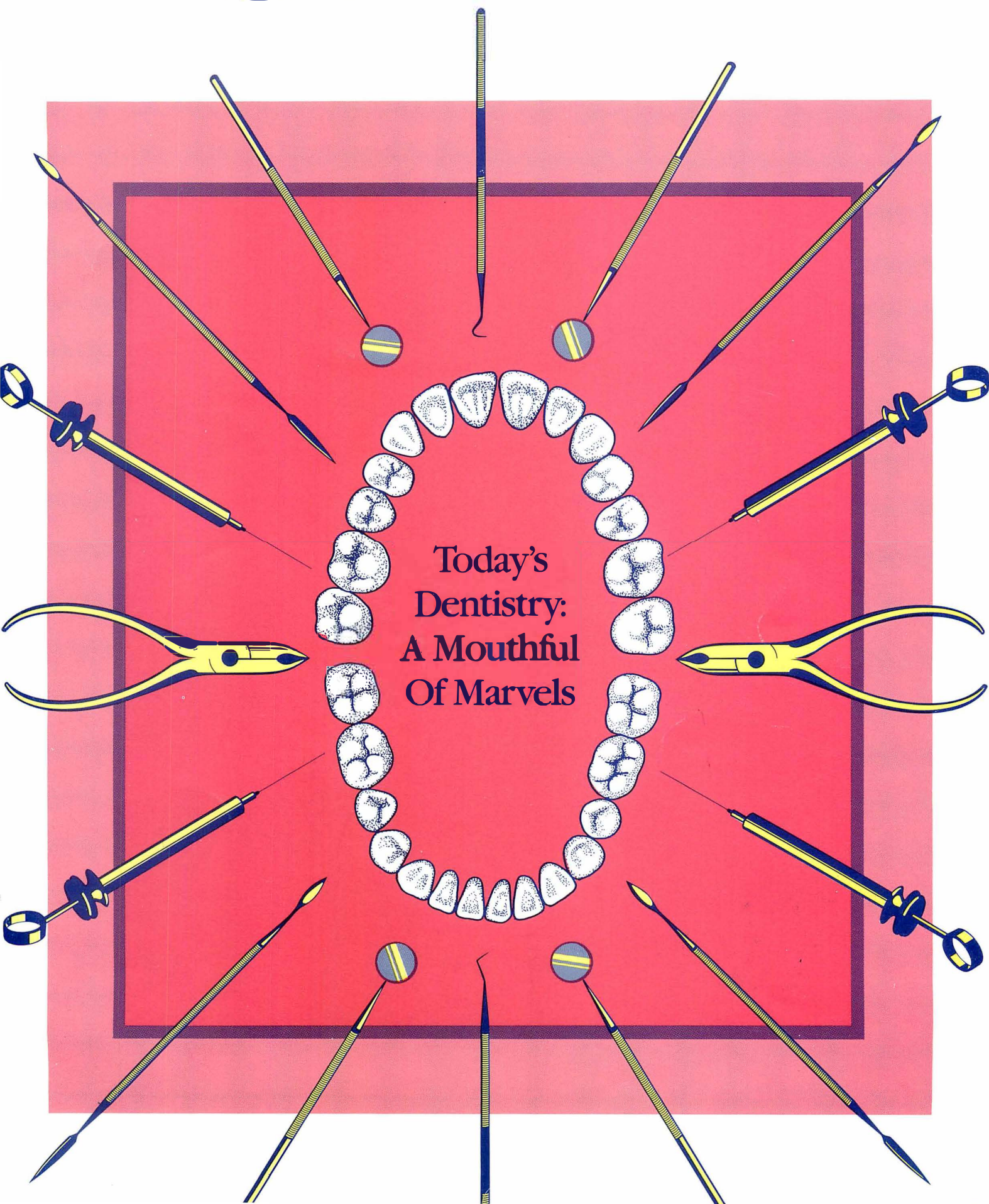


FDA
July-August 1985
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When a hospital has no radiologist to help interpret X-rays, teleradiology may be the next best thing. This new technology—still experimental—enables X-ray pictures to be converted to computerized images and transmitted by telephone lines almost instantly to a distant medical center. There, radiologists or other experts can view the X-rays on a TV screen and send their diagnoses back to the originating hospital. For more on teleradiology, see Bringing X-ray Expertise To Medical Outposts, beginning on page 6.

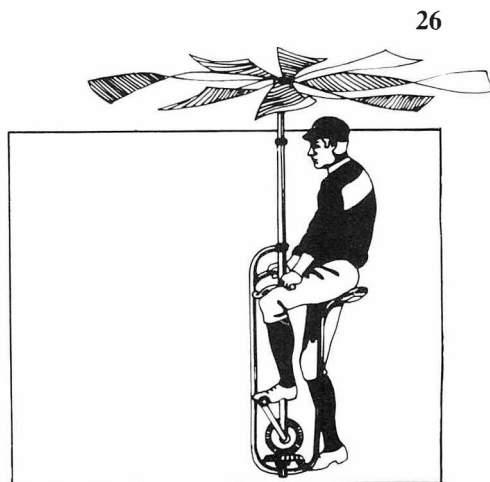
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Threat Of DTP Vaccine Shortage Ends

After a potential shortage of diphtheria-tetanus-pertussis (DTP) vaccine led to recommendations that booster shots be postponed for older children, supplies are now sufficient and normal vaccination schedules can be resumed. Children whose fourth and fifth shots in the DTP series had been deferred can now complete their inoculations, according to a U.S. Public Health Service interagency vaccine group.

The threat of a shortage came about because, for a period of several months during late 1984 and early 1985, only one pharmaceutical company, Lederle Laboratories, was marketing DTP vaccine and that firm encountered production problems with several lots of the vaccine during that time. (Lederle was also marketing vaccine produced by Wyeth Laboratories.)

Because of the potential shortage, last year the PHS Interagency Group to Monitor Vaccine Development, Production and Usage recommended postponing the DTP vaccine doses usually given at 18 months and 4 to 6 years until greater supplies were available.

With physicians and other health-care providers following the recommendations of the interagency group, supplies of the vaccine were sufficient to avoid critical shortages.

On April 25, 1985, Connaught Laboratories announced resumption of full-scale distribution of its DTP vaccine and the availability of 2.2 million doses for immediate shipment. The Canadian firm will continue to produce the vaccine at a level that will help meet U.S. needs.

The PHS interagency group recommendation to resume the complete DTP vaccine schedule was made after consultation with the PHS Advisory Committee on Immunization Practices and the Committee on Infectious Diseases of the American Academy of Pediatrics.

(For more information about pertussis (whooping cough) and the DTP vaccine, see "Whooping Cough Still Threatens U.S. Children" in the June 1985 *FDA Consumer*.)

Herbalife Drops Suit

Herbalife International, a nationwide distributor of a variety of herb-based products promoted for weight-loss and nutrition, has dropped a complaint against the Secretary of Health and Human Services and the Commissioner of Food and Drugs. The organization had filed the complaint in a federal District Court in Los Angeles last

November, charging that the officials and employees of their agencies had defamed the company and its products.

In March 1985, the government filed a motion to dismiss the complaint on the grounds that Herbalife should have brought its claims to FDA before going through the courts.

On April 4, Judge Laughlin E. Waters, at Herbalife's request, signed an order dismissing the case without prejudice.

Sodium Labeling Postponed

Food manufacturers have been given a 12-month extension—to July 1, 1986—to comply with FDA's 1984 regulation that spells out the agency's new requirements for disclosing the sodium content on the product labels of many foods. (See "Food Labels To Tell More About Sodium" in the July-August 1984 *FDA Consumer*.) Many companies have been providing the information voluntarily for several years. The extension will give other companies more time to use up inventories of old labels and make other preparations for complying with the regulation.

In general, sodium content information would be included in the nutritional information section of food labels. Under FDA labeling requirements, the amount of calories, protein, carbohydrate and fat in each serving of a product must be listed, in that order. Sodium—expressed in milligrams per serving—would follow the listing for fat.

Not all food products have to provide such nutrition information. Under FDA regulations, nutrition labeling is mandatory only if a manufacturer adds nutrients to a food or if nutritional claims are made for the product. The inclusion of sodium information with various foods is the result of a government education effort to make consumers more aware of the association between sodium intake and high blood pressure and to encourage private industry to reduce the sodium content of many foods.

Infant Formula Warnings

Twice during April FDA warned parents about illegal and potentially dangerous infant formulas marketed by a California firm. The two formulas, both in powdered form, are Kama-Mil and Nutra-Milk.

The formulas have been marketed as "all natural" products with no preservatives or added sugar. However, FDA warned that they have serious nutrient deficiencies that might retard normal growth and development. If these

products are consumed as the sole source of nutrition for a prolonged period, they would present a chronic, severe hazard to the infant.

The formulas are sold by a Santa Ana, Calif., operation using the names Golden Epoch (on the Nutra-Milk label) and Kama Nutritional (on the Kama-Mil label). Both have been marketed in violation of requirements that such products be pre-registered with FDA.

A man named Scott Treadway has admitted to running the operation, but FDA has not been able to gain his complete cooperation in getting the products off the market.

The agency asked that consumers and health food store owners not only stop using or selling the products but also help the agency trace the distribution. Illegal products and place of purchase should be reported to the nearest FDA office.

A primary distributor of Nutra-Milk, the Wishing Well Distributing Co., Graton, Calif., voluntarily recalled Nutra-Milk powder in 10-ounce plastic amber bottles. The bottles were distributed to 31 health food stores in California, Hawaii, Montana, Texas, Puerto Rico, North Carolina, Utah, Connecticut, Wisconsin and Colorado. Other distributors may have shipped the product beyond these locations.

Wishing Well also cooperated in the recall of Kama-Mil, as did Threshold Enterprises of Santa Cruz, Calif., and Stowe Mills of Brattleboro, Vt.

For more on infant formula, see "Next To Mother's Milk, There's Infant Formula" in the July-August 1980 issue of *FDA Consumer*.

Vaccine Helps Prevent Childhood Meningitis

A vaccine that protects against *Hemophilus influenzae* type b, the most common cause of serious childhood meningitis, has been approved by FDA. A single injection of the vaccine will protect a child who is between 2 and 5 years old. Studies are ongoing to determine whether a booster shot is needed.

Each year, bacterial infections from *Hemophilus influenzae* type b (Hib) cause an estimated 12,000 cases of meningitis, primarily in children under 5. Meningitis is an inflammation of the membranes covering the spine and brain. In addition, Hib is responsible for about 7,500 cases of pneumonia, infectious arthritis, blood infection and epiglottitis, a swelling in the throat that can lead to suffocation. (See "Whatever The Cause, A Sore Throat Is Hard To Swallow" in the March 1985 *FDA Consumer*.)

Hib infection leads to an estimated 1,000 deaths a year

and leaves an estimated 3,000 to 4,000 children with neurological damage—hearing impairment or mild to severe brain damage. Children under 5 who attend day-care facilities appear to be at higher risk of acquiring Hib infections than children not in such facilities. Also at higher risk are Native Americans (both American Indians and Eskimos), blacks, the poor, those with no spleen, and patients with sickle cell disease, Hodgkin's disease and antibody deficiency syndromes.

Unlike some older vaccines for bacterial infections, such as typhoid or pertussis (whooping cough), the *Hemophilus* vaccine is made from a part of the bacteria—the capsular coat—instead of the inactivated whole bacteria. Such a purified vaccine appears to cause fewer adverse reactions. In clinical trials, side effects were infrequent, but there was fever as well as swelling and soreness at the injection site in some children.

In one field trial in Finland involving 98,000 children, the vaccine was shown to be 90 percent effective in children 18 to 71 months of age, but offered no protection to infants under 18 months.

The U.S. Centers for Disease Control makes the following recommendations for the use of the new vaccine:

- Immunization of all children at 24 months of age.
- Immunization of children at 18 months of age, particularly those in known high-risk groups, may be considered. Physicians and parents should be informed that the vaccine is not likely to be as effective in this age group as in older children. These younger children may need a second dose of vaccine within 18 months to ensure protection.
- Immunization of individuals over 2 years who have not yet received Hib vaccine should be based on the individual child's risk of the disease. Because the vaccine is safe and effective, physicians may wish to immunize previously unvaccinated healthy children between 2 and 5 years of age to prevent the Hib disease that does occur in this age group.
- For older children and adults with the chronic conditions associated with an increased risk of Hib disease, insufficient data are available on which to base a recommendation concerning use of the vaccine.
- The vaccine is not recommended for children under 18 months.

The vaccine is manufactured by Praxis Biologics, Rochester, N.Y., and will be distributed by Mead Johnson of Evansville, Ind.

Additional information on vaccines, in general, can be
(Continued on next page)

found in "Vaccines: Precious Ounces Of Prevention" in the May 1983 issue of *FDA Consumer*.

Fighting Health Fraud

Fighting health fraud is one of the top 10 priorities in FDA's new action plan. FDA Commissioner Frank E. Young, M.D., Ph.D., noted in response to an article in the May 1985 issue of *Consumer Reports*. The article, "Foods, Drugs or Frauds," discussed fraudulent and unproven claims for many products sold in this country.

The article cited continuing growth of health fraud and said "lack of an effective policy at the FDA" was contributing to that growth. Fighting health fraud ranks low among the agency's priorities, the article claimed, with only 0.5 percent of FDA's budget going to combat quackery.

In his letter to *Consumer Reports*, Dr. Young called attention to a recent seven-count indictment against a Buffalo, N.Y., firm promoting evening primrose oil for high blood pressure, arthritis and multiple sclerosis. The product has never been proven safe or effective for these or any medical uses. Other recent anti-quackery actions undertaken by FDA include:

- Keeping unproven "sobriety aids" from the market
- Seizing \$2.4 million in unproven products a large mail-order company promoted to enhance breasts, remove "cellulite," build muscles, and produce fast weight loss
- Acting against starch blockers, DHEA and CCK—all unproven diet aids
- Cooperating with New York and California state officials in blocking an unproven cytotoxicity allergy testing operation (see page 31)
- Seeking grand jury indictments in two cases of felony violations related to the unproven cancer treatments Laetrile and calcium pangamate, promoted—fraudulently—for a variety of ailments.

Like all government agencies, FDA has limited resources and has to set priorities, giving first attention to life-threatening situations, Dr. Young pointed out. The agency has worked with the Federal Trade Commission, U.S. Postal Service, U.S. Customs Service, FBI and other federal, state and local agencies to force the most dangerous quack operators out of the country, he said.

An FDA Talk Paper, issued April 24, notes that there were 70 seizures, three injunctions and one prosecution involving fraudulent products in 1983 and 24 seizures, three injunctions and three prosecutions in 1984. In the area of drugs, the fraud branch in FDA's Center for Drugs

and Biologics has processed eight seizures and 22 regulatory letters involving more than 100 products since its creation last September.

FDA has initiated health fraud educational programs in cooperation with the Better Business Bureau and the Pharmaceutical Advertising Council (see "Critiquing Quack Ads" in the March 1985 *FDA Consumer*) and has developed or updated at least two dozen anti-quackery publications.

Unproven Weight-loss Drugs

Two new entries in the weight-loss derby—CCK (cholecystokinin) and DHEA (dehydroepiandrosterone or dehydroandrosterone)—should not be on the market, according to FDA. Manufacturers and distributors of products containing these substances have been told to stop marketing them because no proof of their safety and effectiveness has been submitted to the agency.

CCK is a hormone involved in the human digestive process. Products said to contain this substance have been advertised and sold nationwide by mail and in some health food stores with claims that they decrease hunger and can cause sudden and dramatic weight loss.

DHEA is a steroidal hormone that has been sold nationwide without prescription in retail stores and through the mails for weight management, enhanced sex life, and longer life. It has been promoted in books on extending human life.

DHEA may be manufactured from human urine. FDA considers DHEA products to be drugs. The agency has had few adverse reaction reports on such drugs, but the risks from long-term use are not known. Scientific studies have not established what effect the introduction of concentrated urine might have on the body.

FDA told the firms by letter to discontinue marketing products containing CCK and DHEA, regardless of specific formulation, and to provide the agency with detailed information about their manufacture and distribution. Further regulatory action will be considered against firms that fail to comply within 10 days of receiving the letter.

No CCK product has been approved by FDA for sale for any purpose. Nor has the agency received any applications to conduct human studies with DHEA. Such studies are a requirement for pre-market approval for all drugs.

For more on these and other bad ideas for losing weight, see "The Fad-Free Diet: How To Take Weight Off (And Keep It Off) Without Getting Ripped Off" on page 26.

More Leeway Proposed For OTC Drug Labeling

Manufacturers of over-the-counter (OTC) drugs would be given greater latitude in labeling under a proposed rule that would relax FDA's "exclusivity" policy. This policy, which has been the subject of much debate during the agency's massive review of OTC drugs, has limited the language used on product labels exclusively to specific words and phrases approved by FDA.

The proposed rule would allow three alternatives for stating the indications for use in the labeling. The manufacturer could use:

- The exact wording of the Indications for Use from the OTC monograph, a document setting forth the approved ingredients and labeling for specific OTC drug product classes. This information would appear within a boxed area designated "APPROVED USES" wherever it appears—for example, on the outer carton, inner bottle, or package insert. Other required information (such as warnings or directions) could appear in the boxed area, which would then be designated "APPROVED INFORMATION." A statement that the information was published by FDA would appear within the boxed area or close by. The heading of the boxed area could also read "FDA APPROVED USES," "FDA APPROVED INFORMATION," or "USES (or INFORMATION) APPROVED BY THE FOOD AND DRUG ADMINISTRATION."
- Other truthful and non-misleading language describing the indications for use developed under a relevant OTC drug monograph, subject to prohibitions in the Food, Drug, and Cosmetic Act against the use of false or misleading labeling. Such terminology could not be boxed or be designated "APPROVED USES" or "APPROVED INFORMATION," or suggest the language was FDA-approved.
- A combination of the monograph language in a boxed area and other truthful and non-misleading alternative language elsewhere in the labeling.

The change in policy applies only to language describing the indications for use of the product. All other labeling—statement of identity, warnings and directions—would continue to be subject to the existing exclusivity standard. FDA emphasizes that the monograph language will serve as a benchmark. Alternate language used by manufacturers will be carefully examined to ensure that it does not go beyond the approved indications. Language that is so nondescriptive as to be meaningless or that sug-

gests uses for a new indication would cause the product to be misbranded, or classified as an unapproved new drug, or both, the agency points out.

The proposed policy was published in the April 22 *Federal Register*. Written comments should be sent to the Dockets Management Branch, HFA-305, 5600 Fishers Lane, Rockville, Md. 20857, by July 22.

Growth Hormone Suspected In Deaths

FDA and the National Institutes of Health are investigating the deaths of three men who received human growth hormone from NIH's National Hormone and Pituitary Program to treat pituitary dwarfism. The deaths—possibly caused by Creutzfeldt-Jakob disease—suggest that some of the hormone could have become contaminated.

Creutzfeldt-Jakob disease is a rare, fatal degenerative disease of the central nervous system that normally afflicts persons between 40 and 80 years of age. Its incidence in the U.S. population is one case in a million. Scientists believe that Creutzfeldt-Jakob disease may be caused by a "slow virus"—that is, one with a remarkably long incubation period.

Human growth hormone is prepared from human pituitary glands removed at autopsy.

All three men—ages 21, 23 and 34—were treated with preparations of human growth hormone in the 1960s and 1970s. Samples of the hormone used at that time are now being tested for the Creutzfeldt-Jakob disease infectious agent.

