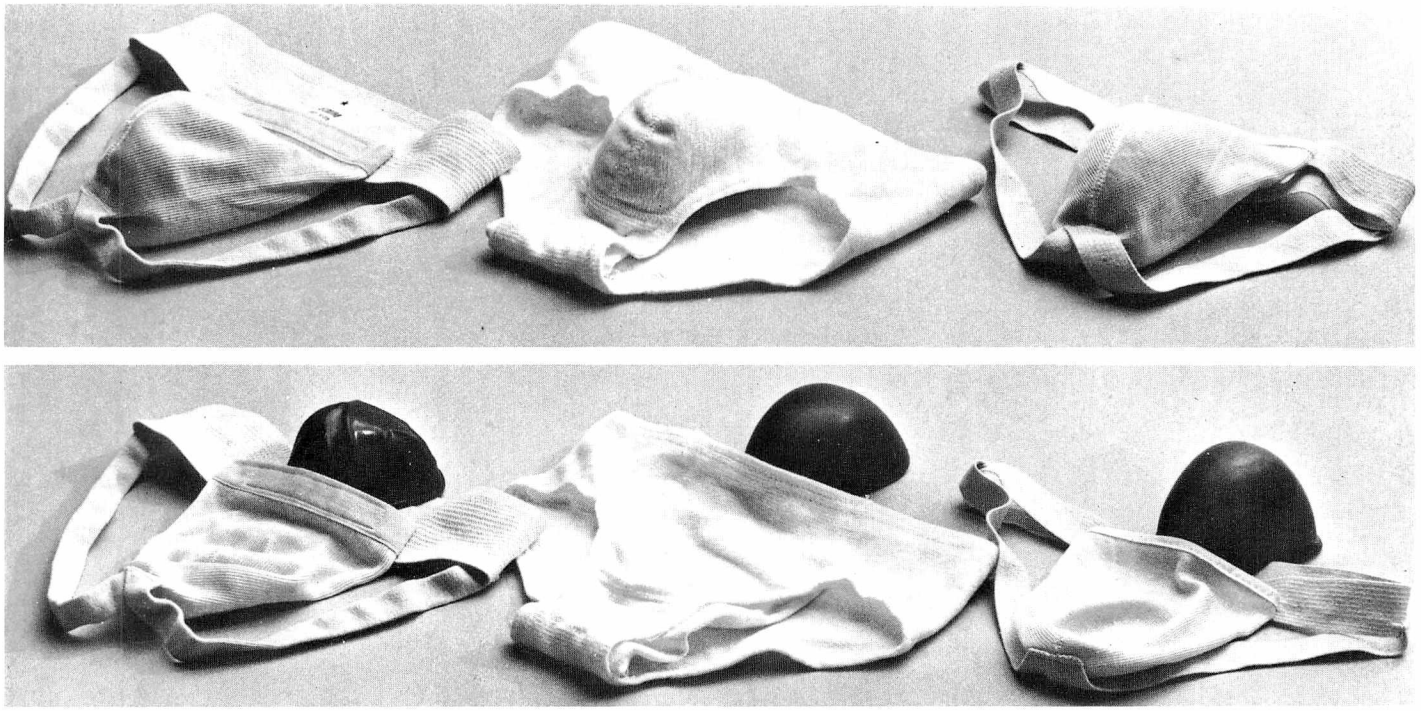
As an important part of its overall program to reduce the risk from x rays, FDA recently published recommendations in the FEDERAL REGISTER concerning the use of gonad shields.

FDA recommends that a gonad shield be used when there is a possibility that the reproductive organs will be in the x-ray beam or close to it. Of course, no shield should be used if the examination is of the reproductive organs themselves or an area so close to them that a shield would interfere with an unobstructed x-ray view of the organs being examined. Whether a gonad shield should be used also depends on whether the patient is potentially capable of bearing or fathering children, now or in the future.

Examinations in which the male reproductive organs are usually in the x-ray beam, and for which shields should be considered, are those of the pelvis, hip, and upper thigh. Shields may also be warranted for x rays of the lower back, abdomen, and other lower parts of the body. Shields are not needed for properly conducted x-ray examinations of areas distant from the reproductive organs, such as the head, teeth, arms, chest, or lower leg, since exposure to the gonads in such procedures is quite minimal.

FDA advises medical facilities to develop their own criteria for use of gonad shields based on age, illness, and other factors related to potential genetic injury and its significance, and notes that children should be protected by gonad shields whenever possible because radiation effects may be cumulative.

Gonad shields are more practical for men than for women because a male's testes are separate from the abdominal area, while the female's ovaries are located in the abdominal area, close to the spine, small and large bowels, and parts of the urinary tract, where use of a shield would often obstruct body areas to be examined. Shielding of the ovaries is recommended where possible, however,



and the University of California Medical Center in San Francisco is carrying out research, under a contract with FDA, on the problems of shielding the ovaries.

There are several types of gonad shields. Wide area shields such as lead aprons are usually used by x-ray technicians or physicians to protect themselves from scattered radiation during their work. Similar shields are used by many dentists to place on the laps of patients who are having their teeth x rayed, but because of their size these shields are not often suitable for patient use during medical x-ray procedures. Smaller shields that cover a specific area are considered best when the gonads are in the x-ray beam or within two inches of the edge of the beam. They come in three types:

- Shadow shields, usually made of lead, are suspended in part of the path of the x-ray beam and absorb most of the radiation in the field they are protecting.
- Flat contact shields are usually strips of lead-impregnated material placed or taped over the gonads.
- Shaped shields, used only for male patients, are lead-impregnated cuplike devices, sometimes held in place by special undershorts or athletic supporters. They can be used in front-to-back and lateral x raying.

All three types of specific area shields have recently come on the market and samples have been tested in clinical settings. They are inexpensive and should add little to the overall cost of diagnostic x rays.

The amount of protection provided by gonad shields varies with the type used, the kind of examination, and other factors. If the testes of the male are directly in the x-ray beam, shields can achieve an 85 percent reduction in exposure to radiation. If the testes are within two inches of the beam, shielding can reduce exposure 50 percent. For women, use of shielding reduces x-ray exposure by 30 to 45 percent. Reduction is smaller for women because the ovaries are located in the abdomen and can't be shielded from internally scattered radiation.

Gonad shielding is not a new technique. A cup-shaped device was described in the medical literature of 1952, and in 1956 the National Academy of Sciences recommended shielding as "a simple and highly effective" way to reduce x-ray exposure of the reproductive organs. In addition, shielding has been endorsed by the National Council on Radiation Protection and the International Commission on Radiological Health.

One reason gonad shields haven't been widely used is that their use has not been taught to x-ray technicians and physicians.

FDA plans to help remedy this situation by recommending that instruction in the use of gonad shields be given in training schools for x-ray technologists and in training programs for physicians who supervise x-ray examination. FDA and the American College of Radiology recently joined in distributing sample shields and literature on shielding to about 10,000 radiologists and literature to over 1,200 schools of radiologic technology. In addition, a special training kit on the use of shielding has been developed by FDA and is being made available to x-ray technology schools across the United States.

FDA's Bureau of Radiological Health estimates there are 5.5 million x rays of male adults and children annually for which the use of shields would be appropriate, but it has been impossible to make a similar estimate for females.

Because shielding is not widely practiced, FDA believes patients can take an active part in encouraging proper use. When an x ray of the lower abdomen, lower back, hip, or thigh is required, the patient or the patient's parent should ask the doctor or technologist whether a gonad shield can be used. Patients should not insist on shielding because in some cases it may interfere with the x-ray view sought in the examination—especially for females. But where shielding is appropriate a simple question may be enough to remind the doctor or technologist that a shield should be used.

James Morrison and Mark Barnett are with the Division of Training and Medical Applications in FDA's Bureau of Radiological Health.

Informing Women About 'The Pill'

FDA has proposed that whenever a woman has a prescription for oral contraceptives filled or refilled she receive a brochure explaining the risks and benefits of using these drugs. The new brochure, which would be written in language understandable to the general public, is one of a series of actions aimed at assuring that women and physicians get the most up-to-date information available on birth control pills.

Approximately 10 million women in the United States are on "The Pill," generally considered the most effective means of birth control now available, except sterilization. As with any drug, there are certain risks involved in the use of birth control pills, and the Food and Drug Administration has proposed that women receive a detailed brochure describing these risks, as well as the benefits, whenever they have a prescription for oral contraceptive pills filled or refilled.

This proposal is one of a series of recent actions taken by FDA to improve the information women and physicians get about birth control pills.

The proposed new patient brochure will contain the latest medical information about The Pill, written in language understandable to the general public. The brochures are to be supplied by the manufacturers of these drugs.

Since 1970, FDA has required that manufacturers provide physicians with a brochure about The Pill which can be given to patients upon request. Under the new FDA proposal, the brochure would be required to accompany every new and refilled prescription; it would be included with the drug by the person who dispenses it, in most cases the pharmacist.

The proposal to require the patient brochure was one of three actions taken by FDA to improve information about The Pill. The Agency also:

- Called for major revisions in the brief summary of information now required in every pill packet. This summary has been required since 1970, but the new summary will contain more information than the current one, will list the most common side effects from The Pill, and will urge that women read the more detailed brochure.
- Ordered major revisions in the information provided to physicians about The Pill. The Agency ordered manufacturers to print and distribute the new physician labeling within 120 days after December 7, 1976, the date all three new actions on oral contraceptive labeling appeared in the FEDERAL REGISTER.

A period of 60 days from December 7 was permitted for public comment on the new patient brochure and the expanded summary for pill packets. After FDA completes evaluating the comments received, it will issue a final regulation requiring distribution of the brochure and revised summary. Manufacturers will be given 60 days from the publication of the final regulations to print and distribute the new materials.

Although the new labeling cannot be required until these procedures have been completed, the Agency is encouraging manufacturers to begin voluntary compliance as soon as possible, even while public comments are being received and reviewed.

The need for the revised information systems stems from new data gathered about The Pill over the past few years. In addition, a survey conducted for FDA in 1975 indicated that women want more information about contraception.

Sherwin Gardner, Acting Commissioner of Food and Drugs, said: "FDA has carefully evaluated all information about birth control pills, and has concluded that these drugs should remain available for those women who, in consultation with their physicians, decide it is the best contraceptive for them. FDA neither advocates nor discourages the use of birth control pills, but believes that women should have this choice of contraceptive method available to those who want to use it.

"The selection of a contraceptive is not like the selection of other drugs. Contraceptives are not intended to alleviate or cure diseases. The choice of a contraceptive is a personal one, and the selection must be based on accurate, balanced information presented in a form that can be understood. The detailed brochure and the expanded summary that we are proposing represent a new dimension in patient information about prescription drugs, and are designed to provide to women the information they need to decide on the best form of contraception for them."

Among the new points to be emphasized in the physician labeling and patient brochure are:

- Birth control pills are the most effective method of contraception except sterilization.
- Women over 40 are advised to use some other method of contraception because of the higher risk of heart attacks associated with birth control pills in women over 40.
- There is no confirmed evidence of cancer resulting from taking birth control pills, though women should be carefully monitored by their physicians for abnormal uterine bleeding and lumps in the breast.
- The Pill should never be taken by pregnant women because it may damage the offspring.
- Women who discontinue The Pill in the hope of becoming pregnant should use another contraceptive method for three months because of the possibility that a fetus conceived immediately after discontinuance of The Pill has a higher risk of malformations.
- Birth control pills appear to be associated with benign liver tumors, although these are rare. If the tumors rupture they can cause internal bleeding and death.
- Birth control pills should be discontinued at least four weeks before surgery of a type that may involve an increased risk of blood clotting or prolonged immobilization. Evidence indicates that users of The Pill are 4 to 6 times more likely to have serious blood clots following surgery than women not taking The Pill.
- Women just starting to use The Pill should take those with an estrogen content of 50 micrograms or less, and physicians generally should prescribe products containing the least amount of estrogen.

The proposed patient brochure and physician labeling also compare The Pill with other forms of contraception and with the risks associated with pregnancy itself.

PBB's: One State's Tragedy

When a fire retardant containing a highly poisonous chemical called polybrominated biphenyls (PBB's) accidentally got mixed into a cattle feed supplement, it triggered an agricultural problem of major proportions. FDA played a key role in pinpointing PBB's as the cause of the contamination and in preventing further distribution of the toxic feed. But the effects of the mishap continue to ripple through the farmlands of Michigan.

by Annabel Hecht

On the wall of the reception room of FDA's Detroit District Office is a modest plaque commending the staff for its part in handling the PBB problem in Michigan. In his office, District Director Alan Hoeting has a six-foot high, and growing, pile of papers and reports documenting the story of what is certainly the most severe agricultural contamination problem ever experienced in this country.

The story started as a mystery, involving two products manufactured by the Michigan Chemical Co. The ending has yet to be written. One of the products was a cattle feed supplement, magnesium oxide, which went by the brand name Nutrimaster. A major purchaser of Nutrimaster was Farm Bureau Services, a subsidiary of a multi-branched farmer cooperative, the Michigan Farm Bureau, which sent Nutrimaster to its mills throughout the State to be mixed with cattle feed.

The other product was a mixture of potent chemicals called polybrominated biphenyls—or PBB's—a fire retardant used by the thermoplastics industry in typewriter, calculator, and microfilm reader housings, radio and TV parts, thermostats, and shaver and hand tool housings. The trade name for this product was Firemaster. Thus was the problem compounded. The two products were not only physically similar, but their names were similar.

Actually there was only one brief period when the two resembled each other—a key factor in unraveling the mystery. In 1974 when the contamination was discovered, Firemaster was coarse and brown and in no way resembled Nutrimaster. But in 1971 and 1972 Michigan Chemical had produced several experimental batches of the fire retardant which had been pulverized to a fine white powder—not precisely identical, but to an unpracticed eye, a pretty close match with magnesium oxide. Normally, the two products were packaged in distinctive red- and blue-trimmed bags, red for Firemaster, blue for Nutrimaster. Because of a paper shortage that occurred at the time, the two products were packaged in identical brown paper bags with only their trade names stenciled on the side. No common or chemical name appeared to alert the user to the contents of the bags marked Firemaster.

