

^{FDA} CONSUMER

VOL. 20 NO. 5

JUNE 1986

Poison Ivy

The Itch Of The Great Outdoors.





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Samples of typical meals from the United States and 10 other countries are being analyzed for harmful substances and certain nutrients. If nutrient deficiencies are found, the solution could be national food fortification programs.

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Immunization isn't just for kids; there are several vaccinations that adults should get, too. But many of us haven't received the shots we need.

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Viroids, prions, virions: Not strange creatures from outer space, but newly discovered members of the submicroscopic world of viruses. Scientists are learning more and more about these disease-causing agents, but many mysteries remain.

The Itch of the Great Outdoors 22

For many, the enjoyment of a trek in the woods is spoiled by the ensuing itch of poison ivy (or oak, or sumac). A number of medications can provide some relief, but the best cure is to learn to avoid the three-leaved devils in the first place.

Food Allergies: Separating Fact from 'Hype' 25

How common are food allergies? Can they cause not only physical reactions—such as hives from strawberries—but also changes in mood and behavior? While scientists debate the issue, FDA searches for solid data on adverse reactions to foods.

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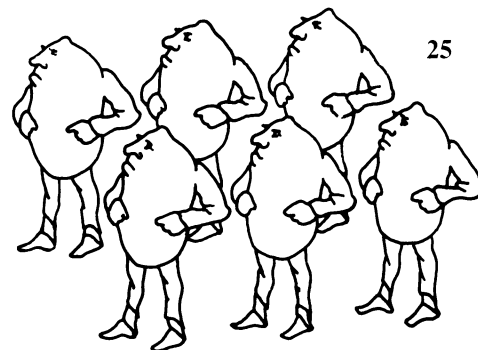
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← **Inside Front Cover**

People with disabilities are on the move as, one by one, environmental barriers succumb to the cutting edge of technology. To learn about the Utah Artificial Arm (shown on facing page), cochlear implants, reading machines for the blind, and other High-Tech Help for the Handicapped, turn to page 8.

(Courtesy University of Utah Center for Engineering Design)

Report on '84 Drug Sales

Americans had more than 1.5 billion prescriptions filled in 1984 and spent \$18.4 billion for them, according to FDA's sixth annual review, "Drug Utilization in the U.S. — 1984."

The number of prescriptions, both new and refills, was up 2 percent from 1983. The 1984 total of 1.53 billion equals the record number reached in 1973. New prescriptions accounted for 49 percent of the 1984 total; refills, 51 percent. Generic drugs represented 11 percent of all new prescriptions.

Patients aged 60 and older accounted for 39 percent of total drug use in 1984, while those under 20 accounted for only 17 percent. Women represented 60 percent of the drug use, according to the review.

Dyazide, a diuretic, was the most frequently prescribed drug in 1984. The second most prescribed product was Inderal, a beta-blocking drug for heart patients. Lanoxin, a brand of digitalis, another heart drug, was third. Valium, the best known of the minor tranquilizers, was fourth, and the combination product of Tylenol and codeine ranked fifth. Five years ago Valium stood in first place, while Dyazide was sixth. Lanoxin moved up from the number eight spot in that time.

Half of all prescriptions dispensed in 1984 were for cardiovascular drugs, systemic anti-infectives (antibiotics), psychotherapeutic drugs, analgesics (painkillers), and diuretics. Diuretics—used mainly to treat cardiovascular conditions—and other cardiovascular drugs together accounted for 22 percent of all prescriptions.

Cardiovascular drug prescriptions increased from 132 million in 1975 to 222 million in 1984. Beta blockers and calcium-channel blockers account for most of the increase. Diuretic use also increased over the past 10 years, going from 78 million prescriptions in 1975 to 110 million in 1984. Prescriptions for thiazide diuretics have stayed fairly constant over the 10 years, but potassium-sparing diuretics have more than doubled.

Antibiotic use overall fluctuates little from year to year and has remained fairly stable over time (208 million prescriptions in 1975 and 196 million in 1984). The type of product prescribed has changed, however, with an eight-fold increase in the use of amoxicillin coupled with a 53 percent decrease in the use of tetracyclines.

Prescriptions for psychotherapeutic drugs dropped significantly between 1975 and 1981, due largely to a decrease in the number of minor tranquilizers prescribed. However, prescriptions for "major tranquilizers" also decreased by about 20 percent. Since 1981 the number of

prescriptions for all types of psychotherapeutic drugs has risen 9 percent with the largest increases in monoamine oxidase inhibitors, lithium, analeptics (such as Ritalin), cyclic antidepressants, and antidepressant tranquilizers.

The annual review of U.S. drug use was prepared by FDA's Office of Epidemiology and Biostatistics. Analyses are based on data derived from three pharmaceutical marketing data bases: The "National Prescription Audit," the "National Disease and Therapeutic Index," and the "U.S. Pharmaceutical Market—Drug Store and Hospital Purchases." The review can be obtained from the National Technical Information Service, 5285 Port Royal Rd., Springfield, Va. 22161, sales desk telephone number (703) 487-4650.

The Advent of Penicillin—Correction

In the article "Syphilis and Gonorrhea: Old-Fashioned VD Still Flourishing" in the April 1986 *FDA Consumer*, the year in which penicillin was discovered was incorrect. Sir Alexander Fleming discovered the antibiotic in 1928, although it did not come into widespread use until World War II.

Consumer Forum

Cold Potatoes

I just received the March 1986 *FDA Consumer*. As usual, I found it very interesting. However, I think there's an error in "The ABCs of Food Storage." On page 14 the article says to store potatoes in a cool, dry place but not in the refrigerator. On page 12, however, the picture showing foods to put in the refrigerator's vegetable bin includes potatoes. Isn't this misleading?

B. J. Almond
Houston, Texas

Yes. The picture should not have included potatoes. They should be stored in a cool, dry place but not in the close confines of a refrigerator. They need ventilation.

What Price Quackery?

In your December 1985-January 1986 article ("Open Season on Quacks") you cite a supposed figure of \$10 billion as the "cost" of quackery. That figure is enor-

mously overinflated, and is not based on any rational or serious research or facts.

The figure apparently derives from a report of hearings by Rep. Claude Pepper's (D.-Fla.) House of Representatives subcommittee. However, when the figure was mentioned in the hearings it was not supported by any evidence. It was picked up, bandied about, and reprinted by people who had a vested interest in creating a "problem" where none actually exists.

The figure originally derived from the U.S. Postal Service, but they admitted to me that their figures were just an estimate and they had no evidence to back them up. . . .

For various political reasons, those people with a vested interest in smearing the wholistic health movement have irrationally lumped all nutritional aids in with actual quackery. The \$10 billion figure, as with much of the supposed FDA "reporting," is wildly exaggerated and based on no research or accuracy.

Joel Amkraut
Washington, D.C.

The statement that quackery costs Americans some \$10 billion a year did, indeed, come from a 1984 report by the Subcommittee on Health and Long-Term Care of the House Select Committee on Aging. In fact, the title of the report was "Quackery: A \$10 Billion Scandal." In the preface to the report, Rep. Pepper noted that "The subcommittee estimates the cost of quackery—the promotion and sale of useless remedies promising relief from chronic and critical health conditions—exceeds \$10 billion a year. The cost of quackery in human terms, measured in disillusion, pain, relief forsaken or postponed because of reliance on unproven methods, is more difficult to measure, but nonetheless real. All too frequently, the purchaser has paid with his life."

While the figure is of necessity an estimate (since quacks are generally reluctant to reveal the extent of their "take"), it is in line with similar estimates made by others involved in the fight against quackery. The Arthritis Foundation, for example, has estimated that Americans spend some \$2 billion annually for worthless or harmful arthritis "cures" alone. (This, incidentally, was estimated by Consumer Reports in 1979 to be 25 times the amount of money spent on arthritis research.)

The point is, there is no denying that quackery is a serious and costly public health problem, a problem that warrants the kinds of regulatory and public education efforts described in the December 1985-January 1986 article.



Steaming Away Caffeine

I enjoyed your article "Cancer, the Law, and Methylene Chloride" (March 1986). Which of the coffee manufacturers use the steam process to remove caffeine from coffee beans?

Susie Kop
Las Vegas, Nev.

None of the U.S. coffee manufacturers uses the steam, or water, process (which is a decaffeination method that does not use chemical solvents), according to the National Coffee Association in New York City. But water-processed decaffeinated coffee is available in this country, usually through specialty stores that sell the imported product. Generally, it is more expensive than domestic brands.

One of the principal manufacturers of such decaffeinated coffee is the Jacobs-Suchard Co., Seefeldquai 17, Zurich, Switzerland 8008. Although the company has no manufacturing plant in the United States, it does have a branch office/distributor: The Jacobs Coffee Co., 1400 E. Wisconsin St., Delavan, Wis. 53115.

The Nestle Foods Corp., White Plains, N.Y., a Swiss-owned company, manufactures two instant coffees in which natural oil from coffee beans is used to remove the caffeine. The process is patented in both the United States and Switzerland, according to a company spokesperson.

From U.S. to Thailand, Scientists Ask 'What's Cooking?'

by Chris Lecos

In a remote village in the Amazon jungle of Brazil, natives preparing their evening meal set aside an extra portion that will be blended into a thick, creamy "cocktail," freeze-dried, shipped thousands of miles away, mashed into powder, and bombarded with neutron radiation.

This same routine is taking place in a mountainous rural province of China, as well as in nine other countries, including the United States, where samples of typical diets are being sent to laboratories for analysis.

Scientists may not be tableside, but they are at their instruments, analyzing what was once breakfast, lunch and dinner as part of an international study of nutrient intakes—and possible deficiencies—in the diets of these diverse populations from around the globe.

The specific objective of the study is to collect samples of what selected groups of people eat daily in each country and to analyze them for the presence of 25 minerals, or trace elements—including some that are essential to human health and others that are toxic but nevertheless present in minute amounts.

In addition, the collected food samples will be analyzed for their food energy (calories), fiber and phytate content. (Phytates are substances found in most plant foods. If consumed in excess, they hamper the body's ability to absorb nutrients.)

The study is officially known as the Coordinated Research Program on Human Dietary Intakes of Biologically Important Trace Elements. The study, which took several years to organize, was initiated in late 1984 by the International Atomic Energy Agency (IAEA), an organization sponsored by the United Nations. The collection of food samples, now under way, probably will be finished in 1987. Analysis of the samples, along with a report of the results, is expected to be completed in 1989. Besides the United States, Brazil and China, the other countries involved are Canada, Iran, Italy, Spain, Sudan, Sweden, Thailand and Turkey.

Dr. G. Venkatesh Iyengar is chief scientist for the U.S. portion of the study. An analytical chemist who was born in India but who now resides in West Germany, Iyengar originally came to the United States through the Food and Drug Administration's Visiting Scientists Program. Most recently, he has been conducting research at the laboratories of the U.S. Department of Commerce's National Bureau of Standards (NBS) in Gaithersburg, Md. His work in the IAEA program has been jointly funded by FDA, NBS and the U.S. Department of Agriculture. Iyengar also worked on an earlier IAEA project to measure the amount of trace elements and other nutrients in the breast milk of women from six countries.

In the current study, Iyengar says that each of the participating countries is expected to provide between 30 and 60 food samples

for each population group chosen for the study. If deficiencies in any of the essential nutrients are found in any of the diets, Iyengar says the countries could develop food fortification programs to correct the problems. They are also being encouraged to do follow-up studies involving other nutrients.

The United States has used food fortification to overcome known widespread nutrient deficiencies for many years. For example, because of iodine deficiencies among many Americans, thyroid enlargement was a serious health problem in parts of this country until iodized salt was introduced in 1924. More than half the table salt now used in this country is iodized. Likewise, addition of fluoride to community water supplies has helped reduce the incidence of tooth cavities.

In the IAEA study, food samples that represent the daily intakes of selected population groups are taken to laboratories in each country where they are mixed in a special blender to create the creamy cocktail. The mixture, or composite, is then freeze-dried and shipped to IAEA's headquarters in Vienna, where the resultant cake-like mass is ground into a powder. IAEA sends the powder to five countries for analysis of the mineral or trace element content.

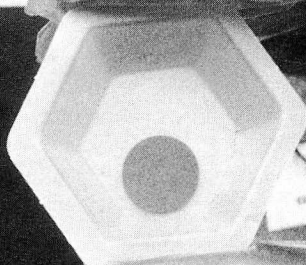
Several techniques are employed to evaluate the content of the foods. For example, at the National Bureau of Standards, a procedure known as neutron activation analysis is being used. This involves exposing the powdered composite to radiation with neutrons, producing radioactive nuclides that can be measured to reveal the elements that are present.

The NBS laboratories will analyze the food samples of a typical American diet for all 25 of the minerals. Samples from the other countries that are sent there will be checked for about half of the elements. Samples will be analyzed for other elements in laboratories in Ljubljana, Yugoslavia, at the University of Manchester in England, the University of Helsinki in Finland, and at IAEA's Vienna labs.

The 25 elements under study include some that are vital to good health, such as calcium, iron, sodium and potassium. Others are toxic, or can be if consumed in excessive amounts;

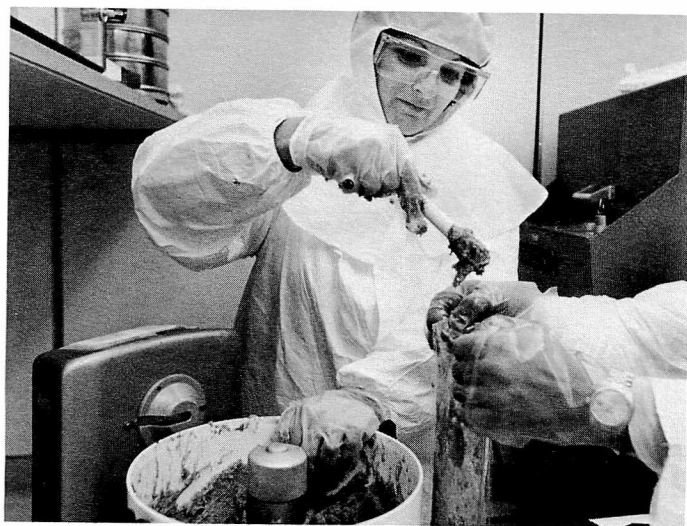
At right, at the National Bureau of Standards in Gaithersburg, Md., U.S. food samples for the international diet study—both liquid (in the jar labeled "cocktail") and solid (which were mixed in a special blender)—have been placed in plastic bags. Some of the samples will be freeze-dried, mashed into powder, and made into pellets, like the one shown, which will be tested for trace elements through a technique known as neutron activation analysis.

FDA-IAEA-NBS-USDA
NUTRITION PROJECT
COCKTAIL



K52 20
PORK, BACON, COOKED

K52 146
MILK, WHOLE



In the top picture, National Bureau of Standards research chemist Susan Stone stores U.S. food samples for the international diet study in a vat of liquid nitrogen, with temperatures from 150 to 180 degrees Fahrenheit below zero. Stone's special clothing helps avoid contaminating the samples. Before going into the super-cold vat, the samples are run through a blender and portioned into plastic bags (lower picture).

these include cadmium, lead, arsenic, mercury and selenium. Rounding out the list are aluminum, antimony, chlorine, chromium, cobalt, copper, fluorine, iodine, magnesium, manganese, molybdenum, nickel, phosphorus, tin, vanadium and zinc.

The current study excluded many other nutrients, such as vitamins. "We wanted a manageable program, so the number of food samples to be collected by each country was limited," Iyengar explained. "If you tried to analyze for all aspects of nutrition in the diets of each country, you'd never finish the project."

For some time, regular surveys have been made of the food intakes of Americans. However, in many other countries, the nutrient content of the diet is a big question mark.

"Our information on trace element nutrition in many parts of the world is very sketchy, and much of it was gathered under questionable scientific methods of sample collection and analyses," says Wayne R. Wolf, Ph.D., a research chemist who specializes in analyzing trace elements at USDA's Human Nutrition Research Center in Beltsville, Md. He predicted that the international program could someday help "raise world consciousness about the importance of trace elements to human health."

The IAEA, which fosters peaceful uses of atomic energy, such as the neutron activation analytical techniques, is coordinating the entire program and seeing that reliable food samples are col-

Dietary Minerals— Macro and Micro

More than 40 chemical elements and compounds—in the form of carbohydrates, fat, protein, vitamins and minerals—are essential parts of the human diet, nutrients the body must have to function properly.

The focus of the 11-nation dietary study in which FDA and other U.S. agencies are participating is on the mineral content of the foods that selected groups of people in each country eat as part of their normal diets. Unlike vitamins, which are organic compounds produced by living things, minerals are inorganic elements that are chemically stable and much less subject to loss from foods during cooking, storage, handling and processing.

Minerals are absorbed in the intestine and transported in the blood to other parts of the body. The amount of each mineral absorbed varies and is influenced by such

factors as its chemical form, other substances in the diet, and the body's need for the mineral.

Minerals perform a variety of functions in the body. Generally, they influence the acid-base balance of body fluids and affect the distribution of water throughout the body. They also play an essential role in the formation of bones and teeth, and in the life processes of cells.

There are two classes of minerals—macrominerals and micronutrients. The former include calcium, phosphorus, magnesium, sodium, potassium and chloride. These are present in the body in larger amounts and are required in the diet in amounts ranging from hundreds of milligrams to grams (28.35 grams equals one ounce).

The micronutrients include iron, manganese, copper, iodine, zinc, fluoride, selenium, molybdenum, chromium, aluminum, arsenic, boron, cadmium, nickel, silicon, tin and vanadium. These micronutrients, trace minerals, are found in the body in tiny amounts—so small that they are often measured in micrograms. (One microgram equals one millionth of a gram.) Some trace elements are found in the body even though there is no known need for them. These include aluminum, antimony, barium, boron, bromine, gallium, germanium, gold, lithium, mercury, silver, strontium and titanium.

The Food and Nutrition Board of the National Academy of Sciences/National Research Council, which determines the Recommended Dietary Allowances—or RDAs—for nutrients, has not established RDAs for 19 of the 25 minerals in the international diet study. RDAs are established by the board only after it has enough scientific data to support the recommended intakes, and the board believes there is adequate data only for calcium, iron, phosphorus, iodine, magnesium and zinc.

For sodium, potassium, copper, manganese, fluoride, chromium, selenium and molybdenum, the board has established what it calls “safe and adequate intakes.” In effect, the board is saying there is enough evidence to offer some dietary guidance but not enough to take the further step of establishing an RDA. For the remaining 11 minerals, there is not even enough data to set safe and adequate intakes.

Generally, most healthy people satisfy their mineral requirements through the foods they eat. However, mineral supplements sometimes are recommended by doctors for pregnant women, small children, people who are chronically or seriously ill, and those in other special medical circumstances. (For more about dietary minerals, see “Tracking Trace Minerals,” July-August 1983 issue of *FDA Consumer*.) ■

lected. FDA is gathering samples of American diets when it makes the periodic food collections for the Total Diet Survey, an ongoing food collection and analysis program started by the agency in 1961. (See “A Hard Look at What We’re Eating” in the April 1984 issue of *FDA Consumer*.)

FDA uses the Total Diet Survey to measure the presence of several hundred chemicals, including pesticides, industrial chemicals, and various trace elements. The foods are purchased four times a year by FDA employees at retail food outlets around the country and are shipped to the agency’s Kansas City, Mo., lab for analysis.

James T. Tanner, Ph.D., an FDA specialist in nutrient surveillance, said the U.S. samples will also be used by FDA for a separate study of their vitamin content. Tanner is in charge of coordinating FDA’s contributions to the international study.

USDA is responsible for analyzing the phytate levels of all the samples, storing the results of the mineral analyses in a computerized data base, and interpreting the information.