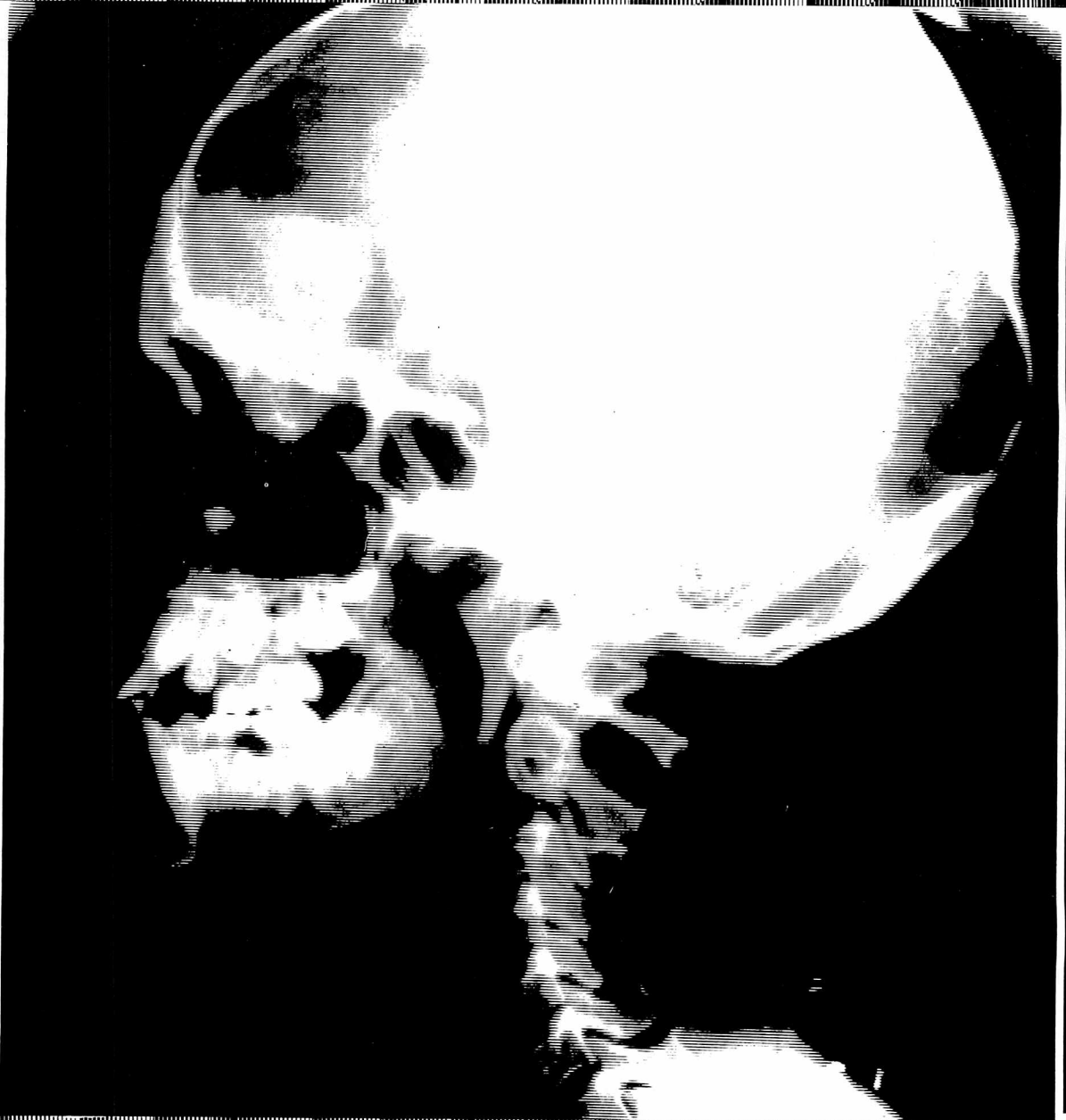
In the meantime, NIH has suspended distribution of the hormone through the National Hormone and Pituitary Program, headquartered in Baltimore, Md., pending further evaluation of the safety of the product.

Reprints Available

Reprints are available of the following articles that appeared in the April 1985 issue of *FDA Consumer*: "Herpes: Drug Eases Symptoms, But Still No Cure" and "Low-Sodium Menus Pass School Tests."

Single copies of these reprints can be obtained from the Food and Drug Administration, HFE-88, 5600 Fishers Lane, Rockville, Md. 20857. Multiple copies are available from FDA, HFW-40, at the Rockville address. Copies of reprints are also available from FDA's consumer affairs officers, who are located in 29 cities around the country.

TELEPHOTOLOGY



TELEPHOTOLOGY

Bringing X-Ray Expertise To Medical Outposts

by Carol Vetter

A 14-year-old girl, the daughter of a soldier stationed at Fort Detrick, Md., had complained to her mother of feeling unusually tired. After the mother took the girl's temperature and found she had a fever, she took her daughter to the fort's medical clinic.

There, a physician checked the girl's breathing with a stethoscope and found no indication of fluid in the lungs. But an X-ray of her chest did show signs of congestion. In any large hospital or medical center, the situation would have called for a consultation between the attending physician and a staff radiologist—a doctor who specializes in the use and interpretation of X-rays and other medical procedures that use radiation. But there was no radiologist at Fort Detrick's small clinic.

What the clinic did have, however, was a new medical technology known as teleradiology. By linking X-rays, computers, television and telephone lines, this still-experimental system enables medical "outposts" to tap, almost instantly, the expertise at major medical centers miles away. Diagnoses that would otherwise take days can be made in minutes.

Here's how teleradiology helped in the Fort Detrick case: First, a technician at the clinic checked the girl's X-ray film to make sure it was of good quality. He then placed the film in a device where a TV camera scanned the image, breaking the picture into tiny squares. A computer assigned a number—representing a shade of gray—to each square. This digitized information was

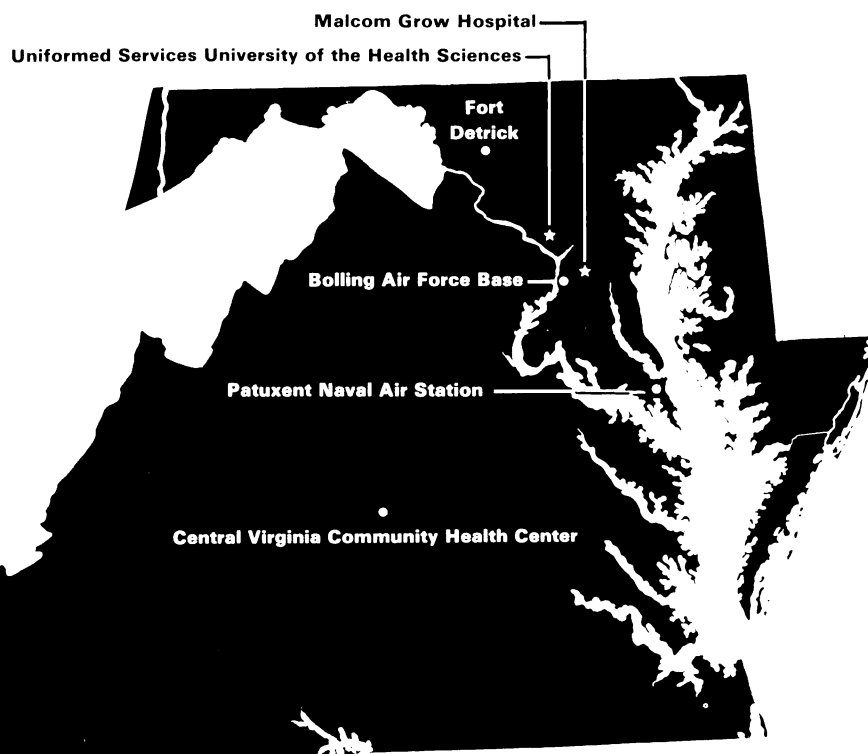
then sent over telephone lines to the radiology department at the Defense Department's Uniformed Services University of the Health Sciences in Bethesda, Md., outside Washington, D.C. There, the numbers were electronically converted back into the shades of gray in the original image. The picture of the girl's lungs were then displayed on a special TV monitor with high resolution to provide almost four times as much visual detail as a home TV set. A radiologist viewed the video display of the girl's X-ray, using controls on a small keyboard to adjust the picture.

After reviewing the girl's medical history, also transmitted over telephone lines, the radiologist consulted by phone with the physician at Fort Detrick. Together they arrived at a diagnosis of bilateral (double—affecting both lungs) pneumonia. Treatment was begun immediately, and a serious illness was soon brought under control.

This case illustrates the problem that the lack of prompt access to medical specialty services poses to the approximately 60 million Americans the U.S. Bureau of the Census says live in rural areas. Many of these men, women and children—especially such groups as Indians and Eskimos—are less healthy and have shorter life expectancies than their urban counterparts. Teleradiology may help meet the health-care needs of rural Americans, and of armed forces personnel who are on ships at sea, are being treated in Mobile Army Surgical Hospitals (M.A.S.H. units), or are living with their dependents on military bases with no radiologists. To help make this a reality, the U.S. Public Health Service has collaborated with the Department of Defense, the MITRE Corp. (for engineering and systems support), and other organizations to develop, field test, and evaluate teleradiology systems.

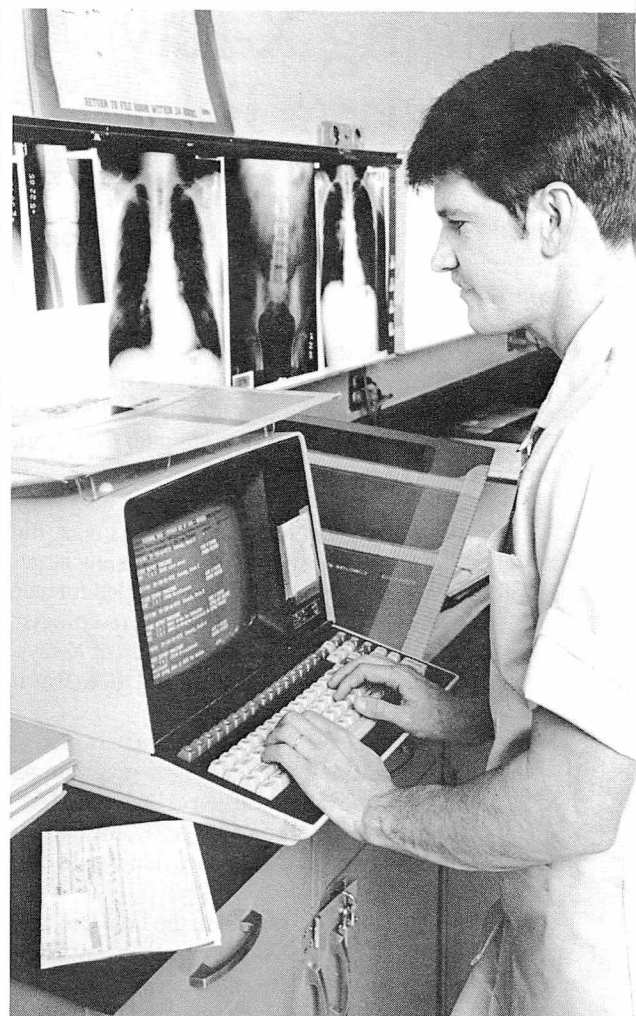
Some of the teleradiology technology being developed could benefit *all* patients needing radiological procedures. Not only can teleradiology aid in prompt medical diagnosis, it also may help to reduce patient exposure to ionizing radiation. Besides transmit-

The health care facilities shown in this map were involved in the first clinical trials of teleradiology. In 1982, Malcom Grow Hospital served as the central location to provide X-ray interpretations to the one civilian and three military clinics. In 1984, the Uniformed Services University took Malcom Grow's place as the hub linking the same four satellite clinics.





Teleradiology's potential to provide prompt radiological expertise may prove a boon to small or remote clinics and hospitals. At the originating clinic, an X-ray is placed in a scanner (above) to be converted into a digitized image that can be stored in a computer. The patient's medical history also can be entered into the computer (right) and transmitted, along with the digitized X-rays, to a major medical center.



ting X-ray images between medical facilities, teleradiology offers the benefits of "filmless" radiology and image enhancement to provide useful medical information with as little radiation exposure as possible.

Here's an example of how patient exposure to radiation might be reduced using filmless, or digitized, images. A young man enters a hospital emergency room complaining of severe pain in his upper back. He has just fallen from a ladder while painting the outside of his house. An X-ray is taken and placed into an electronic scanner to produce a digitized image. The image is then transmitted to a TV monitor for the radiologist to view. The radiologist, pressing buttons on the console's keyboard, takes advantage of the enhancement features to make the image darker or lighter, focus on and magnify the problem area, create more pronounced outlines in the image, and reverse dark and light to make certain features more apparent, such as parts of the spine hidden behind the X-ray shadow of the heart.

By employing these techniques—none of which can be used when viewing conventional X-ray films—the radiologist is able to see in the same picture both a fracture of a vertebra and evidence of internal bleeding due to soft tissue injury in the chest. Without these techniques, two X-ray films—one to detect soft tissue damage and another to see bone fractures—often would be required, meaning more radiation exposure for the patient.

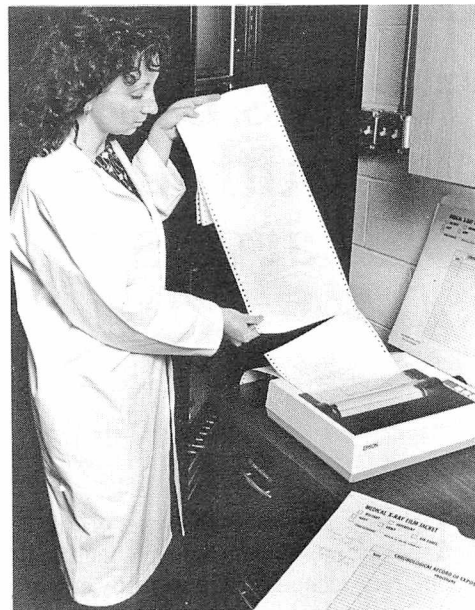
Also, the radiologist's use of these enhancement techniques can improve the clarity of less-than-perfect images. This has increased the radiologist's ability to correctly interpret marginally good images, lessening the need for X-ray retakes and, again,

reducing patient exposure to ionizing radiation.

Another example shows how teleradiology can foster consultation between physicians to provide prompt and correct medical diagnosis even when a radiologist is on hand. A woman's X-rays show a tumor in her femur, or thigh bone. The radiologist is uncertain about whether the growth is malignant and needs an interpretation by another radiologist with more experience in diagnosing bone tumors. The digitized images are transmitted, via telephone lines, to a hospital 1,500 miles away. That same day, the specialist in bone tumors views the images on a TV monitor and, by phone, discusses the interpretation with the referring radiologist.

The testing of teleradiology owes its beginnings to the formation of the Health Underserved Rural Areas (HURA) Program, authorized by Congress in 1975 and placed under the jurisdiction of the Department of Health and Human Services (HHS). The program was among a number of efforts to address specific problems of health-care delivery in rural America.

In 1977, the Public Health Service, which is part of HHS, sponsored studies to evaluate innovative technologies to improve rural health care. Among the technologies reviewed were computers, slow-scan television, and telecommunications. As part of this effort, several laboratory investigations tested the performance of these technologies in a microcomputer-based teleradiology system. Based on the findings from the laboratory evaluations, teleradiology field trials—in clinics and hospitals—were conducted in 1982 and 1984. Those collaborating in these activities included Walter Reed Army Medical Center, the National Naval



At the medical center, the computerized X-rays are displayed on video monitors (left). The terminal's keyboard can be used to enhance the image, to highlight the area of interest, for example. For cases needing prompt diagnosis, consultation between the medical center and clinic can be done by phone. For less urgent cases the radiologist can dictate a report, have it typed into the computer, transmitted back to the originating clinic and printed out (above) for the referring physician.

Medical Center, and the Defense Department's Tri-Service Medical Information Systems. Civilian radiologists' services were provided by the George Washington University Medical Center and Johns Hopkins University Hospital.

The 1982 trial linked three military medical facilities and a Public Health Service-supported clinic to the radiology department of Malcom Grow Hospital, Andrews Air Force Base, near Washington, D.C. Linked to Malcom Grow were Patuxent Naval Air Station, Md.; Fort Detrick; Bolling Air Force Base, Washington, D.C.; and Central Virginia Community Health Center, Canton, Va. An analysis of over 4,000 cases processed during the trial showed that the overall accuracy of radiologists' findings using video-displayed digitized images was only 5 percent lower than that using film X-rays. (Image enhancement techniques were not used in the trial.) The system showed promise and led to the development and testing of a more sophisticated system.

The 1984 trial involved the same clinics that participated in the 1982 study. But this time they were linked to the Uniformed Services University in Bethesda, where the image interpretation center was located (see accompanying map). Three major technological improvements were incorporated into this system: TV monitors with higher resolution, which reproduced images with four times more visual information than those in the 1982 system; image enhancement features; and data compression techniques that speeded transmission and reduced computer storage requirements. The main objective of this study was to develop technical specifications for future systems.

The findings of the 1984 trial will be presented at a teleradiology conference Aug. 12 through 14 at the Uniformed Services University in Bethesda. Findings from other related projects also will be discussed. Presentations will cover the image clarity needed for accurate medical interpretation and systems for storing, retrieving and displaying digital X-ray images.

Proponents of digital or "filmless" radiology look to a day when all images, including those produced by X-rays, ultrasound, magnetic resonance, and nuclear medicine, will be a part of integrated computer systems that will digitize, store, retrieve and transmit the images from one department to another within a hospital (between an intensive-care unit and a radiology department, for example) or from one facility to another.

It is estimated that a system with four satellite clinics linked to one major medical center, as was used in the 1984 trial, would cost less than \$300,000, a figure that may prove appealing in light of the significant health benefits it could provide. (This estimate is based on volume production of such systems, not a one-of-a-kind prototype system.)

Before the potential benefits of teleradiology can be realized by the public, however, the system must be proven and, once validated, accepted as worthwhile by radiologists, other physicians, and medical administrators. Such acceptance, to a great degree, will hinge on the results of the studies conducted by those who are exploring the frontiers of "filmless" radiology. ■

Carol Vetter is a consumer affairs specialist with FDA's Center for Devices and Radiological Health.

Today's Dentistry: A Mouthful Of Marvels

by Dixie Farley

High tech, space age—however people describe today's society, most would agree: Scientific flowering is in full bloom. New technologies constantly emerge. And one profession that's clearly reaping benefits is dentistry.

Oral surgeons reposition and rebuild jawbones. An artificial mouth (see accompanying article) helps researchers achieve years of dental testing within weeks. Dental repairs and bridge-work often involve less drilling and less pain. In fact, scientists are zeroing in on relief for the suffering patient with a new dental research center devoted entirely to the study of anxiety and pain.

Thanks mainly to fluoride, tooth decay is declining and a third of our children are now cavity free. Emphasis in tooth care is shifting from treatment to prevention, and dentistry is determined to conquer gum disease by making prevention the focus in that fight, too.