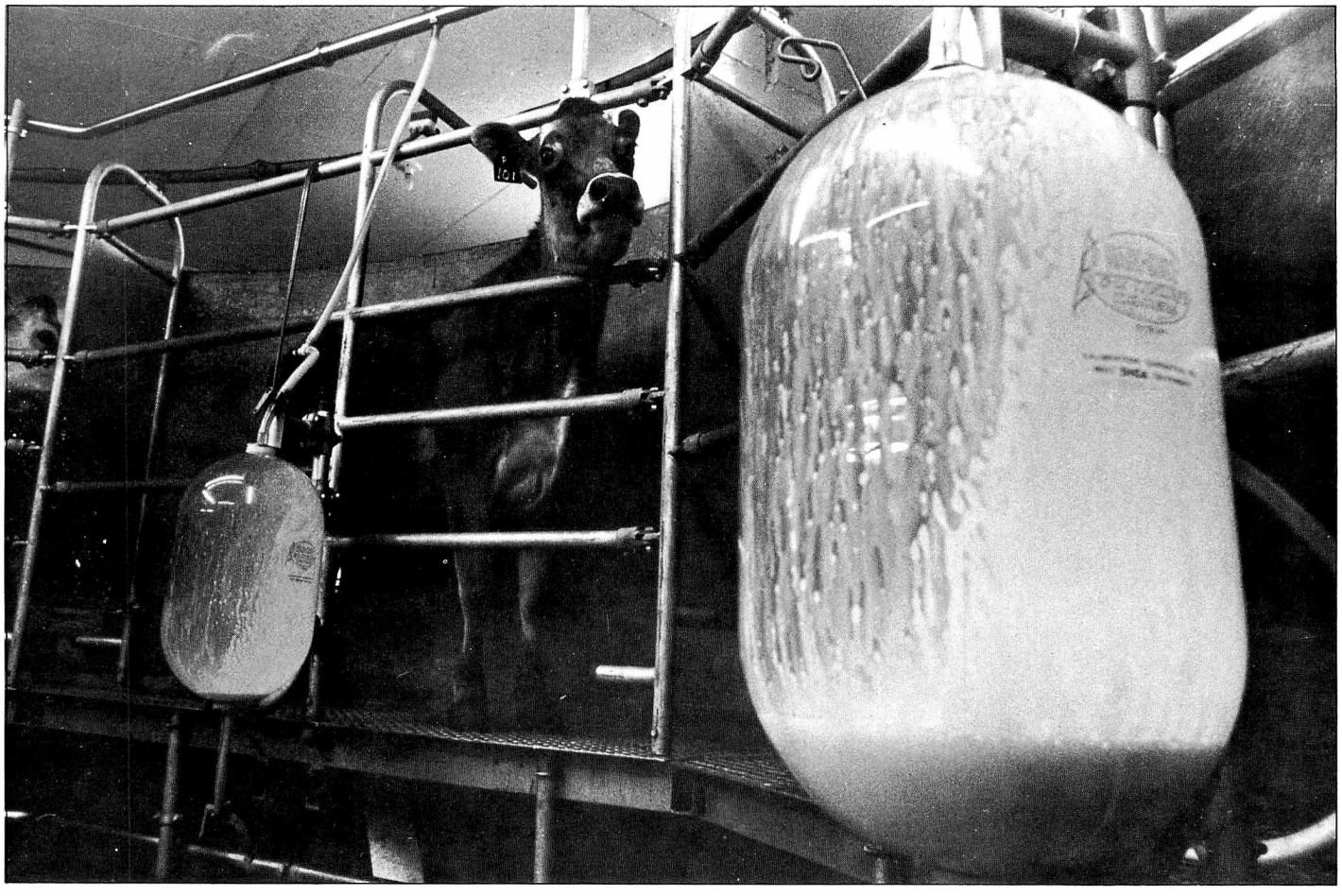
The story then jumps to September 1973.

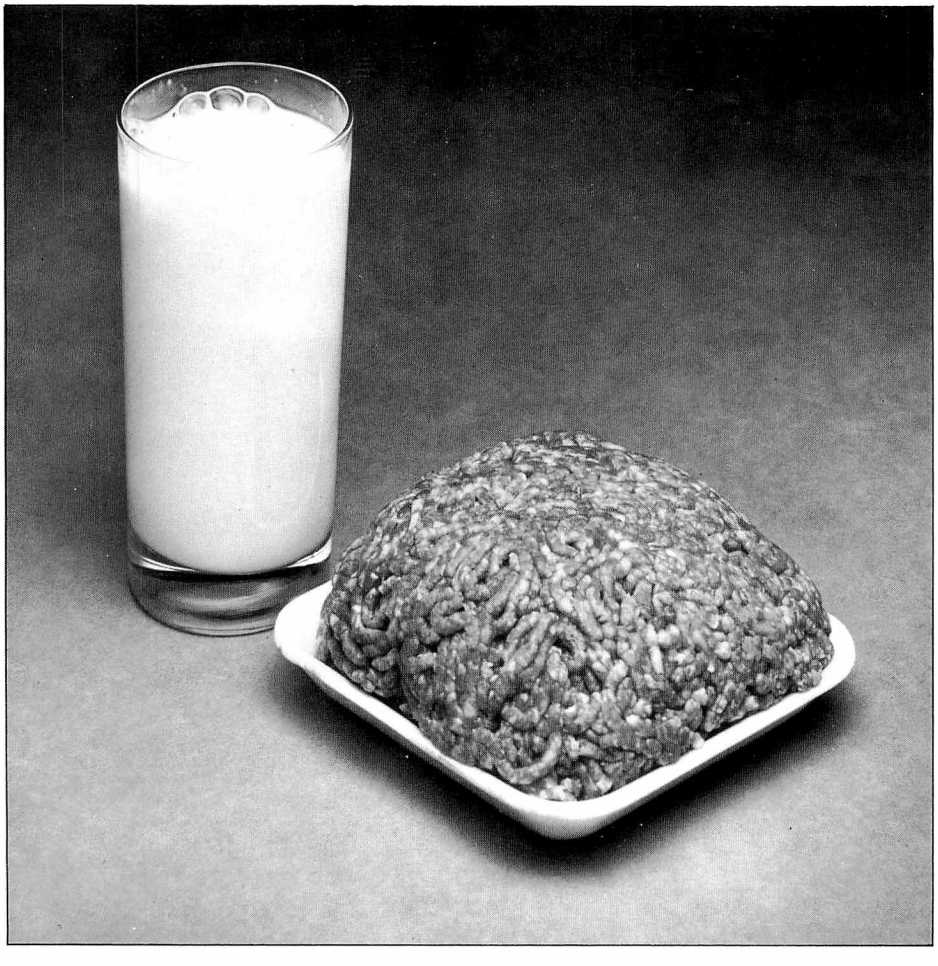
Strange things were happening on Michigan farms. Some milk cows were refusing to eat commercial feed; milk production was down. The animals lost weight and developed abnormal hoof growth and lameness. Sores did not heal. Both cattle and swine aborted and heifers were not breeding. There was a high death rate among newborn calves. Without realizing that the problem was shared by others, each farmer, faced with this mysterious malady, tried to cure it in his own way.

In March 1974, one desperate farmer brought a sample of feed to FDA's Detroit District laboratory for analysis. His cows were "unthrifty," he said, "could the problem be an excess of lead?" The answer was negative. No lead, nor any other unusual chemical could be detected. Determined to do everything possible to save his herd, the farmer, who was also a chemical engineer, sent feed samples to other laboratories, including the U.S. Department of Agriculture's National Animal Disease Center in Ames, Iowa. Here, by chance, the first clue to the identity of the mysterious contaminant was found.

When certain kinds of chemicals are analyzed on a device known as a gas chromatograph, each chemical produces a characteristic peak on a graph, like a fingerprint. At the time of the Michigan tragedy virtually nothing was known about PBB's. Because of their high boiling point, as it turned out, PBB's peak much later on the chromatograph than many other known chemicals. This fact was discovered accidentally when the analytical equipment in the Ames laboratory was left running during a lunch break. When they returned from lunch the lab's chemists found a wildly unfamiliar reading—one that looked more like a mountain range than any known chemical.

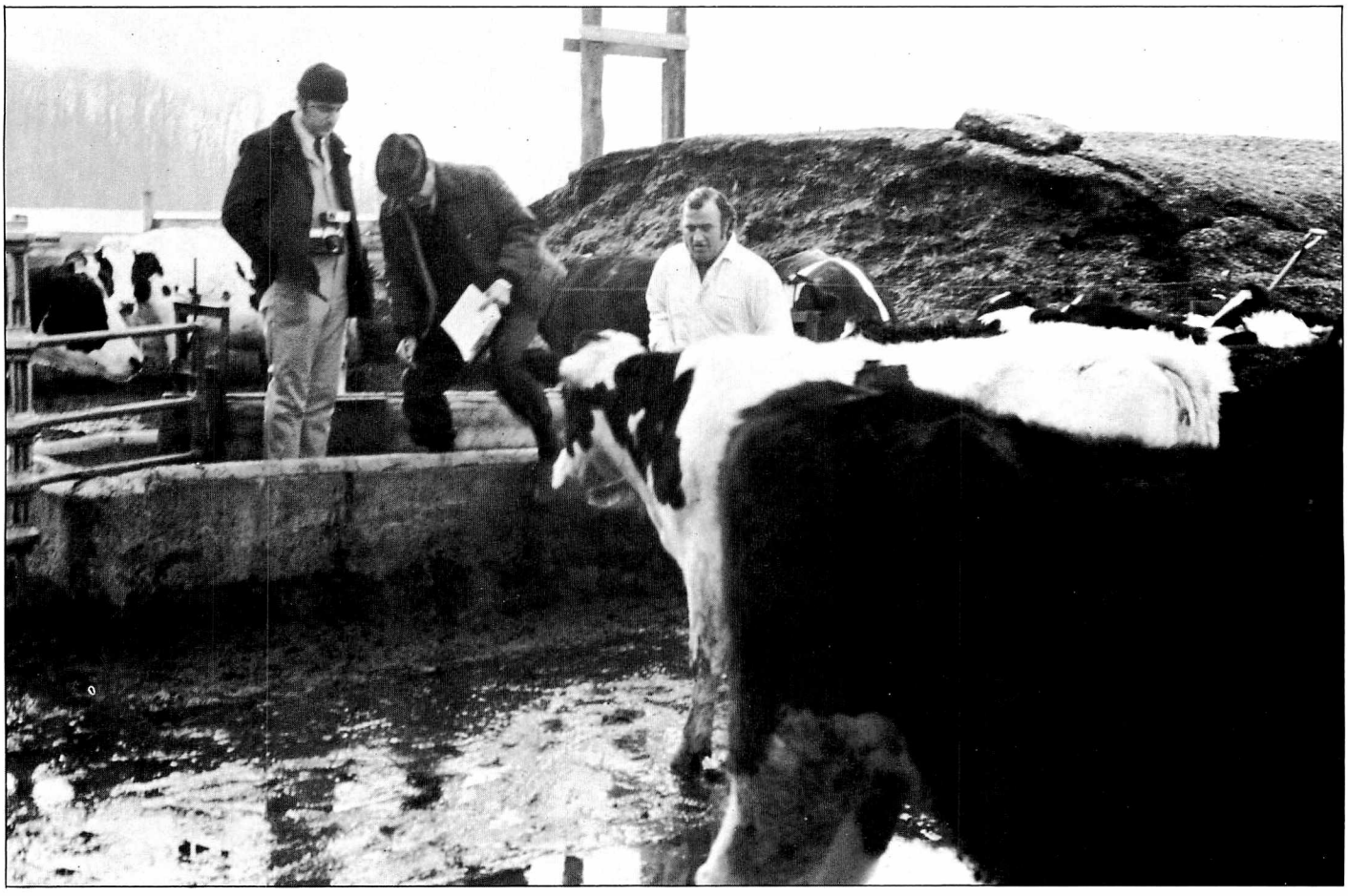
Late in April 1974, Dr. George





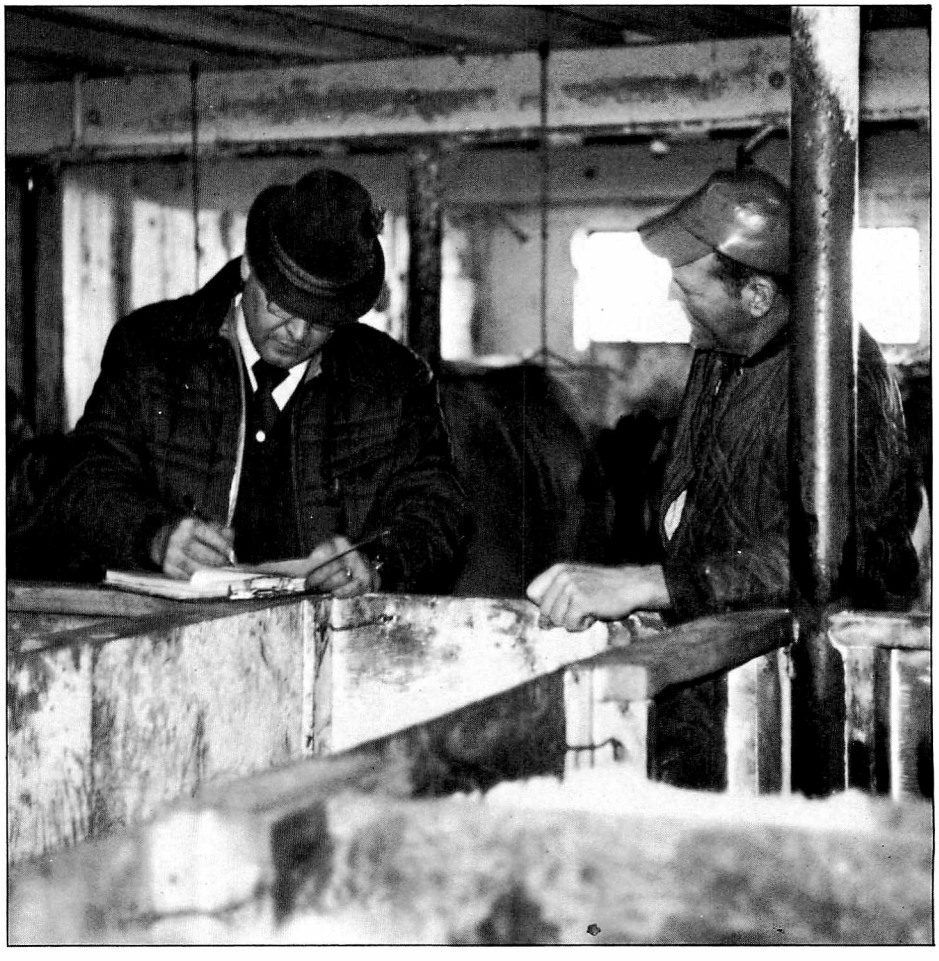
Michigan farmers noticed that milk production was down months before it was determined that this and other health problems suffered by their herds were caused by feed contaminated with PBB's.