Obviously, the diets in the international study are quite diverse. For example, the U.S. samples will be based on 201 items of food and drink that represent the average daily intake of a 25- to 30-year-old, healthy, adult male. That is equivalent to 3,075 grams (more than seven pounds) of food. The sample would include what one might expect a young American male to be eating—

some pizza, steak, eggs, hamburger, milk shakes, and even some beer and whiskey, among other things.

In contrast to the extensive and varied diet of Americans, Brazil is studying a group of poor families from the village of Manaus in the Amazon jungle. Their diet is mainly rice and fish. Brazil also plans to do separate studies on the effects of zinc supplements on infant growth and on the prevalence and duration of diarrheal disease.

China’s food samples reflect the diets of an urban population, of rural residents in a northern province where wheat is a staple, and of predominantly rice-eating families in a rural, southern province. Canada’s food samples are from four regions of the country. The Institute of Nutrition in Thailand is collecting samples of foods consumed by active working adults and pregnant women in two regions.

Hopefully, other countries will use the experience these 11 nations will gain from this study to develop or improve their own nutritional data bases. Iyengar predicted the present project could some day “open the way to linking health problems in some countries to nutritional inadequacies and set the stage for intervention [through food fortification programs], if necessary, to improve the diet of the target population group.” ■

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

High-Tech Help for the Handicapped

by Dixie Farley

The subway train stops, delivering its load of travelers. Some head for an elevator that will take them up and out of the station. While they're waiting, a friendly voice says, "Move to the side, please." The group parts and, as the elevator doors open, a wheelchair glides swiftly into place.

Although the man in the chair can't move his fingers well enough to use conventional stick controls, he maneuvers expertly. To move right, left, forward or back, he simply presses corresponding areas of the control panel he holds on his lap.

According to the National Center for Health Statistics' most recent (1982) household survey, more than 56 million Americans have some type of physical impairment. But, like that man in the wheelchair, many Americans with disabilities now work and play in the mainstream of life—thanks to improved mobility devices, computerized communications aids, artificial body parts, and other products made possible by advanced technology.

In proclaiming 1983 through 1992 as the National Decade of Disabled Persons, President Reagan called attention to U.S. "innovative research and development both in technology and training techniques to assist the disabled." He urged all Americans in both the private and public sectors to join in this work. The president held a special news conference last December to praise those who are working to reduce the impact of disabilities.

Here is a look at some of the high-tech services and products for people with disabilities:

Utah Arm

An artificial arm called the Utah arm has been developed by the University of Utah for use by above-the-elbow amputees. Instead of traditional cables to move the hook or hand, electromyographic signals (electric signals from muscles) in the patient's own upper arm or shoulder are the source of movement. The signals, which are picked up by electrodes placed on the skin surface, pass through microminiaturized circuits to run motors that can move the arm slowly for delicate operations or fast for normal movement. The batteries, circuits and concepts used in the arm are byproducts of the aerospace industry. Weighing about half as much as a human arm, the Utah arm can lift a little over two pounds or support nearly 50 pounds. It can be fitted with a motorized hand developed by a German firm.

Computerized Voice Synthesizers

Portable, computerized voice synthesizers are available to help nonspeaking people to communicate. For those who can't type on a keyboard because they lack finger control, a headband with a light-beam pointer may be used with some models. The person points the light beam at the special keys to give the computer commands.

To "play" a verbal message for a listener, the user presses computer keys, or a sequence of keys, that have picture symbols on them. This recalls the voice-synthesized message from the computer's memory. Both readers and nonreaders can use the system

Utah Arm

(Courtesy University of Utah Center for Engineering Design)



Computerized Voice Synthesizers



(Courtesy Prentke Romich Company)

to communicate words, phrases and sentences. Programmed to individual needs, the system can "grow" as a person's skill with using the system increases: A new keyboard representing a more advanced level is simply attached as an overlay.

Starting with a keyboard of eight pictures, a nonreader could communicate "I love my Dad" by pressing the key with the picture of a man on it. Someone who can read would use a keyboard with many more picture-symbol and letter keys. For instance, pressing a sequence of keys would tell the computer that the person is in a certain environment such as a gas station. The computer would interpret subsequent commands in terms of that environment. Thus, if the user pressed an apple key (for food) and a truck key (for car), the message "Feed my car" would be prompted. Or, as the synthesized voice puts it, "Please fill it up."

Many users can program their own vocabulary into the device. The most advanced systems are flexible enough to adapt to users ranging from very slow learners to someone with a Ph.D. Also, the systems can be adapted to interface with many data and word processors.

Lightweight Wheelchair

Wheelchairs have traditionally been made from metal tubing, which is often heavy and susceptible to frequent breakdowns. Now, an extremely lightweight, durable wheelchair has been designed by Langley Research Center and the University of Virginia Rehabilitation Engineering Center. Composite materials used in the chair were developed by the nation's aerospace program—outer layers of material provide strength and rigidity, but a core of foam keeps the weight down. Thus, the chairs have the same strength and weight-bearing capabilities as metal ones, with about half the weight. They have excellent resistance to wear and corrosion. They fold and store easily, too.

Lightweight Wheelchair



(Courtesy NASA Langley Research Center)

Artificial Ears

A cochlear implant, a kind of artificial ear, is intended to restore a level of sound to someone (18 years or older) who is totally deaf and can't benefit significantly from a hearing aid. The device works by electrically stimulating the ear's auditory nerve. FDA's Center for Devices and Radiological Health approved a single-channel cochlear implant in 1984 and a 22-channel implant (which provides a variety of tones) in 1985.

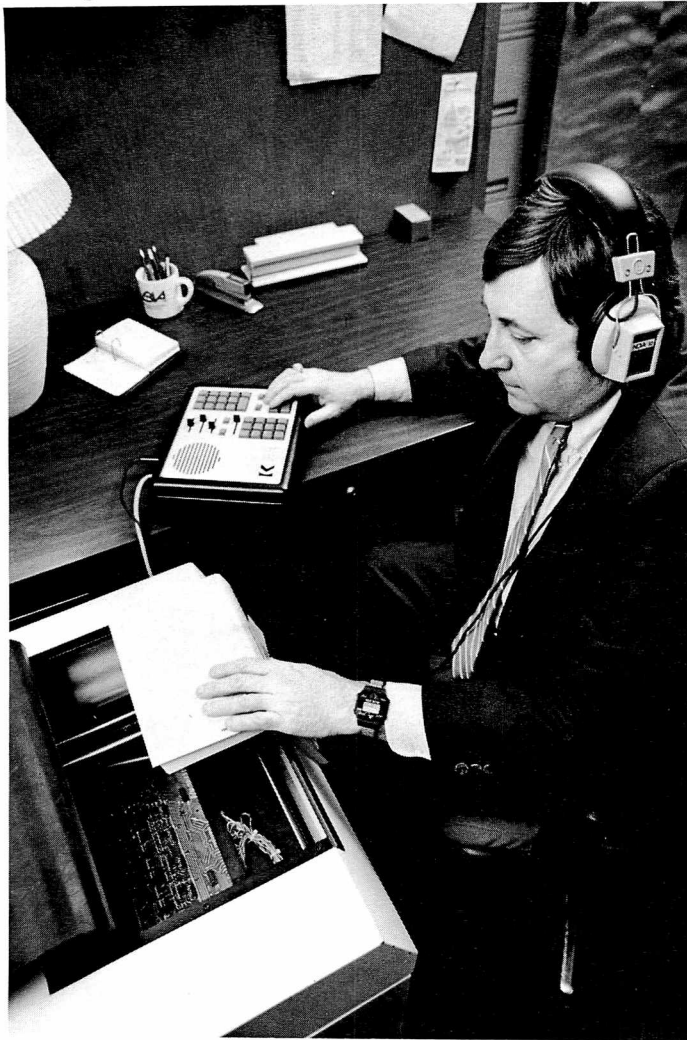
With the implant, a patient can detect such medium-to-loud sounds as doorbells and car horns. While the sound through the implant is too crude to allow spoken words to be discerned, the device does improve the word recognition of lip readers. For a few patients who had developed language skills before becoming deaf, the 22-channel device provides limited improvement both in distinguishing spoken words without lip reading and in recognizing other sounds.

The implant systems consist of a small speech processor, which the patient wears in a pocket or on a belt; an external transmitter, which is positioned behind the ear; and a surgically implanted internal receiver/stimulator with one or more electrodes. The speech processor receives sound through a microphone and converts the sound into an electrical signal, which is then sent to the external transmitter and from there to the implanted receiver/stimulator. The receiver/stimulator transmits the signal to the cochlea, or inner ear, via the electrode(s).

Reading Machines for the Blind

Another application of a voice synthesizer is a reading machine for the blind that's being used at some libraries and schools. It consists of a scanner about the size of a photocopy machine and a separate, compact control panel that's connected by cable to the scanner. By converting print to synthesized speech, the machine

Reading Machine for the Blind



enables a blind person to “read” nearly any typed or printed material.

To use the machine, the person places the text face down on the scanner’s glass surface. A camera scans the print and sends an electronic image of each line to a computer, which processes the information and converts it into synthesized speech. With the control panel, the user can alter how the text is read: Words or lines may be repeated or spelled out, and volume, speed and pitch of the “voice” may be varied.

Telephones for the Deaf

A telecommunications device for the deaf, known as TDD (or TTY for teletypewriter), adapts a regular telephone for use by someone with impaired hearing. Because deaf people often have difficulty speaking clearly, the TDD allows the deaf caller to type a message on a modified typewriter keyboard with a visual character display; this can be printed out on a similar keyboard by the receiver of the call.

To use the TDD, the caller places the telephone handset on the TDD cradle, switches the TDD on, and dials the number. Signal lights indicate a dial tone, busy signal, ring signal, or a signal that the person being called has answered the phone. The person receiving the call picks up the handset, places it on the TDD cradle (some models provide a direct connection), and types a short message ending with “GA” (go ahead) to tell the other person to proceed. By typing “SK” (signal kill) at the end of a

Telecommunications Device for the Deaf



message, the callers indicate they’re ready to hang up.

Some models have a memory for saving and sending messages and automatic answering when the person is away. An external printer with editing capabilities is also available. Thanks to microcomputerization, TDDs are easily portable—some weigh less than two pounds—so that deaf people can place calls anywhere, even from pay telephones.

Today, many communities offer TDD relay centers so that deaf people can communicate with phones that don’t have TDDs. A worker at the center, often a volunteer, receives the TDD call, dials the telephone number the TDD user wants to reach, reads the printed message, listens to the response, and then types it back to the TDD user.

Physicians, lawyers, schools and government agencies are among those who have installed TDDs to provide access to people who are deaf. To call FDA via TDD, dial (301) 433-1818. (The number is in suburban Washington, D.C., and is *not* toll-free.) FDA also is installing TDDs in many of its field offices.

Closed-Captioned Television


Funded by the Department of Education and the private sector, the National Captioning Institute, Inc., permits people with impaired hearing to read what they can’t hear on television and home videos. The institute’s captioning editors translate a program’s audio portion into subtitles, or captions. This is called closed-captioning because access to the captions is closed unless



(Courtesy National Captioning Institute)

the viewer has a special adapter hooked up to the television set.

When closed-captioning a prerecorded program, the editor views it, types the captions, checks for errors, and ensures a comfortable reading rate. For live programs, a shorthand reporter transcribes the audio using a special computer-assisted stenotype machine. That information is sent by telephone lines to television network master control rooms in New York City. There, they are translated into captions and then become part of the television signal broadcast throughout the country.

To identify closed-captioned programs, many newspapers print "CC" after the television listings; *TV Guide* uses the words "Closed Captioned"; and the institute uses its registered service mark , which means that it alone closed-captioned the program.®

Tech-Net

Tech-Net is intended to be a national network of computer data-banks containing many types of information useful to people with disabilities. It will include an index of disability-related services and organizations, an equipment exchange service, a job and skills bank, and the latest information about scientific advances in various medical fields. With a referral service of about 4,000 listings, Seattle's Resource Center for the Handicapped has become the Tech-Net prototype.

The Tech-Net project is part of a National Initiative on Technology and the Disabled that grew from original efforts by Concepts for Independent Living, a private nonprofit corporation in Seattle and Arlington, Va. The initiative was launched with support from the White House, the National Aeronautics and Space Administration, the Department of Defense, and the Department of Health and Human Services. To establish Tech-Net nationwide, more than a million dollars was raised by a coalition of leaders from the aerospace and other industries under the chairmanship of Robert Kirk, president and chief executive officer of LTV Aerospace and Defense Company in Dallas. Kansas, Texas, Massachusetts and Pennsylvania are scheduled to join Tech-Net this year.

Tech Teams

As Tech-Net expands, Concepts for Independent Living will also work with states to organize Tech Teams: local teams of engineers, scientists, and other professionals who donate their high-tech expertise to services for the disabled. A prototype for the Tech Teams is a Lutherville, Md., group, Volunteers for Medical Engineering, Inc. (VME). Funded primarily by Westinghouse Electric Corporation, the volunteers work with

Modified Standing Frame *(Courtesy Volunteers for Medical Engineering, Inc.)*



staff of medical and rehabilitation institutions to evaluate products, design or adapt products and services, and give technical assistance in fitting devices to patients.

Among the products being developed by VME are:

- Compu-Talk, a computer that voice-synthesizes messages typed by the user.
- Blink Writer, a computer that enables people with total paralysis to give computer commands by blinking their eyes while wearing special glasses.
- Modified Standing Frame, a device that allows a person without leg control but with intact muscles and bones to be mobile. VME is working to adapt the device so users can move from sitting to standing and back with ease.
- Steiner Tractor, a small tractor being adapted for use by quadriplegics (those paralyzed from the neck down). They would move the tractor with a chin-controlled device—turning the chin up moves the tractor forward, turning down moves it backward, and so on.

Implantable Computerized Pumps

Scientists have designed a computerized implantable drug pump for chronically ill patients. The still experimental device continuously and precisely delivers medication to specific organs from inside the body. It consists of an infusion-pump system that is implanted and two programming units—one the physician uses to program the dosage schedule and one the patient uses to adjust the schedule within limits set by the physician. The implantable portion includes the pump, a plastic tube from the pump to the target organ, a battery, a computer that controls dosage, and a medication reservoir, which the physician periodically refills by injection through the skin.

People who have disabilities continue to struggle against environmental barriers. But today's high-tech devices and services are helping many to enjoy increased independence and greater opportunities.

Further information about products and other assistance for the disabled can be obtained from these organizations:

Implantable Programmable Infusion Pump

(Courtesy The Johns Hopkins University Applied Physics Laboratory)

Concepts for Independent Living
Suite 900, Crystal Square II
1725 Jefferson Davis Highway
Arlington, Va. 22202
(202) 857-0087

National Captioning Institute, Inc.
Suite 1500
5203 Leesburg Pike
Falls Church, Va. 22041
(703) 998-2462 TDD: (703) 998-2400

National Easter Seal Society (check locally first)
2023 West Ogden Ave.
Chicago, Ill. 60612
(1-800) 221-6827 TDD: (312) 243-8880

National Rehabilitation Information Center
The Catholic University of America
4407 8th St., N.E.
Washington, D.C. 20017
(1-800) 346-2742 TDD: (202) 635-5826

National Rehabilitation Association
633 S. Washington St.
Alexandria, Va. 22314
(703) 836-0850 TDD: (703) 836-0852

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



Shots *Adults* Shouldn't Do Without

by Carol Ballentine

As people pass from childhood to adult status, they put away childish things—skipping rope on sidewalks, wandering through long summer days with “nothing to do,” dressing up in old clothes hidden away in the attic. But there is one item that adults may put away as childish which they shouldn't—vaccinations.

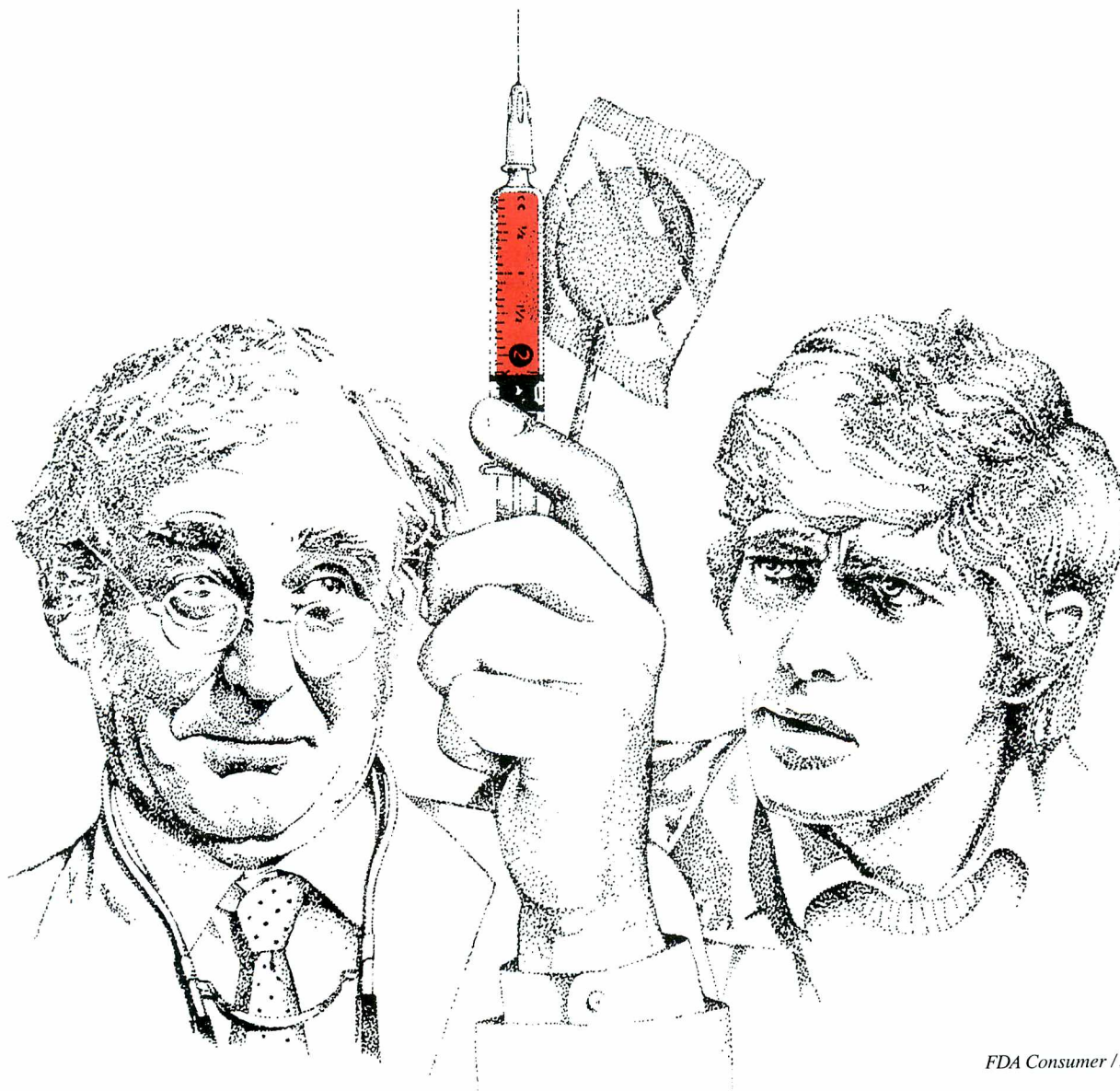
Today, college campuses are experiencing severe outbreaks of measles because many students are not properly vaccinated. An estimated 10 percent to 15 percent of young adults are also susceptible to rubella (German measles), and limited outbreaks are occurring in universities, colleges and workplaces, particularly hospitals. Only half of those over 50 are immunized against tetanus and diphtheria. And among the elderly, pneumonia and influenza are the fifth leading cause of death. (About 90 percent of the deaths attributed to these two diseases occur in adults over 65.)