Here's a close-up look at some techniques and products of this new dentistry:

Anxiety and Pain

Dentists assign high priority to relieving dental pain and allaying patients' fears. Although anesthesia and sedative drugs are required in certain dental situations, many dentists also use a variety of psychological and behavioral approaches. Techniques may vary from dentist to dentist. For example, some dentists use hypnosis. Others teach their patients to use relaxation techniques: deep breathing, exercises to relax muscles, or biofeedback. In biofeedback, the patient is connected to a machine that monitors breathing, heartbeat and body tension and then displays the readings to help the patient relax by controlling these activities. Many dentists use distractions such as cheerful chatting, video games, films or stereo headphones to take the patient's mind off dental procedures.

A procedure called TENS (transcutaneous electrical nerve stimulation) is also being promoted as a way to suppress dental pain, but the Food and Drug Administration—which regulates many dental products—has no scientific evidence verifying the safety and effectiveness of using TENS in dentistry. (Most TENS devices are battery-powered pulse generators that send brief, intense pulses of electrical current through wires to electrodes placed on the skin. For more about TENS, see "Current That Switches Off Pain," November 1982 *FDA Consumer*.)

After reviewing TENS and other neurological devices, a panel of experts advised FDA that TENS could effectively treat some patients for some pain disorders—such as chronic pain resistant to other treatment—but that, because health hazards could occur, safety precautions must be taken. For instance, the safety of using TENS during pregnancy has not been established. Stephen M.

Hinckley, a physiologist with FDA's Center for Devices and Radiological Health, also cautions: "There could be a problem with stimulating a patient in the head and neck region, as would occur in suppressing dental pain. Electrical current through the neck may stimulate any of a number of sensory nerves, and this may affect the heart rate and blood pressure. Electrical stimulation can cause muscles in the neck to constrict in a way that interferes with breathing. And FDA has no scientific information that assures the safe use of a TENS device that requires electrodes to be in contact with the mucous membranes in the mouth."

Unfortunately, the fear of pain remains a major obstacle in restorative dentistry. The American Dental Association reports that nearly 35 million Americans feel excessive anxiety about dentistry and that 12 million suffer dental phobias—that is, they avoid professional dental care regardless of the cost to their oral health.

To study the issue, the National Institute of Dental Research in Bethesda, Md., has formed a pain research unit at its Warren G. Magnuson Clinical Center. The institute reports: "The interest of dental scientists in the control of pain extends beyond the development of practical anesthetics. . . . Inevitably, the study of pain in human patients entails an exploration of the many factors that affect the individual's perceptions and behaviors associated with pain."

Caries Removal System

For those who panic at the thought of the dreaded drill, help—though limited—is here. FDA recently approved a caries (decay) removal system that could reduce, or in some cases eliminate, drilling. The system consists of a delivery apparatus and two solutions. The dentist combines the solutions into one liquid, warms it, and then squirts it in a pulsating stream onto an area of decay. It doesn't harm gums or healthy teeth, but it makes the decay soft enough to be scraped easily away. Since the system doesn't usually require drilling near the nerve where pain is felt, anesthesia may be unnecessary. Still, the dentist will drill to remove decay from hard-to-reach areas; to make decay accessible to the solution—when it's under a filling, for instance; and to shape the tooth for a filling. The caries removal system isn't intended to replace rotary or hand instruments but to be used in conjunction with them. Patients on sodium-restricted diets should know that the solutions used in the system contain sodium.

Orthodontics

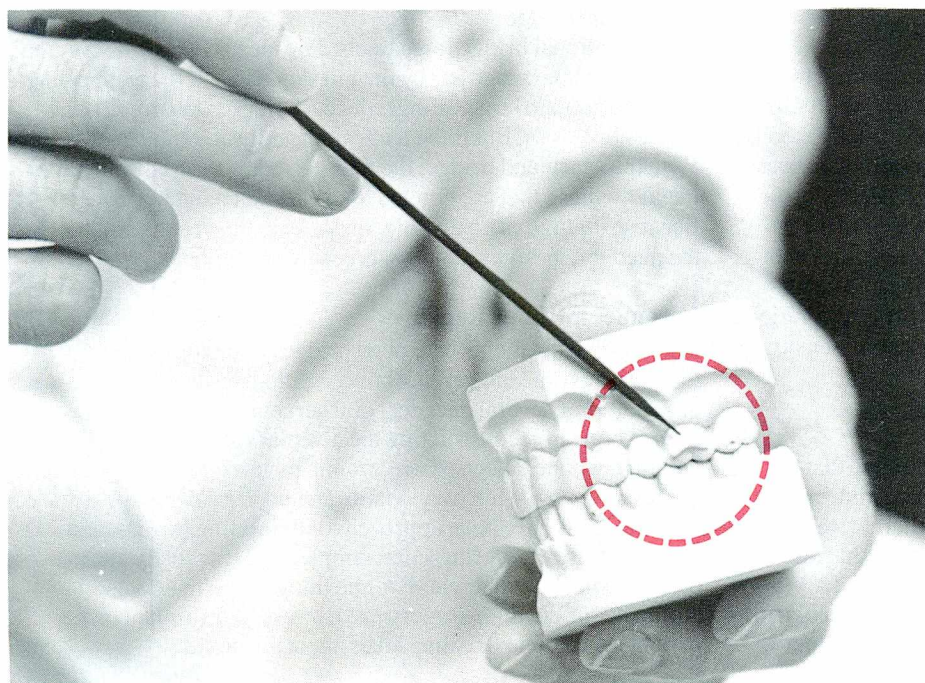
Orthodontics deals with correcting crooked or crowded teeth and fixing associated misaligned facial features. The news in

(Continued on page 12)

Dentists use many approaches to relieve patient anxiety and pain.



At the new Pain Research Unit of the National Institute of Dental Research, studies are designed to diagnose, measure and treat pain. This patient is taking part in a study to assess tooth pulp stimulation.
(Courtesy National Institute of Dental Research)



A small pellet can be attached to a molar to release fluoride at a constant rate. This new device was developed by the National Institute of Dental Research.
(Courtesy National Institute of Dental Research)

***Today's braces are smaller,
lighter and often nearly
invisible.***

braces that's big is that they're not—they're smaller, lighter and often made of plastic instead of metal so that they're nearly invisible. In most cases, they now can be glued to teeth instead of being attached with thick metal bands. However, according to D. Gregory Singleton, D.D.S., an orthodontist with the Center for Devices and Radiological Health: "Plastic appliances do not withstand the pressures of chewing as well as metal braces, so users must be selected carefully. Some modification in eating habits is necessary—refraining from biting into hard foods with the front teeth, for instance."

Orthodontists and oral surgeons work as a team to make facial corrections that even a few years ago were thought to be impossible. Thanks mainly to a better understanding of blood circulation in the jaw, surgeons can actually cut a bone and reposition it; they can relocate parts of the jaw, eye sockets, cheekbones and chins. According to Carla Evans, D.D.S., of the Harvard School of Dental Medicine in Boston, increased understanding about growth patterns and scarring has produced more aesthetically acceptable results for certain corrections. In the *Harvard Medical School Health Letter* (January 1983), Evans writes, "Surgery for cleft palate used to limit growth of the upper jaw, thus leaving the individual with a receding appearance along the upper lip. This result can now be avoided and it can be surgically corrected if it has already occurred."

Crowns and Fillings

An artificial crown is used to replace the top of a natural tooth that's been ground to a nub—due to extensive decay—or to support a denture or improve the appearance of an unattractive tooth. In the past, crowns have been metal, porcelain or porcelain over metal. While these traditional materials still are generally preferred, new ceramic materials are making their way into the marketplace. For use in both crowns and fillings, ceramics show promise of one day providing more natural-looking and better-fitting restorations. And new plastics for fillings offer restorations that look more natural and make teeth less temperature-sensitive than traditional materials.

Bonding

Bonding, or acid-etching, is a tooth-repair technique that has been around since the 1950s. But new materials and improved dental skills are bringing it into wider use as an alternative to crowning, especially for cosmetically restoring teeth that are chipped, malformed, too widely spaced or badly stained.

The bonding procedure first requires that the tooth be isolated with a rubber dam. Then, the dentist cleans and dries the tooth, applies a solution of phosphoric acid to produce microscopic

pores in the enamel, and fills in the etched area with a liquid plastic. Thin layers of tooth-colored plastics called composite resins are painted on, sculpted, hardened (often with a beam of light), given a final contouring, and polished.

Dentists can bond several teeth in one session. Because bonding generally requires no drilling unless decay is present, anesthesia often is unnecessary. Because tooth minerals eventually work into the etched area, the actual tooth surface remains undamaged. This is true even if the bonded layer is later removed. A bond costs far less than a crown.

But bonding has limitations, too. The material does wear away; it can be expected to last only about five years and may require repair. It doesn't stand up as well as metals to chewing or biting pressure. It may stain. Tints may not match exactly, and the restoration makes the tooth thicker than normal. Moreover, some dentists are simply more skilled than others at performing bonding. Still, bonding clearly is an alternative to crowning in some cases.

Maryland Bridge

Crowning faces a challenge to its supporting role in bridgework as well. The University of Maryland's Baltimore College of Dental Surgery has developed a fixed partial denture that eliminates the need for crowns to anchor the false teeth. It's called the "Maryland bridge."

Conventional bridges are attached by means of crowns over the teeth next to the space left by the missing teeth. If the teeth being crowned contain large fillings, the necessary extensive drilling creates little loss. But if the teeth are healthy, it's another story. With the Maryland bridge, the false teeth are secured with hidden metal "wings" that are bonded to the back of neighboring teeth. Because it requires no drilling, it saves healthy teeth, eliminates the need for anesthesia, and cuts costs considerably.

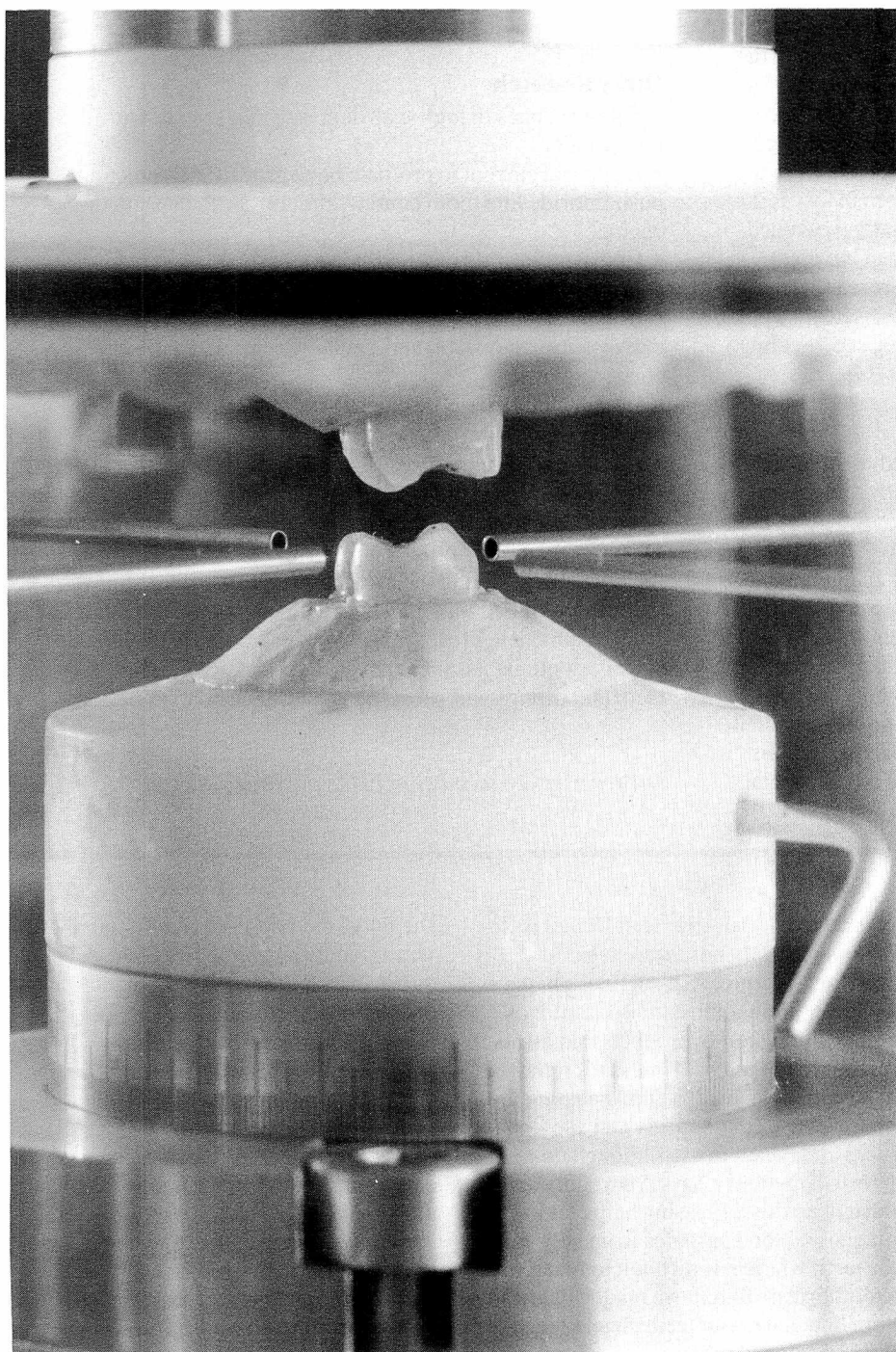
Ceramics for Bone Repair

Sometimes, patients who need bridges or dentures cannot wear them because the underlying bone—called the alveolar ridge—is deficient. For several decades, oral surgeons have been using human bone in reconstructing the alveolar ridge and in repairing certain jawbone defects. Two ceramic materials are now available for such surgery—hydroxylapatite and beta tricalcium phosphate. The materials have been approved for marketing by FDA and show promise of offering safer, simpler and less costly alternatives to using human bone. For one thing, these materials eliminate the need for surgery to "harvest" a transplant of the patient's own bone. Healing takes about six months.

(Continued on page 14)

Although ART, the artificial mouth, can hold an entire set of teeth, tests usually are conducted on only two to four teeth at a time. This view of ART's environmental chamber shows the salivary ducts.

(Courtesy University of Minnesota)



Motor Mouth

How do researchers test new tooth repair techniques and new dental materials to see if they'll hold up under the wear and tear of years of biting and chewing? Thanks to the efforts of a team headed by Dr. William Douglas of the University of Minnesota School of Dentistry in Minneapolis, ART helps out.

ART, which stands for artificial resynthesis technology, is a new mechanical mouth that subjects materials used in fillings, crowns, bridges and dentures to five years of normal wear in just a few weeks. Test results compare favorably with those from traditional clinical studies on humans.

To duplicate the environment of a human mouth, a transparent chamber fits over a mechanical apparatus. Through a system of jets inside the chamber, spurts of synthetic saliva swish around the teeth. Materials react as they would with natural saliva. Controlled "saliva" temperatures simulate the hot-and-cold shock effect on teeth surfaces caused by real-life situations such as eating ice cream and then drinking hot coffee.

In the human mouth, teeth are attached to the periodontal ligament, which allows each tooth to have some movement within its socket. ART also uses human teeth, set in a rubbery base similar to the periodontal ligament. Hydraulic pistons move the teeth up and down and back and forth to accurately duplicate chewing movements.

ART is programmed to chew at the human rate of approximately three cycles every two seconds. Unlike humans, ART can chew all the time—24 hours a day. In human studies, a researcher can detect wear on a tooth surface of about 40 to 50 microns in size. (One micron equals about 0.000039 of an inch.) With ART, wear and tear is measured by a computer that records changes as small as four to five microns. ■

***Bonding is better than ever,
but it's not the answer for
every tooth repair.***

Fluoride-releasing Sealant

With support from the National Institute of Dental Research, researchers have developed a sealant that releases fluoride, thus combining the decay-preventive capability of sealants with the decay-inhibiting, enamel-restoring properties of fluoride. The sealant releases fluoride by ion exchange: Fluoride ions, or negatively charged atoms, within the sealant steadily change places with atoms in saliva. Fluoride is only a small part of the sealant structure and, since it is replaced rather than lost as it's released, the sealant's structure is not significantly weakened.

H. Ralph Rawls, Ph.D., of the Louisiana State University School of Dentistry in New Orleans, heads the research team that developed the sealant and that still is studying the sealant's potential safety. (For more information about sealants, see "Sealing Teeth To Prevent Cavities," April 1984 *FDA Consumer*.)

Cloned Tooth Enamel

Human tooth enamel is produced by the blending of four different proteins, each of which is manufactured by its own gene. Dental scientists have identified one of these genes.

What might this mean for dentistry? Ultimately, this could result in the "cloning" (or duplicating) of tooth enamel in the form of tooth restoration materials with structure and strength that is identical to healthy human teeth. However, before this "natural" filling could become a reality the other three proteins must be identified and reproduced; all four proteins must be shown to combine and to produce enamel with properties identical to natural teeth; and the material must be tested to establish its safety and effectiveness as a dental filling. If the cloned dental

filling is successful, scientists expect that it will be stronger, less temperature-sensitive, and more natural looking than present materials.

Other Research

Other avenues of high-tech dentistry that scientists are exploring include:

- Electrical current to promote bone growth, heal fractures, and push fluoride into tooth dentin—the substance beneath the enamel.
- Constant fluoride protection in a small fluoride-filled, release-controlled pellet attached to a molar.
- Chemical warfare against dental disease, such as mouthwashes that dissolve plaque, an anti-cavity vaccine and antibacterial chewing gum.
- Laser beams to restore enamel and smooth tooth pits and grooves.
- Devices powered by magnets and batteries to straighten teeth.

Some of that research may seem far out but history shows that dentistry can look ahead. At a meeting of the California State Dental Association in 1895, a paper was presented on dentistry in the year 2000. Among the predictions: anti-cavity mouthwashes, natural-looking tooth repairs, a decline in tooth decay, and a shift from treatment to prevention. Most have come true. Should science continue its current explosive advance, perhaps even false teeth and fillings will succumb to high-tech dentistry. ■

Dixie Farley is a member of FDA's public affairs staff.