None of the samples of milk and hamburger and very few of the samples of other foods tested since January 1975 have contained residues of PBB's above the legal limit permitted by FDA.



FDA survey teams visited Michigan farms to check on herd health and to determine whether there was a continued threat of PBB contamination of feed. Here, FDA investigator David Kaszubski (left) and Dr. Alan Furr (center), a veterinary toxicologist from Iowa State University, check the condition of a herd.

A Michigan farmer (right) discusses the health of his herd with Dr. Furr.



Fries, an animal scientist with the Department of Agriculture in Beltsville, Maryland, who was familiar with the unusual analytical behavior of PBB's, confirmed that the contaminant in the Michigan cattle feed was the fire retardant Firemaster.

Within a week, Norbert Fehringer, a chemist in FDA's Detroit District laboratory, modified the standard analytical method used for detecting pesticides in foods and confirmed the presence of PBB's in milk and feed from the chemical engineer's farm. FDA District investigators visited Farm Bureau Services' mills and coordinated a recall of shipments of feeds suspected of containing magnesium oxide. The Michigan Department of Agriculture quarantined affected farms to prevent contaminated milk and other products from reaching the marketplace.

The possibility that Firemaster had been mixed into the feed was at first discounted by the Michigan Chemical Co. After all, the product was packed in bright red-trimmed bags and looked like peanut brittle. No one would mistake it for magnesium oxide. But when a bag of the experimental Firemaster that looked like magnesium oxide was found in a feed mill in Menden, Michigan, the mystery of the contamination was solved, at least in part.

What had happened is known; how it happened is still unexplained. Apparently ten or twenty 50-pound bags of the experimental fire retardant had been included in a shipment of magnesium oxide destined for the Farm Bureau Services' mill in Battle Creek. Because it looked like magnesium oxide, some of the fire retardant was used in feeds at this mill, while other bags were sent on to mills in other parts of the State.

Once it had been established that the experimental Firemaster was the culprit, the Michigan Chemical Co. recalled all supplies of magnesium oxide. FDA's Detroit District laboratory sent copies of its analytical methods to State food and drug laboratories and to each of the FDA district laboratories in areas that could have received magnesium oxide. FDA Detroit District Director Hoeting advised the Central States Association of Food and Drug Officials of the mixup at its 1974 spring meeting.

Liaison was immediately established between the various State and Federal agencies that were to investigate the incident. FDA concentrated its efforts initially on manufactured dairy products. The Michigan Department of Agriculture (MDA), which has played the major role in handling the entire situation, assumed responsibility for fluid milk producers. Feed mills were covered by FDA and MDA. The State agency, working with the U.S. Department of Agriculture, also covered livestock shipped to slaughtering plants, all this in addition to its almost overwhelming job of testing animal herds and poultry and supervising the quarantining of affected farms.

The Michigan Department of Public Health, in cooperation with FDA, and later with the Center for Disease Control, another branch of the U.S. Department of Health, Education, and Welfare, assumed responsibility for the human health implications.

FDA determined the smallest amount of PBB's that could be identified and measured in food. Any food containing higher levels of PBB's was considered adulterated and its shipment in interstate commerce was prohibited. Chemists in FDA's Detroit District laboratory continued to seek methods of detecting PBB's at lower levels.

In the meantime, the search for scientific information on PBB's continued. PBB's' closest relative seemed to be polychlorinated biphenyls (PCB's), a class of chemicals that had some of the same properties of stability and heat resistance. In the ten years since PCB's had been recognized as a health hazard, a substantial amount of research had been done on their effects on humans and animals.

Data from short-term toxicity studies with PBB's initiated by FDA in October 1974, compared with what was known about PCB's, revealed that the Michigan chemical may be up to five times more potent than its cousin. On the basis of this information and the development of more sensitive analytical techniques, FDA, in November 1974, lowered the legal limits for PBB's. The new limits were set at 0.3 parts per million (ppm) in meat, milk, and dairy products, 0.05 ppm in animal feeds, and 0.05 ppm in eggs.

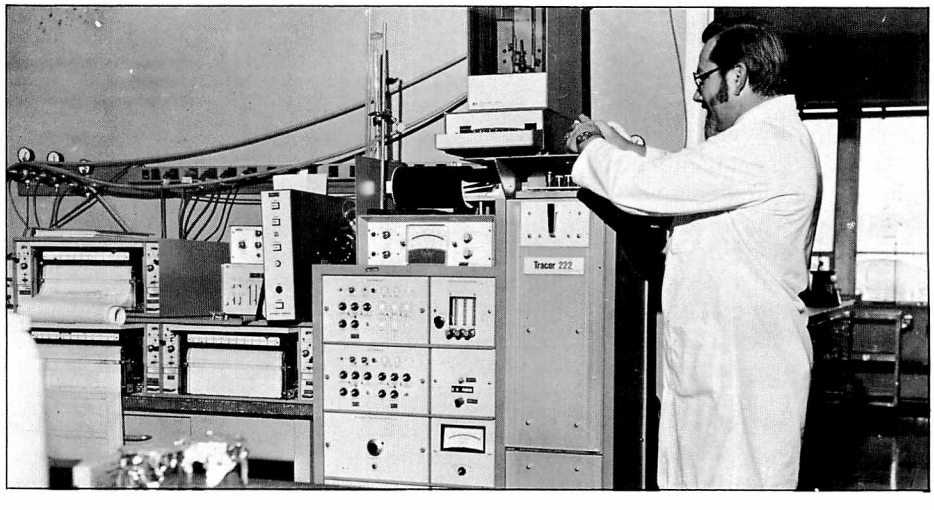
FDA felt, and still feels, that this provides Michigan residents a reasonable margin of safety. Some residents apparently felt otherwise. In the early months of 1975 the Michigan and national press carried stories under such headlines as "Illness Plagues PBB-Exposed Families," or "Liver Damage Found in 15 Who Ate Tainted Products." An FDA statement issued in March expressing confidence that food meeting the guidelines was safe was greeted with charges of "whitewash."

The Michigan Department of Agriculture, following hearings to determine whether food containing any amount of PBB's should be banned, decided in July 1975 to continue with the FDA guidelines. A Special Investigating Committee, established by the Michigan State Senate to study the PBB incident, reported in October 1975 that there was no health hazard to the general population of Michigan.

Sampling of milk and other food products by FDA, the U.S. Department of Agriculture, and State agencies tends to confirm that finding. No

This trench in a remote part of Michigan was part of the mass grave for 25,000 to 30,000 head of livestock that were destroyed after having eaten contaminated feed.

Swine, as well as cattle, sheep, and chickens, had to be destroyed because of the effects of eating PBB-contaminated feed.



Norbert Fehringer, a chemist in FDA's Detroit District laboratory, modified the standard analytical method of detecting pesticides in foods and confirmed the presence of PBB's in samples of milk and feed from a Michigan farm. He is shown with a gas chromatograph, one of the pieces of equipment he used.

PBB's have been found in samples of milk collected in retail packages since January 1975 even though improved techniques have made it possible to detect PBB's at levels lower than the legal limits set in November 1974. Only two out of 130 samples of hamburger contained any chemical and that was below the FDA legal limit. One percent of 1,800 samples of meat collected in slaughterhouses contained PBB's above the FDA limits. To make sure the problem had not spread, FDA field offices tested samples of milk, cheese, animal feeds, and other products from 36 States during 1974 and 1975. These tests indicated the PBB problem was confined to Michigan. As a further precaution, however, testing for PBB's was again included in FDA's national pesticide surveillance program in 1976.

To find out what was happening to farm animals and farm families exposed to the chemical, investigators from FDA's Detroit District office conducted a survey in May and June 1974 of 70 of the affected farms. The survey team checked on herd health and collected feed samples and dust from barn floors and rafters, handy places for the powdery PBB's to settle after feed was mixed. Under FDA and State supervision the feed mills were scrubbed clean, not once, but several times. By the end of 1974, no animal feed was found to contain PBB's above the allowable level of .05 parts per million.

Cattle with high levels of PBB's were destroyed by the State and buried in a remote area on public lands. But questions remain about the condition of animals with low levels of the chemical in their bodies. In the spring of 1975 a team of veterinary toxicologists assembled by FDA surveyed 16 herds exposed to PBB's and 15 control herds. No animal health problems were reported which could be attributed to low levels of PBB's and there were no significant differences in milk production, an important predictor of the health of dairy cattle. Despite these findings, some Michigan farmers continue to report that animals with low levels of the chemical in their bodies are sick.

A two-year study of the toxicological effects of PBB's on cattle, being carried out by the Ohio Agricultural Research and Development Association with FDA funding, will provide further information on animal health. To be completed in 1977, the study has already shown that test animals receiving high levels of PBB's have some of the same symptoms as the Michigan cattle that were first exposed to the contaminated feed. Animals getting small amounts have shown none of these symptoms.

Of primary importance is the health of the citizens of Michigan, thousands of whom unknowingly consumed PBB's in their own farm products before anyone knew what was happening. Despite reports of illness, rashes, loss of hair, and gastrointestinal disturbances, FDA's 1974 survey uncovered no unusual health problems either reported by the people interviewed or noted in medical records. The Michigan Department of Public Health, which conducted an in-depth study of 165 families living on quarantined farms, also was unable to document any human illness that could be linked to PBB's.

These findings do not rule out the possibility of some health problem developing later in life, however. For this reason a long-term evaluation of 4,000 residents of the State is now underway. Jointly sponsored and funded by FDA and three other Federal agencies, the study is being conducted by the Michigan Department of Public Health.

Although the cattle feed-PBB mixup occurred three years ago, its effects undoubtedly will be felt for many years to come. Firemaster is no longer manufactured by the Michigan Chemical Co., but PBB's persist in the Michigan Farm environment and in the bodies of humans and animals exposed to it. Some people continue to claim that they are experiencing strange symptoms of illness. Despite earlier acceptance by State officials of FDA's legal limits for PBB's in food and animal feed, debate continues in Michigan on whether these levels should be lowered. Already the State has lowered its tolerance level for animal feed to .01 ppm. Further reduction of State tolerance levels in meat and milk could mean the State would require destruction of more cattle.

No one knows how long PBB's will remain in the farm environment. An FDA spokesman believes that complete elimination of the chemicals may be impossible. A Michigan State University scientist says sunlight could speed the breakdown of PBB's on the surface of the soil. The Michigan Chemical Co. has said that PBB's will eventually degrade, breaking down into carbon dioxide, water, and a bromide ion.

One thing is known: the cost of this accident has been high. More than 530 Michigan farms were quarantined; 23,000 cattle, 5,000 swine and sheep, 1 1/2 million chickens, 2,600 pounds of butter, 34,000 pounds of dry milk products, 1,500 cases of canned evaporated milk, 18,000 pounds of cheese, about 5 million eggs, and 865 tons of feed were destroyed.

These economic losses have resulted in lawsuits seeking millions of dollars in damages. The final outcome of this aspect of the story, like the long-term health implications and ultimate fate of PBB's in the environment, won't be known for years.

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

News Highlights

Major Study Focuses on Effects of 'The Pill'

The largest long-term study ever undertaken on the effects of oral contraceptives is going on in Yugoslavia under the sponsorship of the Food and Drug Administration. Women in four cities—Zagreb, Ljubljiana, Sarajevo, and Belgrade—are participating in the project, which is expected to shed new light on the effects of "The Pill" on users and on their offspring. The studies are being funded through the Special Foreign Currency Program under which funds are allocated to FDA for cooperative health research projects in certain foreign countries.

The largest of the four Yugoslavian studies is in Ljubljiana. It is designed to show the relationship of oral contraceptives to cervical cancer and abnormality in offspring. A controlled population of 32,000 women is being followed for at least five years with observations of contraceptive practices, Pap smears (a method of diagnosing cervical cancer), and fertility. What the investigators want to learn is whether women who use oral contraceptives have the same or different changes on Pap smears or cervical tissues as women using other methods of contraception or no contraceptives. If the changes are different, possible reasons for the differences will be evaluated.

A group of 100 users of hormonal contraceptives and 100 non-users are also being studied to determine the effects of these contraceptives on pregnancy, the fetus, and the newborn. Preliminary results of these studies are expected within the next year.