The vaccines that can help protect against these diseases are all underused by adults. One reason for this neglect is that too many

adults think immunization shots are only for kids and maybe international travelers. According to the commissioner of the Food and Drug Administration, Dr. Frank E. Young, “Although prevention of a disease is clearly better and cheaper than its treatment, adults in good health, though extremely conscientious about immunizing their children, can be remarkably unaware of the status of their own immunizations.”

Young went on to add that health professionals themselves are guilty when it comes to keeping their adult patients, and themselves, adequately protected against infectious disease. “While pediatric medicine is centered on a program of comprehensive immunizations, treatment of adults too often neglects immunization as an important component of sound preventive care. The fact that only 10 percent of the health professionals at risk have been immunized against hepatitis B indicates that medical people themselves have not sufficiently emphasized prevention.”

Immunization comes mostly at the end of a needle—which may be why adults prefer not to think about it. (There is an occasional



exception, such as the oral polio vaccine on the sugar cube.) For the most part, the needle contains a vaccine, a substance made from the killed or weakened microorganisms (such as bacteria or viruses) that cause a particular disease. In the body, the vaccine causes the formation of antibodies that give immunity to the disease.

Some diseases, such as tetanus, are caused not by microorganisms themselves, but by toxins produced by these microbes. For those diseases, instead of making a vaccine from the microbe, the toxin can be modified—usually with chemicals or heat—to make it nontoxic but still capable of stimulating production of antitoxin (an antibody that acts against a toxin). This substance, called a toxoid, can then be injected to produce immunity.

Recently, guidelines for adult immunization were published by two national health organizations, the U.S. Centers for Disease Control and the American College of Physicians. Both groups made recommendations for people in special categories, such as those in certain occupations or with certain lifestyles, those who have health conditions that put them at risk, and pregnant women. They also recommended the routine use of six vaccines for healthy adults in general:

- **Tetanus-diphtheria toxoid:** Since 1977, surveys of immunity have estimated that 11 percent of adults 18 to 39 years old—and over half those over 60—are not protected against tetanus. The percentage of those unprotected against diphtheria is even higher. (There are few reported cases of diphtheria, but of 15 cases that occurred between 1980 and 1983, 11 were in people over 19.) Both diseases can have severe consequences. Tetanus, also called “lockjaw,” can be fatal in the young and elderly. The respiratory form of diphtheria can progress to inflammation of the nerves and the lining of the heart and, in some cases, can cause death.

All adults should receive a tetanus-diphtheria booster every 10 years. Those who have not received the primary series of immunizations (which is usually administered before entering school as the combined diphtheria-pertussis-tetanus, or DPT, toxoid) should get it.

- **Measles vaccine:** One young adult out of 20 may be susceptible to measles. Adults born before 1957 probably had the disease as children and are therefore immune, but all those born after 1956 should be vaccinated with the live measles vaccine unless they have had the disease. Also, individuals who were vaccinated with the killed measles vaccine, which was only in use between 1963 and 1967, should be revaccinated with the more effective live vaccine. (In the United States, between 600,000 and 900,000 people received the killed vaccine.) College students in particular should be immunized against measles.

Measles can cause encephalitis (inflammation of the brain) or death in one out of every 1,000 people. In pregnant women, the disease increases the risk of spontaneous abortion, premature labor, and low birth-weight in their babies.

- **Mumps vaccine:** Serologic (blood) surveys show that most people have been infected with mumps by age 20, and are thus immune. However, vaccination is recommended for susceptible adults, particularly men. In 20 percent of post-pubertal males, a condition called orchitis, meaning inflammation of the testes, occurs as a complication of mumps; in some cases, orchitis can cause sterility. Mumps can lead to deafness in one out of every 15,000 people and can increase the rate of spontaneous abortion in the first trimester of pregnancy.

- **Rubella (German measles) vaccine:** The primary reason to immunize adults against rubella is to prevent fetal infection. In up

to 80 percent of fetuses, infection during the first trimester can lead to congenital rubella syndrome, commonly characterized by cardiac, visual and hearing defects and mental retardation.

Routine immunization against rubella is recommended for all adults, particularly women and college students, unless they have had the disease. Women should not be vaccinated if they are pregnant and should be advised not to become pregnant for three months after the vaccination.

For adults susceptible to measles, mumps and rubella, a combined vaccine is available.

- **Influenza vaccine:** Everyone over 65 should be vaccinated against influenza. Approximately 60 percent to 80 percent of all influenza deaths are in this age group. In addition, immunization is recommended for people of all ages who suffer certain debilitating conditions, such as heart, lung or kidney disease, diabetes mellitus, anemia, suppressed immunity, or severe asthma.

The flu shot, unfortunately, is an annual event. This is for two reasons: First, influenza viruses are continually changing, and thus the vaccines are also often changed; and second, immunization immediately before the flu season provides the best protection—antibodies wane with time. The vaccines vary in effectiveness from year to year because no one knows for sure which viruses will attack, so a certain amount of guesswork is involved in deciding which antigens (substances that produce antibodies) to use. The choice is made annually by FDA's Center for Drugs and Biologics and its technical advisory groups, with input from the National Institutes of Health and CDC.

- **Pneumococcal vaccine:** Unlike the influenza virus, a person need only be vaccinated against pneumococcal disease once. The vaccine contains purified materials of *Streptococcus pneumoniae*, the bacteria that cause pneumococcal pneumonia, which is the most common bacterial form of the disease.

Again, immunization is recommended for all adults over 65, because they are most likely to die from pneumococcal pneumonia and its complications. Vaccination is also advised for adults with certain medical conditions, including chronic lung or heart disease, diabetes mellitus, alcoholism, cirrhosis, and suppressed immunity.

In addition to these six vaccines, the Centers for Disease Control and the American College of Physicians made specific recommendations for people in certain situations and with certain health conditions.

People with particular lifestyles or who hold certain high-risk jobs, for example, are more likely to get hepatitis B virus infection, a disease transmitted through blood, semen and saliva. Homosexually active men and intravenous drug abusers run a high risk of getting the disease: 10 percent to 20 percent of both groups acquire the virus each year, and at any one time up to 80 percent show evidence of having been infected. Health-care workers also have a greater chance of contracting the infection, particularly those who have frequent contact with blood or infected body tissues. This group includes surgeons, gynecologists, dentists, cardiologists, blood bank personnel, intravenous therapy nurses, and clinical laboratory staff who work directly with blood. Staff in institutions for the mentally retarded—as well as the residents—also run an increased risk of hepatitis B infection because of exposure to human bites and open skin lesions and saliva.

The hepatitis B vaccine, licensed by FDA in 1982, is expensive—about \$100 for the three shots needed to confer immunity. But

The Shots Heard Round the World

People traveling to many foreign countries—particularly developing nations—should put “vaccination” on their travel list, right along with “tooth-paste” and “passport.”

The risk of acquiring measles, mumps and rubella, for instance, is far greater outside the United States because in most countries these diseases are uncontrolled. About half of imported measles cases reported from 1980 to 1983 occurred in citizens returning to the United States. Polio viruses are also extremely common in developing countries, as are diphtheria and pneumococcal pneumonia. Travelers should make sure they are immune to these diseases.

The destination and travel route largely determine what immunizations are neces-

sary. There are, for instance, areas in Africa, Asia, and Central and South America where typhoid fever is common, and travelers to these areas should be vaccinated against it. (The vaccine does not provide 100 percent immunity, however. Even after vaccination, travelers should be careful about what they eat or drink since the bacteria are found in food and water.) Travelers to other areas may need to be vaccinated against such diseases as plague, rabies, or hepatitis A.

There are two diseases for which vaccination might be legally required, depending on the traveler's route and destination: cholera and yellow fever.

Cholera occurs throughout much of Asia, the Middle East, Africa, and some parts of Europe. Like typhoid, it is acquired primarily from contaminated food and water. Although the risk of getting the disease is very slight, some countries require evidence of cholera vac-

cination for entry and may quarantine unvaccinated persons if they come from areas of cholera. Travelers can get a validated international certificate of vaccination against cholera from most city, county and state health departments, as well as many private clinics and physicians' offices.

Yellow fever, transmitted by mosquitoes, occurs only in Africa and South America. In recent years, fatal cases of yellow fever have occurred in unvaccinated tourists. People traveling to areas where the disease exists must be vaccinated with a vaccine approved by the World Health Organization and administered at an approved Yellow Fever Vaccination Center, which can be located through state or local health departments.

Information about vaccination requirements for travelers is available from health departments, travel agencies, and international airlines and shipping lines. ■

for those in the high-risk groups, the price should be worth it. Although most people in the United States have only a 5 percent chance of getting hepatitis B viral infection, those in the highest risk groups (such as homosexually active men and intravenous drug abusers) almost certainly will get it unless they are immunized. Each year, almost 100,000 Americans contract this disease, which can progress to chronic hepatitis, cirrhosis, and liver cancer. Each year some 4,000 people die of hepatitis B virus-related cirrhosis, and 800 die of hepatitis B virus-related liver cancer.

Routine polio vaccination is not recommended for adults in the United States—most are already immune. But there are a few exceptions. Health-care workers should be immunized, as should people traveling to developing countries (see accompanying article). Also, susceptible adults run a small risk of getting polio when children in the household are given the oral polio vaccine. These adults may simply take extra precautions, such as washing thoroughly after changing the child's diapers, or may choose to be immunized before the child is.

Pregnant women form a class all their own when it comes to vaccinations. In general, they should avoid *any* unnecessary drugs or procedures, including vaccines, that might affect the fetus. If vaccination is necessary, however, the risk can be minimized by administering only vaccines made of inactivated microbes and delaying administration until the second or third trimester.

Pregnant women should consult with their physicians about immunization against tetanus and diphtheria. Neonatal tetanus causes significant illness and mortality in offspring of mothers who have been inadequately immunized. Also, women should be immunized against hepatitis B if they are in a high-risk category; the virus can cause severe disease in the mother and chronic infection in the newborn, and the vaccine poses no known risk to the fetus. Similarly, there is no evidence that vaccines for influenza and pneumococcal pneumonia will harm the fetus, so vaccination is indicated in pregnant women with health problems such as

congenital heart disease or lung disease.

Although live virus vaccines ordinarily should not be given to pregnant women, two vaccines—those for polio and yellow fever—should be administered if the woman is traveling to a high-risk area or will otherwise be exposed to these diseases. In such circumstances, the risk of the diseases is far greater than that posed by the vaccines. However, the measles-mumps-rubella vaccine, also live, should not be given to a pregnant woman, but may be administered after delivery.

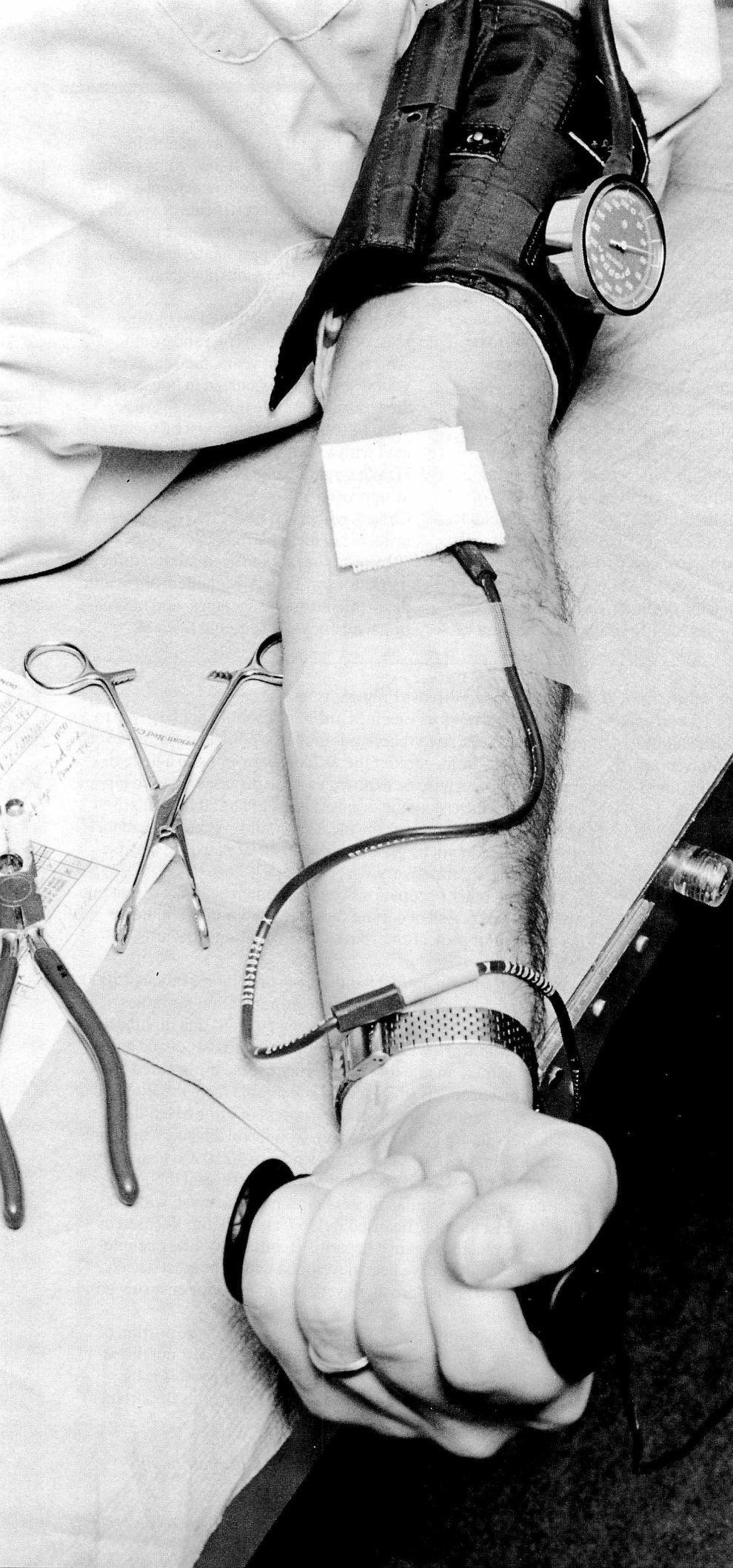
There are other occupations besides human health care that put workers at extra risk of certain diseases. Those who should be immunized for protection from such occupational hazards include:

- veterinarians and animal handlers, against rabies (about 25,000 people each year receive preventive immunization for rabies),
- sanitation and sewage workers, against tetanus and diphtheria,
- people who work with imported animal hides, wool and hair, against anthrax, an infectious bacterial disease transmitted by such animal products (the vaccine is available from the Biologic Products Program, Michigan Department of Public Health).

The last quarter century has seen wonderful advances in immunization. Measles cases have dropped from 400,000 a year before the first vaccine was licensed in 1963 to only several thousand cases a year now. Similar success rates have occurred with vaccines against mumps, licensed in 1967, and rubella, licensed in 1969. The vaccines against hepatitis B, influenza, and pneumococcal pneumonia have been developed within the past decade. Adults should not ignore these very useful tools for ensuring good health.

As FDA Commissioner Young said, “A very large portion of the adult population *assumes* that it is immunized or not threatened by preventable infectious diseases. In reality, this is far from the case. Immunization is not child's play. It is important to all of us.” ■

Carol Ballentine is a member of FDA's public affairs staff.



No Risk of AIDS in Giving Blood

by Bill Rados

Summertime has always been a difficult time for blood banks. As Americans head off for vacation or busy themselves with outdoor activities, they tend to forget about donating blood or put it off till they find the time. But the need for blood—for accident victims, hemophiliacs, and surgery patients—doesn't let up. So blood banks often experience summer shortages, and often must appeal for donors through the news media.

This year, as in the past few years, the seasonal shortage of blood could be even worse than usual because of unwarranted fears about AIDS. A public opinion survey conducted last December for the American Association of Blood Banks (AABB) found that 34 percent of Americans mistakenly believe that they can get AIDS (acquired immunodeficiency syndrome) by donating blood. This unwarranted fear may be scaring many potential donors away from giving blood. Blood banks throughout the nation are reporting declines in their blood supplies as a result of a drop-off in donations. The Greater New York Blood Program, for example, reported earlier this year that its blood reserves had fallen to about a third of their normal level. Many other local blood banks have experienced drops of up to 15 percent from their normal reserves, according to the AABB.

The fact is, there is *no* risk of getting AIDS from donating blood. Donating blood involves absolutely no danger of being exposed to the virus that causes AIDS. According to the U.S. Centers for Disease Control, there have been no reported cases of AIDS from donating blood. As Department of Health and Human Services Secretary Otis R. Bowen, M.D., noted earlier this year, "The plain truth is that you cannot get AIDS from giving blood. Blood is donated under strict

and sterile conditions. Every precaution is taken to protect your safety and the safety of the blood you donate."

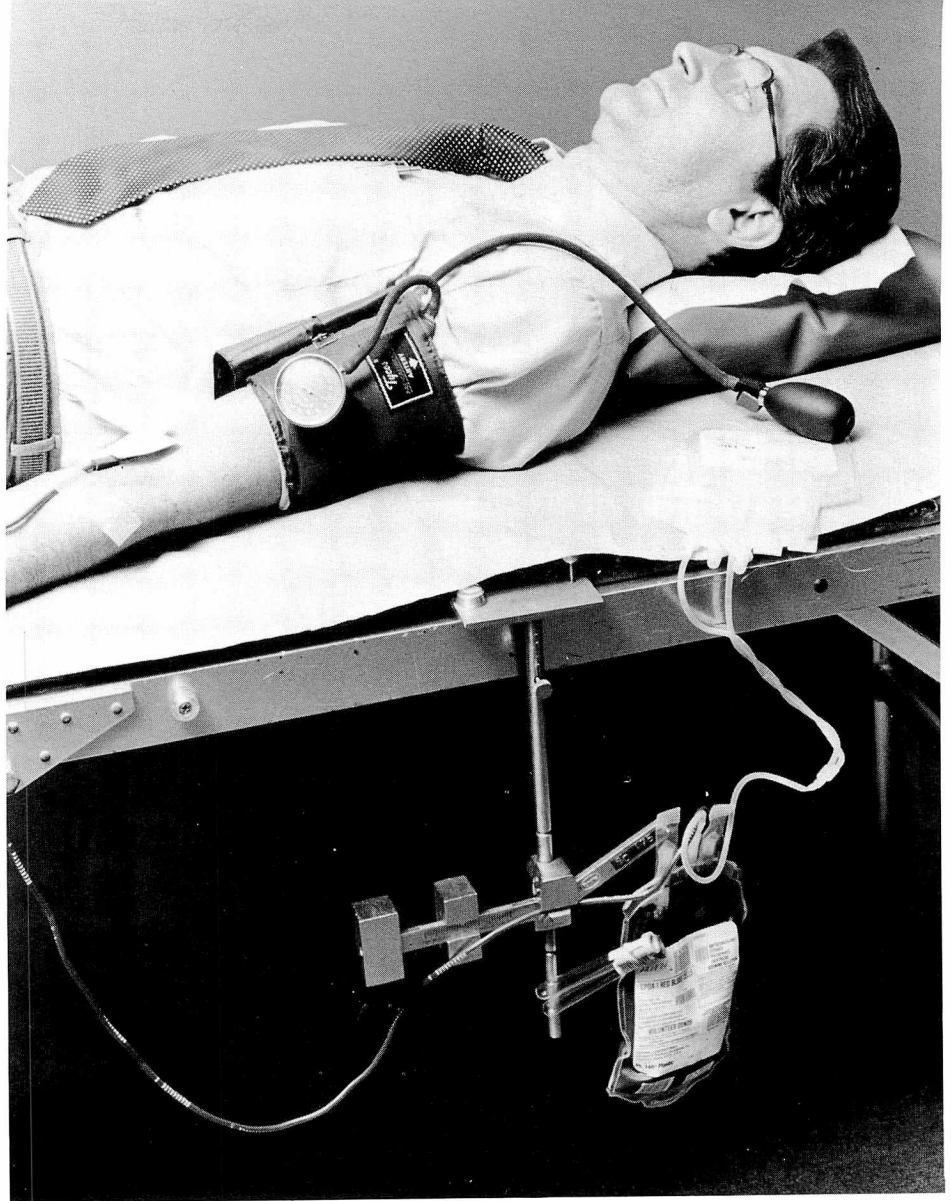
A look at the blood donation process helps in understanding why there is no risk of getting AIDS in being a blood donor. Donating blood involves giving your own blood; it does not place you in contact with anyone else's blood. Here's the way it works: First the donor goes through a few preliminaries, such as a brief medical history and blood pressure and pulse checks. (See "The Reasons Behind Blood Donor Screenings" in the November 1985 *FDA Consumer*.) Then, the blood donor reclines on a cot and a blood bank staff member swabs the inside of one elbow with a disinfectant and inserts a sterile needle into a vein in the arm. The blood is drawn through the needle into a sterile plastic bag via a sterile connecting tube. After several minutes, the needle is withdrawn and disposed of, along with the connecting tube. The bag is sealed and sent off to be safely stored until needed. Each needle, tube and bag (collectively referred to as a blood collection set) is used only once; no donor is ever exposed to any of these that have been used before, or to any substance or equipment that might harbor the AIDS virus.