Tooth-Saving Tips

Toothlessness seldom presents itself as an asset. Even the medical term for it, "edentulous," evokes an unappealing image. Nevertheless, nearly a third of Americans over 45 have no natural teeth. Although 70 percent of adults' tooth loss is due to gum disease, some teeth are claimed by tooth decay. Fortunately, both diseases are largely preventable. To maintain healthy gums and to help keep your

natural teeth, the American Dental Association recommends these steps:

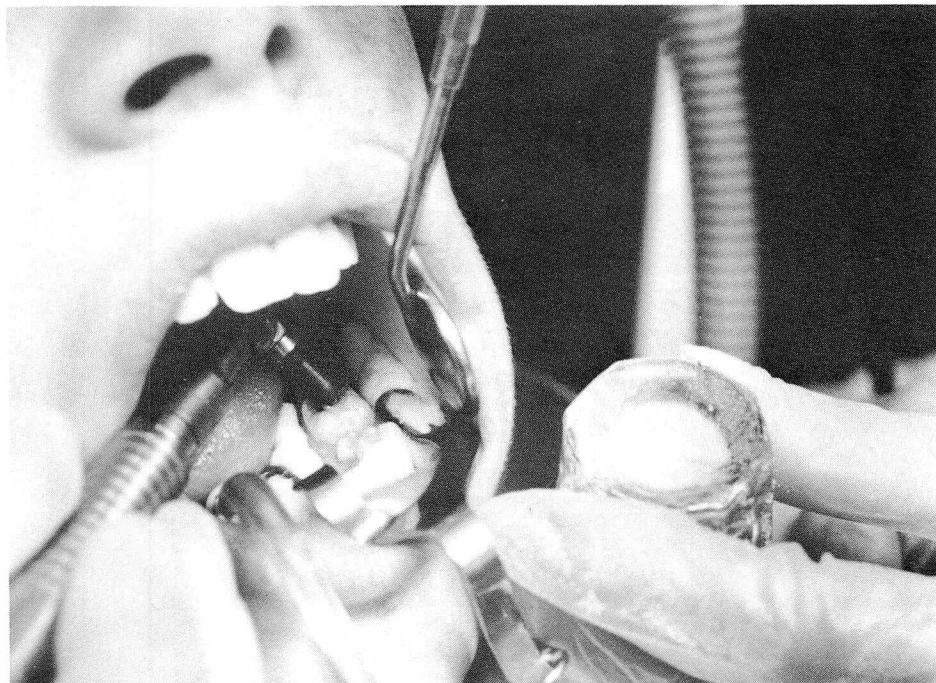
Attack plaque. ADA defines plaque as a "sticky, thin, almost invisible film of bacteria and their byproducts that forms on everyone's teeth." Unless it's removed each day, it can lead to gum disease, so brush your teeth regularly and use toothpicks and dental floss. Although most of us brush regularly, says ADA, only about a third of us floss. Flossing helps remove plaque and food particles from between the teeth where it is difficult to reach with a toothbrush. To remove plaque below the gum line, have your teeth cleaned regularly by a dental practitioner. (Currently,

the Food and Drug Administration is evaluating safety and effectiveness data on substances for the control of plaque, and the National Institute of Dental Research is testing an anti-cavity vaccine. At present, however, no such products have been approved for marketing in the United States.)

Use fluoride. Fluoride protects developing teeth from decay by making them more acid-resistant. Fluoride can increase calcium and phosphate uptake in the enamel, thereby repairing weakened spots on the teeth and even reversing early decay. In adults, fluoride protects by inhibiting root decay, which can develop as

The sealants being applied to this child's molars will provide extra protection against tooth decay.

(Courtesy National Institute of Dental Research)



gums recede with age, and by deterring new decay around old fillings.

The most adequate fluoride protection comes from drinking fluoridated water. However, a 1980 survey by the Centers for Disease Control in Atlanta shows that only 53 percent of our population is served by fluoridated water. If your water isn't fluoridated, ask your dentist about fluoride tablets—drops for small children—or topical fluoride treatments. According to ADA, children who drink fluoridated water from birth have 40 to 65 percent fewer cavities than those who do not. So use fluoride toothpaste and rinse, and help your children follow the dentist's instructions for proper brushing.

Use sealants on children's teeth. With a thin, plastic covering over tooth pits and grooves, sealants protect chewing surfaces on molars and premolars from plaque and acid. A dental professional first cleans the tooth, then applies a material that helps attach the sealant to the tooth, and finally brushes on the sealant. Some sealants

require a special light to help them harden.

Follow eating habits that foster healthy teeth. Eat a well-balanced diet and be aware that plaque bacteria use sugars (including honey and the increasingly used substitutes for refined white sugar such as corn syrup) to produce acids that can cause tooth decay. Since acids can attack the tooth enamel for 20 minutes or longer before they are neutralized, a major factor in cavity development is the frequency of these attacks. Eating sticky foods like raisins and honey, sucking on sugared cough drops or hard candy, and sipping sugared drinks can give the acids more attack time. Even natural sugars in fruit can lead to decay. Still, fruit is nutritious and people do sometimes want desserts. ADA says the best way to handle this is to eat foods containing sugar only at mealtimes, when an increased amount of saliva is produced—saliva helps to neutralize acids.

To keep the number of acid attacks on your teeth at a minimum, limit between-

meal snacking. But when you do snack, stay with sugarless foods. Peanut butter, ketchup, coffee whitener and some other foods often have hidden sugars, so it's important to read labels. Except for people with special dietary needs, ADA suggests these foods as reasonable, pro-dental-health snacks: meat, fish, eggs, nuts, peanut butter without sugar, milk, cheese, plain yogurt, raw vegetables, popcorn, soda crackers, pretzels, toast, olives, dill pickles, sugarless gum or candy, and coffee or tea without sugar.

Take precautions about dental care during pregnancy. Hormonal changes can increase your chance of getting early gum disease, so during pregnancy give extra attention to dental care. While it's best to have dental work done *before* you're pregnant, if it does become necessary, ADA advises that treatment be restricted to months four through six. Talk to your physician and dentist about what anesthetics and drugs to use or avoid and about dental X-rays.

Give early teeth a healthy start. What you eat during pregnancy can affect your baby's dental health, so be certain you eat enough foods with phosphorus, calcium, and vitamins A, C and D—nutrients your baby needs to form healthy teeth, jaws and gums. Begin your baby's oral hygiene soon after birth by gently wiping baby's gums after each feeding with damp gauze. Because primary, or baby, teeth save space for permanent teeth and help guide them into place, primary teeth are important and should be protected from the decay of "nursing bottle mouth." Does baby nap with a bottle? Rather than filling the bottle with juice or formula, use plain water so sugars won't lie around teeth and gums and foster acid attack. ADA recommends a first dental visit at age 2 to 3.

(For more on dental hygiene, see *FDA Consumer*, June 1980, "Brushing And Rinsing To Prevent Cavities," and September 1984, "The Dental Plaque Battle Is Endless But Worth It.") ■

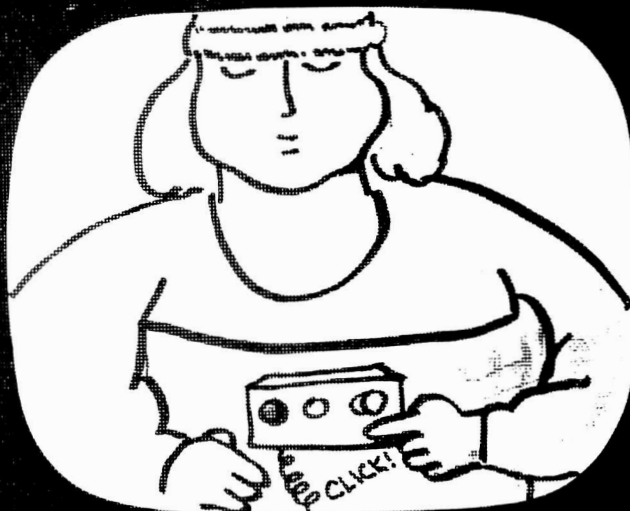
Ad Campaign Will Warn About Health Fraud

A public education campaign on health fraud, or quackery, is scheduled to begin in the fall as a combined effort of the Food and Drug Administration and the Pharmaceutical Advertising Council (PAC), the organization that represents the drug advertising industry. The campaign will include radio and television public service announcements, print ads, and brochures.

In October 1984, FDA Commissioner Frank E. Young, M.D., and Roger O'Neill, then president of the PAC, wrote to advertising and public relations firms requesting ideas for the campaign. Seventy firms submitted a total of more than 100 ideas. A panel of experts will select those to be used in the campaign. The firms will then develop the materials for distribution by FDA.

Three of the "finalists" are shown on the following pages. At right is a proposed TV spot of a woman who finds that a weight-reducing gimmick doesn't work. The conclusion of the 30-second spot notes that "miracles don't come through the mail," a message repeated by the announcer, who is identified on the script as "V/O" ("voice over" the picture).

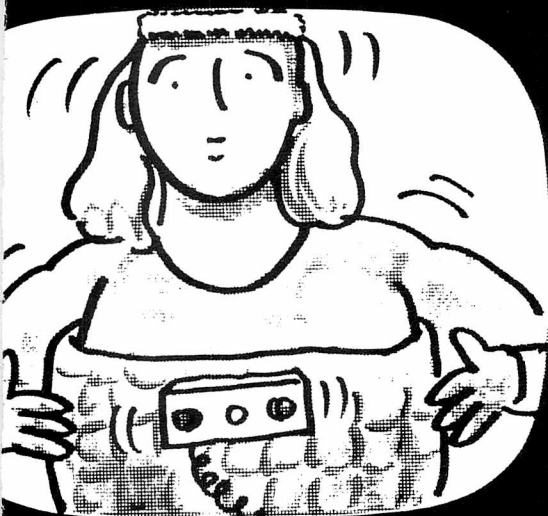
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VIDEO: VERY PLAIN, OVERWEIGHT WOMAN PUTS A WEIRD ELECTRICAL GIZMO AROUND HER WAIST.
AUDIO V/O: EVERYWHERE YOU TURN,

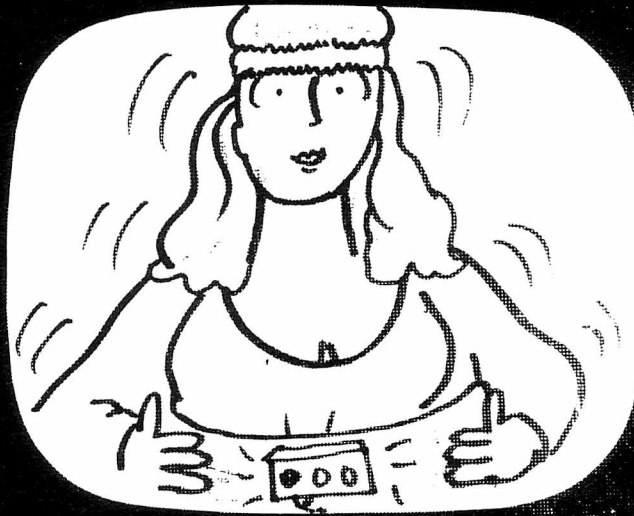


VIDEO: TRANSFORMATION COMPLETE, SHE CLICKS OFF MACHINE.
V/O: ...PROMISES IS THE MONEY YOU...



VIDEO: SHE TURNS ON MACHINE.
(SHE SINGS HALLALUJAH CHORUS BEGINS)

AUDIO: ...SOMEONE IS PROMISING TO
TURN YOU INTO SOMEONE YOU AREN'T.



VIDEO: WOMAN BEGINS TRANSFORMATION
INTO BEAUTIFUL, BUXOM GLAMOUR GIRL.

AUDIO: THE PROBLEM IS... THE ONLY
THING REAL ABOUT THESE...



VIDEO: WOMAN TURNS BACK INTO
PLAIN JANE
... PAY TO FIND OUT THEY DON'T WORK.

**MIRACLES DON'T
COME THROUGH
THE MAIL.**

V/O: REMEMBER... "MIRACLES"
DON'T COME THROUGH THE MAIL.

(Continued from page 16)

The ads at right are typical of the ideas for print media submitted for the campaign. The top three carry the theme "Miracle Cures—We're Not Buying It Anymore" and warn about baldness, diet quackery, and health fraud in general. The bottom row of proposed ads use humor to help get their messages across.

The print ads ultimately chosen for the campaigns will be offered to the nation's newspapers and magazines to be run as a public service. Likewise, some 6,900 radio stations and 900 TV stations will be asked to use 30- and 60-second announcements designed to educate the public about both the financial and health dangers of quackery. Also available to the public will be a general brochure on health fraud produced by the FDA, Federal Trade Commission, U.S. Postal Service, and the drug advertising industry. ■

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MIRACLE CURES
WE'RE NOT BUYING IT ANYMORE

**A GUARANTEED
WAY TO
GROW HAIR AGAIN**



FAT CHANCE



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**MIRACLE CURES
WE'RE NOT BUYING IT ANYMORE**

BUSTED DREAMS

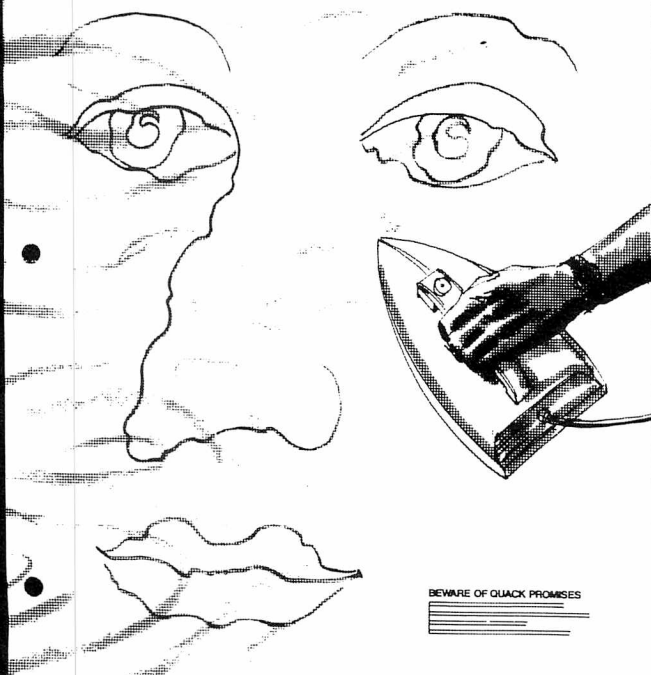


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**MIRACLE CURES
WE'RE NOT BUYING IT ANYMORE**

THE ONLY GUARANTEED METHOD OF REMOVING WRINKLES



BEWARE OF QUACK PROMISES

THESE ARE THE ONLY KIND OF MUSCLES YOU CAN GET IN A WEEK



BEWARE OF QUACK PROMISES

On Yeast Infections And Other Female Irritations

by Evelyn Zamula

A determining point in the history of gynecology is to be found in the fact that sex plays a more important part in the life of a woman than in that of a man, and that she is more burdened by her sex.

—Henry E. Sigerist, M.D., in the *American Journal of Obstetrics and Gynecology*, 1941.

You can say that again, Dr. S. Women are burdened by their sex in ways that men can never completely comprehend. The battle lines in the war between the sexes might be redrawn if just one man could slip inside a woman's skin to experience the discomfort of menstrual cramps, or the propulsive force of labor contractions; could know what torture it is to nurse a baby when nipples are sore, or could feel the rush of blood to the face, the so-called "hot flash" that leaves a woman dissolved in a pool of perspiration.

In the same vein, a late 19th century philosopher once said that man possesses sexual organs, but a woman's sexual organs possess *her*. It's a controversial statement and sexist, too, but the gentleman hit it right on the head. Ever hear of anyone making a fortune, à la Lydia Pinkham, by catering to "male" complaints? Waxing and waning of monthly cycles, pregnancy, childbirth, nursing, menopause, post-menopause—each stage of a woman's life can present her with a sackful of potential problems.

Though any part of the reproductive system can cause problems, the vagina—that multipurpose canal leading from the vulva (outer opening) to the uterus—is especially beset with ills.

In fact, one of the commonest complaints that sends women to doctors is vaginitis—irritation and inflammation of the vagina. The main symptoms are increased vaginal discharge, often accompanied by vaginal soreness, and a burning feeling, especially when urinating. Many women also experience an unbearable itch. The vagina itself doesn't have the necessary nerve endings to itch; the itching really occurs in the vulva.

These symptoms don't always indicate vaginitis since they're also associated with other conditions. Women experience increased vaginal discharge—often blood-tinged—at the time of ovulation, about midway in the monthly cycle, but this is completely normal. A heavy discharge can also result from cervicitis (inflammation of the cervix) caused by any of the sexually transmitted diseases, the most common being gonorrhea, chlamydia and herpes, or from a tumor in the genital tract. Pain on urination is often a symptom of cystitis or urethritis. Vulvar itch has many causes, such as diabetes, leukemia, skin diseases, allergies, pubic lice, ringworm, scabies, and irritation due to contraceptive devices, clothing or dyes. However, when vaginal discharge, pain

and itching occur together, in most cases the diagnosis will be vaginitis, caused by infection with the microorganisms *Trichomonas vaginalis*, *Candida albicans* or *Gardnerella vaginalis*.

T. vaginalis is a protozoan (a type of one-celled organism) responsible for about 3 million cases of vaginal infection each year. It can cause itching, pain, and a watery, bubbly, greenish or yellowish discharge, sometimes with an odor. (It can also produce no symptoms at all, and can only be identified by a doctor during a routine gynecological exam or on the Pap smear.) The doctor diagnoses this form of vaginitis, known specifically as trichomoniasis, by examining the discharge under a microscope (wet smear) or having the sample grown in a culture.

Trichomoniasis is almost always sexually transmitted, but there are some exceptions. (The disease has been found in young girls with no sexual experience.) Since the organism normally lives in the bowels, it can be spread to the vaginal area by improper wiping. There is also a possibility that it can be acquired in swimming pools frequented by infected women, or from contaminated towels, or at public lavatories. Some studies have shown that *T. vaginalis* can survive on a plastic toilet seat for as long as two hours. While the disease is not ordinarily acquired in this manner, females should avoid contact with toilet seats where sanitation is doubtful.

For some reason, trichomoniasis is more common among heavy smokers. In women who are very active sexually, it is often paired with gonorrhea or *Candida*. The body never builds up protective antibodies against trichomoniasis, so it's easy to get one infection after another. (It can also lie low in the body, sometimes for decades, where it develops into a chronic condition, with few or no symptoms.) To prevent reinfection, doctors advocate treating the sex partners of women who have trichomoniasis, even when the males show no symptoms, which is usually the case. Use of condoms is recommended until the infection subsides. However, the *Merck Manual* recommends that sex partners be examined and treated and *abstain* from sex until cured.

Metronidazole given by mouth is the most effective medication. Physicians may prescribe three pills a day over a course of five to seven days, or may prescribe eight pills in one day. Alcoholic drinks should be avoided when taking this antibiotic because the combination can cause many adverse reactions, including abdominal cramps, nausea, vomiting and headaches.

Metronidazole's effect on pregnant women has never been studied, but it has caused genetic damage and harm to the fetus in animal studies. For these reasons, the labeling warns against using it during pregnancy, especially in the first trimester, when the developing fetus can be damaged by drugs crossing the placenta. Instead of metronidazole, doctors usually use local medications to treat the vaginal areas of pregnant women who need relief from the symptoms.

Metronidazole has also been found to cause cancer in rats.

One form of vaginal infection, trichomoniasis, is more common among heavy smokers.

Since it is excreted in breast milk, a mother must not nurse while taking the drug, or should rely on topical treatment alone.

Candida albicans, a yeast-like fungus that likes to grow in warm, moist places, causes a vaginitis known specifically as candidiasis, though most women are more familiar with the term “yeast” infection. (The disease also used to be called moniliasis, but that term is no longer used.) The symptoms are similar to those of trichomoniasis. First comes an itch, which can be maddening, followed by painful urination, soreness of the vulva, and irritation. The vagina may become bright red rather than its normal pink. (Before beginning treatment, doctors must be sure that the painful urination is due to a yeast infection rather than to cystitis, a bladder inflammation, because the yeast infection will become worse if treated with antibiotics.) There may be a discharge, usually a white, creamy or curd-like substance with no odor. Because the vaginitis makes sex uncomfortable, or even painful, it often puts stress on marital relations until the condition is cleared up.

Although about 15 percent of non-pregnant women and 30 percent of pregnant women in their third trimester harbor *C. albicans* in their vaginas at any given time, most show no symptoms of vaginitis. Many women have occasional attacks of vaginal candidiasis that respond well to medication.

Some women, however, get yeast infections regularly no matter what. They experience frequent attacks, sometimes once a month, often about the time of their menstrual periods, that are difficult to treat. These women are often driven to desperate measures that include douching with yogurt or following diets low in refined sugars and fruits, which are thought to aid the growth of fungi. While neither of these practices does any harm, there is no evidence that they do much good, either.