Diabetics Warned on Faulty Test Strips

The Food and Drug Administration has advised diabetics that five lots of Clinistix, plastic strips used by diabetics to test their urine for sugar, have been recalled by the manufacturer, Ames Co., Elkhart, Indiana.

FDA advised diabetics not to use Clinistix from any of the five recalled lots. The recalled lots are 1140046, 2175046, 1175046, 2202046, and 1203046. The lot number is listed on the top of the label of the product and is preceded by the words "control number."

Tests conducted by the company indicate that about 15 percent of the plastic strips may give false positive results—that is, they may show the presence of sugar in the urine when none actually is there. A false positive result may encourage a diabetic to increase the dosage of insulin. Taking too much insulin can result in an abnormally low blood sugar level commonly called an "insulin reaction." If this condition is not recognized in its early stages by the diabetic or a physician the patient can faint or suffer a more serious reaction.

No injuries have been reported.

The test strips come in bottles of 50. Not all the recalled test strips give false positives. But if there is one faulty strip in a bottle, it is likely that all 50 in the bottle will be defective. Distribution of the recalled strips was nationwide and took place from July to November 1976.

Ames began recalling the five lots of Clinistix after receiving complaints of false positive results from companies who use the plastic strips for industrial purposes. One complaint was received from a consumer. Ames has contacted its distributors and all pharmacies.

Dosage Control Sought on Breast X Rays

FDA is cooperating with the National Cancer Institute to make available to all States a program designed to assure that x-ray equipment used to examine women for breast cancer does not give off too much or too little radiation.

The program—known as Breast Exposure: National Trends (BENT)—is intended to help radiological health officials identify facilities where the x-ray exposure appears unnecessarily high or unusually low for the type of equipment being used for breast x rays or mammograms, as they are often called. Machines that are giving off too much or too little radiation will be corrected through consultation with the practitioners who use them.

State agencies participating in the program will mail a "dosimetry" card for measuring x-ray exposure to facilities in their jurisdiction which perform mammographic examinations. The card is to be exposed to the x-ray machine according to the usual practice and returned to the agency where each exposure will be compared with all the other exposures obtained using similar techniques. Radiation experts will then visit facilities with abnormal exposures to check x-ray machines and image-processing systems.

It is expected that FDA will be able to supply dosimetry cards to four States per month beginning February 1, 1977. Results of pilot studies in Pennsylvania, the District of Columbia, Minnesota, Massachusetts, and New Hampshire show that BENT is effective in reducing exposure and improving image quality. Some 14 to 40 percent of the facilities surveyed to date have been identified for follow-up visits, during which recommendations were made which reduced exposures by as much as 75 percent.

Continued Limited Use of Saccharin Approved

FDA has extended its interim food additive regulation for saccharin to authorize continued limited use of the artificial sweetener until studies now being conducted are completed.

Saccharin was removed from the list of food additives that are classified as GRAS (Generally Recognized As Safe) in 1972 after preliminary results from studies indicated it might cause adverse effects. The interim food additive regulation issued at the same time placed limitations on the use of saccharin. The regulation was designed to discourage general use by consumers of saccharin and to prevent an increase in its use. FDA concluded that use of the artificial sweetener under the conditions specified in the

interim food additive regulation would not involve any significant increased risk to public health.

In June 1972 FDA asked the National Academy of Sciences/National Research Council to review the possible cancer-causing potential of saccharin. NAS/NRC said in December 1974 that available data had not established conclusively whether saccharin could cause cancer in test animals, and that additional studies were needed. Since then, the Health Protection Branch of Canada has undertaken two saccharin studies which are expected to provide data that will enable FDA to make a final decision on its use in food. The final report on a rat study to assess the cancer-causing potential of saccharin is expected in January 1978.

The January 7, 1977, FEDERAL REGISTER statement extending the interim food additive regulation for saccharin says: "In the Commissioner's view, allowing continued limited use of saccharin in the interim (until the Canadian studies are completed and evaluated) is appropriate because such use will not significantly increase the risk to the public health. Should new data become available that suggest an increased risk or make it impossible to conclude with reasonable certainty that the limited used of saccharin is safe, the Commissioner will not hesitate to take prompt action . . . FDA will continue to monitor closely the progress of the ongoing Canadian studies and will therefore be in a position to act expeditiously if circumstances warrant."

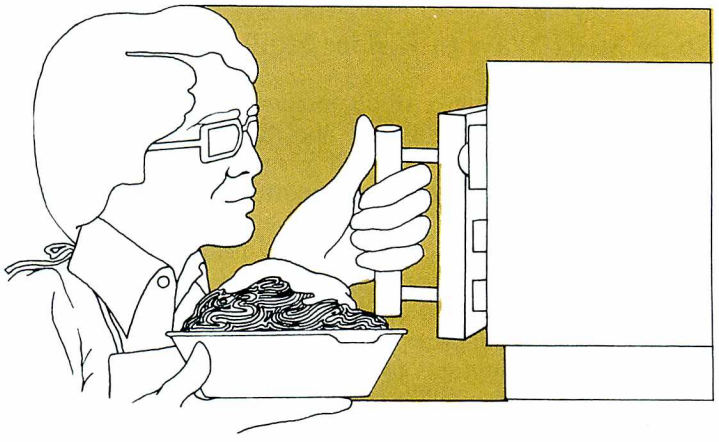
In the same FEDERAL REGISTER, FDA also proposed to amend the interim food additive regulation to establish a tolerance of 25 parts per million for toluenesulfonamide (including ortho-toluenesulfonamide), the major impurity found in commercial saccharin. This is believed to be the lowest level that can be detected with current methodology. Canada is conducting two rat studies to see whether this substance has adverse effects. Results from one study suggest that high doses may cause an increased incidence of bladder stones.

General Electric to Repair Microwave Ovens

The Food and Drug Administration has announced that the General Electric Co. has agreed to repair 36,000 microwave ovens now in the homes of consumers. The ovens may leak microwave radiation in excess of FDA's safety standard.

Under a plan approved by FDA, General Electric will locate and notify the owners of the ovens and make the necessary repairs at no expense to consumers. The repairs will start in February 1977. GE expects to complete repairs on 25,000 ovens by June 1 and the rest by the end of 1977.

The ovens to be repaired are all GE and GE's Hotpoint "Versatronic" and "Cook Center" combination thermal-microwave ovens made from November 1973 through October 1975.



Sherwin Gardner, Acting Commissioner of Food and Drugs, said: "We are requiring this repair program because the door seals on these ovens can deteriorate with use, resulting in a leakage of microwave radiation above that permitted by FDA's strict safety standard. The repair program is designed to assure that the door seals will meet our safety standard for the entire life of the ovens.

"We see no danger from consumer use of the ovens during the time it will take to repair them under this precautionary program," said Acting Commissioner Gardner.

Owners will be notified two weeks before GE service personnel will come to their homes to make necessary repairs.

GE previously had agreed to repair two similar groups of ovens that could leak microwaves above the FDA standard. As of December 1976, GE had repaired as needed about 5,300 of 6,026 ovens manufactured between June and November 1973, and about 9,900 of 12,854 ovens manufactured before June 1973.

X-ray Company Fined Under Radiation Act

The Sheppard X-Ray Co. of Fairless Hills, Pennsylvania, has signed a consent decree to pay a $2,000 fine for failure to certify and report the assembly of certified components into diagnostic x-ray systems, as required by the Federal diagnostic x-ray equipment performance standard. This is the first time a civil penalty has been levied for failure to comply with regulations issued under the Radiation Control for Health and Safety Act of 1968.

The standard requires assemblers of diagnostic x-ray systems to fill out a special form listing all certified components installed and to furnish copies to the purchaser and the FDA within 15 days. This is the assembler's certification that all applicable installation requirements of the standard have been met.

Twice during the summer of 1975 Sheppard X-Ray assembled stationary general-purpose diagnostic x-ray systems with new, certified components but failed to submit the required forms.

Under the enforcement provisions of the Act, U.S. district courts may punish violators of regulations by imposing civil penalties of up to $1,000 for each infraction. In accordance with these provisions, FDA forwarded a formal complaint against the company to the U.S. Attorney in Philadelphia who filed the case with the appropriate district court.

Study Seeks Ways to Reduce Skull X Rays

FDA is sponsoring a study in two Seattle hospitals to determine whether the use of specified selection criteria can reduce the number of skull x rays ordered in injury cases. Some radiologists have reported that as many as half of all such x rays are of no use in the treatment of patients and may result in unnecessary health care costs of as much as $15 million per year.

One of the hospitals participating in the study, the University of Washington Hospital, asks its physicians to use a list of 13 symptoms to determine the need for skull x rays in injury cases. The selection criteria consists of symptoms which increase the probability that an x-ray examination will provide useful diagnostic information. The second hospital does not use such a list.

The study, to be carried out by the University of Washington, will involve a review of all skull x rays made in the emergency departments of both hospitals between July 1, 1975 and June 30, 1976. Information from the two hospitals will be compared to determine whether the use of the selection criteria effectively reduces the number of unnecessary skull x rays and whether modification of the list is necessary.

Scientists to Study Data on Red No. 40

FDA has formed a working group composed of scientists from FDA and the National Cancer Institute to review studies being conducted on the color additive Red No. 40. The group held its first meeting in mid-December.

Red No. 40 has been permanently approved by FDA since 1971 for use in foods, drugs, and cosmetics. Use of the color increased substantially during 1976 after FDA banned Red No. 2, which had been the most widely used red color additive. Red No. 40 is now the second most widely used of all color additives after Yellow No. 5.

In late 1974 and early 1975, Allied Chemical, which holds the patent on Red No. 40, began two feeding studies, one in mice and the other in rats. The studies were undertaken in an effort to secure approval for Red No. 40 from the British and Canadian governments and to supplement data supplied to FDA.

Earlier this year, the preliminary results of the mouse study indicated that six of the animals being fed Red No. 40 developed premature and unexpected lymph cancer. FDA asked the company to sacrifice additional animals. No lymph cancer was detected in any of these animals.

Since then, FDA has required monthly progress reports on this study. These reports have been made available to the public. Dr. Michael Jacobson, co-director of the Center for Science in the Public Interest of Washington, D.C., has informed FDA that his evaluations of the data led him to conclude that action to end the use of Red No. 40 was warranted now. FDA believes further evaluation of the studies is required and has formed the working group to do that.

No adverse findings have been uncovered in the rat study.

At FDA's suggestion, Allied Chemical began a second mouse study in mid-summer. The results thus far are too preliminary for any conclusions to be drawn, but they do suggest a possible duplication of the early onset of lymph cancer noted in the first mouse study.

The working group will evaluate the results of the one rat and two mouse studies to see whether any regulatory action is needed. The group is chaired by Dr. Albert C. Kolbye, Jr., Associate Director for Science for FDA's Bureau of Foods.

No target date has been established for the group's report, since it is not known when the mouse studies will be completed. The working group's report will be made available publicly when it is submitted to the Commissioner of Food and Drugs.

Notice of the formation of the working group was published in the December 7, 1976, FEDERAL REGISTER.

FDA Issues Rules on Public Hearings

FDA has taken several actions recently to improve public understanding of the Agency's internal procedures and to provide ways for the public to participate in setting policy. Here is a summary of these actions:

- FDA has issued final regulations setting forth the procedures it follows when holding public hearings, and is issuing accompanying regulations governing how it handles consumer petitions, issues new regulations, and carries out other responsibilities. Among the requirements in the regulations being issued are: (1) that FDA maintain a Public Calendar that lists meetings of top Agency officials with non-Government people and upcoming meetings open to the public; and (2) that FDA keep minutes of meetings with anyone from outside the Agency and maintain them for public inspection. FDA generally has been operating under these procedures since the regulations were first proposed in May 1975. The final regulations on hearings were published in the FEDERAL REGISTERS of June 28, November 2, November 23, and November 26.

- FDA is publishing revised Freedom of Information (FOI) regulations. FOI regulations have been in effect since January 1975. The new regulations contain minor changes from the present ones, reflecting comments made on the present regulations as well as FDA's experience during the past two years in making available to the public most of the records maintained by the Agency. FDA now receives more than 20,000 FOI requests a year, granting more than 98 percent.

- FDA has begun issuing and will continue to issue regulations setting forth the procedures and policies it follows in enforcing the law. The regulations will cover recall policy, criteria for prosecuting individuals or firms for violations, how pre-prosecution or show-cause (Section 305) hearings are conducted, publicity policy, and regulatory letters policy. The proposals on Section 305 hearings and recall policy were published in the FEDERAL REGISTER on April 7 and June 30 respectively; the ones covering publicity, prosecution criteria, and regulatory letters should be proposed early in 1977.

Regional Reports

"Regional Reports" consists of important information on inspections, product seizures, court proceedings, and other regulatory and administrative actions initiated by FDA's regional and district field offices across the country to provide protection to consumers under Federal laws. "State Actions," the section immediately following "Regional Reports," consists of similar information about the consumer protection activities of State and local governments.

REGION I

Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Imported seafood, flour products, and cheese valued at over $100,000 were detained by FDA's **Boston District** after investigations and laboratory tests by the district confirmed the products were in violation of FDA regulations. The detentions included frozen shrimp from Hong Kong, India, and Indonesia, and frozen lobster tails from Indonesia, all contaminated by *Salmonella*. Lab tests also found shrimp from Taiwan to be short in weight, biscuits from Portugal containing rodent and animal hairs, corn flour—also from Portugal—without the required labeling in the English language, and feta cheese from Austria not labeled in compliance with the Fair Packaging and Labeling Act.

