

FDA
CONSUMER

December 1985-January 1986

**A Fearful
Reminder
Stalks Polio's
Survivors**





please don't
use your
hands...
as or long-handled

**Giant does not
use sulfites on
our salad bar
ingredients.**

Open Season on Quacks 5

Quack-busters from the public and private sectors are rolling out new weapons in their battle against the \$10 billion-a-year health fraud industry.

A Guide to the Proper Use of Tranquilizers 9

Stress abounds in modern life, yet most of us, most of the time, are able to cope. But when anxiety becomes so intense that tranquilizers are needed, it's important to know the pluses and minuses of these drugs.

New Treatments for Impotence 12

An estimated 10 million American males suffer from impotence. Researchers have found that about half the cases are due to physical, rather than psychological, problems. Whatever the cause, most cases can now be successfully treated.

Reacting to Sulfites 17

Sulfites in foods, wine, beer and drugs can cause adverse reactions, even death, in certain individuals. FDA is taking steps to curtail the widespread use of these preservatives and to help warn consumers about products that contain them.

Sweating It Out: The Problem of Profuse Perspiration 21

Doctors call it hyperhidrosis: the production of perspiration beyond all bounds. For those so afflicted, their excessive sweating can bring embarrassment and problems at work and at play. Treatments offer some help, but for most heavy sweaters, dryness remains an elusive dream.

A Fearful Reminder Stalks Polio's Survivors 26

Decades after their battle against polio, survivors of the once-dreaded scourge are now facing the threat of renewed complications. Researchers are hunting for ways to prevent or at least treat this resurgent ordeal.

The Curious Compulsion Called Pica 29

Pica—a craving to eat clay, dirt, laundry starch or other "non-foods"—has a long history and is prevalent even today among certain groups in this country. Its causes may be cultural, psychological, or even due to nutritional deficiencies.

Updates 2 Investigators' Reports 34

The Notebook 33 Summaries of Court Actions 37

Many consumers are concerned about possible adverse reactions to sulfites, chemicals widely used to preserve salad bar vegetables and many other foods. Signs such as the one pictured on the facing page soon may no longer be needed: FDA has proposed to ban sulfites' use on fresh produce. For more on these widely used preservatives, see Reacting to Sulfites, beginning on page 17.

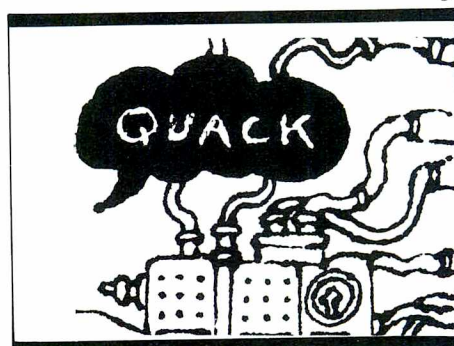
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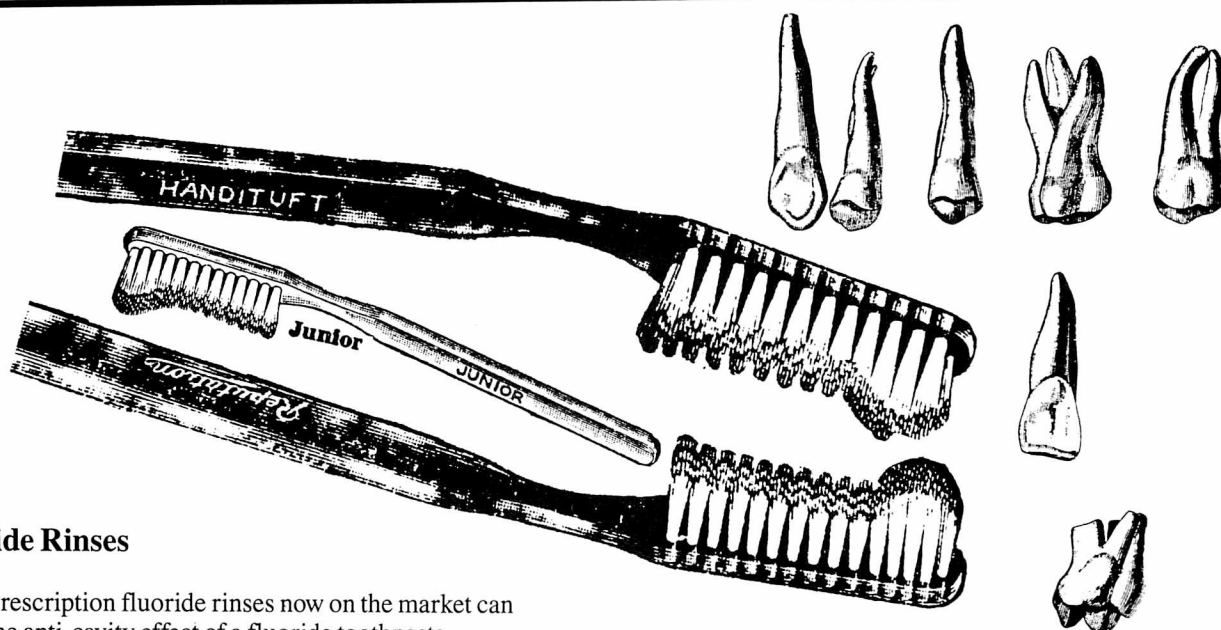
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Fluoride Rinses

Nonprescription fluoride rinses now on the market can add to the anti-cavity effect of a fluoride toothpaste, according to a proposed standard for fluoride dental products published Sept. 30 by FDA.