To ensure the safety of blood donors (and of donated blood), FDA regulates the manufacture of blood collection sets and the operation of all blood donation centers. Under the Food, Drug, and Cosmetic Act, all blood collection establishments must register with FDA and are subject to regular inspections by the agency. FDA can suspend or revoke the licenses of facilities that fail to comply with the agency's standards and can bring criminal charges against the responsible parties.

There are several private organizations that also work to safeguard the blood donation process, among them the AABB, the American Red Cross, and the Council of Community Blood Centers.

That there is no risk of getting AIDS from giving blood is one of the points made in a series of public service announcements produced by the Red Cross and the U.S. Public Health Service. The announcements point out that, contrary to what some people believe, "AIDS is hard to catch."

"It's spread primarily through sexual contact or sharing drug needles," the messages say, not through casual contact, even with people who have AIDS. The



When a donor gives blood, the needle, plastic tube, and plastic bag are sterile and used only once, so there is no risk of transmitting infectious diseases, such as AIDS. The instrument wrapped around the donor's upper arm is to measure blood pressure. The rubber tube in the donor's hand (facing page) is alternately squeezed and released to help the blood flow.

announcements seek to reassure Americans that "You won't get AIDS in restaurants. You won't get AIDS by shaking hands . . . or hugging, even with someone who has AIDS." The announcements have been distributed to radio and TV stations across the country.

To provide reliable information about AIDS, the Public Health Service's toll-free hotline number is advertised at the end of each announcement. The number is 1-800-342-AIDS. Those who call the hotline hear a taped message that explains what AIDS is, what causes it, and what groups are at increased risk of getting it. The message also provides information about a test that can detect whether a person has been infected with the AIDS virus. This test is being used to screen donated blood to help prevent cases of AIDS from

transfusions. The tape also gives recommendations to prevent the spread of AIDS. At the end of the message, callers are given a second toll-free number to call if they need more information.

Americans can best avoid AIDS by not using illicit drugs and not having multiple sex partners. Those at increased risk for getting AIDS—most notably intravenous drug abusers and male homosexuals—should not donate blood. But those who are not at increased risk are urged to continue to donate blood as they have in the past and have no reason to fear getting AIDS from doing so. To donate blood, contact your local hospital, Red Cross chapter, or look under "blood banks" in the Yellow Pages. ■

Bill Rados is editor of FDA Consumer.



Viruses

Invaders from a Small World

by Egon Weck

Of the seemingly endless assortment of microorganisms that cause disease, most are various types of bacteria or viruses. Medical science has found weapons—drugs and vaccines—to combat many of the bacterial diseases, but has been far less successful in dealing with illnesses of viral origin. Strep throat, for example, is just one of many bacterial infections that can usually be knocked out with antibiotics. But there are no comparable “wonder drugs” to treat such common viral infections as the cold or flu.

Why have scientists found it so much harder to fight viruses than bacteria? What weapons are there for combating viral diseases? Why is it especially difficult to find a way to stop the kind of virus that causes AIDS (acquired immunodeficiency syndrome)? And what is a virus anyway?

The search for answers takes us back a few centuries in medical history.

One of the earliest milestones in the centuries-old battle against disease-producing viruses was reached in 1798 by the British physician Edward Jenner. He demonstrated the disease-preventing possibilities of vaccinations when he found that people could be protected against the deadly smallpox virus by inoculating them with the similar (but relatively harmless to humans) cowpox virus.

Nearly one hundred years later, toward the end of the 19th century, the French scientist Louis Pasteur astounded the world of medicine when he developed a vaccine against rabies, a virus-caused infection in dogs, humans and certain other mammals. What made Jenner's and Pasteur's accomplishments even more amazing was that they were able to protect individuals from two viral diseases even though they had no inkling of the existence of viruses.

Scientists of the 18th and 19th centuries

were aware of microscopically small forms of life. As early as 1674 the pioneer Dutch microscopist Antonie van Leeuwenhoek had described the tiny forms of life that he could see with the aid of his crude microscopic lenses as “very little animalcules.” Investigators later identified some of them as bacteria.

Armed with much more sophisticated microscopes, medical scientists working in the late 19th century were able to identify the major disease-producing bacteria. They used fine porcelain filters to screen bacteria from body fluids such as blood plasma, then grew the bacteria outside the body in order to study them. From this work came the erroneous theory that bacteria caused all infectious diseases.

The theory became suspect when no bacteria could be found to account for a number of infectious illnesses. Then, in 1898, another scientist, Martinus Beijerinck, suggested that there were other infectious agents besides bacteria. His evidence came from his studies of tobacco mosaic disease, which stunts the growth of infected plants and imparts a mottled or mosaic effect to the leaves.

Beijerinck's experiments on the disease involved extracting liquids from a diseased plant and passing the disease-bearing extract through porcelain filters capable of capturing the smallest known bacteria. Then he spread the filtered fluid on the leaves of uninfected tobacco plants. Each time, the plants developed the disease.

Beijerinck reasoned that there was an infectious agent present in his filtrates that was small enough to pass through the pores in the filters. An agent that small could not be a bacterium. He called the unknown disease-producer a virus, Latin for poison.

It wasn't until 1935, however, that two American scientists, Bodo Borries and

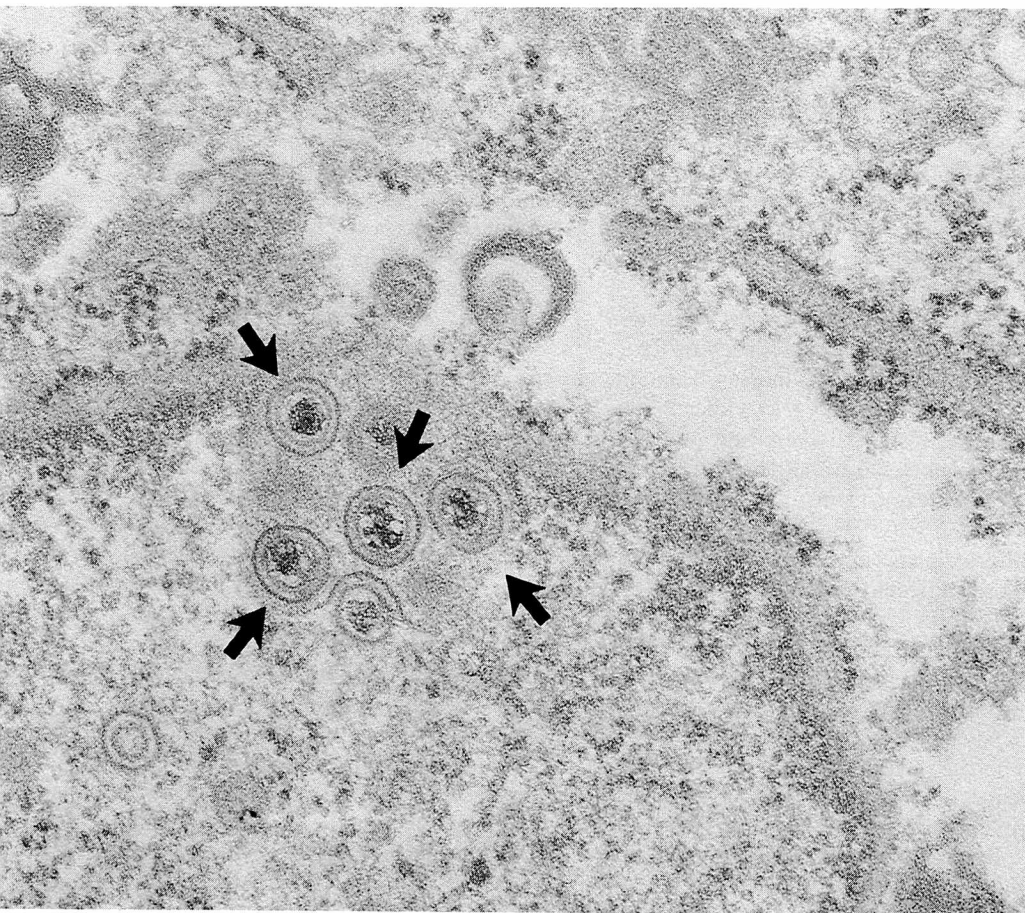
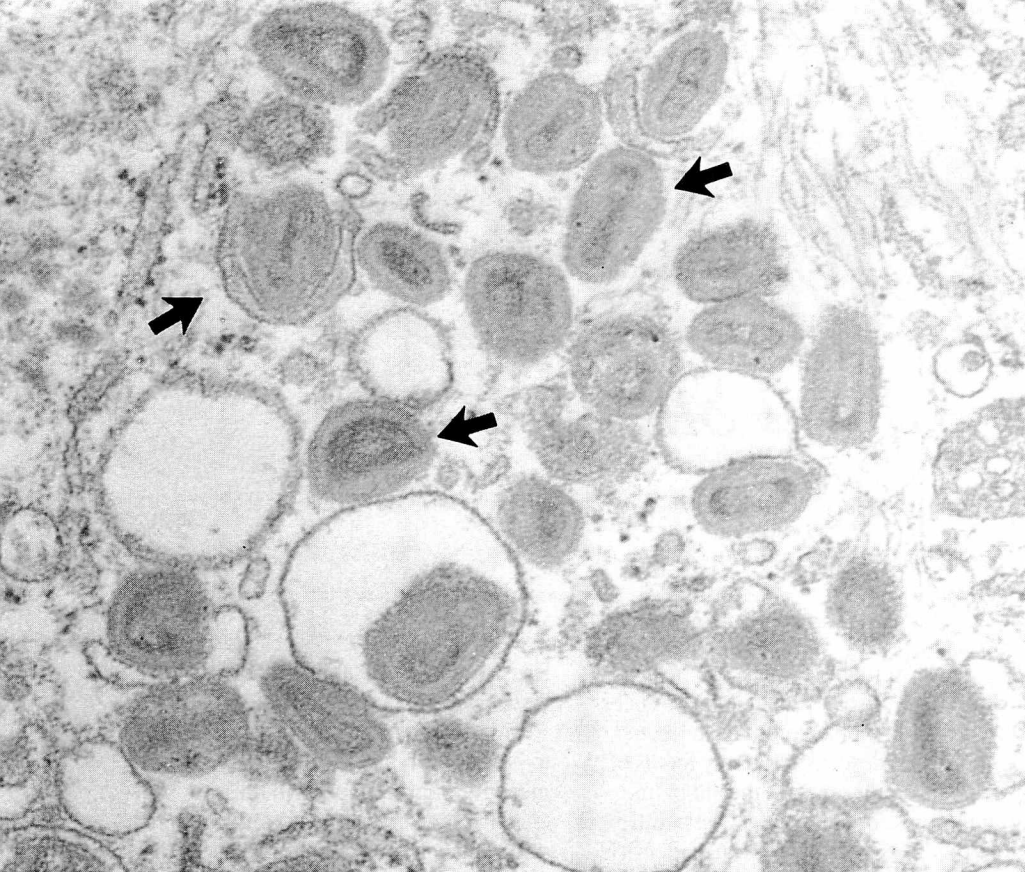
Ernst Ruska, were able to photograph viruses using an electron microscope.

This new instrument enabled scientists to peer into an infinitesimal world, where measurements are made in millimicrons. (A millimicron equals one-millionth of a millimeter; a millimeter equals about 1/25th of an inch.) The scientists found that viruses come in a variety of shapes and sizes, from the spherical polio virus that is about 27 millimicrons in diameter (hardly bigger than a single protein molecule) to the brick-shaped vaccinia virus (which causes cowpox) that, at 210 by 260 millimicrons, is almost the size of the smallest bacteria and is just large enough to be seen under an optical microscope.

In order to study viruses—or any microbes—it's necessary to grow them. But growing viruses poses special difficulties. Bacteriologists are able to grow bacteria outside a living animal body by using nutrient media such as chicken broth and agar. But not viruses. To multiply, these parasitic minutiae depend on living cells.

Since it's obviously not feasible to infect humans with disease-causing viruses in order to grow them in quantity for use in research or vaccine production, they are grown instead by a special technique called tissue culture. First, investigators must find which type of human or animal cell will support a particular virus. (In the case of the polio virus, monkey kidney cells were found to work well.) Then a method of growing the cells outside the body must be devised. And, finally, the conditions that foster maximum growth of the virus on the tissue culture need to be established.

The reason this elaborate process is necessary is that viruses don't reproduce in the same sense that living organisms such as bacteria do. All life forms, down to single-celled plants and animals, grow by



The top picture, showing vaccinia viruses (the dark, round objects), was taken using an electron microscope, magnifying the viruses 66,000 times their actual size. The viruses are inside the cytoplasm of a chicken tissue culture cell. The lower picture, also taken using an electron microscope (at 73,000 magnification), shows monkey herpes viruses in the nucleus of a human tissue culture cell. (Arrows point to some of the viruses.)

a process called metabolism, building cellular tissue from substances such as proteins. Viruses don't have this capacity. They grow and multiply by a process called replication.

To replicate, a virus must get inside a living cell. It first attaches itself to the cell's external surface at a specific receptor site much as a key fits into a lock. The "lock" site is ordinarily found on the surface of the virus while the "key" projects from the cell.

Virologists haven't been able to figure out why cells have receptors that can "open the door" to viruses and the harmful consequences that follow. Currently, one hypothesis is that the receptors also provide sites for other substances, such as enzymes, that are essential to cell function.

After they have attached themselves to a cell's receptor, viruses differ in the way they invade the cell and "reprogram" its activities. Here's one scenario:

With the aid of its own enzymes or ones it commandeers from the cell, the virus breaks through its outer shell, or capsid, and the outer membrane of the cell. Then its genetic material, in the form of DNA (deoxyribonucleic acid), enters the cell. Once inside, the viral DNA marshals the cell's mechanism for making proteins and nucleic acid to make viral protein and viral DNA. Finally, the viral particles assemble to make new viruses. These, in turn, break out or "bud" through the cell's protective membrane to invade other healthy cells, where the process is repeated.

The havoc from this viral onslaught includes a host of dead cells that can impair the function of the body organs, such as the lungs in a case of influenza.

Meanwhile, the body's response to the viral invader provokes symptoms such as fever, coughing, a runny nose, or general malaise. These symptoms are all part of a complex chain reaction that begins when the invading viruses trigger the immune system, mobilizing the body's defenses. As part of the immune response, antibodies are produced that, in sufficient quantity, have the ability to jam the locks, so to speak, on the viruses and render them harmless.

This protective response can be artificially induced by a vaccine. The immune system, besides reacting to "live" viruses, responds to ones that have been "killed" with a chemical or rendered harmless by some other method. A selected fragment of the viral surface—typically one that

includes the lock—may be enough to trigger the immune response. The disease-producing virus itself or the inactivated virus or a viral particle that triggers the immune response, including the production of antibodies, is called an antigen.

Traditionally, to make a vaccine, the production of quantities of a particular virus has involved the use of tissue cultures of animal or human origin. Traditional tissue-culture techniques have been used to develop effective vaccines against viral diseases such as mumps, polio, rubella (German measles), and influenza. But with the new recombinant DNA technology, scientists are developing ways to introduce viral genes into bacteria—typically ubiquitous *E. coli* bacteria. The altered bacterial cells are then used as factories for producing more viruses without the use of tissue cultures.

Immunologists are now using recombinant DNA techniques to work on super vaccines that will combine protection against several disease-producing viruses in a single shot. One such “super shot” would offer protection against herpes, hepatitis B and influenza.

Other researchers are working to develop vaccines by chemical synthesis. Such “artificial” vaccines rely on immunity-stimulating particles that are not taken from viruses. Yet they mimic the viral antigen closely enough to trigger an immune response.

While medical science has made progress in developing vaccines to prevent viral diseases, more elusive has been the quest for drugs that will knock out virus infections once they take hold in the body as effectively as antibiotics fight bacterial infections. But a few drugs have been developed that will provide limited protection against certain viral infections if they are taken *before* the individual is exposed to the virus. The drugs can often reduce the severity of the illness if it occurs. Such drugs include:

- Idoxuridine, for the treatment of herpes simplex keratitis, an eye infection that can cause blindness.
- Amantadine hydrochloride, useful in the prevention and treatment of certain types of influenza.
- Vidarabine, for the treatment of herpes simplex encephalitis, an inflammation of parts of the brain.
- Ribavirin, which may be useful against certain types of viral respiratory tract infections.
- Acyclovir, which alleviates the effects

and shortens the duration of the lesions caused by genital herpes.

The prospects of finding additional therapeutic agents to knock out viruses are by no means bleak. Several agents, including some made by recombinant DNA techniques, are currently being tested in patients.

What about the AIDS virus? Does the progress medical science has made in the field of virus research mean that it is only a matter of time before we have an answer?

The difficulty with AIDS is that it involves a particular kind of virus called a retrovirus. And the AIDS virus strikes at the very immune system whose disease-fighting capabilities immunologists would seek to mobilize with a vaccine.

The AIDS virus wreaks havoc with the immune system by invading, altering and ultimately destroying the so-called helper T-cells, which play a central role in the body's complex disease-fighting response.

The response typically begins when large macrophage cells in the bloodstream detect invading viruses and alert the T-cells. The T-cells, in turn, are transformed into several types, including the T-4 cells—also called helper T-cells—which activate B-cells. The B-cells multiply and produce the antibodies that inactivate the invading viruses.

Like other retroviruses, the AIDS virus has genetic material composed not of DNA but of RNA (ribonucleic acid), which carries a blueprint for making DNA. The AIDS virus enters the T-cell and instructs the cell to use the viral RNA to make viral DNA and incorporate it into the cell's own genetic material. There it may remain dormant; at this stage it is called a provirus. As the cell reproduces, the AIDS provirus is reproduced as well.

Locked inside the genetic material of the T-cells, the DNA for the AIDS virus is well protected. Researchers have yet to find a way to ferret out and destroy it, or to prevent it from breaking out to form new viruses. Scientists are more hopeful of developing a vaccine to stop the AIDS viruses while they are still in the bloodstream (when they are known as virions) before they gain access to the T-cells.

Recent laboratory studies indicate that it may take another agent to trigger the viral DNA to begin producing AIDS viruses. So far, it is suspected that these triggering agents may include the parasite that causes malaria, as well as blood or semen from another individual.