Topco Associates, Inc., Skokie, Illinois, entered into a consent decree of condemnation in the U.S. District Court for the District of Massachusetts as a result of FDA charges that two of the cereals it distributes were misbranded. The legal action resulted from the Federal Government's seizure of 132 cases of 100 percent Natural Cereal and 100 percent Natural Cereal with Raisins and Dates which were stored by Topco at East Bridgewater, Massachusetts. The seizure was based on a Government allegation that the cereals were misbranded since they were pre-sweetened, and this was not shown as part of the common or usual name of the food. FDA's Nashville District had originally sent a regulatory letter to the manufacturer, Sovex, Inc., Collegedale, Tennessee, warning the firm of possible misbranding violations after Nashville District inspectors had collected samples of the cereals at the firm. When the company failed to take corrective action, a U.S. marshal seized the cereals, which had been shipped to Massachusetts. The cereals were subsequently donated to a charitable institution under the terms of the consent decree.

Kalart Victor Corp. has revised procedures used to test radiation emission from its Telebeam II Television projector after the FDA officially declared the firm's testing program unacceptable. Personnel from FDA Headquarters and FDA's Engineering and Analytical Center at Winchester, Massachusetts, visited the Connecticut-based firm to evaluate the manufacturer's testing methods. The evaluation revealed the firm's surveying techniques were not adequately discovering "hot spots," and that radiation levels reported by the firm for some projectors were lower than those measured by FDA for the same units during the evaluation. After revising test procedures and modifying the high voltage limiter circuit, the firm submitted a second sample of the product to the Winchester Center and this was found to be in compliance under all phases of testing.

REGION II

New Jersey, New York, Puerto Rico, Virgin Islands

A New York firm has stopped manufacturing smoked whitefish following a Federal Court ruling that FDA was entitled to seek an injunction against the manufacturers of hot-process smoked fish who do not comply with processing requirements. U.S. District Judge John Dooling, Jr., in the Eastern District of New York, issued the ruling in the case of Nova Scotia Food Products, which FDA had sought to prevent from violating Current Good Manufacturing Practice Regulations in the processing of fish. Judge Dooling narrowed the issues to two major ones—salt content and cooking temperature—which FDA considers factors in preventing the formation of botulism toxins. Both Nova Scotia and the National Fisheries Institute, an industry association that intervened on behalf of the company, contended throughout the three-day hearing that complying with the FDA regulations would result in an unpalatable, unmarketable product. Judge Dooling replied that the background information and research used by FDA in establishing the requirements were readily available to industry experts, and that "FDA had to be concerned not with the fish processors, but with the public safety. . . ."

Several shipments of Spanish peanuts, totaling more than 54,000 pounds and valued at about $13,000, were seized by the Federal Government at the Buffalo Nut Co., a division of Dan-Dee Pretzel & Potato Chip Co. FDA's **Buffalo District** recommended the seizure after inspectors found the nuts were being held under insanitary conditions and could have become contaminated with insects. In another action, an absence of peanuts, combined with a deficiency in cashews resulted in Federal Government seizure of 64 cases of canned mixed nuts at the Empire State Nut Co., in Albany. Inspectors from the Buffalo District discovered during a routine inspection that the product's labeling was false and misleading. The artwork and other labeling on the can indicated peanuts as part of the mix, but no peanuts were found by inspectors.

The label also declared 60 percent cashews, but the actual amount of cashews was less than 40 percent. The canned nuts were turned over to the O. D. Heck Developmental Center near Albany for use by the residents.

A U.S. marshal seized about $1 million worth of botanical foods and drugs stored at S. B. Penick & Co., Lyndhurst, New Jersey, after investigators from FDA's **Newark District** discovered massive insect infestation at the firm. The products seized included botanical drugs prepared from bark, roots, and herbs, and botanical foods such as fennel seeds, herbs, and spices.

H. J. Heinz warehouse in San Juan, Puerto Rico voluntarily recalled 390 cases of Heinz Spaghetti in Tomato Sauce following a consumer complaint to FDA's **San Juan District** about a leaky can purchased at a supermarket in San Juan. FDA investigators collected several leaking cans at supermarkets in Puerto Rico, which were also leaking, and found another 400 cases of cans bearing the same code in the Heinz San Juan warehouse. The lot was part of an original shipment of 790 cases, valued at $12,500, that originated in the Heinz plant in Pittsburgh.

REGION III

Delaware, Maryland, Pennsylvania, Virginia, West Virginia

Richard W. Kissling, Sr., president of A. C. Kissling Co., Philadelphia, and Albert Kissling, secretary and treasurer, have agreed not to produce or distribute any sauerkraut products until insanitary conditions found at their plant by investigators from FDA's **Philadelphia District** are corrected. The firm and its two executives entered into a consent decree of permanent injunction in the U.S. District Court for the Eastern District of Pennsylvania following periodic inspections of the plant by FDA over the last several years, which revealed a continuing problem of insect contamination of sauerkraut. The injunction also requires that the sauerkraut plant and equipment be examined by a qualified person to assure that the food is received, prepared, and stored under proper sanitary procedures. In addition, all sauerkraut on hand must be examined for filth.

The Federal Government seized 37 bottles of procainamide hydrochloride capsules at Pace-Bond Drug Co., a wholesale distributor in Philadelphia, because the drug had not been approved by the FDA for marketing. The capsules, manufactured by Zenith Laboratories, Inc., Northvale, New Jersey, were shipped to the firm's subsidiary company in Philadelphia. FDA's Bureau of Drugs had sent the manufacturer a regulatory letter notifying the firm that the drug had not been approved by FDA. Subsequent investigation by FDA's Newark District traced the shipment to the firm's distributor in Philadelphia.

REGION IV

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

Garcia Bros. Seafood, Inc., Miami, and four company officials have entered into a consent decree of permanent injunction in the U.S. District Court of the Southern District of Florida in Miami to stop the distribution of swordfish which contains excessive amounts of mercury. The injunction prohibits the firm from receiving swordfish caught outside the three-mile territorial limits and from distributing it either in or outside Florida unless tests show the fish contain a mercury level of less than 5 parts per million. The injunction was necessary because an investigation by FDA's **Orlando District** revealed the firm continued to distribute the contaminated swordfish in spite of three recent Federal Government seizures.

A lot of over 28,000 pounds of decomposed frozen shrimp offered for import from Ecuador was detained at the Port of Miami by the Orlando District. The shrimp, valued at over $84,000, was imported by Ambassador Seafoods, Inc., Miami.

REGION V

Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin

A Cincinnati consumer turned her newspaper reading into a public service when she became suspicious of directions for home canning of green beans published in a local newspaper. FDA investigators evaluated the canning process and found it potentially dangerous because it lacked, among other safeguards, proper heat treatment of the beans to kill germs such as *Clostridium botulinum*, which can produce a deadly toxin. Green beans and many other vegetables are low-acid foods and need proper heating to kill these organisms. The food editor of the paper was notified by an investigator from FDA's **Cincinnati District** who explained the inadequacies of the canning method. As a followup feature, the newspaper reported FDA's position on home canning to its readers.

The Cincinnati District has become the first FDA district office to implement a section of the new Medical Device Amendments of 1976 which grants the Agency authority to initiate legal action against a medical device firm without having to prove beforehand that the firm's products were destined for interstate commerce. As a result a U.S. marshal seized over $6,000 worth of devices containing antibiotics at Medical Specialities, Inc., Cleveland, following a routine inspection by FDA's Cleveland resident post. The inspectors found antibiotic substances in unlabeled containers and diagnostic test panels which contained antibiotic preparations not certified by FDA. Following the inspection, FDA's Cincinnati District filed a complaint for forfeiture in the Northern District of Ohio at Cleveland which provided for the seizure based on labeling violations and misbranded diagnostic devices found at the firm.

West Bend Malt and Grain Co., West Bend, Wisconsin, has taken action to eliminate insanitary conditions found at the plant by inspectors from FDA's **Minneapolis District** which resulted in Federal Government seizure of approximately 90,000 bushels of barley malt. The inspectors found some of the malt adulterated with rodent filth; other quantities of malt were stored in rodent-infested areas. FDA contacted the State of Wisconsin which placed an embargo on the malt until it could be seized by a U.S. marshal. When the brewery that bought malt from the

West Bend firm found out about the seizure, it stopped doing business with the firm, and then hired an entomologist whose responsibilities included inspecting for insect and rodent infestations in other malt houses which supply malt to the brewery.

REGION VI

Arkansas, Louisiana, New Mexico, Oklahoma, Texas

Gate-La Llave Rio Grande Storefront, a methadone clinic in Albuquerque, voluntarily destroyed approximately 60,000 milliliters of Red No. 2 food coloring after an inspection by FDA's **Dallas District** revealed the clinic was adding the color additive to bulk quantities of methadone solution under preparation. Red No. 2 was banned by FDA a year ago. Agents from the Drug Enforcement Agency supervised the destruction of the color additive.

An injunction granted by U.S. District Court Judge Jack M. Gordon for the Eastern District of Louisiana has ordered Dr. H. Ray Evers to stop receiving, selling, or delivering to any patient the drug disodium edetate for use in treating arteriosclerosis and other circulatory diseases at Meadowbrook Hospital in Belle Chasse, Louisiana. Disodium edetate is a chelating agent used to treat victims of lead poisoning, and has not been found safe or effective in the treatment of circulatory diseases. The injunction also ordered Dr. Evers to inform all his patients that he can no longer administer disodium edetate, also known as EDTA, to them, and to turn over to a U.S. marshal any of the drug held by him, his associates, or the hospital. The injunction was granted by Judge Gordon after he heard FDA's **New Orleans District** and Dr. Evers present extensive testimony regarding the use of the drug at the hospital. A U.S. marshal and two investigators from FDA's New Orleans District traveled to Belle Chasse to serve Dr. Evers with the injunction order and seize any stock of the drug. When they arrived, however, they found the hospital abandoned and learned that Dr. Evers had left for Montgomery, Alabama, where the injunction was finally served.

REGION VII

Iowa, Kansas, Missouri, Nebraska

Na-Spra, Inc., and Fleming & Co. Pharmaceuticals, both of St. Louis, and their president, Tom E. Fleming, and purchasing agent, Everett L. Boughan, have agreed to a consent decree of permanent injunction filed in the Eastern District Court of Missouri prohibiting the manufacture or distribution of drugs until their operations can comply fully with FDA's Current Good Manufacturing Practice (GMP's) Regulations. The action resulted from a series of inspections by investigators from FDA's **Kansas City District** which revealed serious deviations from GMP's, including inadequate testing and labeling of some drugs and incomplete recordkeeping. Fleming & Co. Pharmaceuticals had previously agreed to a similar injunction last year which prohibited the firm from manufacturing and distributing human and new animal drugs not approved by FDA.

FDA's Kansas City District completed a month-long aflatoxin survey of the 1976 corn harvest by inspecting grain elevators in four midwestern areas. A Kansas City District investigator-chemist team used a mobile laboratory to visit grain elevators in St. Joseph, Missouri; Omaha and Grand Island, Nebraska; and Des Moines and Cedar Rapids, Iowa. They found that only one of 342 corn samples examined contained aflatoxin in amounts not permitted by FDA. Aflatoxin is a toxic substance produced by some molds.

REGION VIII

Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming

Sorenson Research Co., Salt Lake City, Utah, a manufacturer of medical devices, has recalled two products used in hospitals throughout the Nation, as well as in hospitals abroad. The two products are Intraflo, a device used to administer intravenous solutions and for other uses in lines leading to arteries or veins, and monitoring kits containing Intraflo devices as a component. The recall was initiated after a hospital in Ann Arbor, Michigan, reported to FDA's Detroit District that the hospital was finding defects in the Intraflo units. The Detroit District notified FDA's **Denver District** which, in turn, worked with Sorenson to initiate the recall of over 155,000 Intraflo units and 10,000 monitoring kits. No known injuries or deaths were associated with the defective kits.

REGION IX

Arizona, California, Guam, Hawaii, Nevada

The Federal Government seized approximately 26,500 pounds of foodstuffs, valued at an estimated $110,000, at Chuck Lee's Market, San Francisco, after an inspection by FDA's **San Francisco District** confirmed an earlier FDA report that the warehouse area was infested with rodents. The inspection also revealed rodent-contaminated food in the firm's grocery outlet which is part of the same operation. A U.S. marshal, assisted by six FDA investigators and three health inspectors from the State and city and county of San Francisco, seized merchandise in both the warehouse and the retail store.

Chemrich Laboratories, Los Angeles, voluntarily destroyed 519 vials of Brophen injection, a veterinary drug for treating urinary spasms in dogs and cats, after U.S. marshals seized 233 vials of the same product at Hall Veterinary Drug Co., Garden Grove, California. FDA analysis of a sample collected during a routine inspection by the **Los Angeles District** revealed that the drug was not approved for use by FDA. The drug had been manufactured by Titan

Pharmacal Co., Los Angeles, and then shipped to Chemrich Laboratories which, in turn, shipped some of the product to the distributor in Garden Grove.

REGION X

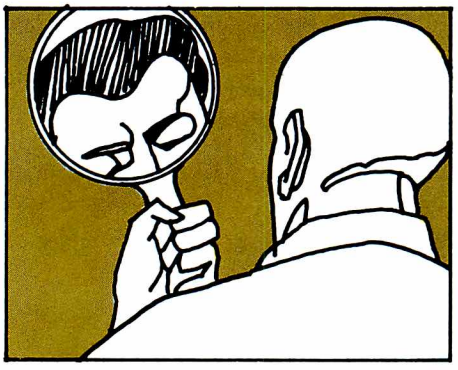
Alaska, Idaho, Oregon, Washington

Sanfair Bakeries, Inc., Fairbanks, Alaska, and its president, Gerald O. Claus, entered into a consent decree of permanent injunction, filed in the U.S. District Court of Alaska, as a result of charges by FDA's **Seattle District** that the firm was preparing and holding food under insanitary conditions despite repeated warnings by FDA. Under the consent decree the firm agreed to stop all production until it could bring its processing operations into compliance with FDA regulations by establishing an effective sanitation control program, including elimination of insects and vermin from its facilities, cleaning and renovation of equipment, and selection of a qualified individual to be responsible for the sanitation aspects of the operation. The decree also required that all food stored at the bakery be examined for filth, and any contaminated food be destroyed or otherwise brought into compliance with the Federal Food, Drug, and Cosmetic Act. The firm also was permanently enjoined from distributing adulterated foods, which means, in effect, that if there are any further violations the firm could be held in contempt of court. The bakery is the primary supplier of baked goods for northern Alaska, including Fairbanks, military bases, and Alaska oil pipeline camps.