The proposal is a follow-up to an expert panel's 1980 report that said fluoride rinses are effective for preventing tooth decay. That report resulted from FDA's request to the scientific community to comment on whether users got additional benefits from more than one source of fluoride, such as fluoride toothpaste, fluoride-containing water, and professionally applied fluoride treatments.

After a review of the comments—including those of the Council on Dental Therapeutics of the American Dental Association—FDA concluded that combining fluoride from several sources (for example, from a toothpaste and a rinse) does produce added anti-decay protection. As a result, the agency has proposed that the labels of fluoride rinses be allowed to state: "The combined daily use of a fluoride rinse and a fluoride toothpaste can aid in reducing the incidence of dental cavities."

FDA said the labeling should indicate that such a rinse is best used after brushing the teeth. The labels should also state that children under 12 should be supervised in their use of the products and that children under 6 should not use them unless a dentist or doctor has been consulted first. Too much fluoride consumption by children under 6 (who often have difficulty spitting out rinses and mouthwashes) can mottle or create dark spots or streaks on the teeth.

The proposed standard would also apply to fluoride gels, but FDA is not aware of any that are sold without prescriptions.

Court Affirms FDA's OK of Aspartame

The Food and Drug Administration followed proper procedures in approving the popular sweetener aspartame, a federal appeals court has ruled. A three-member panel of the U.S. Circuit Court of Appeals for the District of Columbia said that consumer groups opposed to aspartame failed to show there was any issue about whether the product was adequately tested before approval by FDA.

Aspartame is sold under the brand names NutraSweet and Equal by G.D. Searle & Co., Skokie, Ill. It was approved for marketing in dry foods and as a table-top sweetener in 1981 and for use in soft drinks in 1983.

The Community Nutrition Institute, a consumer advocacy group, and several other consumer organizations had contended that FDA approved the use of the sweetener in soft drinks without proper testing and that aspartame could cause adverse health effects, such as behavioral changes, severe headaches, brain damage, and harm to fetuses. The consumer groups asked FDA to hold public hearings on the use of aspartame in soft drinks, but the agency refused, saying all safety issues had been adequately addressed.

The federal appeals court upheld FDA's position, saying in a Sept. 24 ruling that the consumer groups "failed to raise any material issues of fact requiring FDA to hold a hearing." The judges added, "The court will not substitute its judgment on highly technical matters for that of the agency charged with supervision of the industry."



More Counterfeit Contraceptives

Counterfeit birth control pills that may not prevent pregnancy again have been found in pharmacies, but this time only in Texas and Oklahoma.

The bogus pills, discovered in September, are made to look like refills of Ovulen-21 oral contraceptives. They bear the lot number -489, which is found immediately following the expiration date on the right side of the foil blister-pack containing the tablets. (The number is *not* on the outside of the package envelope that holds the blister-pack.) The pills are subpotent, meaning they might not provide effective birth control.

Officials of Fox Meyer Corp., a local distributor in Oklahoma City, said they did not know how the counterfeit product came into the firm's possession, but 50 fake Ovulen-21 refills with the -489 lot number were located in pharmacies supplied by the distributor in the two states, and five cartons were found in a Fox Meyer warehouse.

Two lots of Ovulen-21, -489 and -441, were recalled in the fall of 1984 by the manufacturer, Searle Pharmaceuticals of Skokie, Ill., because of counterfeits. FDA has been working with the FBI to determine the source of the product. According to FDA, none of the two suspect lots was found in Fox Meyer's possession last fall.

People who have Ovulen refills with these lot numbers should contact their pharmacists, who have been advised of the recall.

Rx Drug Ads for Consumers

Once again, consumers may become the targets of prescription drug advertising. FDA has withdrawn its two-year voluntary moratorium on direct-to-consumer Rx ads. For now, says the agency, existing regulations for prescription drug advertising provide sufficient safeguards to protect consumers.

While Rx drug ads traditionally have been offered to health professionals, drug firms began a few years ago to design some ads specifically for consumers. On Feb. 17, 1983, the FDA commissioner asked for a moratorium on consumer-oriented Rx drug ads to allow public dialogue and to conduct and evaluate research on the issue. The pharmaceutical industry agreed.

An FDA policy statement issued Sept. 2, 1983, clarified the moratorium, explaining that FDA needed further information before making decisions about regulating consumer-oriented Rx drug advertising.