As the viruses replicate, they break out

of their host T-cells, destroying them and leaving the body defenseless against other infections.

These other “opportunistic” infections are very often fatal. The diseases include Kaposi's sarcoma, a very rare form of cancer, and *Pneumocystis carinii* pneumonia, a devastating lung infection, as well as a host of other bacterial, viral and parasitic infections.

Besides viruses and retroviruses, researchers are finding even more unusual viral pathogens (disease-producing organisms) that are at least as destructive to human life as their more conventional cousins.

Scrapie, a disease in sheep and goats, and Creutzfeldt-Jakob disease, which afflicts humans, are members of a group of “slow viruses” that cause a variety of degenerative diseases. After a long period of incubation, varying from two months to several decades, these viruses begin to attack the nervous system with increasing intensity. This active phase of the disease may last from six months to two years and invariably leads to death.

Another slow virus disease is kuru, which is prevalent among the cannibals of New Guinea. Some researchers believe slow viruses also may be responsible for Alzheimer's disease and other devastating afflictions of the brain and nervous systems.

Some investigators call these slow viruses prions. To them, the prions appear to be made up of just a single protein. Scientists suspect that a nucleotide, a compound found in nucleic acid, plays a role in the replication of prions.

Biological fragments called viroids constitute another class of sub-viral particles. Viroids, which seem to be made up solely of single-stranded RNA molecules, have no protein coat. They are at least three times smaller than the most minute virus. Viroids attack plants but are not known to cause disease in humans.

Viroids, prions, virions, proviruses, retroviruses. As researchers advance on viral diseases such as AIDS, they are finding that this submicroscopic world is one of intricate complexity. For each piece of the puzzle they find, they seem to uncover new gaps in their knowledge. It is a world that Jenner, Pasteur and Beijerinck would never have imagined. ■

Egon Weck, a free-lance writer, has written extensively on health and medical issues.

The Itch of the Great Outdoors

by Annabel Hecht



On these hot summer days, when the realization dawns that the tiny blisters on legs or arms or wherever can only have come from a brush with poison ivy, there may be some small comfort in knowing that you are not alone. Most Americans are sensitive in some degree to this ubiquitous three-leafed plant. Only about 15 percent of the population is not affected.

Poison ivy and its cousins, poison oak and poison sumac, are responsible for more of those itchy, oozing blisters (a condition known medically as allergic contact dermatitis) than any other cause, including industrial chemicals, household products, and cosmetics. While it may be only a summer annoyance for some, for others poison ivy dermatitis can be disabling and is responsible for a considerable amount of time lost from work. Fire-fighters are particularly vulnerable. They not only come in contact with the plants themselves, but are exposed to smoke carrying plant particles, which when inhaled can have severe internal as well as external effects.

Despite the toll it takes in discomfort and disability, no one has come up with a way—other than avoidance—to prevent or cure this condition known simply as “poison ivy.”

What causes those familiar itching blisters is a chemical called urushiol (pronounced oo roo’ shee ohl). Urushiol is found in the resin, or sap, that is carried in canals within the bark, stem, leaflets, and certain flower parts of the plants. Since these canals do not connect with the plant’s surface, the plant has to be broken or crushed before it can do its itchy work.

Surprising as it may seem, brushing against an intact plant will not cause a reaction. In fact, you could have a garden full of poison ivy and not get a single blister—provided, of course, the plants were undisturbed. However, what may look like an intact plant may not be, for insects chewing on the plants can cause breaks in the surface, releasing the sap.

On the other hand, you don’t have to come in contact with a plant to develop dermatitis. Urushiol is sticky and can be carried on the fur of animals (they are not sensitive to it) and on garden tools, golf balls, and other objects that have come in contact with a broken plant. Touching these objects can transfer the urushiol and lead to a reaction. Once in contact with the skin, the urushiol begins to penetrate in a matter of minutes. In about 12 to 48 hours there is a visible reaction on the skin as the body marshals its forces to combat the invader. First, there is redness and swelling, followed by blisters. Itching is inevitable.

In a few days the blisters become crusted and then begin to scale. If there are no complications, such as an infection due to scratching, the dermatitis clears up in about 10 days.

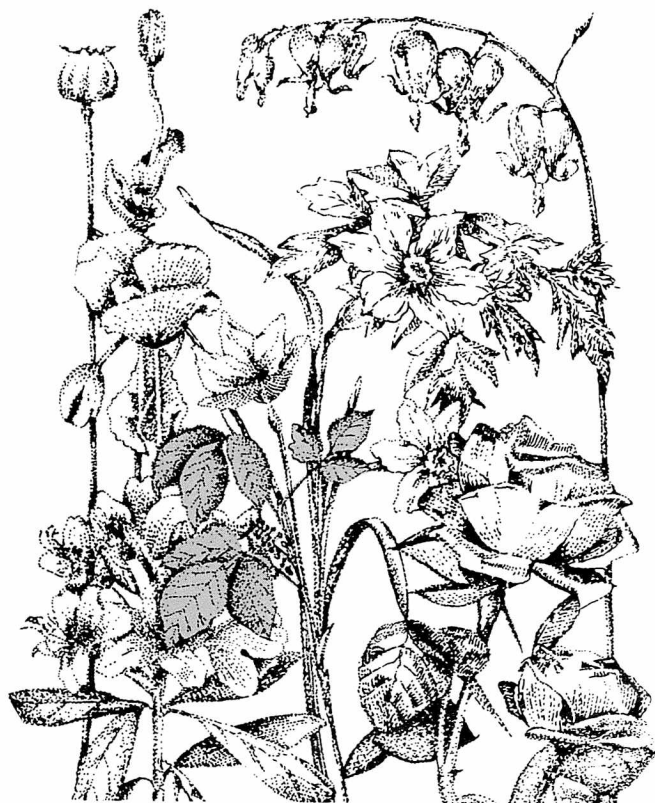
One of the many myths about poison ivy dermatitis is that it can be spread from one part of the body to another, or even to other people, via the oozing material in the blisters. Not so. The blisters contain not urushiol but a fluid from the clear portion of the blood, produced as part of the body’s reaction to the urushiol. This fluid cannot spread the dermatitis. The victim does the spreading before the blisters have formed, while there is still urushiol on the skin. Urushiol on the hands can be carried to other parts of the body, for instance by scratching the nose or wiping the forehead. While poison ivy dermatitis usually occurs on exposed areas of the skin, it can crop up in unlikely places, such as under clothing, thanks to this self-spreading.

Spreading the dermatitis from person to person can only occur if one person comes in contact with the urushiol on the other’s body or clothing.

Sensitivity to poison ivy is not something people are born with. It develops after several encounters with the plants, sometimes over many years. Once a person has become sensitive to poison ivy, he or she is sensitive to all of the “poison”-type plants. Contact with the sticky urushiol can cause almost any part of the body to break out with the characteristic linear (in a line) rash. The soles of the feet and the palms of the hands are less sensitive, while areas where the skin is thinner are more sensitive to the ivy sap. The severity of the dermatitis may also depend on how big a dose of urushiol the person got. Other allergies a person may have play no part in poison ivy dermatitis.

If you suspect you’ve gotten into poison ivy, the first thing to do is to thoroughly wash the exposed areas. Washing may not stop the initial outbreak of the rash if too much time has elapsed, but it can help prevent further spread.

Harold Baer, an FDA expert on poison ivy, advises washing with soap. The sap of the ivy and oak plants is very sticky and not very water soluble. Soap helps to break it down so that it can be removed, Baer says. Myth has it that a strong yellow soap is



Know Thine Enemy

That old saying, "Leaflets three, let it be," is a good rule of thumb for anyone who wants to avoid the miseries of poison ivy dermatitis. The best way to identify poison ivy and poison oak is to look for the characteristic three leaves. However, there are variations depending on where the plants are growing. One or the other of these plants is found in every part of the United States except some desert areas of Nevada. They are also found in Canada and parts of Mexico, South America and the West Indies, but not in Europe.

Poison ivy grows throughout the United States except in the extreme Southwest. It can be a woody, ropelike vine, a trailing shrub on the ground, or a free-standing shrub. Its leaves are green in the summer and red in the fall. Small greenish-white to cream-colored flowers appear after the leaves open in the spring. The fruit ripens into tan to yellowish berries.

Eastern poison ivy leaves have smooth

margins; those in the central states have notches or teeth on the leaflets. From Oklahoma to Texas, poison ivy plants have a deep, acute lobe (a so-called thumb) on either side of the end leaflet and on the outer edge of the other two. Those from the Rio Grande basin may look like the club in a deck of playing cards.

Eastern poison oak is a low shrub found from New Jersey to eastern Texas. It grows on poor sandy soils where poison ivy generally does not. The center leaf of the three looks like an oak leaf.

Western poison oak grows on the Pacific coast from southern California to Canada in several forms: As an upright shrub it can grow into large spreading clumps six feet tall; in forests it can be a vine up to 30 feet tall. The three leaflets are irregularly lobed and resemble oak leaves.

Poison sumac is a tall rangy shrub that may reach a height of 15 feet. The bright green leaflets have no teeth on their edges, while the leaves of the nonpoisonous sumac do. The fruits are glossy pale yellow or cream colored and hang down when they are ripe. Nonpoisonous sumac fruit is red

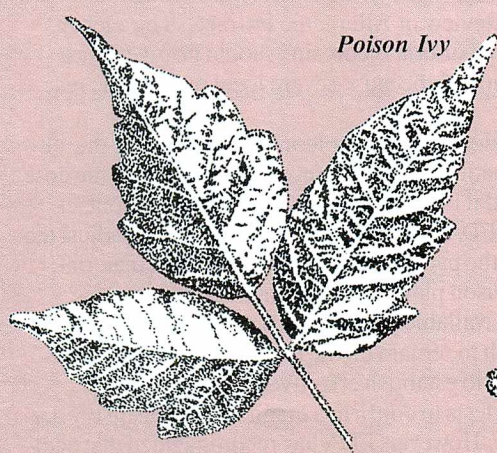
and stands erect. Poison sumac grows in damp, swampy areas, particularly east of the Mississippi River.

All of these poisonous plants are members of the *Anacardiaceae* family, which includes the mango, lacquer tree, and cashew nut tree. A person who is sensitive to poison ivy, oak and sumac will be sensitive to these plants as well.

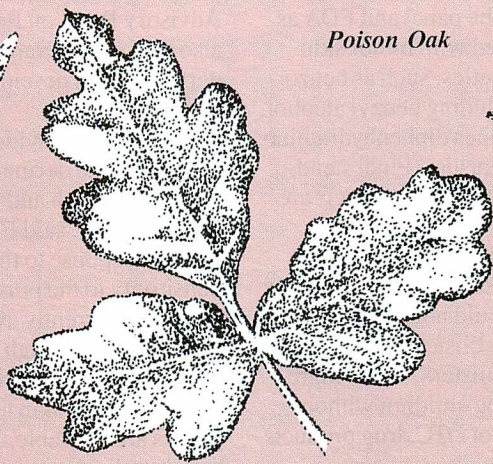
Poison ivy, oak and sumac are most dangerous in the spring and summer, when there is plenty of sap, the urushiol content is high, and the plants are easily bruised.

Poison ivy dermatitis is generally regarded as a summer complaint, but it can be contracted in the winter when the plants are dormant, too. Cases have been reported in individuals who cut wood for the fireplace or used the vine in Christmas wreaths.

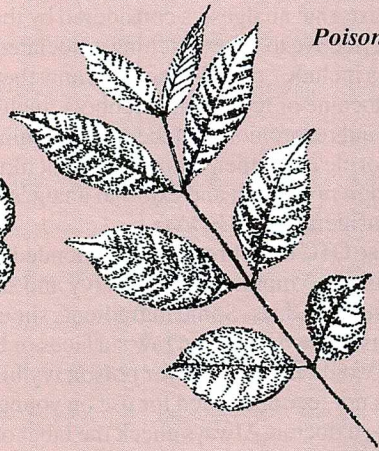
If you have poison ivy in your garden and want to get rid of it, don't burn it. Plant parts can be transported in the smoke from burning plants to affect the unwary gardener. It is better to dispose of unwanted plants in sealed plastic bags or kill them with a herbicide and then bury them. ■



Poison Ivy



Poison Oak



Poison Sumac

required. Not so, according to Baer. Any soap will do.

Clothing that has picked up the sticky sap should also be washed as soon as possible. Be sure to handle it carefully, with gloves, if necessary, to prevent any more exposure to the sap.

Considering that poison ivy has been recorded since the days of Captain John Smith, it is not surprising that a wealth of home remedies has evolved to treat this dermatitis. Not the least creative—though hardly to be recommended—are bathing in horse urine, cleaning the skin with gasoline or strychnine, and rubbing on a variety of products such as ammonia, hair spray, clear nail polish, meat tenderizer, or mouse-ear herb boiled in milk. The juice of crushed leaves of plantain, a common weed found in many yards, is favored by many hikers today. There is no scientific proof that it works.

When all is said and done, the simplest treatment is still the best. Mild cases of poison ivy may require no more than wet compresses or soaking in cool water to relieve the itching. Dilute

aluminum acetate (Burrows solution), saline (salt), or sodium bicarbonate (baking soda) solutions are often recommended to dry up the oozing blisters.

Oatmeal is a drying agent as well as a cereal. You can buy an oatmeal preparation (Aveeno) for use in a bath or make your own by tying up about half a cupful of uncooked oatmeal in a clean cloth, such as a large handkerchief, and soaking it in water. Squeezing releases an oatmeal solution that will help dry up oozing blisters. Be warned, however, that it is messy and can make the tub extra slippery.

A variety of nonprescription drug products is also available to dry up the oozing and weeping blisters. Among the skin protectant ingredients FDA's expert advisors say are safe and effective are aluminum hydroxide gel, calamine, kaolin, zinc acetate, zinc carbonate, and zinc oxide. These ingredients were given the green light by the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention



and Treatment Drug Products, one of 17 panels of outside experts assisting FDA in its massive review of all OTC (over-the-counter) drug products.

The same panel recommended, and FDA has concurred, that hydrocortisone preparations—hydrocortisone 0.25 and 0.5 percent and hydrocortisone acetate 0.25 and 0.5 percent—be used for the temporary relief of itching associated with poison ivy, poison oak, or poison sumac.

Other external analgesics considered by the panel and FDA as safe and effective to relieve itching associated with minor skin irritations include “caine”-type local anesthetics, such as benzocaine, lidocaine or tetracaine; alcohols, including benzyl alcohol, menthol and resorcinol; and the antihistamines diphenhydramine hydrochloride and tripelemnamine hydrochloride. (Final standards for skin protectant and external analgesic drug products are under consideration by FDA.)

All these OTC drug products are intended only for the treatment of minor symptoms of poison ivy and should not be used for more than seven days. Some ingredients should not be used over large areas of the body or on raw surfaces or blistered areas and therefore would not be good for poison ivy blisters. A few ingredients are not recommended for use on young children without consulting a doctor. Always check the label of OTC drug products for specific instructions for use.

Severe poison ivy dermatitis should be treated by a doctor, who may prescribe a stronger topical steroid preparation or oral medication to be used for several days. Because side effects can be serious, such treatment is not given lightly.

Preventing poison ivy miseries should be easy—just stay away from plants. However, this is not always possible for those whose work takes them into the woods and fields where the oak and ivy grow. Unfortunately, there are no OTC products that can prevent poison ivy, oak or sumac dermatitis, according to the Advisory Review Panel on OTC Miscellaneous External Drug Products.

Another approach to preventing, or at least lessening, the consequences of poison ivy is desensitization with extracts of the plant itself. American Indians are said to have eaten poison ivy leaves for protection against the sap. This is not a practice to be recommended, however, for a nasty side effect is dermatitis at both ends of the gastrointestinal tract—the mouth and the anus. (The middle portion seems to be immune to these effects.)

Researchers at the University of California, San Francisco, are

working on a potential vaccine. They claim to have found a way to neutralize the urushiol molecules, thus eliminating the itching. More testing is needed to see if the vaccine is truly safe and effective.

Because of severe reactions, injections with plant extracts (called oleoresins) to prevent poison ivy are not recommended, FDA noted in a proposal to establish standards for allergenic products. The proposal was based on the recommendations of the Advisory Panel on Review of Allergenic Extracts. The agency also said no injectable or oral oleoresins should be given once dermatitis has developed, because severe local or systemic reactions may occur.

There is good evidence that oral oleoresins can reduce the severity of the dermatitis—but not prevent it entirely—if the dose is strong enough and it is given for long enough *before* contact with the plant, said FDA. It is important that the doctor adjust the dose in response to the patient’s reactions to the plant material. Sensitivity to the poison plants returns when the treatment is stopped. Currently available products in both liquid and tablet form are safe enough to remain on the market, but FDA recommended further tests to establish effectiveness.

A number of skin tests to confirm a diagnosis of poison ivy dermatitis are available. However, FDA has recommended that additional studies are needed to standardize these products.

A two-stage patch test to determine who is sensitive to poison ivy is being developed by the Forest Service of the U.S. Department of the Interior, to aid in assigning firefighters. The more sensitive people can be assigned to areas where there is less chance of exposure to the plants.

Until effective vaccines are available, the bottom line still remains—if you want to prevent poison ivy dermatitis, avoid the offending plants. Learn to recognize them in all seasons. If you’re going to be in areas where they are likely to lurk, protect yourself by wearing long pants and long sleeves.

As soon as you realize that you have been in contact with poison ivy, oak or sumac, thoroughly wash all exposed areas of skin. Launder your clothes and wipe off footwear, tools and other items that may have been in contact with the sap as soon as possible.

Summertime doesn’t have to be spoiled by poison ivy itches if you stay alert. ■

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

Food Allergies

Separating Fact From 'Hype'

Americans' fascination with so-called health foods began its present cycle about 20 years ago and has not yet run its course. But now there is also a fascination with foods and food ingredients that are seen as *unhealthy*, that supposedly can produce mild to severe mental, physical and emotional symptoms and cause changes in work performance and social behavior.

It seems to be the other side of the health food coin, and it has an appealing, simplistic logic: Some foods are good; others are bad, at least for you. So if you have or think you have symptoms of whatever kind that cannot be explained to your satisfaction, blame it on a "food allergy."

Those who encourage the belief that food allergies are everywhere are usually promoting products and theories. Some are opportunists; others have worked out their own private theories of illness and disease, often with little regard for scientific fact.

But Dr. Jordan Fink, chief allergist at the Medical College of Wisconsin and past president of the American Academy of Allergy and Immunology (AAAI), puts the whole issue in perspective.

We are talking about less than 2 percent of the American population as having true food allergies, he says. Among adults who are thoroughly tested, he continues, "perhaps five percent who think they have allergies will turn out to have one."

Science writer Jane Brody of *The New York Times* says the link between what people eat and how they behave is being recklessly expanded, "with everything from intellectual performance and muscular prowess to hyperactivity and criminality now related—without justification—to consumption of various foods and their constituents."

She sees this as having some strange results. "In homes, schools and institutions around the country," she writes, "hyperactive children, prisoners and juvenile delinquents are being placed on special diets that restrict sugars, additives and in some instances, milk, in the belief that this can improve their disruptive behavior."

"In California, for example, the county juvenile justice systems

have changed the way that detained juveniles are being fed. The specifics may vary but all seek to reduce sugars and additives. Dr. Stephen Schoenthaler, whose preliminary findings on diet and antisocial behavior may have triggered these measures, says educational and correctional institutions in 44 states have asked his office for help in changing dietary practices," according to Brody.

She adds that there is a price to pay for this misapplication of scientific research. "In attributing criminal or delinquent behavior to a food allergy or sensitivity, the person in effect is excused from that behavior."