For years it has been widely taught in medical schools that certain factors—diabetes, pregnancy, use of oral contraceptives, corticosteroids or post-menopausal hormones, or prolonged use of antibiotics—predispose some women to yeast infections. But there are some dissenting voices. Dr. Jack Sobel (*Annals of Internal Medicine*, September 1984) states that, “Women with recurrent vulvovaginal candidiasis who have strictly avoided all these risk factors continue to have frequent episodes of symptomatic infections.” In a recent conference on diseases of the vulva and vagina given at the Baylor College of Medicine, some doctors agreed that chronic, recurrent candidiasis may be due to a transient immune deficiency, in the absence of other predisposing factors.

For a long time, nystatin suppositories were used in combating candidal infections, but in the past few years FDA has approved more effective anti-fungal agents—miconazole or clotrimazole in creams applied topically to the vulva and in vaginal suppositories. In fact, doctors report that just a single 500-milligram tablet of clotrimazole, inserted high in the vagina, is as effective against the fungus as long-term therapy.



Candidiasis can occur for no apparent reason, though it can be transmitted sexually. A woman's sex partner should be treated when he has a moist, white, scaling rash on his penis or an itch or inflammation under his foreskin, or when the woman continually has yeast infections. Like genital herpes, this is a disease that can be passed on from mother to baby during childbirth (as thrush, a mouth or throat infection), so it's important for pregnant women with yeast infections to seek medical help.

Itching, burning and pain are not always present in the vaginitis caused by the *Gardnerella* bacterium, formerly known as nonspecific vaginitis or *Hemophilus* vaginitis. Other bacteria are also implicated in this type of infection, making it difficult to diagnose. *Gardnerella* vaginitis is usually suspected when trichomoniasis and candidiasis have been ruled out. The symptoms are a heavy clear-to-grayish discharge with a foul or fishy odor and a

Vaginitis can be caused by allergies to vaginal sprays and deodorants.



milk-like consistency. The discharge coats the vagina, but the tissues are not inflamed.

This is yet one more disease that men seem to transmit without showing any symptoms of it themselves. Symptomless males should be treated if they continually reinfect their female partners. Like other forms of vaginitis, *Gardnerella* can also occur without sexual contact.

Metronidazole may be effective in treating *Gardnerella*. Ampicillin, an antibiotic, may also be effective and is prescribed for pregnant women who cannot use metronidazole.

While infections with trichomonads, yeast or bacteria are the principal causes of vaginitis—responsible for about 63 percent of all cases, according to one study—other agents may be involved in vaginal itching, burning, pain or discharge. When little girls have these symptoms, they may be due to foreign objects in the

vagina. Doctors have removed many interesting items from little girls' vaginas, including paper clips, toothpicks and matches. Women occasionally leave tampons or diaphragms in too long, and these may also cause infection.

When estrogen levels are low, as in post-menopausal women, the lining of the vagina becomes thin and dry and can become infected with bacteria that normally would not affect a vagina with an adequate estrogen supply. Older women who have the usual symptoms of vaginitis plus a bloody discharge should check with their doctors to rule out other causative factors. Often, all that is needed is the topical application of an estrogen-containing cream, or estrogen taken by mouth.

Vaginitis can also be caused by allergies to vaginal sprays and deodorants. Discontinuing their use will usually clear up the irritation.

When symptoms of vaginitis—itching, irritation and abnormal discharge—persist for more than two days, it's wise to seek medical help. If yeast infections are allowed to continue too long untreated, swelling and discomfort can actually interfere with walking.

Since diagnosis may depend on examination of the discharge, it is important not to douche for 24 hours before seeing the doctor; washing out the vagina may make it impossible to get a proper sample.

There are some things women can do when they have vaginitis or when they want to prevent future attacks:

- Discontinue use of tampons while under treatment. Also, since underwear and pantyhose made from synthetic fibers often increase heat and moisture in the vulval area, switch to cotton underwear and pantyhose with cotton crotches if you are prone to frequent infections. For the same reason, don't wear skintight pants.
- Avoid sexual intercourse while undergoing treatment. Have your sex partner checked by the doctor if you get repeated infections.
- Practice good feminine hygiene. Wash the vulval and anal areas with mild soap and water at least once daily, and after each bowel movement, if possible. Always wipe from front to back, away from the vagina. The bowels harbor bacteria and fungi that can travel over to the vulval area.
- Don't douche unless the doctor says to. By disturbing the normal acidity of vaginal secretions, douching may create more problems than it cures.
- Make it a rule that anything that goes into the vagina—pessaries, diaphragms, and other contraceptive devices, for example—be scrupulously clean.
- Take the medication for as long as the doctor prescribes. Some women stop the medication when they feel better, but that's an invitation to recurrent infections.

Evelyn Zamula is a member of FDA's public affairs staff.

Speaking Up About FDA Regulations

by Richard C. Thompson

Americans tend to be outspoken and opinionated, and when something is happening that they think affects them, they are likely to speak up.

The Food and Drug Administration knows this more than most because FDA—which regulates food, drugs, cosmetics and other products—is probably closer to American daily life than any other federal agency.

Because FDA's actions can have great effect on the public health, on the industries it regulates, and even on the nation's economy, the agency conducts its rule-making in public so that all interested parties can be heard. It deliberately makes the public a part of the process.

When FDA intends to issue a new regulation or change one that already exists, it will—like any federal agency—announce that fact as a “notice of proposed rulemaking” in the *Federal Register*, the federal government's publication of record.

The *Federal Register* is published each weekday by the Government Printing Office and carries announcements of actions proposed and taken by the federal agencies. It is available by mail subscription and can also be found in many libraries, government offices, and congressional district offices.

The rule-making notice will give the text of the proposed regulation, describe the issues involved, and invite public comment. It will also explain in a preamble why FDA is proposing the regulation. Anyone wanting to comment will then know the reasoning behind the proposal and its legal and scientific background.

Besides telling what FDA intends, the notice will announce the “comment period.” This is the deadline—usually several months away—for getting comments to the agency so that they can be considered and perhaps affect the decision. The notice will also give the name of the FDA staff member working on the proposal who can provide more information.

There are no forms to be filled out in order to submit a comment, and the comments need not follow any particular style. Some have arrived handwritten, some typed; on stationery, post cards and scribbled notes. But however they are submitted, the comment should say whether the writer is for or against the proposal, and why.

Comments should be mailed to the FDA Dockets Management Branch, Room 462, 5600 Fishers Lane, Rockville, Md. 20857.

FDA also welcomes comments and questions not related to any particular proposal. They should be addressed to the Consumer Inquiries Staff, Room 1686, 5600 Fishers Lane, Rockville, Md. 20857, or to FDA offices around the country (check the government listings in local telephone directories).

Comments are logged as they are received, then placed in the file for the proposal to which they refer. They are available with all other comments on that proposal to anyone who asks to see them in the agency's public reading room.

FDA staff will evaluate the comments in the course of reaching

a decision and, when the decision is published in the *Federal Register*, will tell the effect the comments had on that decision.

Persons wanting to react to an FDA proposal do not have to have a title or official position. All that is needed is an informed opinion and the willingness to express it. In fact, persons making comments do not have to be citizens of the United States if what FDA is proposing concerns them.

One classic example of individual action affecting an FDA decision was the repeated efforts by a New Jersey pharmacist to get camphorated oil off the market as a dangerous and unnecessary product. (See “What Ever Happened To Camphorated Oil?” in *FDA Consumer*, July-August 1983.) The pharmacist first made his point to an FDA panel in 1978; then, over a two-year period, he submitted cases, comments and documentation that showed camphorated oil—sold for years as a liniment—had no medical uses and had caused many deaths and much illness when it was mistakenly ingested, most often by children. Based on his persistence and presentations, FDA ruled that camphorated oil could no longer be marketed and credited him with leading the agency to this decision.

In the first two months of 1985, the docket staff logged 1,968 comments on proposed rules that FDA had published. Of those, 615 came from individual consumers, 40 from commercial organizations, 32 from professional groups, and six from consumer organizations. Just over 800 were from other interests, such as universities, state and local governments, the news media, and organized constituencies sending form letters.

The subject of these comments covered a broad range of topics, such as setting new standards for bottled water, requiring a warning label on an acne drug, preserving various foods with irradiation, and changing a drug from prescription to nonprescription. A consumer group asked for the acne drug warning because it believed the medication should not be given to pregnant women for fear of birth defects, and they want the label to say so. New standards for bottled water would affect an entire industry, and the industry's comments reflect its concerns. The large number of comments on food irradiation show how strongly both the public and the food companies feel—both pro and con—about this subject and how they want FDA to be guided by their opinions.

Many persons believe that comments by business, industry and organized consumer groups count most with FDA. They are mistaken: To FDA, a comment is a comment and is judged on its legal and scientific merits, regardless of the source. However, the total volume of public comments can be a factor, as happened with the agency's proposal to ban saccharin in 1978. The thousands of comments opposing the ban showed how strongly people felt about keeping that artificial sweetener.

But one advantage that consumer groups and industry have over individuals is that they know what FDA is doing. They follow the subjects that interest them very closely. They understand the government's comment and petition system and how to make it work for them. Also, their presentations are often fully developed and can go on for several pages with scientific data and charts. But however well prepared, an industry comment for a proposal can be offset by another against it, or by comments from, say, a consumer group taking yet another position.

It's not enough for the comment to be for or against a proposal; it should also say why. FDA regulatory decisions are primarily based on science, and agency reviewers look for reasoning and logic and good science in the comments that come to them. Especially helpful are any new data not considered in the proposal.

While the notice-and-comment process is the way to make

Comments received on food irradiation

Individual consumers	4,146
Consumer organizations	41
Commercial organizations	190
Professional organizations	48
Universities, government agencies, news media, etc.	332
Form letters	4,779
Total	9,536

Using irradiation to preserve food has been a controversial issue for several years. (See "Irradiation Proposed To Treat Food" in the May 1984 FDA Consumer.) As of June 1985, almost 10,000 comments had been logged by the dockets staff since FDA proposed in 1981 to permit food irradiation, making it one of the most attention-getting proposals in FDA's history. The letter at top, from the Hawaii Department of Agriculture, urges irradiation for fruit exports; the letter below it wants irradiated foods to say so on the label; the form letter at bottom—one of hundreds received—was headed "Yes, We'll Take a Risk But We Want a Label!" Professional organizations shown in the chart include physician and scientist groups.

Dear Dr. Young:

The Food and Drug Administration has had under review for a considerable length of time a proposed regulation to expand the use of ionizing radiation as a food preservation and disinfection process. Because an alternative treatment method is desperately needed by our papaya industry, we are writing to urge expeditious action by FDA on this long-pending review.

Following the Environmental Protection Agency's ban on the use of ethylene dibromide as a fumigant on September 1, 1984, Hawaii's papaya industry has been forced to utilize a double-dip hot water process to insure disinfection of fruit destined for export. Although the process meets the quarantine requirements of the U.S. Department of Agriculture, it has numerous drawbacks which affect the quality and marketability of the fruit. This hot water treatment has greatly reduced the quantity of fruit being shipped to the mainland U.S. with consequent loss of markets.

Fortunately, there are several firms in our State capable of building and operating irradiators for the treatment of papayas and other products. Irradiation, of course, would open the Mainland markets for our other fruits such as lychee, mango and avocado.

Dear Dr. Young:
I am writing to express my strong support for Irradiation Labeling if indeed our food is to become irradiated. The unknown factors and results in such a process make it imperative to give the consumer a choice in what food is purchased.

I understand the new regulation would open the door for food processors to use irradiation, or together with, highly toxic chemical pesticides and fumigants to destroy insects and extend the shelf life of fresh fruits and vegetables.

I also understand that irradiation of a food at the proposed levels does not make food radioactive. This, however, is NOT the basis of my safety concerns. I am concerned with other radiolytic changes that DO occur.

I do NOT agree with FDA's conclusion that simply because the food does not become radioactive it is therefore "safe" and has the identical nutritional value as similar foods which have not been irradiated.

Instead I share the concern expressed by Dr. Samuel S. Epstein and John W. Gofman that "While not radioactive, irradiated food contains stable radiolytic products whose chemical identity and toxicology are poorly defined." (The Washington Post, February 25; p. A-16)

These new formed radiolytic products may or may not be highly toxic. At this time we simply don't know.

Dr. Epstein and Gofman pointed out that FDA's assurance they are safe does not come from critical, long term feeding tests of concentrated extracts of these radiolytic products for mutagenic, carcinogenic and other chronic toxic effects.

FDA states in its proposal that "Ionizing radiation, like other forms of energy used to process food, causes chemical changes in food."

At the dosage proposed by FDA irradiation of food "would produce approximately 30 parts per million of radiolytic products." Three parts per million or 10% of these may be entirely new substances that have never been tested for safety by any agency of any government. Thirty or three parts per million is an extremely high amount of very toxic poisons.

Drs. Epstein and Gofman said "Industry claims for the safety of irradiated food largely depend on insensitive conventional animal feeding tests, rather than the more critical long term feeding tests of concentrated extracts for carcinogenic and other chronic toxic effects." FDA should extend the comment time for nine months or more until at least one long-term feeding test of concentrated extracts of these newly discovered radiolytic products has been completed.

The Language Of Regulation

Code of Federal Regulations (CFR):

A compilation of the current regulations of all federal agencies, revised and published once a year and kept up to date by the *Federal Register*. FDA's regulations are in Title 21 of the 50 titles that make up the CFR.

Federal Register (FR): The five-day-a-week government publication in which new, changed or proposed regulations of the federal agencies, as well as certain other government information and directives, are announced. Appearance of a document in the *Federal Register* gives an action or announcement legal standing and makes it official.

Copies of the *CFR* and *FR* are available in many libraries, courthouses and federal office buildings. They can also be pur-

chased from the Superintendent of Documents, Government Printing Office (GPO), Washington, D.C. 20402. Write to GPO for prices.

Regulations: Detailed statements that describe exactly how the agency interprets and will apply the general legal authority it has been given through laws passed by Congress. FDA's basic authority comes from the Food, Drug, and Cosmetic Act; the Fair Packaging and Labeling Act; the Radiation Control for Health and Safety Act; and the Public Health Service Act. FDA enforces these laws in regulating food, drugs, cosmetics, medical devices, radiation-emitting products, and animal feed.

Advance Notices of Proposed Rule-making (or Notices of Intent): An-

nouncements intended to publicize an action the agency is considering. Such notices frequently precede issuance of a proposed regulation, and response to the notice can affect the form and substance of the proposal.

Proposed Regulations: Statements in the *Federal Register* that declare an agency's intention to revise existing or to issue new regulations. These proposals invite public comment as described in the accompanying article.

Petition: A formal request by an individual, firm or organization to the FDA commissioner that a certain action be taken or not be taken, or that a regulation or order be established, revoked or revised. ■

opinions known to FDA on proposals the agency has already issued, there is also a petition process to urge FDA to initiate—or refrain from—a particular action.

Petitions are a formal request that FDA issue, amend or revoke a regulation. Unlike comments, petitions require considerable preparation.

The petitioner must cite appropriate statutes and regulations; submit a statement of the factual and legal basis for the petition, even including data unfavorable to the petition; and discuss any economic and environmental impact the requested action might have. Petitions should be filed with the Dockets Management Branch, and DMB staff can explain the requirements.

Unlike comments, a petition sets regulatory machinery in motion and involves considerable time, money and effort on the part of FDA. The process is there to be used, but it should not be used lightly.

The formality of a petition may discourage individuals, but it does not discourage business, industry and consumer organizations. There are some 200 petitions now in the agency awaiting resolution, not necessarily urgent and certainly not to be decided without proper study.

Most of these petitions are from commercial firms and deal with very specific and technical situations. They ask, for example, that nutrient listings in animal feed be revised; that permitted weights for margarine products be changed; that charcoal tablets be exempt from drug warnings; that labeling be changed on various food and drug products. Some ask, in effect, that the petitioner's product be excused from some provision of a regulation or that a competitor's be more closely regulated.

Petitioners often hope to obtain an economic advantage or to protect one that already exists. This happened most recently when a new nonprescription analgesic was introduced, and a firm that had long dominated the market petitioned FDA to take action that would have restricted the newcomer's ability to advertise. The purpose was so obvious and so criticized that the petitioner

asked to withdraw the request.

There have been petitions from professional organizations—such as physician groups who do not want prescription drugs to be advertised directly to consumers, and from pharmacists who believe a new medication should be dispensed only by them. Others are from consumer groups, asking that certain products, which they believe are unsafe or ineffective, be taken off the market. Only a few petitions are from individuals.

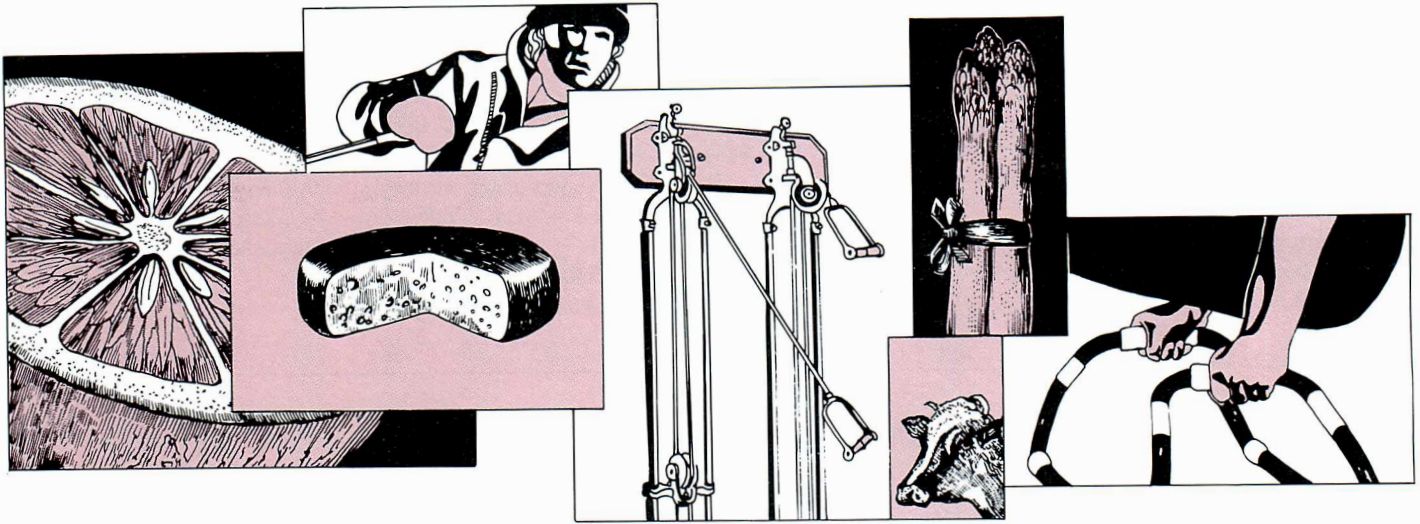
Petitions must be directed to the FDA commissioner and ultimately must be decided by him. The merits of the petition will first be weighed by agency staff and this can take several months or, if sufficiently complicated, more than a year. Then—knowing the pros and cons of the requested action—the commissioner will either grant or deny the petition, announcing the decision in the *Federal Register* as well as directly notifying the petitioner. If the result is not satisfactory, the petitioner may take the matter to court.