The decision to lift the moratorium reflects FDA's conclusion that public discussion and research on Rx drug consumer advertising have been adequate. FDA and other organizations arranged a number of meetings at which spokespersons for industry, consumers, and the health professions were invited to discuss Rx drug ads. Also, studies were conducted on the issue by FDA and others.

In accordance with the Food, Drug, and Cosmetic Act and applicable regulations, the agency will continue to regulate all prescription drug advertising. Under the law, ads for Rx drugs—regardless of the audience—must carry a "brief summary" about side effects, including precautions, adverse reactions, and contraindications.

For more information about direct-to-consumer advertising, see the *FDA Consumer*, October 1983, "Would Rx Ads Make People Learn or Yearn?"; November 1983, "Would You Buy This Drug?"; and June 1984, "A Public View of Rx Drug Ads."



Quack Diet Products Curbed

Three unapproved weight-loss products—Anorex-CCK, Intercal-SX, and Metabolite-2050—cannot be marketed through the mail, the U.S. Postal Service has ruled.

Anorex-CCK is marketed by Connor-Freeman Labs, Intercal-SX by the W.G. Charles Co., and Metabolite-2050 by the Robertson-Taylor Co. All three companies are owned by Mitchell K. Friedlander of Fort Lauderdale, Fla.

During extensive hearings, expert witnesses testified that Anorex, which contains the hormone cholecystokinin (CCK), is ineffective when taken orally to curb appetite or cause weight loss. Witnesses also testified that the active ingredient in the other two products—guar, a dietary fiber—does not cause significant weight loss.

Under a federal court injunction, the Postal Service has been holding thousands of orders for these products, some for over a year. The Postal Service's decision, announced Sept. 13, requires that all these detained and all future orders for the three weight-loss drugs be returned to the senders. The agency also ordered the companies, Friedlander, and two other company officials to stop making false claims for the products or face the possibility of \$10,000-a-day penalties.

The Federal Trade Commission, the Food and Drug Administration, and Florida state officials have also taken enforcement actions against these companies and Friedlander. (See "Unapproved Drugs Probed" in *Updates*, *FDA Consumer*, October 1984, and "The Fad-Free Diet" in the July-August 1985 issue of the magazine.)

Food and Drug Review on Microfilm

Devoted readers of *FDA Consumer* may be interested to know that the granddaddy of the magazine, the *Food and Drug Review*, is now available on microfilm.

The *Review*, first published in 1917 on a monthly basis, served as a clearinghouse for official information on all kinds of federal and state activities, rather than as a vehi-

cle for public health education and information, as *FDA Consumer* does. Though the *Review's* main emphasis from the start was regulatory, as time went by features such as personnel matters, accounts of investigations and trials, organizational changes, and other types of articles were added.

When the means of transmitting regulatory information improved, it no longer became necessary to use the *Review* for that purpose. Publication ended after the December 1966 issue, and a paid subscription journal known as *FDA Papers* came into being. In 1972, the name was changed to *FDA Consumer*.

As a contemporary record of what was going on in FDA, the *Food and Drug Review* is a major resource on both the history of the agency and of federal and state food and drug law enforcement. Covering the half century that overlapped two world wars, it reflects the extraordinary changes in laws and regulations brought about by a technological revolution in the production of foods and drugs.

The *Food and Drug Review* (Microfilm 85/662 MicRR) is reproduced on 12 reels of microfilm. The complete set costs \$276, packing and shipping included, or \$23 for an individual reel. For foreign delivery, add \$1.25 per reel for surface postage. Address orders and inquiries to the Library of Congress Photoduplication Service, Department C, Washington, D.C. 20540, and make checks payable to the Library of Congress Photoduplication Service.