The most bizarre use of this theory may be the "Twinkie" defense that helped win a reduced penalty in 1978 for a murderer in San Francisco. The defense claimed, and the jury accepted the premise, that the defendant's habit of overeating sugary snack foods, potato chips, soft drinks, and the like produced his violent behavior. With that success—the charge reduced from murder to manslaughter—a number of lawyers handling criminal cases began seeking acquittal of their clients on the basis of "temporary insanity induced by a food-caused mental derangement."

Hoping to control their hyperactive children, many parents will not allow them to eat foods that contain artificial colors and flavors and added sugar. This widely used diet became popular after reports by the late Dr. Benjamin Feingold that such diet restrictions would affect the often frantic behavior of these children. Even though repeated studies do not support these claims, some parents—not wanting to medicate their children—opt for the diet over drug treatment shown to be effective.

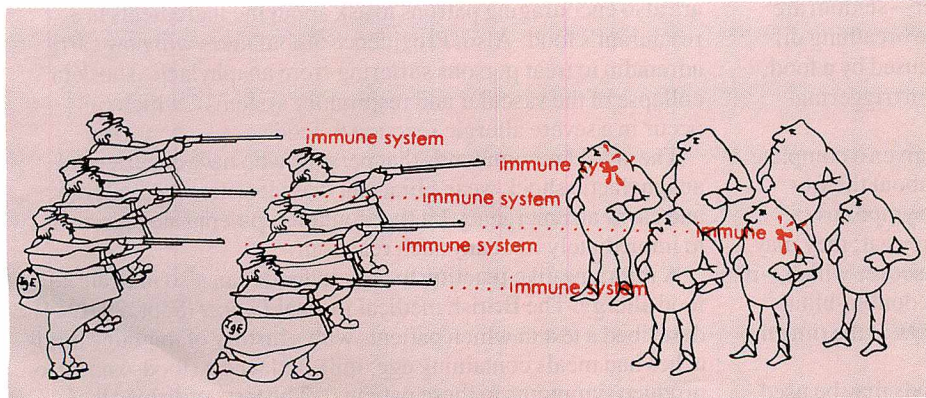
Those who claim—for whatever reason—that dietary changes will produce dramatic improvements in behavior are not willing to wait for scientific confirmation. They do not care that the treatment may be unscientific or that the apparent benefits could be a placebo effect or the result of other variables. What matters is that it seems to work.

Public acceptance of links between diet and behavior is alarming to serious medical researchers, who say that the evidence that certain foods might affect emotions and behavior is not ready to be put to use.

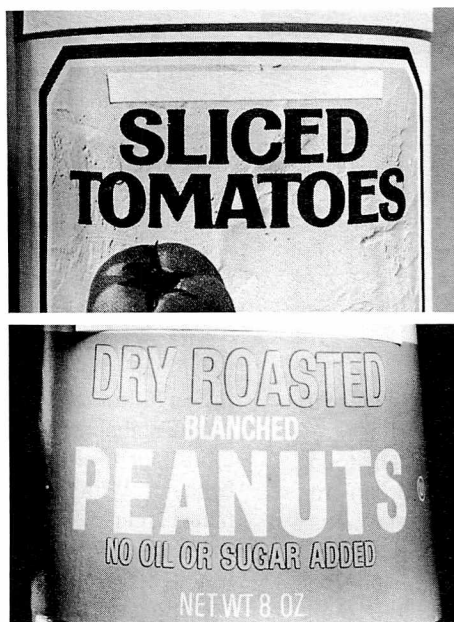
Dr. Richard Wurtman, neuroendocrinologist at the Massachusetts Institute of Technology, was one of the first to show that foods can affect the brain. He says that food allergy studies are being applied before they have been confirmed as scientific fact. He is uneasy that anecdotal evidence about dietary effects is being accepted as truth and "solidified as social policy."

Dr. Michael Yogman, pediatric researcher at Harvard, says people are much too ready to apply study results, that work in this area is only beginning.

Dr. John Crayton of the University of Chicago is another researcher who has found a possible link between food and mood



People who suffer from allergies have excess immunoglobulin E (IgE) circulating in their blood. IgE activates the body's defenses—the immune system—causing a reaction to substances that other persons' bodies would ignore.



The American Academy of Allergy and Immunology cites peanuts, soy and tomatoes as foods to which people can be allergic. The academy also lists egg white, cow's milk, codfish, shrimp, crab, and the gluten in wheat and rye among the more common food allergens in the United States. Once an allergy is identified, avoiding that food and looking for substitutes may be the simplest way to handle the situation, not easy with something as basic as wheat.

but is quick to point out the limitations of such findings. In his study, a group of 35 volunteers—some with complaints of food sensitivity—were fed capsules of powdered wheat, milk or chocolate, foods often associated with allergies. He found that changes in mood, coincidental with changes in their immune systems, did occur in this group. He theorizes that food-induced reactions may cause local swelling in the brain that leads to mood swings, but cautions that this is early work and not yet understood.

In its patient's guide, the AAAI says that a true food allergy is a response in which the body's immune system overreacts to substances in food. These responses occur in very few people, are usually the result of a genetic factor, and can be noticed almost at once when only a small quantity of a food has been eaten. Infants with certain food allergies may outgrow them as their immune systems mature.

Those parts of food that cause reactions are called allergens. They are usually proteins, and the body responds through its immune defense system—as it should—to what it thinks are threatening foreign invaders. The most common protein allergens in the United States, according to the AAAI, appear to be cow's milk, egg white, peanuts, wheat and soy, although shrimp, tomato, codfish and crab contain proteins to which some people are allergic, too. Cooking can reduce the effect of some protein allergens but may increase the effect of others.

A food allergy may show up as hives, a skin reaction in which red, itchy, swollen areas suddenly appear, then soon disappear. Eye and nasal symptoms—like those of hay fever—seldom are caused by food allergies. The AAAI says that the breathing difficulty known as asthma may—in infants—be caused by a food, but foods are not thought to play a frequent role in triggering asthma in adults.

Patients with suspected food allergies will be given a complete physical examination and asked by their doctor about the frequency, severity, seasonality and nature of their symptoms.

They may have to keep a "food diary" of all they eat; they may have to eliminate certain foods, one by one, to discover which—if any—are at fault; they may have to participate in double-blind studies in which neither they nor their doctor know at the time the food they are eating.

Skin testing with a liquid extract of suspect foods may be used,

but the technique is not as reliable as when testing for pollen allergies. Blood tests are also useful for diagnosis for some patients in some instances.

Promoters of unproved methods for detecting food allergies—who are adept at linking food, mood and behavior—say that everyone is at risk and that their tests will find your allergy. (See "The Flaw in Cytotoxic Testing: There's No Proof It Works" in the October 1984 *FDA Consumer*.) But everyone is not at risk and there's no evidence that cytotoxic testing—dropping food extracts on a patient's white blood cells in a laboratory dish—or sublingual testing—placing a bit of the suspect food under the patient's tongue—will detect anything.

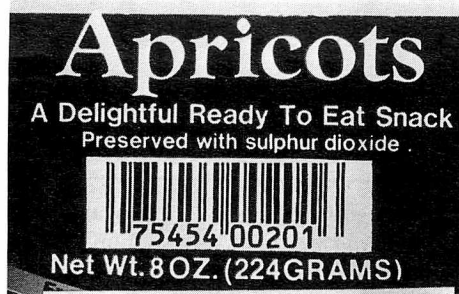
One recognized food allergy is a reaction to sulfites. These are preservatives added to foods, usually during manufacturing but sometimes at the point of sale, as with some restaurant salad bars. Sulfites are harmless to most people but can cause reactions that are severe and sometimes fatal to those sensitive to them, especially to persons with asthma. FDA requires that products containing sulfites be labeled so that consumers who wish to can avoid them. Less than 1 percent of the population is thought to be sensitive to sulfites. (See "Reacting to Sulfites" in the December 1985-January 1986 *FDA Consumer*.)

Nuts are another allergen that can be threatening. The recent death from anaphylactic shock of a college student in Providence, Rhode Island, who ate chili that—unknown to her—contained peanut butter prompted health officials to ask that restaurants list "highly unusual ingredients" that are in their foods. The officials are also encouraging patrons to ask about the ingredients in a restaurant's food. Also, Providence ambulances will now carry adrenalin to treat persons suffering from anaphylactic shock (a collapse of the vascular and respiratory systems), which can occur in a severe allergic reaction to food.

The AAAI recommends that persons who have experienced anaphylactic shock wear a bracelet that identifies their allergy and carry an emergency kit that contains epinephrine (adrenalin) to immediately treat any such reaction.

A migraine-like reaction to certain foods can also indicate a food allergy. The British medical journal *Lancet* (Sept. 29, 1984) described a test in which patients with a history of migraine headaches had meals containing egg, milk and wheat (foods known to produce symptoms in these patients). The test confirmed that

MSG
PURE
MONOSODIUM GLUTAMATE



Salt, Egg White Solids, Confectioner's
Color Including FD&C Yellow No. 5.



By law, labels must state if a food contains monosodium glutamate (the popular flavor enhancer), Yellow No. 5 (a widely used color additive shown here with candy corn), or a sulfite preservative (shown here as sulfur dioxide). All are known allergens that can have severe effects on sensitive individuals. Another ingredient that must be listed on labels of foods and beverages that contain it is aspartame. People with the metabolic disorder known as phenylketonuria cannot process the artificial sweetener.

migraine in these particular cases was an immune response to an allergen.

Public interest in food allergies—real or imagined—will not go away, according to Dr. A. Elizabeth Sloan, director of the Good Housekeeping Institute. In fact, she said, it has the potential to become the major consumer food issue of the next decade.

Sloan said a survey by *Good Housekeeping* showed that 30 percent of the women interviewed believed that they or a member of their families were allergic to a food or food ingredient. Twenty-two percent said they actually avoided certain foods on the chance that they might contain an allergen.

Their greatest concerns were with sulfites, the artificial sweetener aspartame, the color additive tartrazine (FD&C Yellow No. 5), and the flavor enhancer monosodium glutamate. The women's fear of having an allergic reaction to food ingredients was comparable to their fear of getting cancer from certain additives, a marked increase from surveys taken in previous years by the magazine.

Sloan said that it is essential to find the true incidence of allergic reactions to these and other food substances. If only a few in the population are sensitive to it, she says the ingredient should be noted on the label. If it is found to be a risk to a great many people, the ingredient should no longer be used or the amount used should be reduced so that it does not cause a reaction.

To give FDA a better understanding and data base on the extent and seriousness of allergic reactions to food, the agency has established a new reporting and surveillance system in its Center for Food Safety and Applied Nutrition.

Using reporting forms like those long used for adverse drug reactions, physicians and other health professionals are being asked to inform FDA of any severe and well-documented allergic reactions to food.

The center currently monitors adverse reactions to sulfites and aspartame and needs to receive reliable information on reactions that appear to be associated with these or similar foods, food additives, and dietary practices.

The new allergic reaction reporting system will be an adjunct to the center's system for reporting illness or injury caused by microbial contamination and adulterated food products.

Microbial contamination can cause food poisonings such as salmonellosis, but the illness is not allergic in nature. The new

system will not duplicate reporting of food poisonings already being coordinated by the states and the U.S. Centers for Disease Control.

Reports to FDA of allergic reactions will be investigated by the FDA field office that receives the complaint.

The headquarters emergency operations staff receives copies of all consumer complaints that come to agency field offices. Currently, FDA receives 12,000 to 15,000 consumer complaints of all kinds each year. Some 70 percent of these are food related. The others are reports of illness or injuries related to medication, medical devices, and other products that FDA regulates.

Health professionals who become aware of non-microbial (allergic) reactions to foods can report the incident by using the form on the back of the *FDA Drug Bulletin* that is mailed several times a year to 1 million physicians and other health professionals in the United States.

In addition to the new reporting system, FDA has established an advisory committee on hypersensitivity to food constituents. In announcing the committee, Commissioner Frank E. Young, M.D., noted that—because medically accepted tests for sensitivity have never been conducted on a large segment of the population—accurate estimates of adverse reactions to foods cannot be made.

The committee will consider the prevalence of allergic reactions, the need for research, the effectiveness of present labeling for hypersensitive substances, methods to protect that small part of the population that is sensitive to substances that are harmless to the general population, and other aspects of reactions to foods and food ingredients.

Consumers who feel they may be allergic to some food or food ingredient in their diet should discuss the matter with a physician. There are legitimate tests that can help determine whether a food is really at fault, but they can be fairly expensive, time-consuming, and will require a good deal of dedication on the part of the patient in controlling diet and scrupulously keeping track of what foods are consumed. But those who blame their state of mind on the state of their diet should remember that—despite all the attention given to the food, mood and behavior link—the evidence that does exist shows that such relationships are rare. ■

—Richard C. Thompson

The Notebook

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.

■ The final report of the **Color Additive** Scientific Review Panel on D&C Red No. 19, D&C Red No. 37, D&C Orange No. 17, and FD&C Red No. 3 is available from FDA's Dockets Management Branch, HFA-305, 5600 Fishers Lane, Rockville, Md. 20857. Send two self-addressed adhesive labels (FR March 6).

■ Public comments and other information concerning the possible over-the-counter marketing of beta-adrenergic **bronchodilators** in metered-dose inhalers can be sent to FDA's Dockets Management Branch, HFA-305, 5600 Fishers Lane, Rockville, Md. 20857 (Docket No. 86N-0063). Drug products in this class are albuterol, isotharine, isoproterenol and metaproterenol (FR March 21).

■ The World Health Organization is seeking information on 25 **non-barbiturate sedative drugs** to determine whether international restrictions are needed. Six are currently available in the United States: acecarbromal, buspirone, dichloralphenazone, etomidate, propiomazine and triclofos (FR March 5).

■ The U.S. Customs Service wants comments on when to implement a requirement that the country of origin be marked on labels of frozen concentrated and reconstituted **orange juice** products that contain imported concentrate (FR March 3).

■ From March case reports of the National Advertising Division (NAD), Council of **Better Business Bureaus**: Citrus Hill Select **orange juice commercials** showing the interior of an orange trimmed to a cube would not mislead consumers into thinking the product was superior to other juices. The advertiser proved to NAD's satisfaction that the ads were not comparative.

Ad claims that Pompeian Inc. virgin **olive oil** is more digestible, more versatile, and better than "pure" olive oil have been discontinued, according to the advertiser. Studies cited by the advertiser did not substantiate some of the claims while data was lacking to support others, NAD said.

Royal Crown ads depicting Diet Rite Cola as salt/sodium free while competing brands were depicted as having 35 milligrams of sodium were challenged by a competitor. The advertiser stood by the claims, but said the ads were run on a short-term basis and would not be used in the future.

■ FDA is proposing to establish a uniform set of specifications for all regulated uses of **D&C Green No. 6** and to remove an obsolete restriction on its use in sutures. The agency also has issued a final rule increasing the level at which Green No. 6 can be used to color certain surgical sutures (FR March 21).

■ The Drug Enforcement Administration has put the benzodiazepine drugs **quazepam** and **midazolam** into schedule IV of the Controlled Substances Act, limiting prescription refills to five times in six months (FR March 25).

■ Reports available from the Department of Health and Human Services' Toxicology Program:

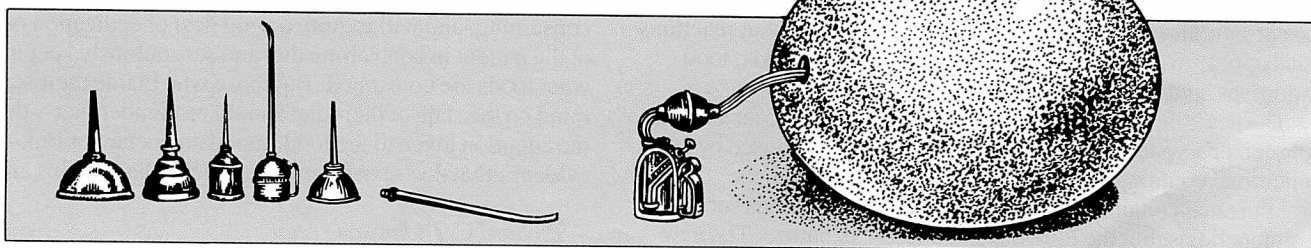
Studies of dichloromethane (**methylene chloride**), widely used in industrial processes, food preparation, and agriculture, show some evidence of being carcinogenic (able to cause cancer) in male rats and clear evidence of carcinogenicity in female rats.

Studies of **dimethyl morpholinophosphoramidate**, used to simulate the physical (not biological) properties of nerve agents in chemical defense training, show some evidence of carcinogenicity for rats, but not for mice.

Studies of **HC Red No. 3**, used exclusively as a semi-permanent hair dye, show no evidence of carcinogenicity for male or female rats and equivocal evidence for male mice. Data for female mice were inadequate.

All reports are available from the National Toxicology Program Public Information Office, MDS B2-04, P.O. Box 12233, Research Triangle Park, N.C. 27709 (FR March 27).

■ FDA's Center for Devices and Radiological Health has prepared "Draft **Anesthesia Apparatus** Checkout Recommendations" describing procedures to ensure that all parts of the anesthesia apparatus are correctly connected and functioning as intended. Single copies are available from the center (HFZ-240, FDA, 5600 Fishers Lane, Rockville, Md. 20857) (FR March 28).





X-Ray Installation Scam Exposed

by Carolyn Hommel and
Richard C. Thompson

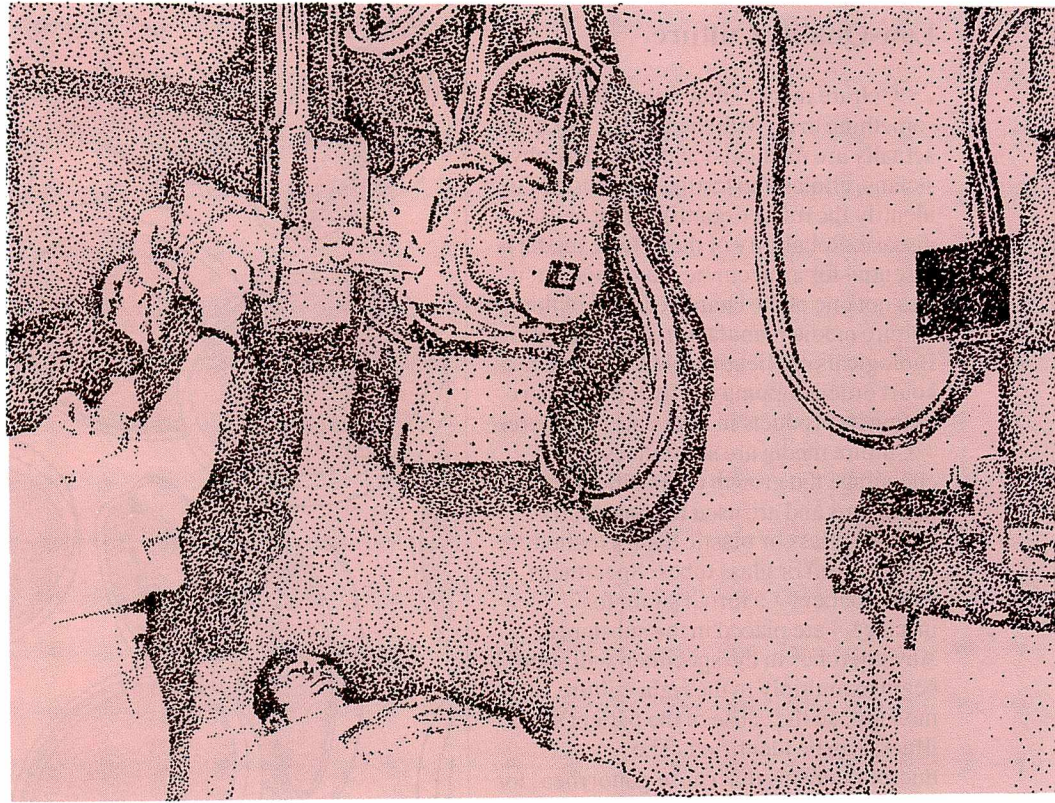
The owner of a South Carolina firm that assembles and installs medical X-ray systems thought he had found a sure-fire way to make some extra profit and undercut his competition. He had an elaborate scheme to skirt FDA safety rules that protect patients from unnecessary radiation caused by improperly installed X-ray systems. By pulling the wool over FDA's eyes, he could save \$2,500 on each such installation.