State Actions

Hair Restorer Seized

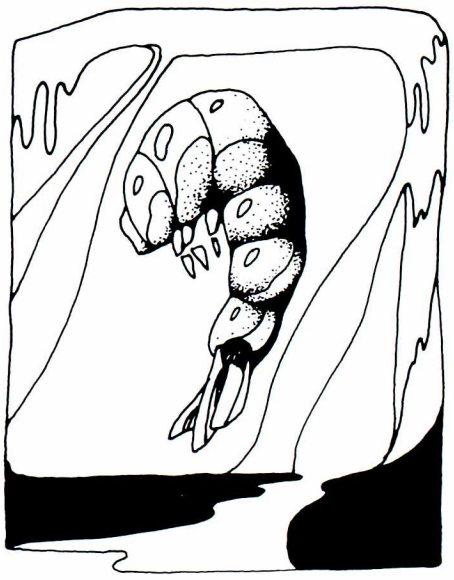
An investigation of Hairdresser's Ltd., La Place, Louisiana, by Louisiana State food and drug inspectors and investigators from FDA's New Orleans District resulted in the State's seizure of $540 worth of Jane's Hair Restorer because of grossly inadequate labeling and false and misleading claims. The joint investigation began after FDA's New Orleans District received an inquiry from the New Orleans Better Business Bureau about the



truthfulness of the firm's claim that its product was approved by FDA. A follow-up investigation at the manufacturer, J.A.C.E.S. Co., Pearl River, Louisiana, by the State, assisted by FDA's New Orleans District, revealed the firm was manufacturing the restorer by mixing three well-known hair conditioning products and adding water. Since the firm was not licensed in the State, a hearing was held by the State Attorney General's office in which the firm agreed to recall all outstanding stock. The firm was also ordered to make refunds to all customers.

Contaminated Feed Recalled

The Ralston Purina Co., Gainesville, Georgia, voluntarily recalled 12,000 pounds of contaminated horse feed after six of 30 horses who ate some of the feed died. Autopsies performed on the horses at the owner's request revealed cardiac damage. An investigation by Purina of the remaining feed revealed the presence of 95 to 123 grams per ton of feed of the drug Monensin, which is toxic to horses at this level. The contamination was traced to a pneumatic slide gate which malfunctioned and added the Monensin and two other drugs, Roxarsone and Lincomycin, to the Omolene Checkers brand horse feed. The drugs were supposed to have been mixed with a medicated feed which was being processed ahead of the horse feed. FDA's Atlanta District was notified of the contaminated feed and its burial in a local landfill. Subsequent inspection of the plant by the Atlanta District and the Georgia Department of Agriculture found that the company had installed a switch for the mixing system which automatically stops the mixing in case the slide gate malfunctions.



Frozen Shrimp Detained

The Maryland Department of Health detained a shipment of 3,000 cartons of frozen shrimp from Taiwan after an alert truck driver, who was at the Baltimore Port to transport the shipment, noticed the shrimp appeared to be decomposed. He notified the State Department of Health, which detained the shipment pending an investigation. It was found that the refrigeration on the vessel had failed and permitted the shrimp to decompose. FDA's Baltimore District collected samples for a laboratory analysis, which confirmed that the shrimp was decomposed and unfit for human consumption. The lot was denied entry into the United States.

Seizures and Postal Service Cases

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

A total of 51 actions to remove from the consumer market products charged to be violative was reported in December. These included 23 seizures of foods: 3 involved charges concerning poisonous and deleterious substances, 17 involved charged concerning contamination, and 3 involved charges concerning economic and labeling violations. Other seizures included 5 of food additives, 2 of color additives, 19 of drugs (including 1 of veterinary/medicated feed), and 2 of medical devices.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
	FOOD/Poisonous and Deleterious Substances	
Apricot kernels/Portland, Oreg. 8/31/76	Earth Products/Marina Del Rey, Calif.(S)	Contains the poisonous and deleterious substance hydrocyanic acid (hydrogen cyanide), and is unfit for food due to the hydrocyanic acid.
Swordfish/Miami, Fla. 7/28/76	Fishing vessels *Alvien* and *Still Water II* (S)	Contains the added poisonous and deleterious substance mercury.
Miami, Fla. 8/12/76	Garcia Bros. Seafood, Inc./Miami, Fla. (S,D)	
	Contamination, Spoilage, Insanitary Handling	
Beans, pink/Mount Summit, Ind. 10/4/76	Brooks Foods, Div. Curtice Burns, Inc./Mount Summit, Ind. (D)	Held under insanitary conditions.
Cereals, puffed wheat & puffed rice/Springfield, Mo. 8/3/76	Finkbiner Transfer & Storage Co./Springfield, Mo. (D)	Held under insanitary conditions; puffed wheat rodent contaminated.
Chili peppers; sesame seeds/Brooklyn, N.Y. 7/30/76	Gel Spice Co., Inc./Brooklyn, N.Y. (D)	Held under insanitary conditions; rodent contaminated.
Coffee beans/Houston, Tex. 9/13/76	Strachan Shipping Co./Houston, Tex. (D)	Held under insanitary conditions; bird contaminated.
New Orleans, La. 10/28/76	TTT Ship Agencies, Inc./New Orleans, La. (D)	"
San Francisco, Calif. 10/29/76	Pacific-Oriental Terminal Co./San Francisco, Calif. (D)	"
Corn, shelled/Snowflake, Ariz. 10/20/76	Silver Creek Mill/Snowflake, Ariz. (D)	Held under insanitary conditions; rodent and insect contaminated.
Corn flour; sugar/Milwaukee, Wis. 8/18/76	Pick-A-Treat, Inc./Milwaukee, Wis. (D)	Held under insanitary conditions.
Flour/Hato Rey, P.R. 8/31/76	Molinos de P.R., Inc./Catano, P.R. (M)	Contains insects.
Flour, rice, cornstarch, sweet rice, and other food stocks/Edgewater, N.J. 8/30/76	Merse Bros. Trucking Co./Edgewater, N.J. (D)	Six lots of flour insect infested; all the foods held under insanitary conditions.
Macaroni, spaghetti, rice, textured protein, and other retail stocks/Grand Prairie, Tex. 9/24/76	Basic Needs, Inc./Grand Prairie, Tex. (D)	Held under insanitary conditions; contains rodent and insect filth.
Paprika/Oxnard, Calif. 8/4/76	Gentry International, Inc./Oxnard, Calif. (D)	Held under insanitary conditions; rodent gnawed.
Pineapple, crushed, canned/Catano, P.R. 8/12/76	Imported from Brazil.	Unfit for food due to presence of pieces of interior can lining.
Popcorn, white/Winona, Minn. 7/29/76	Quinn Popcorn Co., Inc./Lakeview, Iowa (S)	Contains insects.
Rice/Jersey City, N.J. 10/4/76	Shipped from New Orleans, La.	"
Soybeans/San Francisco, Calif. 10/6/76	Azumaya, Inc./San Francisco, Calif. (D)	Held under insanitary conditions.
Sugar/Ooltewah, Tenn. 9/3/76	Collegedale Distributors, Inc./Ooltewah, Tenn. (D)	"
	Economic and Labeling Violations	
Juices, pineapple, tomato, prune, apple, and grape; cranberry juice cocktail; apricot nectar/Nashville, Tenn. 9/3/76	Ardmore Farms, Inc./Deland, Fla. (M,S)	Short volume (cranberry juice cocktail, apple and grape juices); fail to conform to definition and standard of identity (pineapple, tomato, and prune juices); label fails to declare common or usual name of each ingredient (grape juice); quantity of contents statement in too small type size (all articles).

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Nuts, mixed/Albany, N.Y. 10/8/76	Empire State Nut Co., Inc./Albany, N.Y. (P)	False and misleading statement as to percent of cashews; fails to comply with standard of identity for mixed nuts; false and misleading vignette picturing some peanuts when there were no peanuts in mix.
Snacks of rice and corn, Andy Capp's Bacon Strips/S. Portland, Maine 8/17/76	Slim Jim Div. of Goodmark, Inc./Folcroft, Pa. (M,S)	False and misleading statement "Bacon Strips," offered for sale under name of Bacon Strips when product does not contain bacon; not conspicuous.
	FOOD ADDITIVES	
Glass liquor bottles, prunes, coffee beans, dried milk, and other foods and feeds/Minneapolis, Minn. 9/16 & 17/76	Broker's Warehouse, Inc./Minneapolis, Minn. (D)	Some lots contain nonconforming food additives—Eptam, Dyfonate, and Vernam; some containers composed in part of poisonous and deleterious substances—Eptam and Dyfonate which might render their contents injurious to health; held under insanitary conditions (all lots).
Sodium pangamate tablets and Vitamin B-15-related articles/Hollywood, Fla. 7/26/76	Generix Drug Corp./Hollywood, Fla. (D)	Contains nonconforming food additives, such as sodium pangamate, calcium pangamate, and/or glycine; false and misleading claims concerning nature of product; lack common or usual name of each ingredient.
Passaic, N.J. 10/6/76	Manufactured in N.J. from interstate ingredients.	"
North Bergen, N.J. 10/10/76	Shipped from outside of State of N.J.	"
Union, N.J. 9/27/76	International Vitamin Corp./Union, N.J. (M)	"
	COLOR ADDITIVES	
Caviar, whitefish/New York, N.Y. 8/23/76	Purepak Foods, Inc./New York, N.Y. (D,P)	Contains delisted color additive FD&C Red No. 2.
Red food color, bulk and repacked/Des Moines, Iowa 7/29/76	Tone Bros., Inc./Des Moines, Iowa (D,P)	Contains the delisted color additive FD&C Red No. 2.
	DRUGS/Human Use	
Chlorothiazide tablets/Miami, Fla. 7/28/76	Bolar Pharmaceutical Co., Inc./Copiague, N.Y. (M,S)	Article is a new drug without an effective approved New Drug Application, and no Notice of Claimed Investigational Exemption is on file for such drug.
San Diego, Calif. 8/10/76	"	"
San Diego, Calif. 8/10/76	"	"
Cumberland, Md. 8/18/76	"	"
Blairsville, Ga. 8/19/76	"	"
Philadelphia, Pa. 10/20/76	"	"
Philadelphia, Pa. 10/21/76	"	"
Chorionic gonadotropin injectable, phendimetrazine tartrate tablets/Ronkonkoma, N.Y. 7/28/76	Sherry Pharmaceutical, Inc./Ronkonkoma, N.Y. (D); Barr Laboratories, Inc./Northvale, N.J. (M,S)	Labeling of both drugs fails to bear adequate directions for use; phendimetrazine tartrate tablets lacked an effective approved New Drug Application.
Hydrogenated Ergot Alkaloids tablets/San Diego, Calif. 8/10/76	Bolar Pharmaceutical Co., Inc./Copiague, N.Y. (M,S)	No effective approved New Drug Application, and no Notice of Claimed Investigational Exemption is on file for such drug.
San Diego, Calif. 8/10/76	Riker Labs, Inc./Northridge, Calif. (M); Pharmacon, Inc./Farmington, Mich. (S)	"
Hialeah, Fla. 9/9/76	Bolar Pharmaceutical Co., Inc./Copiague, N.Y. (M,S)	"
Hydrogenated Ergot Alkaloids tablets/Hollywood, Fla. 7/26/76	"	"
Hydrogenated Ergot Alkaloids tablets and chlorothiazide tablets/Portland, Oreg. 8/25/76	"	"
Phendorex TD caps (phendimetrazine tartrate)/Melville, N.Y. 10/20/76	Cord Laboratories, Inc./Broomfield, Colo. (M,S)	"
Plasma, source/Dallas, Tex. 10/14/76	Dallas Plasma Corp./Dallas, Tex. (M,D)	Produced under circumstances lacking current good manufacturing practice.
Procainamide HCl/Philadelphia, Pa. 10/20/76	Zenith Laboratories, Inc./Northvale, N.J. (M,S)	No effective approved New Drug Application, and no Notice of Claimed Investigational Exemption is on file for such drug.
Quinidine sulfate tablets/Dallas, Tex. 10/26/76	Vitarine Co., Inc./Springfield Gardens, N.Y. (M,S)	No effective approved New Drug Application.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Triple sulfa tablets/Columbus, Ohio 10/22/76	Cord Laboratories, Inc./Broomfield, Colo. (M,S)	No effective approved New Drug Application, and no Notice of Claimed Investigational Exemption is on file for such drug.
	Veterinary/Medicated Feed	
"606" Penicillin-dihydrostreptomycin ointment w/sulfamethazine hydrocortisone; "707" penicillin-neomycin ointment; "808" penicillin-neomycin ointment w/sulfamethazine hydrocortisone/Broad Brook, Conn. 10/14/76	Pharm-House, Inc./Hope Valley, R.I. (M,S)	New animal drugs subject to antibiotic certification, and were not from a certified batch.
	MEDICAL DEVICES	
Solarama microthermal panels/Lebanon, Oreg. 9/3/76	The World of Solarama/Greenville, S.C. (M,S)	False and misleading therapeutic claims for conditions such as asthma, peptic ulcers, neurosis, acute colitis, cataracts, arthritis, and aging; inadequate directions for use.
Therapuncteur device; Punctoscope device/Salt Lake City, Utah 7/12/76	Shores Medical Electronics/Tulsa, Okla. (M,S)	False and misleading claims for diagnosis and treatment of a number of body organs and areas, and diseases such as toothache, hepatitis, and urticaria; labeling fails to bear adequate directions for use.