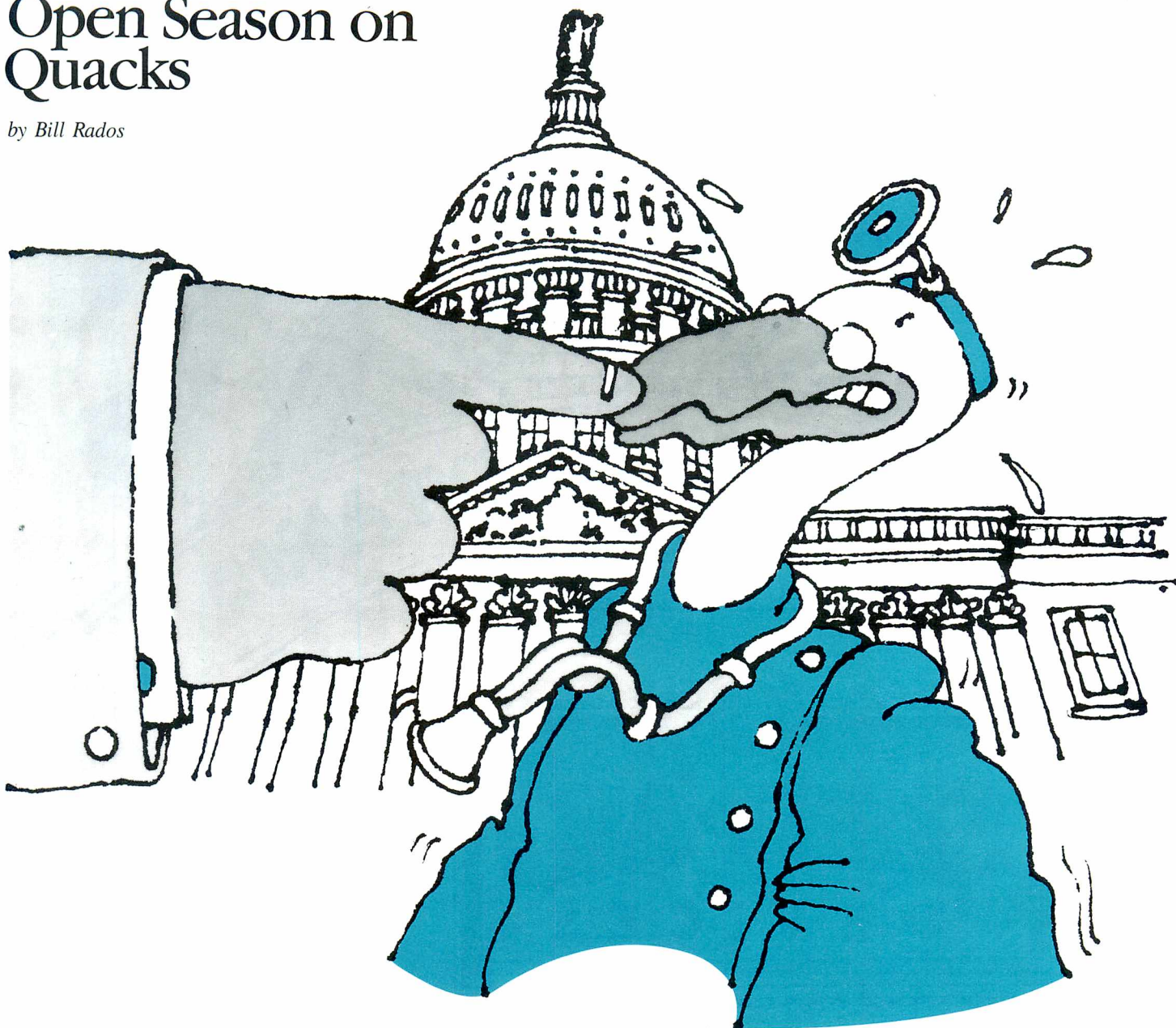
Reprints Available

Reprints are available of the following articles that appeared in the September 1985 issue of *FDA Consumer*: "Good Nutrition for the Highchair Set," "New Vaccine Protects Against Serious 'Day-Care Diseases,'" and "The Essential Guide to Amino Acids."

Copies can be obtained from the Food and Drug Administration, HFE-88, 5600 Fishers Lane, Rockville, Md. 20857, or from FDA's consumer affairs officers, located in 29 cities around the country (check your local phone directory).

Open Season on Quacks

by Bill Rados



Government and private agencies will wield an array of weapons as they join forces in a stepped-up war against health fraud. New public education campaigns, an information-exchange network, a speakers' bureau, state surveillance teams, and special projects directed at Hispanic consumers are among the programs in the anti-quackery effort.

Health fraud, or quackery, robs Americans of an estimated \$10 billion annually through worthless and often harmful products, from phony baldness cures to dangerous and useless cancer treatments.

The weapons were unveiled at a one-day conference last September sponsored by the Food and Drug Administration, the Federal Trade Commission,

and the U.S. Postal Service. FDA is responsible for ensuring that drugs and medical devices are safe and do what they purport to do. FTC oversees advertising of consumer products, and the Postal Service seeks to prevent the use of the mails to promote health fraud.

The conference was attended by some 250 representatives of state and local health and consumer agencies, independent public interest groups, and industry associations. The meeting was to encourage an exchange of information among the groups and local efforts to combat quackery.

Addressing the conference, FDA Commissioner Frank E. Young, M.D., defined health fraud as "the promotion of a false or unproven product or therapy for profit" and described it as a



disease. "Like any disease," Young said, "it can be a deliberate, devouring, destroying entity if left unchecked. It's also contagious. It increases in numbers of offenders and victims.

"Those who practice health fraud are astute observers of human nature," Young said. "They know that even the best educated and most rational of us are likely to have a vulnerable spot. We may secretly want to believe that it's possible to indulge in all sorts of delectable things to eat and then lose weight while we sleep. Or we may want to believe in a secret chemical that cures cancer. And our wish to believe in miracles may conquer our common sense at times."

While everyone is susceptible to health fraud, Young said that certain

groups—the elderly, the terminally ill, and minorities—are particularly vulnerable and should be the special target of anti-quackery efforts.