When FDA, with the help of state officials, uncovered the scheme, the firm, X-Ray of Greenville, Inc., and its owner, Walter Wilder, not only lost all their extra profit, but also ended up with the dubious distinction of coming out on the losing end of the first case ever to go to trial under the 1968 Radiation Control for Health and Safety Act.

The FDA regulation that was the object of Wilder's evasion calls for the use of a safety feature called positive beam limitation (PBL) on X-ray systems. PBL protects patients by making sure the size of the X-ray beam is no larger than necessary to expose the film. One way of achieving PBL is with a device called an automatic collimator that senses the size and shape of the film being used and automatically adjusts the X-ray beam to those dimensions. If the two don't match, the machine won't operate.

PBL is required for X-ray equipment assembled after 1973, unless the machine is designed to X-ray only certain areas of the body, such as orthopedic X-rays of the back. For those units, FDA permits the use of manual collimators, which the X-ray technician must adjust by hand. Manual collimators are not as good as PBL because of the possibility of operator error. For example, the technician might have difficulty positioning the patient and might slightly enlarge the X-ray beam to be certain the entire film is exposed. If the film is smaller than the beam, the patient gets unneeded radiation.

Wilder was using these manual devices



—which are less expensive than PBL collimators—on his firm's installations. He thought he could get away with it by simply not reporting the faulty installations to FDA, as required by law. FDA would have no way of knowing where the units were or even that they existed, he apparently believed. In fact, Wilder had prepared fictitious bills of sale showing that each unit had previously belonged to a physician. This allowed him to say that he was simply upgrading old equipment, as permitted by FDA regulations without requiring the PBL safety feature.

The scheme began to fall apart in February 1983 when an FDA inspector checked an installation at a chiropractic clinic in Raleigh, N.C. The unit did not have the all-important PBL.

X-Ray of Greenville was identified as the installer, and FDA sent a letter to the firm, telling it to correct the violation or face legal action. When that letter went unanswered, an investigator from the

agency's Atlanta office visited Wilder to ask about the Raleigh unit and any other installations he had not reported. Wilder said he had answered the letter but could not find his response. He also refused access to the firm's records, except for his "doctored" bills of sale.

With the aid of North Carolina and South Carolina state radiation control officials, the FDA investigator located 11 systems that had been installed by Wilder's firm. In no instance had an assembly report been filed.

With this and other evidence, FDA filed a complaint for injunction and civil penalties against Wilder and his firm in the U.S. District Court in Greenville. The case was heard by Magistrate William F. Catoe in October 1985.

Two days of testimony by some of Wilder's customers and a former employee showed that failure to report installation of these systems was a deliberate scheme to hide them from FDA. The former

employee also described the phony sales procedures by which "used" equipment was sold on paper but never assembled, then "upgraded" to avoid the PBL requirement.

Wilder's illegal cost-cutting was wiped out in the court's Nov. 20 decision. Find-

ing against Wilder on all counts, the magistrate ordered him to provide PBL on systems he had installed or to refund the purchase price to his customers; to give FDA access to all sales invoices and other relevant business records; to file reports of assembly and certification for all units that

he had installed but not reported; and to pay \$6,900 in civil penalties. ■

Richard C. Thompson is a member of FDA's public affairs staff. Carolyn Hommel is a consumer affairs officer with the agency's Atlanta district office.

Low-Quality Culture

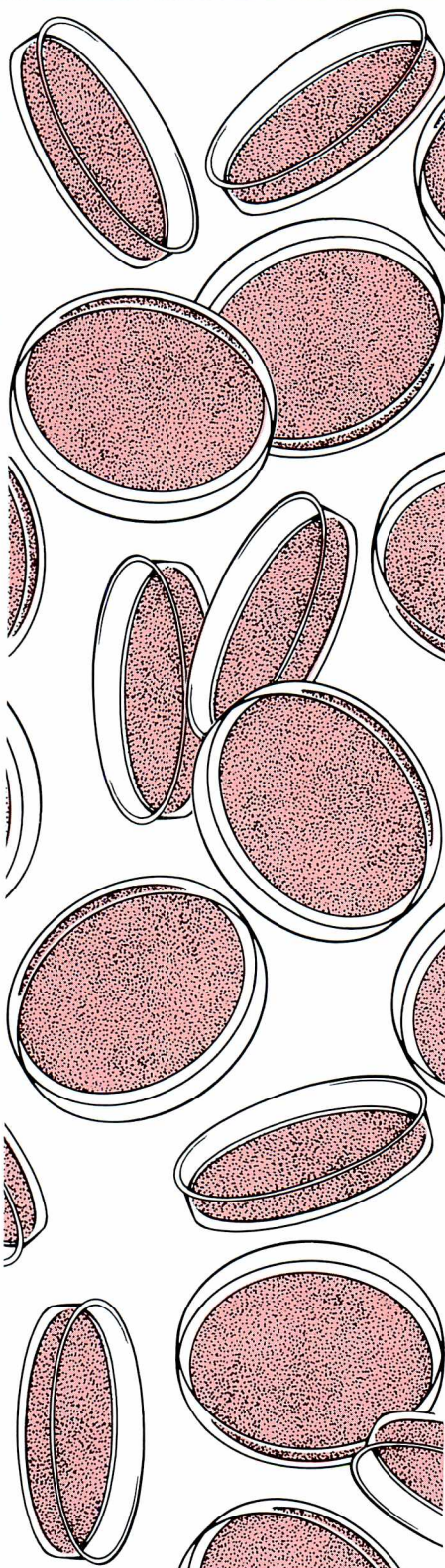
"Culture media" may sound like something to do with the theater, but they actually are medical devices used by physicians, clinics and testing laboratories to identify the microorganisms that cause disease. Reliability of the culture media is essential for an accurate diagnosis, but it was not one of the characteristics of the culture media manufactured by Blue Ridge Biologicals of Hickory, N.C. This led to a court order stopping the firm from distributing its products in interstate commerce.

Culture media are substances that encourage the growth of specific microorganisms and are used to coat small, covered, glass or plastic dishes (called Petri dishes) or glass tubes. Specimens from a patient—a throat swab, for instance—are placed in the substance. Any microbes in the specimen will soon begin to multiply in the right culture medium, so the cause of the patient's illness can be identified. The microorganisms that cause gonorrhea, for example, grow best in a medium called "chocolate agar" (so called because it looks like chocolate). The media for staphylococcus and streptococcus contain blood. Potato dextrose is used to test for *Candida*, a yeast-like fungus that can cause vaginal and other infections.

If a culture medium doesn't properly support the growth of a particular organism or has become contaminated with competing organisms, there could be a delay or error in a diagnosis. To ensure accurate and reliable results, FDA has established good manufacturing practice (GMP) regulations for these devices, which set forth the minimum standards for methods, facilities and controls to be used in their manufacture, packaging and storing.

In October and November 1984, an investigator from FDA's Charlotte, N.C., office inspected Blue Ridge Biologicals and learned that the firm distributed culture media that had failed quality control tests. Some media were not tested at all.

The firm also failed to calibrate measurement equipment and autoclaves,



machines used to sterilize the media. And there were no written procedures to prevent contamination of its aseptic (clean) production area.

FDA sent the firm a letter in January 1985 spelling out the conditions that needed to be corrected. In August the investigator reinspected the firm to find out if promised corrections had been made.

Unfortunately, the firm still had significant problems. Although some procedures had been written, they were incomplete or not routinely followed. Sterility testing, production, and growth testing records had not been maintained or were missing for most products manufactured since November 1984.

Finished lots of media were still being released without testing; before quality control results were reviewed; or in spite of the product's failing quality checks. For instance, media intended for the identification of three intestinal organisms could only support growth of two of them.

In light of these continued deficiencies, FDA asked for a court injunction against the firm in December 1985. On Jan. 21, 1986, Blue Ridge Biologicals signed a consent decree of permanent injunction in the U.S. District Court for the Western District of North Carolina. Under the terms of the injunction, the firm promised not to distribute culture media until good manufacturing practices were in place, and agreed to make any recalls FDA felt were necessary and to reimburse the agency for costs incurred in supervising the destruction or reconditioning of devices that were defective.

Keeping Surgical Devices Sterile

Surgical utensils must be sterile or the patient risks infection. No room for compromise there. But in April and May 1984, when FDA's Buffalo district investigator Mary Carden performed routine inspections of subcontractors of the Healthmed Corporation in Fairport, N.Y., she found faulty package seals on surgical brushes, blades, eye sponges and clamps—in fact, 47 percent of the clamps were packaged

with incomplete seals.

During follow-up inspections of the subcontractors that did Healthmed's assembling, packaging, sterilizing, delivering and warehousing, Carden found serious, continuing violations of FDA's good manufacturing practice regulations. For instance, the packager failed to test incoming products for defects, failed to completely seal the packages, failed to test the seals for defects, and failed to perform "finished product" tests before shipping the products to the sterilization firm.

While the sterilization firm conducted sterility quality assurance tests, it too failed to test the seals on the finished products. Further, Healthmed's specifications and quality control procedures were incomplete. The firm failed to identify which subcontractors and individuals were responsible for ensuring the packages would keep the products sterile.

On April 17, 1985, Carden ordered all Healthmed's surgical instruments placed under administrative detention to keep the unsafe devices from sale. (Healthmed cooperated in quickly recalling products that had already been distributed.) Administrative detention, authorized under the Medical Device Amendments to the Food, Drug, and Cosmetic Act, allows FDA to hold such items from sale only temporarily, to allow time for the agency to determine if a problem exists.

So the detained products were subsequently seized by the government and, under court agreement, returned to the firm to be reconditioned (repackaged and relabeled as nonsterile products) under FDA supervision. Reinspection in January 1985 revealed the firm had not corrected the problem. So, FDA's Buffalo district office requested the U.S. District Court for the Western District of New York to grant an injunction against the firm, and on May 15, 1985, a consent decree of permanent injunction was filed. Under the consent decree, the judge, FDA and Healthmed agreed to work together to solve the firm's problems.

Subsequently, Healthmed stopped shipping the products and notified its customers of the potentially contaminated devices. In correcting the violations, Healthmed saw to it that its subcontractors hired more competent personnel and installed improved sterilization equipment. Under FDA guidance, Healthmed developed internal good manufacturing practices that were required to meet FDA approval and is now marketing safe, sterile surgical utensils.

Bad Trip Bones

Something was in the rawhide chew bones sold in northern California Safeway stores that sent a number of dogs into an unpleasant Wonderland. But what that something was remains a mystery.

FDA's San Francisco district office received three complaints about Amigo brand rawhide chews having a most unfortunate effect on dogs. The animals had episodes of hysterical barking and running around, involuntary urination and defecation, and fearfulness. Two of the dogs had recovered, but blood tests of the third were

manufactured in Korea by Ssang Yong Corp. The Amigo brand chews had been manufactured in Korea and Taiwan, but the manufacturer was unknown.

The rawhide chews had been distributed to the Safeway stores by Awards Service, Inc., Mountain View, Calif. When an FDA investigator inquired at the firm, he learned that the management there had recently received similar complaints, relayed by the firm's own truck drivers, from Safeway managers. Awards Service had asked that Safeway put its complaints in writing, but the managers had not done so.



still abnormal.

The dogs' veterinarians agreed that the animals' behavior was very similar to that produced by Mister Max bleached rawhide chews in 1982. That product had been

Based on the information provided by FDA, Awards Service recalled approximately 2,000 packages of rawhide chew products in various forms, including bones, sticks, chips and rolls. The firm's

drivers retrieved the packages during their biweekly deliveries. The recall was designated by FDA as Class II, meaning that the product might cause temporary or medically reversible health effects, and was monitored by the San Francisco district office.

In the case of the Mister Max chews, extensive testing for heavy metals, hallucinogens and foreign chemicals, as well as tests on the affected dogs, failed to find the cause of the problem. Similarly, laboratory testing on the Amigo brand chews found nothing that could account for the dogs' bizarre behavior. The official reason remains "an unidentified poisonous and deleterious substance."

Drug with a Double Message

Florida is billed as the land of sunshine and oranges. It's also where many elderly folks go to retire. It's also where some other folks go to set up shop to peddle fake cures for the illnesses that often go along with old age.

One such quack peddler was the Kelly-Lane Company in Deerfield Beach. The company manufactured a variety of over-the-counter drugs aimed at the elderly, including "Arthritis Formula Cream with Copper and Gold," "Procaine H-3 Cream," and "H-3 Formula Tablets." The procaine was accompanied by a brochure titled "Procaine—Can It Answer Your Prayers About Aging?" The H-3 formula was billed as a "rejuvenation therapy."

An investigator from FDA's Orlando district office made a routine inspection of the firm and found it had an unusual approach to manufacturing. The drugs were prepared in the garage of a private residence, owned by the president and sole owner of Kelly-Lane.

The company had an equally unusual approach to promoting its products. For the Procaine H-3 Cream and H-3 Formula Tablets, the firm used a four-page brochure claiming that the products could retard aging, promote rejuvenation, and treat arthritis, rheumatism, and atherosclerosis. On the front page of the brochure, however, the firm stated that it did

not endorse the therapeutic claims and that "more testing must be done before such claims can be adequately substantiated." Similarly, the arthritis cream was labeled prominently as "Arthritis Formula Cream with Copper and Gold," but the brochure for the product stated that "federal regulations would prevent us making any therapeutic claims about their [copper and gold] benefits."

The Orlando district office was not taken in by this ploy and sent a letter to the firm's president explaining that the products she was selling were considered by FDA to be unapproved new drugs. The president asked for clarification of some

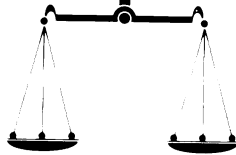
points, which Orlando staff provided. The president then denied that she was violating the law.

An FDA investigator reinspected the firm, accompanied by a county inspector, who placed a Stop-Sale order on the three products, preventing their sale until the Orlando staff could have a judge order the products seized. Eventually they were seized by a U.S. marshal and subsequently destroyed.

—This small sample of reports from the field was prepared by Annabel Hecht, Carol Ballentine, Dixie Farley, Carolyn Hommel, and Dennis Linsley.



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: **Batter mix, pancake mixes, and other food stocks**, at Midvale, Dist. Utah; Civil No. 85C-0530J.

CHARGED 5-2-85: While held by Livingstone Distributing Co. (W. Dick Livingstone), Midvale, Utah, the articles had been held under insanitary conditions—402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 64593; S. No. 85-320-364; S.J. No. 1)

PRODUCT: **Cornstarch, textured vegetable protein, desiccated coconut, and other bakery stocks**, at Bayamon, Dist. Puerto Rico; Civil No. 85-2073(PG).

CHARGED 10-3-85: While held by Laffitte Bakery Distributors, Inc., Bayamon, Puerto Rico, all of the articles had been held under insanitary conditions, and some of the articles contained mammalian and/or insect filth—402(a)(3), 402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 64720; S. No. 85-364-866 et al.; S.J. No. 2)

PRODUCT: **Jellyfish, dried, and canned jackfruit**, at New York, S. Dist. N.Y.; Civil No. 85-Civ-4934(SWK).

CHARGED 6-26-85: When the jellyfish was shipped by Jackson Import Co., San Francisco, Calif., that article (labeled "Dried Jellyfish . . . Cock Brand . . . Exporter: Thai World Import & Export Co., Ltd. . . . Bangkok . . . Thailand") contained insect and rodent filth—402(a)(3); and when the jackfruit was shipped by YHS (USA), Inc., San Jose, Calif., that article (labeled "Yeo's . . . Jackfruit In Extra Heavy Syrup . . . Prepared By . . . YHS Yeo Hiap Seng Limited . . . Singapore") was unfit for food because of a chemical interaction between the jackfruit and the metal interior of the cans—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64650;

S. No. 85-381-988 et al.; S.J. No. 3)

PRODUCT: **Pepper, black, in bulk, and dried mulberries**, at Los Angeles, C. Dist. Calif.; Civil No. 85-2376-MRP(Kx).

CHARGED 4-10-85: While held by Soofer Co., Inc., Los Angeles, Calif., the articles had been held under insanitary conditions, and the dried mulberries contained rodent and insect filth—402(a)(3), 402(a)(4).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64582; S. Nos. 85-355-114/5; S.J. No. 4)

PRODUCT: **Shrimp, peeled, frozen**, at Garden City, S. Dist. Ga.; Civil No. CV-485-113.

CHARGED 3-22-85: While held for sale, the article contained decomposed shrimp—402(a)(3).

DISPOSITION: Consent—ordered destruction. (F.D.C. No. 64544; S. No. 85-378-609 et al.; S.J. No. 5)

PRODUCT: **Soybeans**, at Los Angeles, C. Dist. Calif.; Civil No. CV-85-3753-R.

CHARGED 6-6-85: While held by D.Y. Import Co., Inc., t/a C.R. Foods, Inc., Los Angeles, Calif., the article had been held under insanitary conditions—402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 64640; S. No. 85-259-137; S.J. No. 6)

PRODUCT: **Wheat**, at Chesapeake, E. Dist. Va.; Civil No. 85-159-N.

CHARGED 2-26-85: While held for sale, the article was unfit for food because it contained a gray pelletized foreign material containing ammonium—402(a)(3).

DISPOSITION: Consent—authorized release to Cargill, Inc., Minneapolis, Minn., for reconditioning. (F.D.C. No. 64516; S. No. 85-398-659; S.J. No. 7)

Foods/Economic and Labeling Violations

PRODUCT: **"Feta" cheese**, at Brooklyn, E. Dist. N.Y.; Civil No. CV-85-1721.

CHARGED 5-8-85: While held for sale, the article's labeling was misleading in representing the product as "Feta Cheese," when the product lacked the physical characteristics of traditional feta cheese, and was also misleading in lacking nutritional labeling information required for a product with a nutritional claim regarding its fat content (i.e., "MG 22% FF")—403(a)(1), 201(n); and the quantity of contents declaration was expressed in terms of weight, but lacked the words "Net Weight" or "Net Wt."—15 U.S.C. 1453(a)(3)(A)(ii).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64577; S. No. 85-381-983; S.J. No. 8)

PRODUCT: **Tuna, grated, canned, Tuxedo Brand**, at Buffalo

and Rochester, W. Dist. N.Y.; Civil No. 84-1184-E.

CHARGED 10-22-84: When shipped by Castle & Cooke Foods, Division of Castle & Cooke, Inc., San Jose, Calif., the article failed to conform to the standard of identity for canned tuna, since scales, blood clots, bones and gills had not been freed from the tuna loin—403(g).