U.S. POSTAL SERVICE

actions taken in medical cases as authorized in the Mail Fraud Statute (18 U.S.C. 1341) and/or the False Representation Statute (39 U.S.C. 3005) as reported by the Chief Postal Inspector.

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

October 26, 1976: **Sara Micheals,** P.O. Box 33002, St. Petersburg, Florida. Advertising and sale through the mail of an alleged protein powder, representing the ability to cause firmer, fuller, and increased bustlines.

October 27, 1976: **Shore Products,** Box 174, Edison, New Jersey. Advertising and sale through the mail of the product, "Pure Skin," representing the ability to remove wrinkles, oiliness, acne, pimples, and other cosmetic disorders.

November 2, 1976: **Shore Products,** Box 174, Edison, New Jersey. Advertising and sale through the mail of a cream representing the ability to soften and alleviate stretch marks.

November 11, 1976: **American Image Industries, Inc.,** 276 Park Avenue, South, New York, New York. Advertising and sale through the mail of a cream representing the ability to make hair longer and thicker.

November 19, 1976: **Modern Age Products, Inc.,** P.O. Box 35, Plainview, New York. Advertising and sale through the mail of the product, "Chartham Method," representing the ability to increase the size of the male organ, both in the flaccid and erect state.

November 19, 1976: **Modern Age Products, Inc.,** P.O. Box 35, Plainview, New York. Advertising and sale through the mail of the product, "Dr. Richard's Ring," representing the ability to maintain an erection.

November 24, 1976: **Pompie,** P.O. Box 9313, Fort Lauderdale, Florida. Advertising and sale through the mail of the product, "Firm Up Bust Massage Cream," representing the ability to cause finer, curvier, and shaplier busts.

November 30, 1976: **Action Products,** P.O. Box 231, Santa Monica, California. Advertising and sale through the mail of the product, "The Commander," representing the ability to cause and maintain an erection.

December 2, 1976: **Hair Vitamins,** P.O. Box 14139-90, Philadelphia, Pennsylvania. Advertising and sale through the mail of the product, "Hair and Body Vitamins Plus Minerals," representing the ability to cause hair to grow longer and thicker.

December 2, 1976: **Sans Egal,** 380 Madison Avenue, New York, New York. Advertising and sale through the mail of the product, "Sans Egal," representing the ability to reduce wrinkles, tighten sagging skin, and remedy other cosmetic disorders.

December 6, 1976: **National Consumer,** 888 Toulon, Pacific Palisades, California. Advertising and sale through the mail of the product, "Celluglove and Trimassage," representing the ability to remove cellulite.

December 8, 1976: **Firma-Figure,** P.O. Box 72, Freeport, New York. Advertising and sale through the mail of the product, "Firma-Figure Trim-Gel," representing the ability to cause weight loss.

December 20, 1976: **Hollywood Medical Labs,** Box 4261, North Hollywood, California. Advertising and sale through the mail of certain formulas represented as aphrodisiacs.

December 21, 1976: **Progressive Sales Group,** P.O. Box 310, New Rochelle, New York 10804. Advertising and sale through the mail of the product, "P.S.G. Pumpometer," representing the ability to enlarge the penis.

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

November 15, 1976: Against **Sophistication Plus,** 1 Wolfs Lane, Pelham, New York 10803. Advertising and sale through the mail of a pamphlet containing information representing the ability to increase the bustline.

November 29, 1976: Against **Kelp Diet,** 2001 N.W. 7th Street, Miami, Florida. Advertising and sale through the mail of the product, "Kelp Tablets," representing the ability to cause weight loss without changing eating habits.

December 10, 1976: Against **World Wide,** 1236 South La Cienega Blvd., Los Angeles, California. Advertising and sale through the mail of the products "Super Pulsator and Penis Enlarger," representing the ability to tone and develop specific genital muscles that contribute to erection of the penis.

December 10, 1976: Against **Omega,** Dept. 1605, P.O. Box 199, Woodland Hills, California. Advertising and sale through the mail of the products, "Passion Plus with Ginseng," and "The Original Erecto," tablets representing the ability to cause and maintain an erection of the male organ and cause sexual desire in women.

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Cottonseed oil, cottonseed meal, and **cottonseed feed mix,** at Tunica, N. Dist. Miss.
Charged 12-19-75: when the cottonseed meal and cottonseed feed mix were recalled to Tunica, Miss., after being distributed for animal feed use in Alabama, Louisiana, Tennessee, Mississippi, and Florida, and while the oil was held by Planters Oil Mill, Inc., Tunica, Miss., after being expressed from cottonseed shipped in interstate commerce, the articles contained the added poisonous and deleterious substance mercury; and the articles contained the nonconforming food additives pentachloronitrobenzene and 0,0-diethyl S-(2-(ethylthio) ethyl) phosphorodithioate; 402(a)(1), 402(a)(2)(C). Consent decree authorized release to the mill for salvaging. (F.D.C. No. 60582; S. No. 76-00-154 et al.; N.J. No. 1)

Swordfish fillets, at Treasure Island, M. Dist. Fla.
Charged 7-30-76: when shipped as whole fish by Garcia Bros. Seafood, Inc., Miami, Fla., after being caught in Atlantic Ocean waters outside the limits of Florida, the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 60840; S. No. 77-43-741; N.J. No. 2)

FOOD/Contamination, Spoilage, Insanitary Handling

Beans, mung, dried, at Cleveland, N. Dist. Ohio.
Charged 8-6-76: while held by Sam Wah Yick Kee Co., Cleveland, Ohio, the article contained insects and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60832; S. No. 77-12-075; N.J. No. 3)

Beans, navy, dried, at Fort Worth, N. Dist. Tex.
Charged 3-11-74: while held by Great Western Foods, Fort Worth, Tex., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to claimant for salvaging. (F.D.C. No. 59671; S. No. 104-831 G; N.J. No. 4)

Beer, at Nome, Dist. Alaska.
Charged on or about 4-1-75: while held for sale, the article (which had been submerged under flood waters contaminated with sewage) had been held under insanitary conditions whereby it might have become contaminated with filth and might have been rendered injurious to health; 402(a)(4). The article was claimed by K&L Distributors, Inc., Belleville, Wash. Subsequently, a consent decree ordered the article destroyed. (F.D.C. No. 60242; S. No. 19-600 H; N.J. No. 5)

Candy bars, Palmer's Bing and **Palmer's Twin Bing,** at Norfolk, Dist. Nebr.
Charged 8-10-76: when shipped by Palmer Candy Co., Sioux City, Iowa, the articles had been prepared, packed, and held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60842; S. Nos. 76-24-737/8; N.J. No. 6)

Candy bars, Palmer's Twin Bing, 2 seizure actions, at Omaha, Dist. Nebr. and Lincoln, Dist. Nebr.
Charged 8-10-76 and 8-10-76: when shipped by Palmer Candy Co., Sioux City, Iowa, the article had been prepared, packed, and held under insanitary conditions; 402(a)(4). Default decrees ordered destruction. (F.D.C. Nos. 60756, 60841; S. Nos. 76-24-734, 76-24-736; N.J. No. 7)

Cereal, pudding & pie filling mix, and **gelatin dessert mix,** at Harahan, E. Dist. La.
Charged 1-5-76: while held by Louisiana Grocers Co-Op, Harahan, La., all of the articles except the cereal, contained rodent filth, and all were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60606; S. Nos. 76-38-427/9; N.J. No. 8)

Cheese, rice, dried milk, black-eyed beans, and **flour,** at New Orleans, E. Dist. La.
Charged 9-15-76: while held by Dan Kelly Warehouse, Inc., New Orleans, La., the flour and dried milk contained rodent filth, and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 60899; S. No. 77-38-585 et al.; N.J. No. 9)

Chili sauce and **chili paste,** at New York, S. Dist. N.Y.
Charged 9-18-75: while held for sale, the articles were contained in glass jars with swollen and leaking lids; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60475; S. Nos. 76-40-502/3; N.J. No. 10)

Coffee beans, at New Orleans, E. Dist. La.
Charged 5-28-74: while held for sale, the article contained bird filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to claimant for salvaging. (F.D.C. No. 59792; S. No. 54-072 H; N.J. No. 11)

Coffee beans, 2 seizure actions, at New Orleans, E. Dist. La.
Charged on or about 3-1-74 and 3-8-74: while held for sale, the articles contained bird filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to claimants for salvaging. (F.D.C. Nos. 59680, 59684; S. No. 68-371 G et al.; N.J. No. 12)

Crabmeat, claw, at Port Arthur, E. Dist. Tex.
Charged 8-30-76: when shipped by Shell Key Packing Co., Franklin, La., the article contained added *E. coli, staphylococci,* and bacterial filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60870; S. No. 77-23-013; N.J. No. 13)

Flour, at Hato Rey, Dist. P.R.
Charged 8-18-76: while held for sale, after being milled by Molinos de Puerto Rico, Inc., Catano, P.R., from wheat shipped in interstate commerce, the article contained insects; 402(a)(3). Consent decree authorized release to Donas Aymat, Hato Rey, P.R., for conversion to animal feed. (F.D.C. No. 60861; S. No. 77-50-477; N.J. No. 14)

Oats, rolled, at Ann Arbor, E. Dist. Mich.
Charged 6-1-76: while held by Eden Foods, Inc., Ann Arbor, Mich., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for reconditioning. (F.D.C. No. 60741; S. No. 76-67-188; N.J. No. 15)

Pepper strips, green, canned, at South Boston, Dist. Mass.
Charged 10-31-75 and amended 1-8-76: while held for sale, the article was contained in swollen and leaking cans; 402(a)(3). The article was claimed by H.D.R. Enterprises, Inc., Brighton, Mass., who joined with the Government in moving for postseizure samples. Subsequently, a consent decree authorized release to the claimant for salvaging. (F.D.C. No. 60529; S. No. 76-05-458 H; N.J. No. 16)

Shrimp, frozen, at Warren, E. Dist. Mich.
Charged 4-8-76: when shipped by Ben Kozloff, Inc., Chicago, Ill., the article, labeled in part "Geisha Brand . . . Frozen Shrimp Peeled and Deveined . . . Nozaki Assoc. Inc. Importers New York, N.Y. . . . Packed in Taiwan," consisted in part of decomposed shrimp; 402(a)(3). Consent decree authorized release to the shipper for export to the original foreign supplier. Subsequently, the decree was amended to permit the destruction of the article. (F.D.C. No. 60684; S. No. 76-21-477; N.J. No. 17)

Sugar, at Ooltewah, E. Dist. Tenn.
Charged 8-30-76: while held by Collegedale Distributors, Inc., Ooltewah, Tenn., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 60877; S. No. 77-32-689; N.J. No. 18)

Sugar, granulated, bagged and bulk, at Seattle, W. Dist. Wash.
Charged on or about 5-20-75: while held for sale, the article was unfit for food due to its objectionable, sour, musty, and/or fishy odor; 402(a)(3). The article was claimed by Amalgamated Sugar Co., Ogdon, Utah. Consent decree authorized release to the claimant for reconditioning.

Charged on or about 6-17-76 in bond forfeiture action: that the claimant had, contrary to the conditions of the bond required by the consent decree, diverted the 1,689 pounds of bulk sugar from the rest of the condemned sugar (21,200 pounds in bags) so that it was unavailable for reconditioning under FDA supervision. After a hearing, the court declared half of the $10,000 bond forfeited. (F.D.C. No. 60352; S. No. 21-728 H; N.J. No. 19)

Whiskey, wine, beer, nonalcoholic beverages, and **miscellaneous food items,** at Nome, Dist. Alaska.
Charged on or about 4-1-75: while held for sale, the articles (which had been submerged under flood waters contaminated with

sewage) were held under insanitary conditions whereby they might have become contaminated with filth and might have been rendered injurious to health; 402(a)(4). The articles were claimed by K&L Distributors, Inc., Belleville, Wash. Subsequently, the claimant withdrew its claim, and a default decree ordered the articles destroyed. (F.D.C. No. 60245; S. No. 19–603 H; N.J. No. 20)

FOOD/Economic and Labeling Violations

Cane, glucose and citric acid combination syrup, at Hammond, E. Dist. La.
Charged 2-17-76: when shipped by Oliver Anthony, Philadelphia, Miss., glucose had been substituted in part for cane syrup; the article, labeled in part "ANTHONE'S RIBBON CANE SYRUP A syrup . . . from cane juice, glucose, citric acid . . . Oliver Anthony," purported to be cane syrup, and it failed to conform to the definition and standard of identity for cane syrup since it contained glucose; 402(b)(2), 403(g)(1). Consent decree authorized release to shipper for relabeling. However, the required bond was never posted and, upon motion of the Government, a default decree of condemnation was entered which authorized the donation of the article to a charitable institution. (F.D.C. No. 60647; S. No. 76–38–351; N.J. No. 21)

Cereals, presweetened, at E. Bridgewater, Dist. Mass.
Charged 4-22-76 and amended 5-6-76: when shipped by Sovex, Inc., Collegedale, Tenn., and Topco-Sovex, Inc., Bridgeview, Ill., the labels of articles, labeled in part "Food Club 100% Natural Cereal [or "100% Natural Cereal with Raisins & Dates"] . . . Distributed By Topco Associates, Inc., Skokie, Illinois," failed to bear the common or usual name of the foods, since "100% Natural Cereal" and "100% Natural Cereal With Raisins & Dates" were not the common or usual names of presweetened cereals—403(i)(1). Consent decree authorized donation to charitable institution. (F.D.C. No. 60719; S. Nos. 76–56–010/11; N.J. No. 22)