Young stressed that health fraud can be conquered. "Its cures are education and enforcement," he explained, adding that FDA would continue to marshal its limited enforcement resources against those forms of quackery that may actually harm their victims. Schemes that bilk consumers of their money but pose no health risk are so numerous that education is a more cost-effective tool in combating them, according to the FDA commissioner. And both education and enforcement can be enhanced by cooperative efforts among government and private agencies at the national, state and local levels, he added.



**SKIN CARE
&
YOUTH PROLONGING
DEVICES**

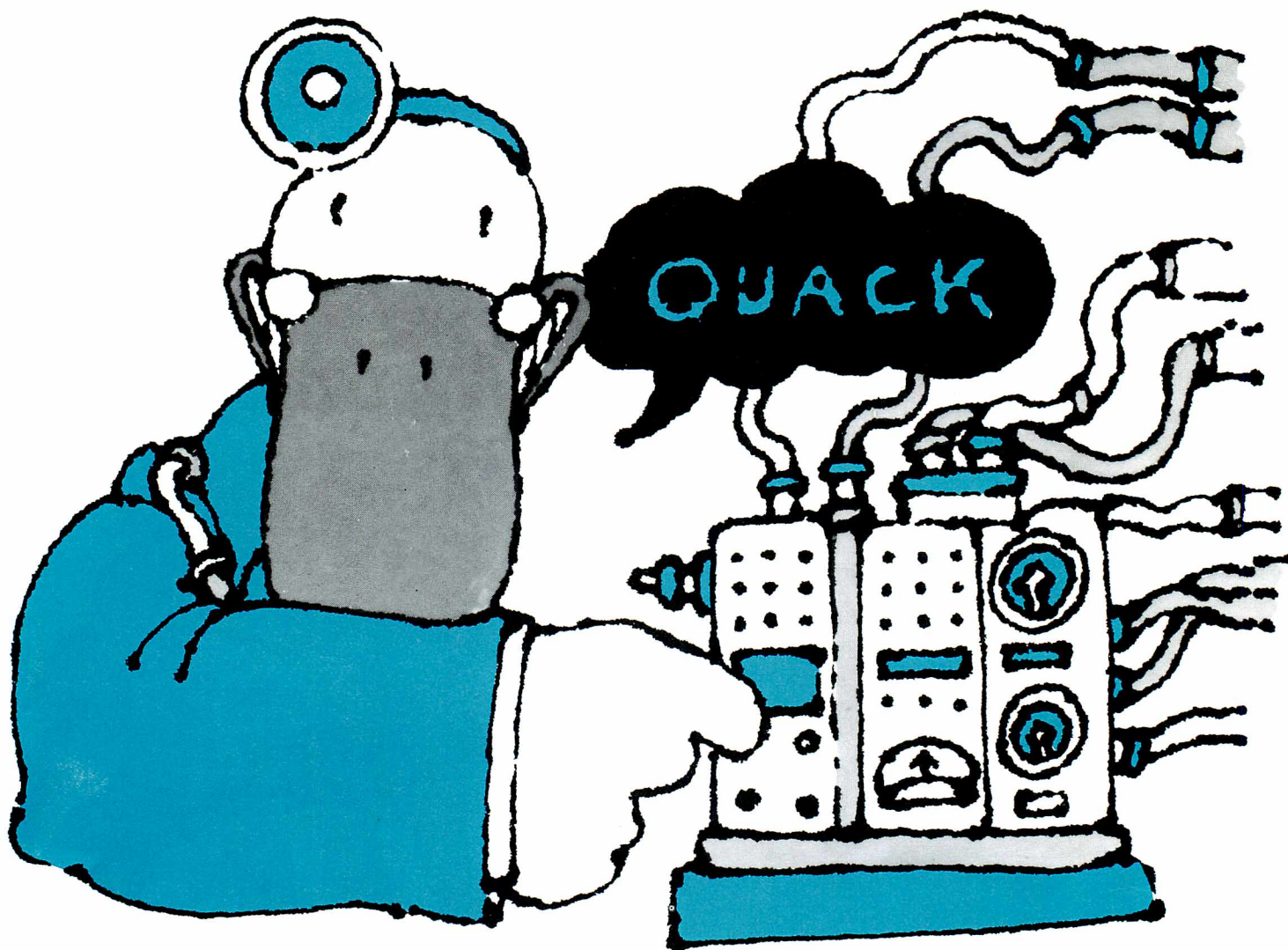


**FIGURE
ENHANCING
DEVICES**

HAIR

The conference participants discussed plans for a number of cooperative fraud-fighting efforts. Among them:

- Plans by the Association of Food and Drug Officials, an organization of state health officials, for state surveillance and action teams to coordinate regulatory and educational efforts concerning health fraud.
- A program jointly sponsored by FDA and the Pharmaceutical Advertising Council, the organization that represents the drug advertising industry. Scheduled to begin this fall, the program is intended to "vaccinate" the public through use of public service ads on how to recognize, avoid and help stop health fraud. (See "Ad Campaign Will Warn About Health Fraud" in the July-August 1985 *FDA Consumer*.)
- A speakers' bureau consisting of experts from the private and public sectors to talk at national and regional meetings.
- A media alert on diet aids to be issued by FDA and the Council of Better Business Bureaus. The materials will help advertising managers of newspapers, magazines, and radio and TV stations screen proposed advertisements for quack products. FDA and the council have already issued similar alerts on general health fraud and on arthritis quackery.
- A resource booklet summarizing health fraud-fighting activities and educational materials of many of the organizations participating in the conference. The booklet is intended to encourage cooperation among the



groups and avoid duplication of effort.