DISPOSITION: The article was claimed by the shipper. The parties agreed to a consent decree authorizing release of the article to the shipper for segregating the article into codes for destruction and codes for release. The State of New York Commissioner of Agriculture and Markets moved to intervene in the action, asserting that (based upon the article's compliance with "military standards" as to the amount and size of skin, scales, blood clots, bones, gills and vascular tissue) the government and the claimant were seeking to release 60 percent of the seized goods even though all codes fell below the FDA standard for the article. The government and the claimant opposed the motion to intervene. The court found that the state commissioner could not intervene as a matter of right, because his argument was fundamentally a challenge to the federal government's interpretation and application of the relevant federal statute and regulations, and such a challenge did not suffice as the requisite strong affirmative showing. The court found further that the state commissioner was not to be permitted to intervene, because a claim for permissive intervention had to be supported by independent jurisdictional grounds and the commissioner had not shown that such grounds existed. In denying the commissioner's motion, the court concluded as follows: The similarity of state and federal interests in this area, the lack of any real showing that the federal government had not acted in good faith to protect those interests, and the apparent availability of state remedies worked against permitting intervention in this case. Subsequently, a consent decree of condemnation ordered nine code numbers of the seized food destroyed and authorized the release of 14 code numbers of the article after segregation from the prior codes. (F.D.C. Nos. 64393 and 64396; S. No. 84-479-226 et al; S.J. No. 9)

Food Additives

PRODUCT: **Stevia leaves, dried (a component of Trusweet Extract)**, at Orem, Dist. Utah; Civil No. C-84-0666W.

CHARGED 7-30-84: While held by Sunrider Corp., Orem, Utah, who was manufacturing Trusweet Extract using interstate *Stevia rebaudiana* leaves and was promoting the extract for regulating blood sugar, metabolic functions, and arterial pressure, the article was a nonconforming food additive—402(a)(2)(C); the article was a new drug without an effective approved New Drug Application—505(a); and the accompanying labeling failed to bear adequate directions for use and was not exempt due to its new drug status—502(f)(1).

DISPOSITION: The article was claimed by the manufacturer, who filed an answer to the complaint. Subsequently, a consent decree of condemnation authorized release of the article to the claimant for salvaging. The decree also permanently enjoined the claimant from receiving or shipping in interstate commerce Sunrider Trusweet Extract, its components, or any product containing the herb stevia that was labeled, advertised or promoted as either a

food or drug. (F.D.C. No. 64287; S. No. 84-321-151 et al.; S.J. No. 10)

Drugs/Human Use

PRODUCT: **Allopurinol tablets, chlorthalidone tablets, and other new drugs**, at Memphis, W. Dist. Tenn.; Civil No. C-81-2159-H.

CHARGED 2-23-81: When shipped by Premo Pharmaceuticals, Inc., South Hackensack, N.J., the articles were new drugs without effective approved New Drug Applications—505(a); and the labeling of the articles lacked adequate directions for use, and the articles were not exempted due to their new drug status—502(f)(1).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63343; S. No. 81-275-634; S.J. No. 11)

PRODUCT: **Daily Greens diet supplement tablets**, at San Francisco, N. Dist. Calif.; Civil No. C-84-0886-SAW.

CHARGED 3-1-84: When returned by interstate consignees to San Francisco, Calif., after shipment by PharmTech, Inc., San Francisco, the article (which bore labeling reading "Diet, Nutrition and Cancer" and "The idea behind Daily Greens . . . associated with a reduction in the incidence of cancer") was a new drug without an effective approved New Drug Application—505(a). **DISPOSITION:** Default—ordered destroyed. (F.D.C. No. 64191; S. No. 83-323-978 et al.; S.J. No. 12)

PRODUCT: **Diethylpropion HCl tablets**, at Ferndale, E. Dist. Mich.; Civil No. 81-70968.

CHARGED 3-30-81: When shipped by Premo Pharmaceutical Laboratories, Inc., South Hackensack, N.J., the article was a new drug without an effective approved New Drug Application—505(a); and the article's labeling lacked adequate directions for use and the article was not exempted due to its new drug status—502(f)(1).

DISPOSITION: The article was claimed by the shipper. Upon motion of the parties, the action was transferred to the District of New Jersey for consolidation with a similar action. Ultimately, a consent decree ordered destruction. (F.D.C. No. 63344; S. No. 81-185-256; S.J. No. 13)

PRODUCT: **Foot powder, medicated**, at Lynchburg, W. Dist. Va.; Civil No. 85-72-9.

CHARGED 4-25-85: While held by Frances Denney, Inc., Lynchburg, Va., who had manufactured the article using interstate zinc undecylenate, the article (labeled "Blair Foot Care Medicated Anti-Fungal Foot Powder . . . Blair Lynchburg, Va., Div. of the Merchandising Co.") contained cat/dog hairs and insect filth; the article had been prepared and packed under insanitary conditions; and the circumstances used for the article's manufacture, processing, packing and holding failed to conform with current good manufacturing practice—501(a)(1), 501(a)(2)(A), 501(a)(2)(B). **DISPOSITION:** Default—ordered destroyed. (F.D.C. No. 64587; S. No. 85-468-231; S.J. No. 14)

PRODUCT: **Furosemide tablets**, at Washington, Dist. Columbia; Civil No. 81-2697.

CHARGED 11-9-81: When shipped by Premo Pharmaceutical

Laboratories, Inc., South Hackensack, N.J., the article (labeled "Furosemide Tablets, U.S.P. . . . Federal Pharmacal, Inc., Kingshill, St. Croix, U.S.V.I.") was a new drug without an effective approved New Drug Application—505(a); and the article's labeling lacked adequate directions for use and the article was not exempted due to its new drug status—502(f)(1).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63594; S. No. 82-283-941; S.J. No. 15)

PRODUCT: **Nystatin antibiotic capsules**, and **Nystatin antibiotic powder**, at Mineral Wells, N. Dist. Texas; Civil No. 4-85-508-E.
CHARGED 8-6-85: While held by The Dews Co., Inc., Mineral Wells, Texas, the circumstances used for the manufacture, processing, packing and holding of the articles failed to conform with current good manufacturing practice; and the articles were antibiotic drugs which were not exempt from certification since they had not been approved as required by regulation—501(a)(2)(B), 502(l).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64680; S. No. 85-350-081; S.J. No. 16)

Drugs/Veterinary

PRODUCT: **Chloramphenicol oral solutions**, at Kearney, Dist. Neb.; Civil No. 84-0-475.
CHARGED 7-25-84: While held by Glenwood Veterinary Clinic, Kearney, Neb., for use in baby pigs and calves, the articles were new animal drugs and approved New Animal Drug Applications were not effective for such uses—501(a)(5).
DISPOSITION: Consent—authorized release to Allen R. Deets, D.V.M., Glenwood Veterinary Clinic, Kearney, Neb., for return to the original supplier from whom the articles had been obtained, if the claimant paid any and all costs of shipping or transporting the articles to the supplier. The original supplier had returned to it, by the claimant, all (59 bottles) of the 250-mg solution of chloramphenicol and 84 bottles (out of a total of 96 bottles) of the 100-mg solution of chloramphenicol. The shipment of the remaining 12 bottles of the 100-mg solution had been sent C.O.D., had not been accepted by the supplier, and had been returned to the sender for proper delivery. After some delay by the claimant, the court issued an order to show cause why the claimant should not be held in contempt. However, all of the articles were ultimately returned to the original supplier, and the government filed a satisfaction of judgment. (F.D.C. No. 64315; S. No. 84-263-748; S.J. No. 17)

PRODUCT: **Dextroamphetamine sulfate capsules**, at Madison, E. Dist. Mich.; Civil No. 85-CV-73656-DT.
CHARGED 8-13-85: When shipped by Calvin Scott & Co., Inc., Albuquerque, N. Mex., who had repacked the article (which was labeled "Dipylets (Dextroamphetamine Sulfate) 15 mg. . . . GRANUCAPS Distributed by Tutag Pharmaceuticals, Broomfield, Colorado," the circumstances used for the article's manufacture and processing failed to conform with current good manufacturing practice, since the labeled expiration date was not supported by adequate stability testing—501(a)(2)(B)
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64684;

S. No. 85-414-754; S.J. No. 18)

PRODUCT: **Gentaject gentamicin sulfate for injectable use**, at Springdale, W. Dist. Ark.; Civil No. 83-5045.
CHARGED 3-9-83: When shipped by Tri-Bio Laboratories, Inc., State College, Pa., the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to the article's use and intended use—501(a)(5).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63977; S. No. 83-372-181; S.J. No. 19)

PRODUCT: **Mebroin-V mephobarbital & phenytoin combination tablets for dogs**, at N. Billerica, Dist. Mass.; Civil No. 84-715-T.
CHARGED 3-13-84: When shipped by Winthrop Laboratories, Secaucus, N.J., the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to the article—501(a)(5).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64219; S. No. 84-400-922; S.J. No. 20)

PRODUCT: **Wormer for horses**, at Harrington, Dist. Del.; Civil No. 84-703-WK.
CHARGED on or about 11-29-84: When shipped by Rocky Mountain Manufacturing Co., Spanish Fork, Utah, the article (labeled "Ban-A-Bot with Trichlorfon . . . Manufactured for Equine Wholesalers, Harrington, DE.") 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 destruction. (F.D.C. No. 64403; S. No. 84-361-547; S.J. No. 21)

CRIMINAL ACTIONS

DEFENDANTS: **Purity Condiments, Inc.**, and **Bernard B. Jaffe**, president, and **Daniel H. Jaffe**, secretary treasurer, Miami, S. Dist. Fla.; Criminal No. 83-179-Cr-JAG.
CHARGED 2-25-83: Paprika, citric acid granules, mustard seed, crackers, dextrin, ground mustard, and three lots of rice were held under insanitary conditions in a building accessible to rodents and were exposed to contamination; and the paprika, citric acid granules, mustard seed, crackers and dextrin were contaminated with rodent filth—402(a)(3), 402(a)(4).
DISPOSITION: The defendants pleaded not guilty, and the case came on for trial by court and jury. The jury found the defendants guilty of the counts where the articles were actually contaminated with filth and found the defendants **not guilty** of the other counts. The corporation was fined \$2,500; and, in lieu of suspended fines, the individuals were each permitted to donate \$2,500 to a local charity. The court denied the government's motion for taxation of costs of \$2,048.44.

The individuals moved to expunge their criminal conviction, on the ground that a balancing of the equities compelled such a remedy. The court looked to precedent, and found that expungement was granted only in cases involving infringement of constitutional rights or in cases where some unconscionable action had

been taken by the authorities.

Since the individual defendants' sole complaint appeared to be the inherent unfairness of the statute under which they were convicted, the court found that any harm (i.e., "a minor technical violation by the corporation may ultimately result in their individual future status as convicted felons") which may flow from the present convictions did not fall within the class of cases where expungement was appropriate. (F.D.C. No. 63628; S. No. 78-142-221 et al; S.J. No. 22)

INJUNCTION ACTIONS

DEFENDANT: Alice E. Parreira, Tulare, E. Dist. Calif.; Civil No. F-82-529-EDP.

CHARGED 12-29-82 in a complaint for injunction: That the defendant did business as a livestock trader who purchased calves from local producers and sold them, typically on the day of purchase, at USDA posted auction yards; that the defendant's activities resulted in the sale and slaughter of calves and the interstate and intrastate shipment of veal; that such calves, upon slaughter shortly after sale, contained unlawful amounts of antibiotic drug residues since such food contained a nonconforming New Animal Drug; that, through the defendant's failure to take adequate precautions to ensure that such veal calves did not contain unlawful drug residues, the defendant caused the delivery for introduction into interstate commerce of adulterated food; and that the defendant had been notified numerous times that the veal contained unlawful amounts of antibiotic residues and nevertheless had continued to market veal calves without taking necessary precautions—402(a)(2)(D).

DISPOSITION: A consent decree of temporary injunction was entered pending disposition of a motion for preliminary injunction. Subsequently, a consent decree of permanent injunction was filed which permanently enjoined the complained-of violations, but which made defensive provisions for a record-keeping system to identify each animal; provision for statements from each seller of livestock which attested that the purchased animal had either not been medicated or, if medicated, provided the name of the drug, date of medication, and termination date of withdrawal period, and provisions for notifying purchasers of such information concerning medicated animals. The decree also provided for written notice of the decree provisions to all of the defendants' agents, servants, employees, et al., who participated in the distribution of livestock intended for use as food. (Inj. 1001; S. No. 82-345-648; S.J. No. 23)

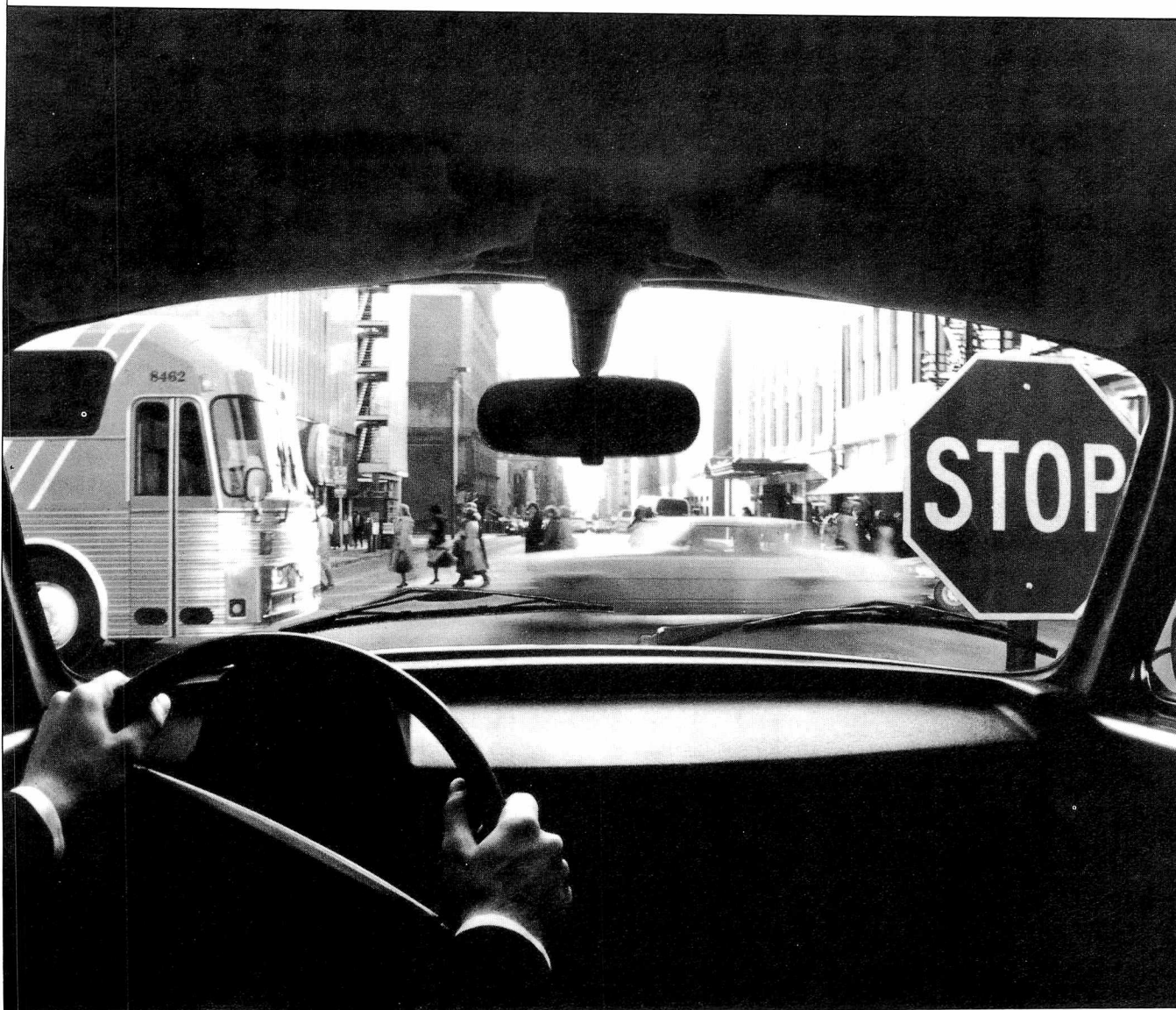
MISCELLANEOUS ACTIONS

SUBJECT: Sodium content labeling for processed foods, and FDA's denial of petition for mandatory labeling of salt (sodium chloride) content, Washington, Dist. Columbia; Civil No. 83-0801.

CHARGED 3-22-83 and amended 5-2-83 by Center for Science in the Public Interest (CSPI), a nonprofit corporation, Washington, D.C., and Michael Jacobson, executive director of the corporation, Washington, D.C., against FDA Commissioner Arthur Hull Hayes Jr. and HEW Secretary Margaret Heckler, in a complaint

for declaratory judgment and injunction: That FDA's regulations failed to regulate the amount of salt in processed foods and allowed food manufacturers to fail to reveal material facts relating to sodium content; that, consequently, many of the plaintiff corporation's 30,000 individual members may have a high sodium intake which adversely affects their health; that FDA had recognized that American adults consumed sodium in excess of their physiological needs; that hypertension was among the major health concerns in America; that salt as a factor in the development and aggravation of hypertension was acknowledged by FDA as a matter of broad scientific consensus; that the plaintiffs had petitioned for a regulation requiring sodium content on the labels of processed foods; that FDA's proposed regulation would require sodium content only when nutritional labeling was required or provided voluntarily; that such proposed regulation would result in only half of all processed food being labeled for sodium content; that FDA had rejected plaintiff CSPI's petition to require mandatory labeling; that an FDA advisory panel report recommended that FDA develop guidelines for restricting salt content in processed foods, but FDA decided to defer indefinitely a determination on the safety of current salt consumption (based on FDA's policy of encouraging voluntary efforts); that FDA's indefinite deferral constituted unreasonable delay; that, accordingly, the plaintiffs sought judgment by the court against FDA, as follows: declaring as misbranded those foods whose labels lacked sodium content disclosure; declaring as arbitrary and capricious the FDA denial of the plaintiffs' petition; enjoining FDA's failure to enforce sodium content disclosure; declaring that the indefinite deferral of regulatory action by FDA violated FDA's procedures and was an unreasonable delay contrary to the Administrative Procedures Act; and compelling FDA to complete the safety review of current levels of salt consumption within a reasonable time set by the court. **DISPOSITION:** The government moved to dismiss or for summary judgment. The plaintiffs opposed the government's motion and moved for summary judgment in the plaintiffs' favor. The American Public Health Association submitted an *amicus curiae* memorandum in favor of CSPI's position. After hearing oral argument of the parties on the motions, the court ruled for the government. Under the circumstances of the case, the court declined "to overturn FDA's decision not to institute rulemaking with respect to mandatory labeling or to find that food labels lacking sodium content information are misbranded," because FDA had carefully considered the plaintiffs' petition and had made a rational decision that a voluntary labeling program was the most appropriate course of action at present. As to the plaintiffs' contention that FDA violated the APA and FD&C Act by issuing a final policy notice (a deferral of a decision on the regulatory status of salt) relating to the GRAS review of sodium chloride, the court noted that FDA must make a decision on the GRAS status of salt after it had "completed its review, i.e., after the voluntary programs have been in effect for a reasonable period of time and FDA has had an opportunity to assess their impact and to review new scientific studies in sodium chloride consumption." The court found that the delay in FDA decisions had been reasonable and that it would not be appropriate or feasible to impose a specific timetable for further action in this case at present. (Misc. No. 710; S.J. No. 24)

Go ahead and run it.



Maybe there's a car coming and maybe there isn't. Fortunately, most people figure the risk isn't worth the chance.

But oddly enough, it doesn't work that way with the warning signs of a heart attack. Most people ignore the signals. Or chalk it up to indigestion. Or wait to see what happens next.

Every year 350,000 heart attack victims die before they reach the hospital.

You don't have to be one of them.

If you feel an uncomfortable pressure, fullness, squeezing or pain in the center of your chest that lasts for two minutes or longer, you may be having a heart attack. In some cases, the sensation may spread to the shoulders, neck or arms—and be accompanied by sweating, dizziness, fainting, nausea or shortness of breath.

The important thing is to accept the possibility of a heart attack and get help. Either by calling the local emergency medical service (EMS) or by asking someone to drive you to a hospital emergency room.

If you ignore the signs of a heart attack, you'll have no one to blame.

Not even yourself.

WE'RE FIGHTING FOR
YOUR LIFE



**American Heart
Association**