In addition to using comments and petitions to reach FDA, the agency schedules public meetings to discuss and explain its actions and proposals. Meetings with consumer groups and industry representatives—but open to anyone—are held in Washington, D.C. Others are held across the country, especially if the issues are highly controversial or will affect a great number of people. The meetings are announced in the *Federal Register* and through the news media.

Consumer groups, businesses and industry know how to affect FDA's decision-making process. They do it every day with comments and petitions. But average citizens with an opinion on an FDA action or proposal may be intimidated at the thought of approaching a federal agency. They need not be. For those who have a well-thought-out position on an issue affecting the public health in which FDA has a role, the process is well worth the effort. ■

Richard C. Thompson is a member of FDA's public affairs staff.

The Fad-Free Diet: How To Take Weight Off (And Keep It Off) Without Getting Ripped Off



by Judith Willis

What does it take to lose weight?

Millions of dieting Americans who try to starve it off, melt it off, and sometimes even sleep it off would like to know.

Some people claim to be unable to lose any appreciable amount of weight. But even among those who are successful at losing, fewer than 20 percent are able to keep off the pounds they shed. The rest regain the lost weight—and often then some.

Is there some deep, dark secret that, once revealed, will enable dieters to lose weight and keep it off? Promoters of some diet products would like the public to think so. But the answer lies not in complicated hocus-pocus, but in a few easily understood scientific principles.

The most basic of these principles is that the body needs a certain amount of energy, expressed as calories, to maintain its weight. To lose weight, you have to use up more energy (read: calories) than you take in through food. This means either eating less or exercising more, or some combination of the two.

Most of us who want to lose weight are probably aware of this concept. But putting it into practice is easier said than done. It takes a good deal of effort and time, and dieters are easily tempted away from this rather unglamorous regimen by the vast array of articles, books, pills, potions and devices that promise to get the excess pounds off quickly and effortlessly. Many of these are promoted as heretofore closely guarded “secrets” or new “discoveries.”

Some of these products can produce quick weight loss. But they rarely have any permanent effect and often send dieters into a

cycle of quick weight loss, rebound weight gain when normal eating is resumed, and even more difficulty losing when the next diet is attempted.

FAD DIETS

It seems that not a season goes by without at least one diet book high on the best-seller list. Some diets advocated by these books are simply variations of a basic, safe 1,000- to 1,200-calorie balanced diet. But others may be downright dangerous, as they emphasize one food or food group and the elimination of others—in other words, they advocate diets that are unbalanced.

Some of these diets fraudulently claim that certain foods have the ability to “burn fat.” No food can do that. Body fat is “burned” or gotten rid of only by using more energy than is supplied by food. For example, in the 1970s, diets high in protein and low in carbohydrates and calories were promoted as panaceas for the overweight, with promises that they would “burn fat” more quickly than a regular balanced diet. This is the type of diet that provides a quick and substantial—but only temporary—weight loss because fatty acids are incompletely broken down. The technical name for this process is ketosis and it can lead to an acid and alkaline imbalance. Ketone bodies, formed when fat deposits are broken down for energy more quickly than the body can use them, must be excreted in the urine.

Another reason for quick weight loss with these ketogenic diets is that the body is getting energy from muscles and major organs (known technically as “lean body mass”) rather than fat. Balanced diets contain enough carbohydrates to provide glucose (a

form of sugar)—the body's basic energy source. But when carbohydrates are lacking, the body must obtain glucose from other sources, such as the protein in lean body mass. At such times, the body may draw upon the muscles and major organs such as the heart for the needed glucose. While the body must expend 3,500 calories to "burn off" a pound of body fat, only about 480 calories are needed to get rid of a pound of lean body mass. Thus, the weight loss is predominantly water and protein rather than predominantly body fat during the first week to 10 days of the diet, and the weight is quickly regained when normal eating is resumed.

One extreme form of this type of diet—a liquid protein diet containing less than 400 calories a day—was linked to 17 deaths in 1977 and 1978. Scientists who studied the deaths found that the dieters had died of irregular heart rhythms and cardiac arrest.

The Food and Drug Administration now requires warning labels on weight-reduction products when more than 50 percent of the product's calories come from protein.

Other very-low-calorie liquid and powdered products have appeared on the market recently with a lower proportion of protein. But consumers should be aware that any diet of fewer than 800 calories a day is potentially dangerous and should be undertaken only under medical supervision.

PILLS, POTIONS AND DEVICES

In addition to "magic" foods and fad diets, people often are lured by promises that pills, potions or devices will take off and keep off unwanted pounds.

Such products are sold in health food stores, drugstores, and special clinics or salons. In addition, they're often available through the mail.

A few of these—like appetite-suppressing eyeglasses with colored lenses that are supposed to project an image to the retina that dampens the desire to eat—border on the ridiculous. Yet hundreds of seekers of the svelte look are duped by such products before authorities step in.

One recently promoted device, the electrical muscle stimulator (EMS), has legitimate medical uses in physical therapy but is worthless for weight loss or figure firming. Claims that stimulation from these devices has the figure-toning ability of 3,000 sit-ups, for example, are without any scientific basis. Further, these devices, often promoted through mail-order for home use, can be dangerous if not handled correctly. There have been reports of electrical shocks and burns, and the devices can be particularly hazardous to pregnant women and to people with heart problems, pacemakers or epilepsy.

A wide assortment of wraps and garments, some with accompanying lotions to be rubbed on the body before donning the apparel, have been promoted as ways to "burn fat." But facts show that only the consumer gets "burned," only the wallet gets lighter. The creams, gels, wraps, belts and sweatsuits reduce body dimensions by removing fluids—that is, the user sweats it off. This is a very temporary loss because the fluid is regained when the person eats or drinks. Moreover, the rapid and excessive fluid loss is potentially dangerous because it can cause severe dehydration and chemical imbalance. FDA has taken legal action against several promoters of these products for making unsubstantiated weight-loss claims.

If shocking or sweating it off isn't the answer, then perhaps a pill—a "magic bullet"—will work. Or so many dieters dream.

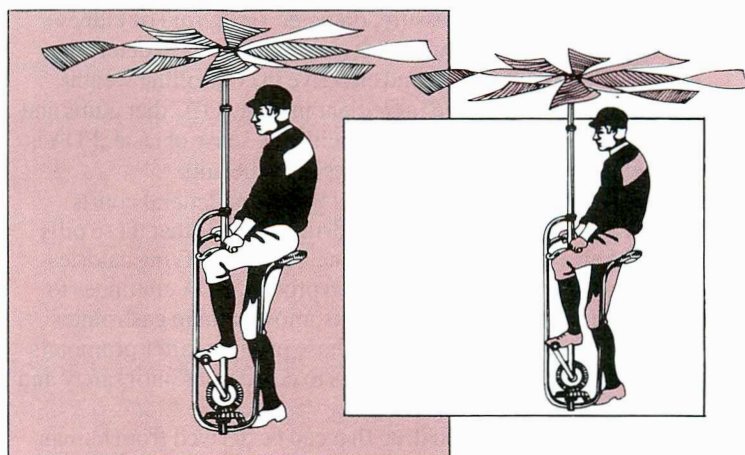
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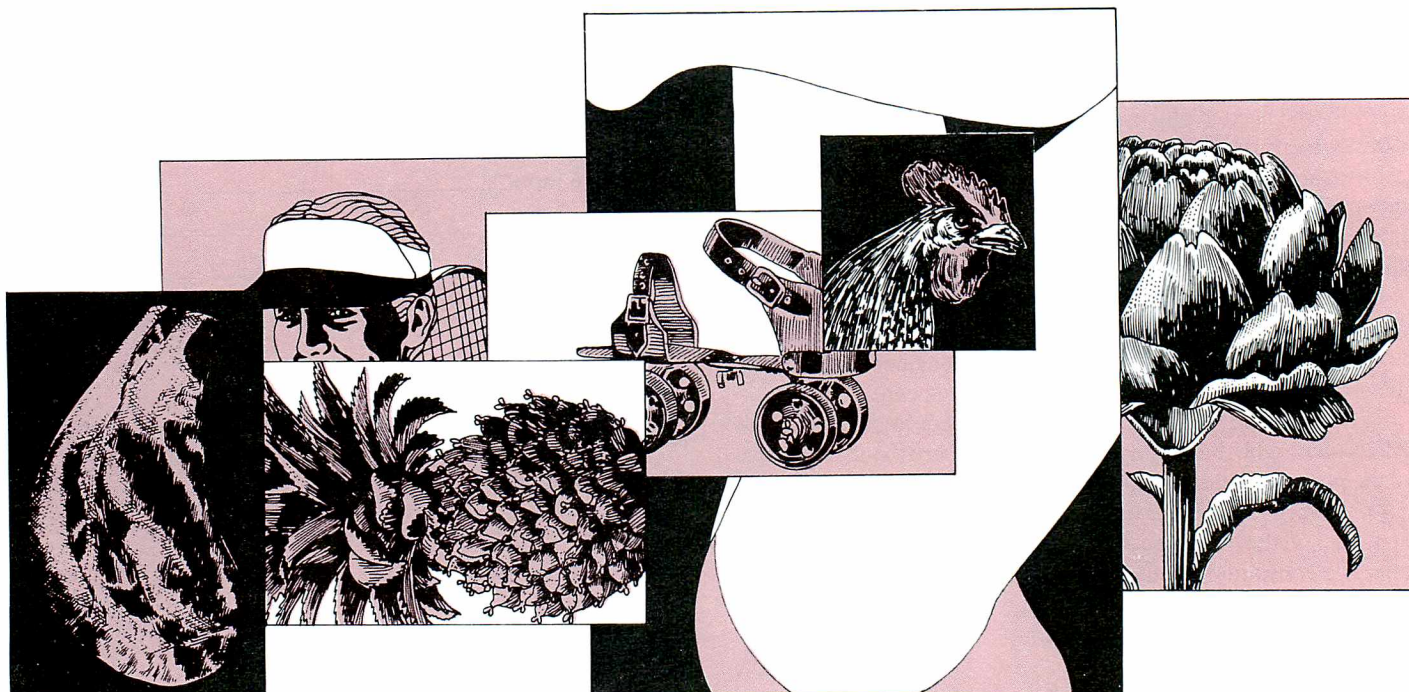
Exercise And Calorie Expenditure

Activity (for one hour)	Calories
Bicycling 6 mph _____	240
Bicycling 12 mph _____	410
Cross-country skiing _____	700
Jogging 5 1/2 mph _____	740
Jogging 7 mph _____	920
Jumping rope _____	750
Running in place _____	650
Running 10 mph _____	1,280
Swimming 25 yds/min. _____	275
Swimming 50 yds/min. _____	500
Tennis—singles _____	400
Walking 2 mph _____	240
Walking 3 mph _____	320
Walking 4 1/2 mph _____	440

Source: Exercise and Your Heart; NIH Publication No. 83-1677

This chart, prepared by the National Institutes of Health, shows the average calories spent per hour in various activities by a 150-pound person. Precise figures are not available for most activities, but these figures, averaged from several sources, can be used as approximations when assessing the relative vigor of activities. A lighter person will burn fewer calories and a heavier one will burn more. For example, a 100-pound person would burn about one-third fewer calories than shown in the chart, and a 200-pound person would burn about one-third more calories. Exercising harder or faster for a given activity will only slightly increase the calories spent. A better way to burn more calories, says NIH, is to exercise longer and cover more distance.





(Continued from page 27)

But science has yet to come up with a low-risk "magic bullet" for weight loss. Some pills and aids may help control the appetite, but they may have serious side effects. Others are utterly worthless.

Here is a brief description of some of them:

Amphetamines: Prescription-only appetite suppressants. Their use in treating obesity has greatly diminished over the last several years because they are highly addictive and have adverse reactions on the heart and central nervous system.

Human chorionic gonadotropin (HCG): Given by injection in some clinics as a cure for obesity. Both FDA and the American Medical Association have stated that this substance is useless for weight loss. HCG is a hormone extracted from the urine of pregnant women and is approved for treating reproductive problems. FDA requires all labeling and advertising for HCG to state that it has not been shown to be safe and effective for weight control.

Phenylpropanolamine (PPA): The active ingredient in many over-the-counter (OTC) diet pills. Medical experts who examined diet products for FDA advised that PPA seems to be safe and effective. However, it should not be taken by everyone, especially those with high blood pressure, diabetes, or thyroid or kidney problems. FDA is currently reviewing safety data to determine whether PPA really is safe and effective in controlling weight.

Benzocaine: The active ingredient in many OTC diet gums and candies. It numbs the tongue, reducing the sense of taste. FDA is reviewing its safety and effectiveness as a diet aid.

Starch blockers: Declared illegal by several federal courts because they are unapproved new drugs. Claims that these pills block the absorption of carbohydrates, thus nullifying calories from starchy foods, have never been proven. FDA continues to investigate reports of adverse effects, most of them gastrointestinal. The government has seized these products after promoters failed to comply with FDA requests to cease sales until safety and effectiveness could be established.

DHEA: An unapproved drug that can be derived from human urine and other sources. Touted as a "natural" weight-loss product, DHEA is known chemically as dehydroepiandrosterone or

dehydroandrosterone. FDA has not received any data to substantiate claims made for DHEA, and it is not known what the effect might be of reintroducing into the body this concentrated hormonal breakdown product that people normally excrete. FDA recently wrote to manufacturers and distributors of DHEA stating that it is an unapproved new drug and that they must stop selling it.

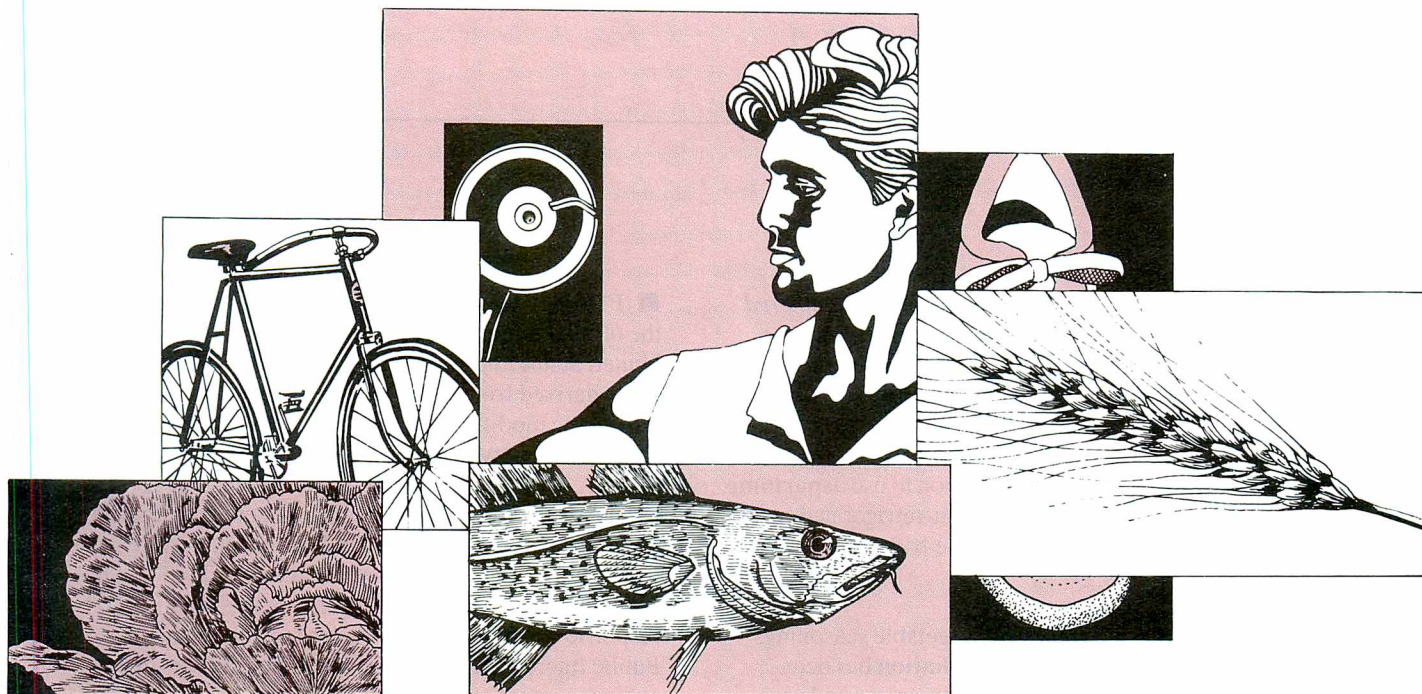
Cholecystikinin (CCK): CCK is a hormone involved in digestion. No CCK product has been approved by FDA for public sale for any purpose, yet products said to contain this substance have been advertised and sold with claims that they decrease hunger and can cause sudden and dramatic weight loss.

No data to support such claims or to show CCK's safety have been provided to FDA, as required by law. FDA recently sent letters to marketers of these products telling them to discontinue selling CCK in any formulation. Although injections of CCK appear to decrease hunger in test animals, FDA scientists say that this research is not applicable to pills for human use and that the chemical cannot survive in the human digestive tract. However, CCK is believed to cause contraction of the gallbladder and increase bile secretion, altering normal body functions and presenting unknown hazards to long-term users.

Arginine and ornithine: Manufacturers claim that pills made of these amino acids stimulate human growth hormone, causing the user to "burn fat" overnight. No data has been submitted to FDA to support this claim. Some very preliminary studies show that these amino acids may be able to stimulate human growth hormone, but whether this causes a person to lose weight is not known. If these pills do what the manufacturers claim, they could be dangerous because, in the process, they would also stimulate other hormones, altering insulin levels and carbohydrate metabolism, among other things.

Spirulina: A dark-green powder or pill derived from algae, it can be legally marketed as a food if it is correctly labeled and is not contaminated or adulterated. Claims that a component of spirulina, phenylalanine, is an appetite suppressant have not been scientifically proven.

Glucomannan: Advertised as an Oriental "weight loss secret,"



this substance is chemically processed from konjac root, a food used in Japan and other Eastern countries. Konjac root is a fiber source, but there is no scientific evidence that Glucomannan does anything other than create a feeling of fullness similar to ordinary bulky foods such as whole grains, apples, carrots and sprouts.

THE SENSIBLE APPROACH

If fad diets, pills, potions and devices can pose more health problems than they solve, what is the dieter to do? Is there a safe, effective way to lose weight?

The answer does not involve miracles or new discoveries. Losing and maintaining weight is a scientific matter. To lose weight, a person must use more calories than are taken in. This can be done either by eating less or by exercising more; but most experts recommend a combination of the two. The benefits of increased exercise, by the way, go beyond their calorie-burning capability during the activity. Some authorities believe that exercise decreases the appetite in addition to burning calories at a higher rate for some time following the exercise period. Also, many people find that when they exercise they feel better, not an unimportant advantage to the dieter.

Before embarking on any weight-loss program, would-be dieters should consult their physicians to be sure there are no underlying medical problems and that the diet and exercise program they are contemplating is right for them. Talking to a registered dietitian or qualified nutritionist can also be helpful.

Women should be aware that they face more of a challenge in losing weight than men do. Because they generally need fewer calories than men simply to maintain their weight, women have to reduce calories to a lower level in order to lose. For example, most men can lose one to two pounds a week consuming 1,500 to 1,600 calories a day, whereas many women may have to cut down to 1,000 to 1,200 calories a day to achieve the same weight loss.