- Two projects involving Hispanic consumers: A Hispanic health fraud conference to be held early in 1986 in San Antonio, Texas, sponsored by FDA and the National Coalition of Hispanic Mental Health and Human Services Organizations; and a survey of Hispanic magazines and newspapers for health fraud promotions involving the use of the mails, cosponsored by FDA, the National Coalition, and the Postal Service.

- A pilot Health Fraud Information Exchange Network, sponsored by FDA and the National Association of Consumer Agency Administrators. The network will share information from national, state and local agencies on

consumer inquiries about fraudulent products and regulatory actions against quack firms.

The conference also agreed to continue holding regional health fraud meetings across the country.

"From these activities," remarked FDA Commissioner Young, "it's clear that we recognize that we can't do it all. Again and again, we have found that working with other organizations against health fraud adds up to a stronger effort. We seek a partnership between the public and private sectors in meeting the challenge of curing health fraud."

Bill Rados is editor of FDA Consumer.

A Guide to the Proper Use of Tranquilizers

by Annabel Hecht



“**M**inor” tranquilizers are medicines used primarily to treat anxiety. They are also called anti-anxiety drugs or anxiolytics. (The “major” tranquilizers are prescribed principally for the treatment of psychotic disorders such as schizophrenia.)

Anxiety is something everyone experiences at one time or another. It is a common reaction when someone is faced with a stressful situation such as illness, concerns about financial security, an accident, or death of a loved one. While drugs are not always the answer in treating anxiety, there may be times when anxiety is so intense that a person finds it very difficult to function without medication. Then the doctor may prescribe a minor tranquilizer.

At one time drugs such as the barbiturates (phenobarbital) and meprobamate (Miltown and Equanil) were used to treat anxiety. However, because their use may lead to dependency and withdrawal seizures, such drugs are no longer recommended. The most frequently prescribed anti-anxiety drugs today are the benzodiazepines, which are considered to be relatively safe. The most familiar drug of this class is probably diazepam, sold under the brand name Valium and also available generically.

In addition to diazepam, currently available benzodiazepines (with brand names in parentheses) include:

- Alprazolam (Xanax)
- Chlordiazepoxide hydrochloride (Librium, SK-Lygen and others)
- Clonazepam (Clonopin)
- Clorazepate dipotassium (Tranxene)
- Flurazepam hydrochloride (Dalmane)
- Halazepam (Paxipam)
- Lorazepam (Ativan)
- Oxazepam (Serax)
- Prazepam (Centrax)
- Temazepam (Restoril)
- Triazolam (Halcion)

Most of these drugs are prescribed for anxiety disorders or for the short-term relief of symptoms of anxiety. The exceptions are clonazepam, which is used for certain types of seizures; and flurazepam, temazepam, and triazolam, which may be prescribed for insomnia.

Some of these drugs may have other uses as well, such as relieving the symptoms of acute alcohol withdrawal or reducing a patient's tension before an operation. Others may be prescribed for painful muscle spasm or for epilepsy.

The benzodiazepines should not be used to relieve the anxieties that are a part of the ordinary stresses of everyday life, and they should not be taken for

more than four months at a time.

Patients who are afraid they will not be able to manage their problems without medication sometimes insist that their doctors prescribe anti-anxiety medications for extended periods. There are many reasons why this is not a good idea. People using these drugs for long periods may become dependent on them, making it very hard to give them up. Older people have another important reason to avoid long-term use of minor tranquilizers: As people grow older, they become more sensitive to the effects of the anti-anxiety drugs and can easily become sedated and confused.

What type of anti-anxiety drug a doctor prescribes may be determined by how long it stays in the system. Chlordiazepoxide and diazepam stay in the body longer, while the other anti-anxiety drugs are short-acting. The advantage of the long-acting drugs is that they need to be taken only once a day or even every other day. However, the effects of the drug often persist for days, or even weeks, after the patient has stopped taking it.

The short-acting drugs may have to be taken more often during the day, but they are eliminated more quickly from



Abrupt cessation of minor tranquilizers can lead to withdrawal symptoms such as convulsions, tremor, abdominal and muscle cramps, vomiting and sweating.

the system, and their effects do not continue for a long time after the medication has been stopped.

The benzodiazepines are CNS (central nervous system) depressants—that is, they are medicines that slow down the nervous system. Some patients, particularly older ones, may become drowsy, dizzy, lightheaded, unsteady and less alert when they are taking these drugs. These effects may be felt the next day if the medication is taken at night. Anyone taking any of the benzodiazepines should be very cautious about driving, operating machinery, or doing jobs that require alertness.