Snacks of corn and rice, bacon-flavored, Andy Capp's Bacon Strips, at South Portland, Dist. Maine.
Charged 8-17-76: when shipped by Slim Jim Division of Good-Mark, Inc. (Division of General Mills), Folcroft, Pa., the label statement "Bacon Strips" was false and misleading for a product that did not contain bacon; the article was offered for sale under the name of another food—bacon strips; and the required label information, i.e., the common or usual name of the article, was not prominently placed on the label; 403(a), 403(b), 403(f). Default decree authorized donation to a Government institution. (F.D.C. No. 60837; S. No. 76–06–730; N.J. No. 23)

Vegetable oils, water, and nonfat dry milk combination, Blue Bonnet, at Mount Kisco, S. Dist. N.Y.
Charged 12-31-75: when shipped by Standard Brands, Inc., Pennsauken, N.J., the article, labeled in part "Blue Bonnet . . . Spread The all-purpose spread with MORE natural flavor ingredients than margarine, but 25% LESS fat . . . Ingr: Partially Hydrogenated Soy and Cottonseed Oils, Water, Nonfat Dry Milk, Salt . . . Preservatives, artificially flavored and colored . . . 59.6% Fat, 1.8% Carbohydrate, 1.2% Protein. Mfd by Standard Brands, Inc., New York, N.Y.," the label (including the "MORE natural flavor" statement) was false or misleading because it failed to reveal with equal conspicuousness that the product was artificially flavored as well as naturally flavored; and the article was an imitation of margarine but was not labeled as imitation margarine; 403(a), 403(c). The article was claimed by the shipper who denied the charges. A consent decree condemned the article as being in violation of 403(a) and ordered that the claimant might not ship, sell, offer for sale, or otherwise dispose of any food of the nature and type condemned which bore a label stating "The all-purpose spread with MORE natural flavor ingredients than margarine," or which failed to bear a common or usual name complying with regulations, or (in the absence of such common or usual name) an appropriately descriptive term other than "spread" that was not false or misleading. The consent decree also ordered the article destroyed. (F.D.C. No. 60548; S. No. 76–39–406; N.J. No. 24)

ANIMAL FEED

Grass pellets, dehydrated, at Mer Rouge, W. Dist. La.
Charged 9-19-74: while held for sale, the article contained the nonconforming food additives endrin and toxaphene; 402(a)(2)(C). The article was claimed by Pellets, Inc., Mer Rouge, La. The claimant moved for postseizure sampling and for the withdrawal of not more than 400 tons of the 1,500 tons of such dehydrated coastal bermuda grass pellets, on the grounds that there was a real danger of fire that would be substantially lessened by such withdrawal to an adjacent storage tank. With the consent of the Government, the court authorized such withdrawal of some of the pellets. In accordance with the order of the court, the claimant transferred 225 tons of the pellets into silo #2. At that time the claimant's general manager stated that he hoped that such transfer would remove the contaminated pellets, and that, dependent upon the results of future sample analyses, additional pellets might be transferred. The Government alleged that the purpose of the transfer was not to protect the article, but was a subterfuge to attempt to rehabilitate the article without following statutory procedures. Accordingly, the Government moved for, and was granted, an order that prohibited further withdrawals, conveyances, or transfers of the article and that ordered no postseizure sampling be conducted without the further order of the court and the posting of bond for FDA expenses. Ultimately, a consent decree authorized release to the claimant for reprocessing of the article and destruction of such portions as could not be successfully reprocessed. (F.D.C. No. 59944; S. No. 54–123 H; N.J. No. 25)

DRUGS/Human Use

Aspirin tablets, enteric-coated, U.S.P., at Rio Piedras, Dist. P.R.
Charged 3-12-76: when shipped by Pharmacal Specialties Mfg., St. Louis, Mo., the quality of the article, labeled in part "Enteryn Analgesico Con Cubierta Enterica . . . Fabricado para: Farmaco Specialities Rio Piedras, P.R.," failed the U.S.P. standard for disintegration; 501(b). Default decree ordered destruction. (F.D.C. No. 60658; S. No. 76–51–180 et al.; N.J. No. 26)

Phenazopyridine hydrochloride tablets, N.F., at Bronx, S. Dist. N.Y.
Charged 5-20-75: while held by West-Ward, Inc., Bronx, N.Y., who had repacked bulk tablets shipped from Philadelphia, Pa., the article's strength differed from the N.F. standard, since the article contained from approximately 105.4 percent to 111 percent of the labeled amount of phenazopyridine hydrochloride; 501(b). Default decree ordered destruction. (F.D.C. No. 60734; S. No. 76–40–617; N.J. No. 27)

T–4–L topical camphor tincture, Itch-Me-Not benzocaine palliative combination solution for eczema, Bukets extract of buchu combination tablets, and **BQ+6 analgesic tablets,** at Mechanicsburg, S. Dist. Ohio.
Charged 2-24-76: while held by The Keller Co., Mechanicsburg, Ohio, the T–4–L and Itch-Me-Not solutions (which had been manufactured by the dealer using ingredients shipped in interstate commerce) and the Bukets and BQ+6 tablets (which the dealer was repackaging) were drugs, and the circumstances used for their manufacture, processing, packing, and holding failed to conform with Current Good Manufacturing Practice Regulations; 501(a)(2)(B). Consent decree authorized release to the dealer for bringing into compliance with the law. (F.D.C. No. 60653; S. Nos. 76–13–696/700; N.J. No. 28)

DRUGS /Veterinary

A+ phenothiazine horse wormer in syringe-style applicators, and **bulk phenothiazine,** at Spanish Fork, Dist. Utah.
Charged 5-27-76: while held by Rocky Mountain Manufacturing Co., Spanish Fork, Utah, who manufactured the horse wormer using the bulk phenothiazine which had been shipped in interstate commerce, the articles 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; and circumstances used for the manufacturing, processing, packing, and holding of the horse wormer failed to conform with Current Good Manufacturing Practice Regulations; 501(a)(5), 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 60744; S. No. 76–18–366; N.J. No. 29)

MEDICAL DEVICES

Bio-Lectronic panels for humans, and **Bio-Lectronic panels for horses,** at

Hollywood, S. Dist. Fla.
Charged 4-14-76: when the panels for horses were shipped by Solarama of Kentucky, Inc., Louisville, Ky., and were held for sale by Bio-Lectron Products of Florida, Inc., Hollywood Fla., the dealer's accompanying brochure entitled "Questions and Answers Concerning The Electron Panel For Horses" contained false and misleading claims for the cure or mitigation of arthritis, bursitis, sinusitis, thrush, bowed tendons, wobbles, leg trouble, and stiffness and soreness; and the labeling of the panels for horses lacked adequate directions for use for such intended purposes—502(a), 502(f)(1); when the panels for humans were shipped by Solarama of Kentucky, Inc., Louisville, Ky., and were held by Bio-Lectronic Products of Florida, Inc., Hollywood, Fla., the dealer's accompanying booklet entitled "Bio-Lectron Product Questions and Answers" contained false and misleading claims for supplying healing, healthful, lifegiving negative electrons to the body; to restore natural electrical balance to the body; to speed healing; to relieve pain and anxiety; to cure insomnia; to prevent arthritis, bursitis, backaches, and nervous tension; and the labeling of the panels for humans lacked adequate directions for use for their intended purposes and neither adequate directions for lay use nor adequate information for use by licensed practitioners could be prepared—502(a), 502(f)(1). Default decree ordered destruction. (F.D.C. No. 60697; S. Nos. 76–43–327/8; N.J. No. 30)

Solarama 18" x 18" bedboards, at Almont, Dist. Colo.

Charged 7-3-75: when shipped by World of Solarama, Greenville, S.C., the article's package insert "Directions For Using Jimmy Scribner's Thermo Plant Board . . . The World of Solarama, Ltd., Greenville, South Carolina," contained false and misleading claims for helping pets that had been hurt, relieving the pain and suffering of such animals, and healing and rehabilitating them; and the labeling lacked adequate directions for use for the article's intended therapeutic purposes and such could not be written because the article was useless for such purposes—502(a), 502(f)(1); and while held by Solarama of Colorado (Charles C. Barnett), Almont, Colo., the label of the article, and the dealer's promotional pamphlets which accompanied the article, contained false and misleading claims for relaxation of tension by thermal electron emission; false and misleading claims for providing free electrons as an aid to the life processes, reducing tension, inducing natural and healthy relaxation, and relieving pain; and false and misleading claims for lengthening the human life span, arthritis and other deteriorating diseases, preventing sickness in fish and mammals, and making humans less subject to abnormalities and feeling better—502(a). Consent decree ordered destruction. (F.D.C. No. 60274; S. No. 80–508 H; N.J. No. 31)

Therapuncteur and **Punctoscope,** at Oklahoma City, W. Dist. Okla.
Charged 7-26-76: when shipped by Med-E-Prise, Orlando, Fla., and while held by Dr. Vincent G. Devine, D.O., Oklahoma City, Okla., the articles' accompanying book "Treatise of Auriculotherapy P.F.M. Nogier, M.D." and the accompanying leaflet printed by the dealer, contained false and misleading claims to the effect that the auricle of the ear corresponds to an embryo in utero, that points on the auricle correspond to various areas and organs of the body, that when these points are located and stimulated these devices are adequate and effective as a treatment for diseases of various parts of the body and various generalized disease states including: diseases of the lower limb; upper limb; abdomen; rachis; thorax glands; cephalic extremity; spinal column; knee; hip; fifth lumbar; palm of the hand; coccyx; dorso lumbar hinge; vasomotor nerves; arteries; veins; lymphatics; cervicobrachial neuralgia; scapula; clavicle; sternum; rib cage; sacroiliac joint; iliac bone; buttock; pubis; thumb; wrist; thenar eminence; elbow; phalango-phalangeal thumb joint; finger tips; cervicobrachial plexus; femur tibia fibula; arm; foot; all toes; tip of the thumb; all fingers; fracture of the malleolus; hypertension; solar plexus; chronic cases; osteoarticular system; muscular system inflammatory infections; rheumatic or gout; all nutritional disorders; functional troubles; organic disorders of the liver, pancreas, kidneys, stomach; paralysis; nervous twitch; hypertrophy of the sternocleidomastoidian; genitals; reducing fatigue; thyroid; parathyroid; joint pain; calcic disorders; muscular cramps due to hypocalcemia chronic ailments; severe symptoms; trauma; postoperative conditions; stiffness; cramps; disorders caused by immobility; rachialgia; cephalic complaints; parietal pains; arthrosis; facial neuralgia; shingles; neuralgia of amputated limbs; plantar pains; circulatory troubles; arthritis; Raynaud's disease; motorial disorders; Parkinson's disease; muscular contractures; writer's cramp; reflex contractures; spasmodic torticollis; tics; chronic inflammation; osteomyelitis; fistulated abscesses; ulcers; benign neoformations; pain of cancer; axillary hydrosadentitis; trembling of the hands—502(a); and the articles' labeling lacked adequate directions for their intended purposes, since neither adequate directions for lay use nor adequate information for use by licensed practitioners could be provided—502(f)(1). Default decree ordered destruction. (F.D.C. No. 60796; S. No. 76–15–112; N.J. No. 32)

COSMETICS/BEAUTY PRODUCTS

Jeneal pressed eye shadow, at Houston, S. Dist. Tex.
Charged 6-2-76: while held by Jeneal Studios, Inc., Houston, Tex., who was repackaging the article from bulk eye shadow, the article's label lacked the name and place of business of the manufacturer, packer, or distributor, and lacked a quantity of contents statement; 602(b)(1), 602(b)(2). Default decree ordered destruction. (F.D.C. No. 60739; S. No. 76–22–390; N.J. No. 33)

NOTICE OF JUDGMENT on Criminal Action

FOOD

Dolgin Grocery & Tobacco Co., and **Eugene Dolgin,** president, St. Louis, E. Dist. Mo.
Charged 8-6-76: cake mix (count 1) and rice (count 2) and 5 other lots of food (counts 3–7) were held in a building accessible to insects and were contaminated with insect filth; 402(a)(3), 402(a)(4). The defendants initially pleaded not guilty. The defendants moved to dismiss the information on a number of grounds including: indefiniteness and duplicitousness of the complaint; uncertainty as to the statute in its failure to set up standards of conduct both as to the meaning of the statute and as to persons within its scope; the charging of the same criminal act in seven counts; and double jeopardy based on previous punishment by reason of a complaint for forfeiture and a default decree of condemnation and destruction as to some of the foods. The defendants also moved for a bill of particulars and to inspect all evidence favorable to the defendants. The Government generally agreed to provide all such particulars and evidence. Subsequently, the defendants waived their right to jury trial and submitted the case for decision upon a stipulation as to the facts as to counts 1 and 2 against the corporation and as to count 1 against the individual. The court found the individual guilty as to count 1 and fined him $500. The court found the corporation guilty as to counts 1 and 2 and fined it $2,000. (F.D.C. No. 60662; S. Nos. 76–25–565, 76–25–568/9; N.J. No. 34)

Nelson Brokerage Co., Charles W. Robinson, president & treasurer, and **Cleland K. Nelson,** vice president & secretary, Atlanta, N. Dist. Ga.
Charged 10-22-76: wheat bran, sugar, rolled oats, dextrose, and salt were held in a building accessible to rodents and, except for the dextrose, were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (F.D.C. No. 60266; S. No. 5–152 G et al.; N.J. No. 35)

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

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

Published by direction of the Secretary of Health, Education, and Welfare.

Sherwin Gardner, *Acting Commissioner of Food and Drugs*
Washington, D.C., February 1, 1977

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A Child's World Is Full of Pretty Poisons

There are pink pills and yellow pills that look like candy. There are cleaning fluids just the color of soft drinks.

And a child can't tell the difference.

But we adults can. So we have to see that medicine is locked in cabinets and kept in containers with safety closures. We have to refrain from teaching kids that medicines "taste like candy." We have to keep household chemicals out of children's reach. And we have to keep the telephone number of the nearest Poison Control Center handy—just in case.

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