Because she is consuming fewer calories, a female dieter needs to pay especially close attention to the nutrient value of the foods she eats. Anyone—male or female—considering a diet of 1,000

calories or less should discuss with a physician whether a vitamin-mineral supplement at the level of the U.S. Recommended Daily Allowances is advisable.

Although women may have more of an uphill battle than men when it comes to weight loss, the same basic principles of a healthy way to lose weight apply to both:

- Consult a physician and, if possible, a dietitian before embarking on any very restricted diet.
- Aim for a moderate weight loss of one to two pounds a week. Research has shown that losses in excess of this tend to be losses not of body fat but of water and lean muscle.
- Reduce portion sizes but maintain a balanced diet from the four basic food groups: grains and cereals; eggs and dairy products; fruits and vegetables; and meat, poultry and fish.
- Limit intake of fats, sweets, and high-calorie foods.
- Exercise regularly—increase exercise if possible.

Some dieters also find it helpful to count calories in order to keep track of how much they're taking in. It also can be helpful to eat several smaller meals, rather than three large meals a day.

As for weight maintenance, once the pounds are shed, many experts recommend that dieters become aware of the eating habits that made them gain weight in the first place so that they won't return to them. One way to keep weight down is to stay with the same foods that were eaten during the diet, but with somewhat larger portions. After weight loss, some people find it useful to continue counting calories to make sure they are not starting to overeat again. And any exercise program undertaken while dieting should be continued as part of life's daily routine.

Much of the failure and relapse experienced by dieters is due to unrealistic expectations that fad diets, pills, potions or devices will quickly and magically "burn away" excess pounds. Losing weight is not magic. It is the result of applying basic scientific principles to eating and exercise habits. A lasting weight loss cannot happen overnight; it is a lifetime endeavor. ■

Judith Willis is editor of FDA's Drug Bulletin, a publication for health professionals.

The Notebook: a potpourri of items of interest gathered from FDA news releases, other news sources, and the Federal Register (designated FR, with date of publication). The Federal Register is available in many large public libraries.

■ Squirt & Co. has asked permission to use **aspartame** as a sweetener in ready-to-serve, non-refrigerated, pasteurized, aseptically packaged dilute fruit juice beverages (FR April 2).

■ FDA's list of dried spices and vegetable seasonings that can be treated with **gamma radiation** has been expanded to include additional herbs, spices and vegetable seasonings and blends of these seasonings. The action was taken in response to a petition from Radiation Technology Inc., Rockaway, N.J. (FR April 18).

■ **Asthmatics** were advised in April that a prescription inhaler sold by Dorsey Laboratories under the names Metaprel Asthma Mist and Metaprel Metered Dose Inhaler were recalled for subpotency. Other Metaprel products were not involved in the recall.

■ Research and research support activities at FDA's **National Center for Toxicological Research** will be consolidated in a new Office of Research and an Office of Research Services. The Office of Scientific Intelligence has been abolished (FR April 24).

■ **Oral acetazolamide** may now be used to prevent or treat acute mountain sickness, and FDA has asked manufacturers to include this recommendation in their labeling. Other approved uses of the drug include treatment of edema (fluid retention) due to congestive heart failure, certain epileptic seizures, and open-angle glaucoma (FR April 17).



■ FDA will begin certifying **human insulins** as soon as the official reference standard becomes available from the United States Pharmacopeial Convention. Human insulin is not derived from humans but may be manufactured by enzymatic modification of pork insulin or by recombinant DNA technology (FR April 11).

■ Food-grade **salt sales** dropped 17 percent in the late 1970s and early 1980s, William Dickinson, president of the Salt Institute, told a recent meeting of FDA's Sodium Education Task Force. The revelation was made in response to a report by the Center for Science in the Public Interest indicating there was no decrease in the sodium content of processed food products between 1983 and 1984.

■ **Bacon** manufacturers would be permitted to lower the amount of **nitrite** added to their products under a proposed regulation of the U.S. Department of Agriculture. Implementation of the proposal would reduce the incidence of nitrosamines while retaining the same level of protection against botulism (FR April 15).

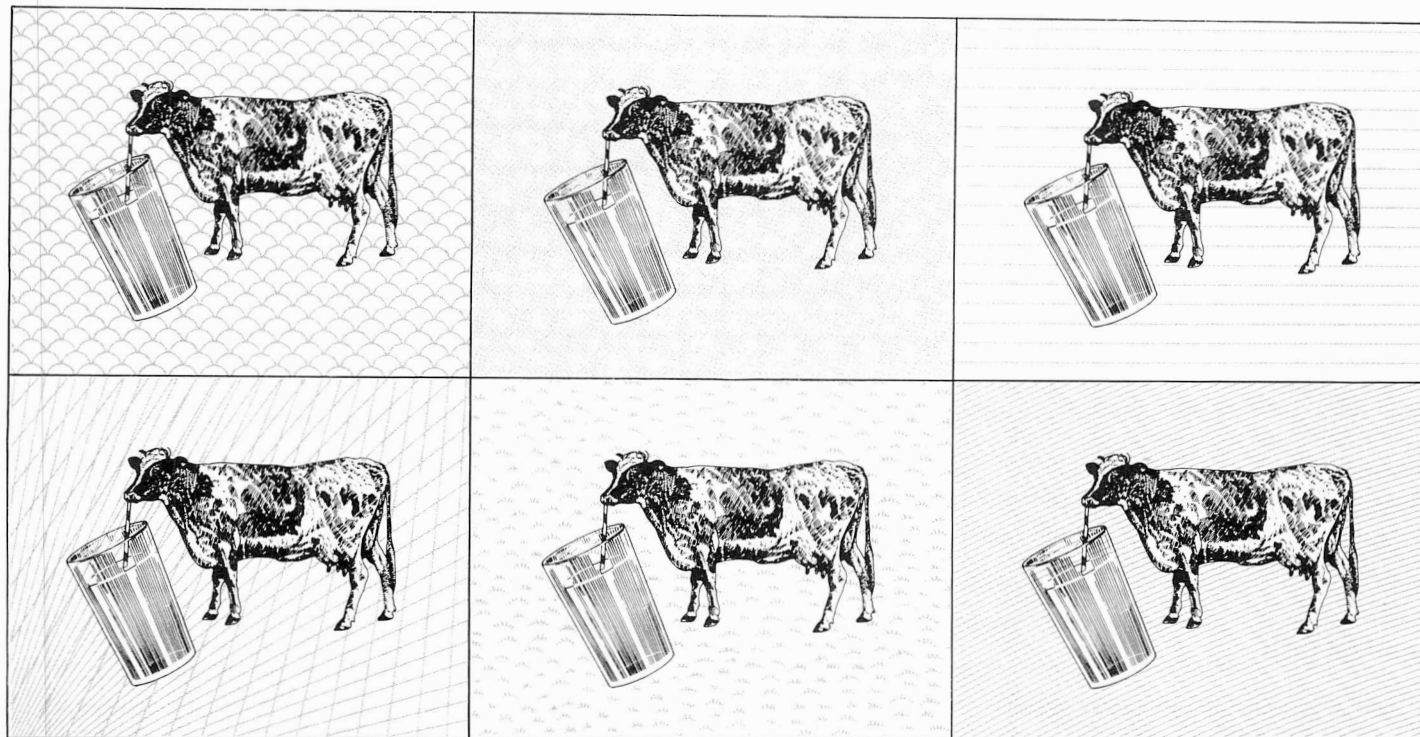
■ The concentration of **lead in canned foods** today is less than half that of four years ago, according to FDA's Center for Food Safety and Applied Nutrition and the National Food Processors Association (NFPA). The level today is 0.12 parts per million compared to levels of 0.31 parts per million four years ago. FDA and NFPA data also show that lead levels in non-lead soldered cans average about one-fifth those in soldered cans.

■ **Cytotoxic testing** for allergic diseases is unreliable as a diagnostic tool and is not generally recognized by qualified experts as effective, says FDA in a new compliance policy guide. Cytotoxic test kits marketed for use in the diagnosis of allergic diseases are adulterated and misbranded devices under the Food, Drug, and Cosmetic Act. Single copies of the policy guide, "Cytotoxic Testing for Allergic Diseases," are available from the Dockets Management Branch (HFA-305), 5600 Fishers Lane, Rockville, Md. 20857 (FR April 9).

■ Three prescription **topical anti-infective drugs** have been reformulated for over-the-counter (OTC) use: a cream product that originally contained neomycin sulfate, polymyxin B sulfate and gramicidin and now contains only the first two ingredients; and an aerosol and a powder containing bacitracin zinc and polymyxin B sulfate. Neomycin sulfate was in the prescription version of the aerosol and powder but was dropped from the OTC products (FR April 17).



Lab Warns Cow: Don't Drink Your Milk



by Annabel Hecht

"Disaster Linked To The Food You Eat!" screamed the headline on advertisements in a number of upstate New York newspapers last August. Headaches, stomachaches, sinus problems, and skin problems are all linked to the food we eat, according to the ads. The Cytotoxic III testing program provides "detailed examination of food and chemical sensitivities," the ads explained. Interested persons were invited to attend clinics in hotels in Buffalo, Albany and Rochester to learn about this revolutionary new blood test, offered by a California firm called Bio Health Centers.

So enticing were the ads that investigators from both FDA and the New York health department independently decided to investigate. The FDA investigator's interest was not personal food allergies but, rather, possible fraud. The New York officials also were concerned about fraud and about violations of the state's public health laws governing laboratories. When the two agencies learned of one another's investigations, they worked together to put Bio

Health Centers out of business in New York. All of this with the help of some cow's blood from a local slaughterhouse.

Bio Health Centers (BHC) is a division of Tannare International Inc., a corporation with its principal place of business in Costa Mesa, Calif. Director of operations is David Diem, and Dr. Roger J. Palmieri, Newport Beach, Calif., is directing physician. BHC conducts the Cytotoxic III food sensitivity testing program through a mail-order operation as well as in clinics in hotels and other establishments.

Cytotoxic testing is being touted by some allergy clinics, health centers, and testing laboratories as a means of detecting food allergies that supposedly are the cause of a variety of bodily ills. The theory behind the procedure is that the white cells in a sample of blood taken from a patient will react in some way (such as disintegrating, collapsing or changing shape) when exposed to a food to which the patient is allergic. The testing is supposedly done with specially prepared extracts of foods. (See "The Flaw In Cytotoxic Testing: There's No Proof It Works" in the October 1984 *FDA Consumer*.)

One problem with this theory is that there are no products on the market that have been demonstrated to be effective in cytotoxic testing, according to FDA, and no manufacturer has submitted evidence to support the marketing of any product for this use. As far as the agency is concerned, the cytotoxic test is an unproven diagnostic procedure.

BHC's method of operating in New York was to set up blood collection clinics in local hotels and solicit clients through newspaper advertisements. Those who responded were offered the Cytotoxic III testing program. All they had to do was part with some blood and \$350. The blood sample was to be sent to California for analysis. In due course, the clients were to receive a diagnosis of their food and chemical sensitivities, which would enable them to determine what foods to avoid in order to cure or alleviate obesity, fatigue, high blood pressure, and a wide variety of other ailments.

Investigator Frank Golden of FDA's Buffalo office made an appointment to attend one of BHC's clinics, but before he got there, the testing program was

abruptly canceled. The New York investigators were similarly thwarted.

The firm was not about to lose these potential customers, however. Golden and the state investigators were told that the Cytotoxic III test was available through the mail and were subsequently sent a packet of information. Both federal and state investigators ordered BHC's blood collection kit—at a cost of \$50—and received an empty tube for the blood sample, a styrofoam shipping container, and a cold pack (which was to be frozen and packed in the container to preserve the blood sample when it was shipped).

Also included were two pages of directions, a four-page questionnaire, a "client agreement," and an "authorization for venipuncture" over Palmieri's stamped signature. Peter Eiss, an investigator employed by the New York attorney general, filled out the questionnaire with his own health history, but he submitted blood provided by a doctor employed by the state health department. The cytotoxic analysis that came back, duly signed by

Palmieri, indicated that the patient was sensitive to a variety of foods, such as halibut, watermelon, string beans, cheese, pork, turkey and goat's milk. In fact, the woman who gave the blood sample enjoys excellent health and has never had an allergic reaction to any of the foods listed.

FDA's Golden went one better. He obtained cow's blood from a local slaughterhouse and submitted it as his own, along with the questionnaire, completed with partially factual and partially fictitious data, and \$300, the balance due.

In just over a week, the laboratory sent back the blood analysis, an insurance claim form, a suggested diet, and various pieces of promotional literature for Cytotoxic III. Apparently, whoever did the testing didn't recognize that Golden had sent something other than human blood, for the analysis showed that the cow was allergic to 22 of 187 substances tested, including cow's milk, cottage cheese and yogurt.

In February, the New York attorney general obtained a temporary restraining

order against BHC, based in part on evidence provided by FDA's Golden. The order prevents BHC from soliciting or accepting blood specimens for laboratory examinations and from collecting, processing or storing human blood or blood derivatives within the state of New York without a permit pursuant to the state's public health laws. Cooperating with the Buffalo district office and New York officials, FDA's Santa Ana, Calif., resident post served the restraining order.

The story hasn't ended for Bio Health Centers. Even before New York's action was initiated, California's Board of Medical Quality Assurance had already become interested in the firm's activities. Investigator Golden was asked for an affidavit as evidence in support of California's case. In addition, FDA's Los Angeles district office is also investigating BHC and two possible suppliers of the blood-testing kits.

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

Smoked Fish

There was something about the Panamanian vessel *Fatuk* that roused the suspicions of U.S. customs officials in Providence, R.I., when the vessel docked there on the first of March—suspicions that, by the end of the day, put FDA's Boston laboratory on overtime status.

The *Fatuk*'s journey had begun in Senegal, West Africa, in January, with a side trip to Colombia. What made the customs officials suspicious was that the *Fatuk* was built for long-line fishing, but March is the wrong time of the year for long-line fishing in the waters around Providence. And it's not likely that a Panamanian vessel

would be engaged in this type of fishing. There also was something "fishy" about the cargo—more than 84,000 pounds of frozen shark. There was no consignee in the area for that kind of cargo.

District Director of Customs Joe Kenney initially detained the *Fatuk* for safety violations, but when he investigated further his suspicions were confirmed. Buried under the frozen shark was 26 tons of marijuana.

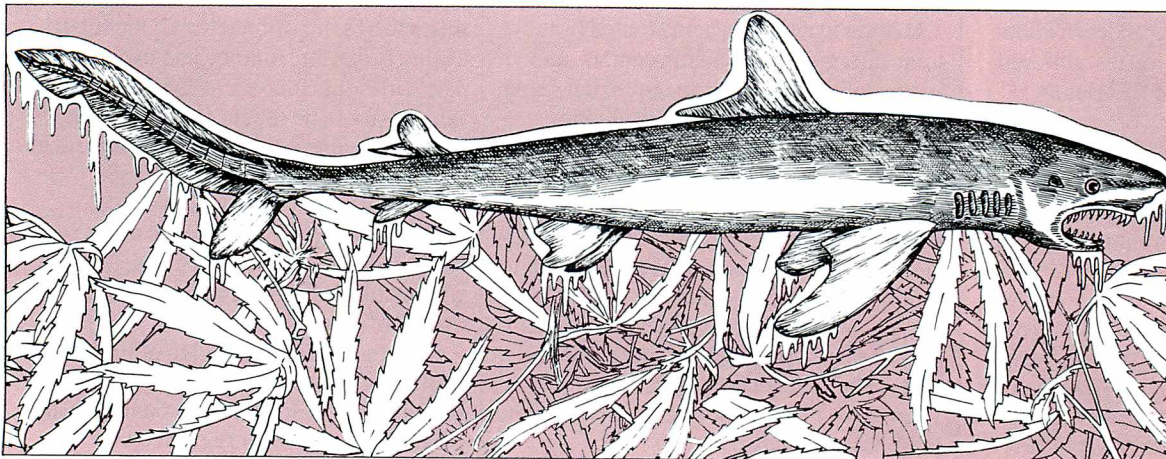
Customs promptly seized the *Fatuk* and thereby became the new owner of the frozen shark, which was to be sold. Because of concerns about the quality of the fish, FDA's Providence office was called for help. However, it was Friday and

the cargo could not be kept on board over the weekend, so samples had to be analyzed right away. FDA investigators John Biello and Jay Beckwith took 12 samples of edible flesh, each weighing four pounds. The samples were taken to the Boston district office laboratory.

Working into the late evening hours, chemists Ken Couture and Ken Panaro found that the shark contained 1.65 to 1.76 parts per million of methyl mercury. The accepted level of mercury in fish to be sold in the United States has been set at 1 part per million.

Armed with this information, Customs sold the shark to the Fulton Lobster Co., Elizabeth, N.J., with the stipulation that

the fish not be marketed in the United States. The captain and the first mate of the *Fatuk* left the ship just before the marijuana was discovered and have not been heard of since. Crew members who signed on in Venezuela were deported, and the marijuana was destroyed.



That Prison Flavor

The president and vice president of S.N. Long Warehouses Inc., a food warehouse in St. Louis, Mo., were each fined \$500 and sentenced to 14 days in jail because they had tried to sell food contaminated with rodents and insects.

The fines and sentencing were the final chapter in a case that began with an anonymous phone call to an investigator at FDA's St. Louis station late one afternoon in 1982 (see "Shell Game," Investigators' Reports, *FDA Consumer*, June 1983). The caller asked about reconditioning rodent-contaminated peanuts but hung up when the investigator pressed for details and the man's name.

From fragments of information the caller had furnished, the firm was identified as S.N. Long, and the consequent inspection resulted in the embargo of approximately 200,000 pounds of peanuts and 10,000 pounds of pumpkin seeds.

In addition, Gary Reeve and Raymond Laidet Jr., president and vice president of the company, and the corporation itself were later charged with seven counts of improperly storing food. The corporation pleaded guilty to all seven counts and was fined \$3,500. The officials each pleaded guilty to two counts, one of which was dismissed. They were sentenced on the other count to 14 days in prison, 200 hours of community service, and two years' supervised probation, in addition to the fine. U.S. Magistrate Robert Kingsland called the prison term "a flavor of prison life" and said he was "concerned for citizens of the community who assume that food is not adulterated when they buy it from the shelves."

No Drugs In The Milk

What do obstetricians and veterinarians have in common? Both must be careful that the drugs they give to their patients do not end up in someone else's body, too. For obstetricians, there is (usually) only one other body to worry about. But veterinarians who treat food-producing animals (such as cattle, swine and chickens) have to be concerned with a much larger population. And when veterinarians are not careful enough, FDA steps in.

In March 1984, FDA sent letters to more than 40,000 veterinarians warning that they should not use chloramphenicol to treat food-producing animals. Chloramphenicol is a potent antibiotic used in

human and veterinary medicine. In veterinary practice, it is approved only for use in dogs but has been widely used to treat infections and respiratory illnesses in food-producing animals. This use could result in harmful residues in the meat or milk from the treated animals. (The drug is so potent that fatal aplastic anemia has occurred in persons exposed to chloramphenicol while administering it to animals.)

Several months after the letters were sent, investigator Mark Lynch from the agency's Buffalo district office saw a veterinarian using chloramphenicol to treat a sick cow. The district office sent a letter to the clinic where the veterinarian worked, Mooers Animal Clinic, Mooers, N.Y., warning that this use of chloramphenicol was illegal and must stop.