The sedating effect of these drugs also can be greatly increased if taken with other drugs that are CNS depressants, such as antihistamines or other medicines for allergies or colds, sedatives, sleeping medicine, and prescription pain relievers, including narcotics.

It is particularly important to avoid alcohol when taking a benzodiazepine. Alcohol is a powerful CNS depressant. Combining large amounts of these two substances can lead to unconsciousness and even death.

Use of the ulcer drug cimetidine (Tagamet) along with diazepam or chlordiazepoxide may slow down the metabolism of the anti-anxiety drugs,

thus keeping them in the bloodstream longer and prolonging their effects.

Patients who have questions about what drugs are safe to take with benzodiazepines should check with their doctors or pharmacists. Of course, patients should always tell their doctors what medicines they are taking—both prescription and over-the-counter drugs—whenever a new medication is considered.

In addition to drowsiness and fatigue, benzodiazepines may cause a variety of side effects, such as confusion, constipation, depression, headache, skin rash, slurred speech and tremor. Paradoxical reactions, including over-excitability, hallucinations, insomnia, and rage have also been reported. (Not all benzodiazepines have the same side effects. Patients should always ask their doctors what reactions they might experience when they begin to take any new drug.)

Patients should never stop taking a benzodiazepine abruptly. This can lead to withdrawal symptoms such as convulsions, tremor, abdominal and muscle cramps, vomiting and sweating. When it is time to discontinue the medication, the doctor will probably reduce the dosage gradually to avoid withdrawal symptoms.

Patients who follow their prescribed

medication schedules carefully should have no problems. However, sometimes a patient accidentally takes too much medication, which can result in continuing confusion, severe drowsiness, shakiness, slurred speech, staggering, unusually slow heartbeat, and severe weakness. Anyone experiencing these reactions should seek medical help at once.

Here are some additional pointers to remember about tranquilizers:

- Don't take your medicine longer than you really need it. Overdoing it can lead to dependence.
- Don't stop taking your medicine abruptly. You may end up with withdrawal symptoms.
- If you miss a dose, don't double the next dose. If you remember within an hour of the regular time, take it; otherwise skip that dose and continue on with your regular schedule.
- If you think you have taken an overdose, get emergency help at once.
- Store your medicine away from heat and light and out of the reach of children.

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

New Treatments for Impotence

by Egon Weck

At least as far back as Biblical times, sexual impotence has been equated with the destruction of the essence of masculinity. In the Old Testament, for instance, once King David was shown to be sexually impotent he was considered no longer fit to rule.

We now know that impotence can strike teenaged boys as well as aging kings. But today we no more believe that impotence renders a king unfit to govern than that it makes a student unqualified to pursue his studies. Nor does impotence mean that its victims are incapable of fathering children. Even so, impotence can still be psychologically crippling, seriously damage or disrupt marital and social relationships, lead to divorce, and constitute a source of great personal insecurity and unhappiness.

Fortunately, a new understanding of impotence, coupled with new forms of treatment and a variety of surgically implanted prosthetic devices, can bring happier and more normal lives to nearly all impotent men. But unfortunately, many of the estimated 10 million American males who suffer from impotence don't know that effective therapies *are* available. Many continue to be misled by misinformation that leads them to fall prey to ineffective or dangerous quack cures.

Throughout history, even to our own day, people have believed in the powers of nostrums and magic as a cure for impotence. Included in the list of worthless "cures" are powdered rhinoceros horn, menstrual blood, and a variety of plants. From ancient Chinese medical writings, we know that the ginseng plant has been used for thousands of years, but there is no scientific evidence to show that it is effective.

So-called "Spanish fly," a preparation made when the cantharis beetle is dried and heated until it turns into a

powder, also has been widely touted for improving sexual performance. But while it produces a warm sensation in the penis, it is useless in treating impotence. In fact, too large a dose of Spanish fly can damage the urinary and digestive tracts.

Besides such nostrums, impotent men have resorted to mechanical devices. Confronted by impotence in a romantic moment, some men have reached for any handy rigid implement, such as a swizzle stick, inserting it into the opening in the penis as a kind of internal splint. The use of such aids is risky. They can work their way up through the urethra and into the bladder, requiring surgery to remove them.

Other, more refined mechanical devices have been promoted in magazines and medical journals. One, a "Coitus Training Apparatus," consisted of a type of rigid sheath to surround the penis. Other devices in the form of rings were designed to maintain an erection by keeping the blood trapped in the major blood vessels of the penis. Another device, which was attached to the base of the scrotum, was supposed to emit a weak electrical current. The current was said to stimulate the natural process of erection. Devices such as these have been either hazardous or simply ineffective.

Medical specialists define impotence as the persistent inability to achieve an erection of the penis. Sex therapists such as the noted researchers Drs. William H. Masters and Virginia E. Johnson have formulated a more precise definition: the inability to achieve or maintain enough of an erection for sexual intercourse—sufficient to penetrate the vagina—at least once in four attempts.