Investigator Lynch returned to the clinic several months later for a follow-up inspection. He found no stocks of chloramphenicol, but he did find that the clinic was using another drug in an unapproved way. The drug was xylazine hydrochloride (brand name Rompun), which is approved as an analgesic and sedative for use in horses, dogs and cats. The clinic staff was using it to sedate cows and goats. FDA was concerned that harmful residues might end up in the milk from these animals.

The head of the clinic, Dr. Wayne Evans, D.V.M., said that Rompun was important to his practice. He said that it was usually given together with various antibiotics and that he felt the withdrawal times used for the antibiotics would also be adequate for the sedative. (FDA requires that when food-producing animals are treated with drugs, specified withdrawal times be followed so that harmful amounts of the drug will not be in the animal's meat, milk or eggs by the time the animals or their products are marketed.)

But FDA also questioned the withdrawal times used by the clinic for the antibiotics and sent another letter requesting that the clinic alter its practices, specifically in regard to drug withdrawal times. The letter also noted that xylazine is a suspect carcinogen and that there is insufficient data to prove that its use in food-producing animals is safe. The letter concluded, "We object to the manner in which you use xylazine without an extended withdrawal period."

The clinic asked for and received FDA's help in dealing with the problem; a follow-up inspection will determine if these efforts are successful.

Sweet Secret

Companies that follow the rules in making and selling their products do not appreciate having to compete with those that don't. For that reason, the Food and Drug Administration gets a fair number of what are called "trade complaints," objections by other companies that a competitor is behaving illegally and unfairly.

One such complaint came to FDA's Brooklyn district office earlier this year, saying that the William J. Elwood firm in Copiague, Long Island, was using saccharin in its line of dietetic foods but not showing it as an ingredient on the label and not displaying the required warning that saccharin has been linked to cancer in laboratory animals. The suspicious complainant had had the Elwood products tested by an independent laboratory, which found saccharin in ketchup, jellies and food dressings.

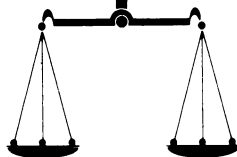
One of the resident investigators at FDA's Hicksville, N.Y., office inspected the Elwood firm and found calcium saccharin in the bulk storage area. But Elwood management would not allow the investigator to review production records—a perfectly legitimate request—to determine the extent of saccharin use. Management also would not allow him to see the shipping records—another legitimate request—which would have told who was receiving the mislabeled products.

However, the investigator did learn the names of several customers, and an investigator in FDA's Newark office was asked to get product samples and records from a New Jersey customer. The shipping records and invoices established that the goods had moved in interstate commerce, giving FDA clear jurisdiction.

The samples were tested in FDA's New York regional laboratory and saccharin was found in them. Based on these findings, FDA obtained a federal court order, and a U.S. marshal seized 125 cartons of Elwood's mislabeled products, valued at \$4,000, at the New Jersey customer's location. Since labeling is the problem, Elwood has the option of relabeling the products to show that saccharin is an ingredient. Or the company can allow the seizure to stand and the products to go unclaimed and perhaps be destroyed.

—This small sample of reports from the field was prepared by Annabel Hecht, Carol Ballentine, Gary Lloyd and Richard Thompson.

Summaries of Court Actions



Summaries of Court Actions are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act. Summaries of Court Actions 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.

Summaries of Court Actions are prepared by Food and Drug Division, Office of the General Counsel, HHS.

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

SEIZURE ACTIONS

Foods/Contamination, Spoilage, Insanitary Handling

PRODUCT: Beans, dried, creamed coconut bars, and dried green peas, at Bronx, S. Dist. N.Y.; Civil No. 82-Civ. 3014(PNL).
CHARGED on or about 3-21-82: While held by Kwak's Trading Co. Inc., Bronx, N.Y., the creamed coconut bars contained rodent filth, and all of the article had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 63663; S. No. 82-138-311 et al.; S.J. No. 1)

PRODUCT: Catsup, bottled, at Atlanta, N. Dist. Ga.; Civil No. C-82-823A.

CHARGED 4-21-82: When shipped by KMC Foods Inc., the article (labeled "Big Star Tomato Catsup . . . Dist. by Big Star Products, Inc. . . . Atlanta, Ga.") contained decomposed tomato material—402(a)(3).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 63707; S. No. 82-288-870; S.J. No. 2)

PRODUCT: Chili peppers, at Chicago, N. Dist. Ill.; Civil No. 80-C-3005.

CHARGED 6-12-80: While held by Herrera Brothers Co., Chicago, Ill., the article had been held under insanitary conditions—402(a)(4).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 62857; S. No. 80-248-505; S.J. No. 3)

PRODUCT: Corn, white, frozen, at Birmingham, N. Dist. Ala.;

Civil No. CV 84-L-31-S.

CHARGED 1-3-84: While held for sale, the article contained rodent filth—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64166; S. No. 84-403-312; S.J. No. 4)

PRODUCT: Corn husks, at El Paso, W. Dist. Texas; Civil No. EP-83-CA-257.

CHARGED 8-9-83: While held for sale by Bueno Foods Inc., El Paso, Texas, the article had been held under insanitary conditions—402(a)(4).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64064; S. No. 83-296-880; S.J. No. 5)

PRODUCT: Cream of coconut beverage mixer, canned, at El Paso, W. Dist. Texas; Civil No. EP-83-CA-245.

CHARGED 8-4-83: While held for sale, the article was unfit for food since it was in swollen cans—402(a)(3).

DISPOSITION: The article was claimed by Cover-Tex Inc., El Paso, Texas, who denied the charge. Subsequently, the claimant failed to appear. Default—ordered destruction. (F.D.C. No. 64059; S. No. 83-296-879; S.J. No. 6)

PRODUCT: Flour, cornmeal, and other grocery stocks, at Shreveport, W. Dist. La.; Civil No. CV 83-0085.

CHARGED 1-5-83: While held by Malone & Hyde Inc., Shreveport, La., some of the articles contained rodent filth, and all of the articles had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 63940; S. No. 83-383-254 et al.; S.J. No. 7)

PRODUCT: Rice, at Seattle, W. Dist. Wash.; Civil No. C 84 1089.

CHARGED 8-17-84: While held by Golden International Import & Export, Seattle, Wash., the article contained insect filth and had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64358; S. No. 84-416-481; S.J. No. 8)

PRODUCT: Rice flour, and chili powder, at Houston, S. Dist. Texas; Civil No. H-83-5094.

CHARGED 8-16-83: While held by Overseas Supply Center, Houston, Texas, the articles contained rodent and insect filth, and the articles had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 64061; S. Nos. 83-292-742/3; S.J. No. 9)

PRODUCT: Tomato paste, canned, at North East, W. Dist. Pa.;

Civil No. 82-264-Erie.

CHARGED 11-15-82: When imported from Brazil, the article (labeled "Tomato Paste . . . Product of Brazil . . . Cipelli") contained decomposed tomato material—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63891; S. No. 83-252-578; S.J. No. 10)

Foods/Economic and Labeling Violations

PRODUCT: **Concentrated orange juice, frozen**, at Lansing, W. Dist. Mich.; Civil No. G84-714-CA5.

CHARGED 6-26-84: When shipped by Citrus Concentrates Inc., Plymouth, Ind., the article failed to conform to the definition and standard of identity for frozen concentrated orange juice, since the article contained the added ingredient sodium benzoate—403(g)(1).

DISPOSITION: Default—destruction. (F.D.C. No. 64322; S. No. 84-329-347; S.J. No. 11)

Drugs/Human Use

PRODUCT: **Laxative and stool softener capsules**, at Murray, W. Dist. Ky.; Civil No. 80-0131-P.

CHARGED 6-19-80: When shipped by Pharmacaps Inc., Elizabeth, N.J., the article had been manufactured, processed and held under circumstances that failed to conform with current good manufacturing practice—501(a)(2)(B).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63075; S. No. 80-209-003; S.J. No. 12)

PRODUCT: **Phenobarbital, ergotamine & belladonna capsules**, at Memphis, W. Dist. Tenn.; Civil No. 83-2886-HA.

CHARGED 10-26-83: [When shipped] by D. M. Graham Laboratories Inc., Hobart, N.Y., the article (labeled "Bergotal . . . Capsules . . . Manufactured for Stewart-Jackson Pharmacal Inc., Memphis, Tennessee . . . Mfg. By D. Graham, Hobart, N.Y.") had been processed, packed and held under circumstances that failed to conform with current good manufacturing practice—501(a)(2)(B); and the article was a new drug without an effective approved New Drug Application—505(a).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64113; S. No. 83-380-325; S.J. No. 13)

PRODUCT: **Prednisone tablets**, at Plainview, E. Dist. N.Y.; Civil No. CV-80-1148.

CHARGED 4-28-80: When shipped by Zenith Laboratories Inc., Northvale, N.J., the article (labeled "Prednisone Tablets U.S.P. . . . Manufactured For Interstate Drug Exchange, Inc., Plainview, L.I., N.Y.") was a new drug without an effective approved New Drug Application since it had been fabricated according to a revised formulation that had not been the subject of an approved supplemental New Drug Application—505(a); and the article's strength and quality fell below its represented strength and quality since it failed the U.S.P. content uniformity requirements—501(b). DISPOSITION: Default—ordered destroyed. (F.D.C. No. 62978; S. No. 80-208-749; S.J. No. 14)

Drugs/Veterinary Use

PRODUCT: **Anthelmintic liquid for dogs**, at Pine Bluff, E. Dist.

Ark.; Civil No. PB-C-82-418.

CHARGED 12-20-82: While held by Ms. Marty Neeley, Pine Bluff, Ark., the article (labeled "Heartworm, Red Mange Infection Treatment . . . for Dogs . . . At Last Product . . . Manufactured By: At Last Laboratories, Theodore, AL. . . . Distributed By: Summit Distributors . . . Huntsville, AL." and accompanied by labeling such as [pamphlet] "Attention Dog Owners! The At Last Product . . . At Last Arkansas Distributors, Pine Bluff, Arkansas" and [poster] "The At Last Product Sold Here . . . Distributed by At Last Of Arkansas Distributors . . . Pine Bluff, Arkansas") was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to its use and intended use—501(a)(5).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63779; S. No. 82-341-420; S.J. No. 15)

PRODUCT: **Chloramphenicol oral solution**, at Abington, W. Dist. Va.; Civil No. 84-0262-A.

CHARGED 8-1-84: While held by Washington County Veterinary Service, Abington, Va., the article was a new animal drug (approved for use in treating dogs), and no approved New Animal Drug Application was in effect with respect to the article's intended use in cattle (food-producing animals)—501(a)(5).

DISPOSITION: Default decree—ordered destroyed. (F.D.C. No. 64296; S. No. 84-360-644; S.J. No. 16)

PRODUCT: **Chloramphenicol oral solution**, at Harrisonburg, W. Dist. Va.; Civil No. 84-0104-H.

CHARGED 8-15-84: While held by John F. Spangler, D.V.M., Harrisonburg, Va., the article was a new animal drug (approved for use in treating dogs), and no approved New Animal Drug Application was in effect for the article's intended use in cattle (food-producing animals)—501(a)(5).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64297; S. No. 84-360-449; S.J. No. 17)

PRODUCT: **Diethylstilbestrol pellets**, at Kingfisher, W. Dist. Okla.; Civil No. 80-549-T.

CHARGED 5-8-80: While held for sale, the article was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to its use or intended use—501(a)(5).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 62992; S. No. 80-209-944; S.J. No. 18)

PRODUCT: **Neo-Terramycin neomycin oxytetracycline HCl soluble powder concentrate**, at Seattle, W. Dist. Wash.; Civil No. C-84-801R.

CHARGED 6-18-84: When shipped by Veterinary & Poultry Supply Inc., Goshen, Ind., the article (labeled "Neo-Terramycin . . . antibiotic . . . Distributed by Pfizer Agricultural Division, New York, N.Y.") was a new animal drug, and no approved New Animal Drug Application was in effect with respect to the article's use or intended use—501(a)(5).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64289; S. No. 84-398-087; S.J. No. 19)

PRODUCT: **Prednisone & chlorpheniramine maleate combination tablets and emulsion, ammonium chloride & guaifenesin expectorant compound, and iodinated casein mix**, at Shenan-

doah, S. Dist. Iowa; Civil No. 83-37-W.

CHARGED 5-6-83: While held by Vet-A-Mix Inc., Shenandoah, Iowa, who manufactured the articles using interstate components (and who used labels such as "Derma-Form Chewable Tablets [or "CorTabs", "Cortol . . . emulsion", "An-Tuss . . . expectorant" or "Vet-A-Mix Thyronex . . . Casein"] . . . Vet-A-Mix, Inc., Shenandoah, Iowa"), the articles were new animal drugs, and no approved New Animal Drug Application was in effect with respect to the articles' uses and intended uses—501(a)(5).

DISPOSITION: The articles were claimed by the manufacturer, who denied the charges and asserted that even if the drugs were found to be new animal drugs, the government had acted unlawfully in failing to approve the claimants' New Animal Drug Applications. The claimant served written interrogatories on the government. Subsequently, a consent decree ordered the articles destroyed. (F.D.C. No. 64005; S. No. 83-382-141 et al.; S.J. No. 20)

PRODUCT: Yeast, phosphate & calcium carbonate tablets, at La Mesa, Calif.; Civil No. 82-0074-GT(M).

CHARGED 1-25-82: While held by Solid Gold Health Products For Pets Inc., La Mesa, Calif., the article (labeled "PETZYMES . . . Manufactured for Solid Gold Health Products For Pets Inc. . . . La Mesa, CA. . . . Made in England") failed to bear adequate directions for use as an oral flea repellent for dogs and cats (as promoted by the dealer on local television, in retail outlets, and at a dealer display booth)—502(f)(1); and the article, when labeled as a flea repellent (e.g., with the handwritten phrase "Against Fleas" on the label), was a new animal drug and there was no approval of a New Animal Drug Application in effect with respect to such use and intended use—501(a)(5).

DISPOSITION: Consent—authorized release to the dealer for bringing into compliance. (F.D.C. No. 63475; S. No. 81-215-873; S.J. No. 21)

INJUNCTION ACTIONS

DEFENDANT: Harry A. Robinson, t/a Microbiological Media, San Ramon, N. Dist. Calif.; Civil No. C-81-3535-TEH.

CHARGED 9-4-81 in a Complaint for Injunction: That the defendant, at his San Ramon, Calif., plant, manufactured, processed, packed, labeled, stored and distributed in interstate commerce various microbiological culture media in plates, tubes and bottles (in vitro diagnostic products defined by statute as devices): that the labeling of some of such products had been false and misleading in that: (a) some "starch agar" lacked the starch (without which the product could not perform as intended) and (b) some products bore expiration dates (implying effectiveness for that length of time) when, in fact, the expiration dates had not been established—502(a); that some of the "starch agar" differed from its purported strength, quality and purity, since it did not contain starch—501(c); that a product represented as Tryptic Soy Agar with Yeast and 8% Sheep Blood (TSAY 8%) differed from its purported strength, quality and purity, since it contained surface and subsurface microbial growth (which could interfere with its diagnostic capabilities and could result in delayed patient treatment)—501(c); that all of such products were manufactured, packed and stored under circumstances that failed to conform with current good manufacturing practice—501(h); that FDA inspections revealed a number of specified deviations from current good manufacturing practice regulations; and that the defendant was well aware that his activities were in violation of the law.

DISPOSITION: A consent decree of injunction enjoined the violations complained of and enjoined any further operations concerning any in vitro diagnostic products involved in interstate commerce where FDA inspection finds non-conformance with current good manufacturing practice regulations. (Inj. No. 982; S. No. 80-220-525 et al.; S.J. No. 22)

MISCELLANEOUS ACTIONS

SUBJECT: Caffeine and its listing as a GRAS substance for cola-type beverages, Washington, Dist. Columbia; Civil No. 80-1581.

CHARGED 7-3-80 by Federation of Homemakers Inc., Washington, D.C., against HEW Secretary Patricia Harris and FDA Commissioner Dr. Jere E. Goyan, in a Complaint for Injunction, mandamus and declaratory judgment: That caffeine was listed in federal regulations as a multiple purpose GRAS (generally recognized as safe) food substance, limited to cola-type beverages; that beginning in 1969 FDA undertook a systematic scientific review of the status of all GRAS ingredients and that a committee established by the Life Sciences Research Office examined the world's scientific literature and FDA's data files, held a hearing, and reported that it was "inappropriate" to include caffeine as a GRAS substance, and that at current levels of consumption of cola-type beverages the dose of caffeine could induce effects such as central nervous system stimulation; that such reported conclusions rendered caffeine ineligible to be GRAS and without a lawful basis to be listed as GRAS; that the plaintiff had filed a citizen's petition requesting the FDA commissioner to strike caffeine from the GRAS list; that FDA had no alternative but to remove caffeine from the GRAS list; that the FDA commissioner had stated that if he acted to remove caffeine from the GRAS list, he would issue an interim food additive regulation; that the continued use of caffeine in cola-type soda-water beverages was not in the interest of the consumer; and that the court should order caffeine stricken from the GRAS list, should enjoin the inclusion of caffeine on any GRAS list, should enjoin any interim food additive regulation, and should declare that the issuance of any interim food additive regulation under 21 C.F.R. §180 was unlawful.

DISPOSITION: The government denied some of the substance and many of the conclusions of the plaintiff's charges, asserted that an order of mandamus was inappropriate, and asserted that the plaintiff had failed to exhaust available administrative remedies. The plaintiff moved for summary judgment, and the government opposed such motion and moved for either dismissal of the action or summary judgment on its own behalf.

On March 25, 1981, the court denied the plaintiff's motion for summary judgment and granted the government's motion of dismissal because the plaintiff's action ran counter to "all accepted principles of exhaustion of administrative remedies, administrative finality, primary jurisdiction, and ripeness for review." The court found that the report of caffeine being inappropriate as a GRAS substance was not a final administrative action, and that such an independent report did not require removal of caffeine from the GRAS list. It was also found that this was not a case where undue delay justified judicial intervention since the defendants were conscientiously and expeditiously attempting to resolve a complex matter in a reasoned manner and were complying with applicable procedural regulations. Finally, the court found that the commissioner's proposed interim regulations were within his authority. (Misc. No. 601; S.J. No. 23)



HAVE YOU HEARD?

The ticking of a watch...
The dripping of a faucet...
The soft music of a violin. To some people, those sounds go unheard. Those people are among the almost 20 million Americans who suffer from hearing loss.

Today, hearing loss often can be treated, through surgery or drugs or, in many cases, with a hearing aid. Whatever treatment is needed, the first step in correcting a hearing loss is to see a licensed medical doctor, preferably an ear specialist.

In fact, the Food and Drug Administration requires that before a hearing aid can be sold,

the seller must obtain a written statement from the patient signed by a physician stating that the patient's hearing has been medically evaluated and that the patient is considered a candidate for a hearing aid. (Patients over 18 may waive this requirement, but the seller must make it clear that to do so is not in their best health interests.)

FDA has prepared a slide/tape show on hearing aids and how to select and purchase the best one to correct a particular hearing problem. Important questions are answered on hearing tests, how hearing aids work, FDA's regulations of hearing aids, different types of aids, fitting, rental, sales, warranties and service of hearing aids, and what to do if you have a complaint about your hearing aid or a hearing aid salesperson.

Groups and clubs can borrow a copy of this slide/tape show, titled "Have You Heard?", by contacting the nearest FDA office. (For the address and phone number, see the government listings in your phone directory.)