(Continued on page 14)

Many of the estimated 10 million American males who suffer from impotence don't know that effective therapies are available.



'Sleep and Peek'

As long as physicians and sex therapists believed that impotence was mostly an emotional or psychological problem, the best they could do was to help roughly half the impotent men who came to them for treatment. Once it was recognized—beginning in the 1970s—that physical causes were at least as important, the “cure” rate began to increase. But the experts needed a way to screen patients. So they devised ways to determine whether impotent men were having an erection during sleep, as most men routinely do.

Several methods of monitoring erectile performance during sleep have been worked out. They vary in reliability and diagnostic usefulness. The most rudimentary has been dubbed the “sleep and peek” technique. Arrangements are made so that a second person, typically the subject's wife, can stay awake and observe whether a subject is having erections while asleep.

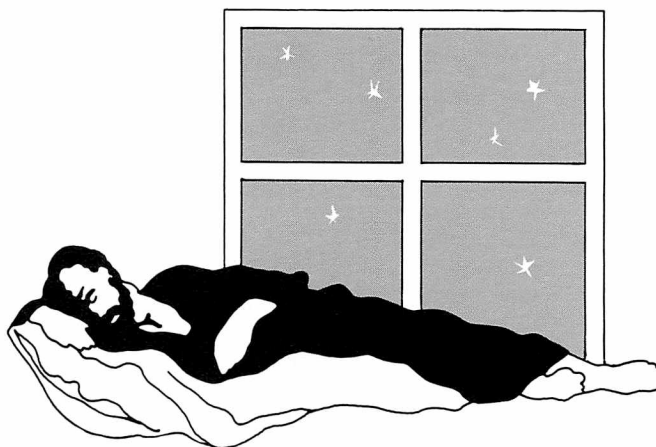
In some cases, subjects find it difficult or impossible to arrange for “sleep and peek” nights. In other cases, more systematic observation is needed. For example, some men have erections that are simply too soft for intercourse. So other methods of erectile measurement have been devised.

The simplest, the stamp test, makes use of a strip of stamps that is wrapped around the penis before the subject retires. The ends are pasted together so that the strip fits snugly around the organ's circumference. When, upon awakening, the strip of stamps is found torn along one of the perforated borders, it's good evidence that the subject experienced an erection while asleep. When it occurs after three or more nights of sleep, the evidence becomes even more convincing, but even then this procedure is not entirely reliable. A more reliable device that also provides a rough measurement of the degree of rigidity is called the snap gauge band. The band, made of elastic fabric and Velcro, has three snaps

designed to open at progressively higher degrees of penile rigidity.

The most comprehensive measurement of penile performance is made with an instrument called a Nocturnal Penile Tumescence Monitor. It employs two circular elastic silicone bands that are attached to the base and head of the penis. Wires connect the bands, which act as sensors, to an apparatus similar to an electrocardiograph machine.

The device tells when erections occur during sleep, for how long, at what rigidity, and to what extent the whole length of the penis (including the head) is involved. When used in a sleep laboratory, the readings recorded by the machine can be supplemented by having a trained observer present. ■



(Continued from page 12)

All men experience temporary periods of impotence at some time in their lives, and these need not cause alarm. But recent studies have shown that a surprisingly large number of men suffer from more long-lasting impotence. While men may experience impotence at any age, it afflicts middle-aged and elderly men more frequently. In a 1983 study of 1,180 older (mid-50s to late 60s) hospital outpatients in Minnesota, 34 percent were found to be impotent. Nevertheless, sex researchers have found that while sexual prowess gradually diminishes with age, men should expect to be able to enjoy sex well into their later years.

As recently as 1979, medical specialists were estimating that 90 percent of impotence cases were caused by psychological factors. So, when diagnosing the cause of impotence, few bothered to probe deeply for physical causes.

During the '70s, however, surprising new information was coming from an unexpected source. Scientific investigations of sleep and sleep patterns revealed that most men experienced erections during those periods of sleep that are characterized by rapid eye movements, or REM. During a single night, most normal men will experience several periods of erection lasting for a total of one to three hours. Interestingly, these periods occur irrespective of erotic dreams or other stimuli.

When investigators checked impotent men during sleep, they were surprised to find that only half of them experienced erections during REM sleep.

Following more detailed studies (see accompanying article), investigators found that the occurrence of erections during REM sleep was almost always evidence that a man's physical erectile capacity was intact. The subject was then considered a candidate for therapy that focused on psychological causes. When an impotent male did not have erections during REM sleep, in all likelihood his impotence had some physical cause.

The conclusion from subsequent studies that 50 to 60 percent of impotence had a physical basis came as a surprise and resulted in more interest being focused on research and therapy in that area.

As every male knows, an erection is not a conscious action. The complex process that underlies an erection is controlled by two sets of nerves. One is governed by a reflexive response that is triggered by touching or stroking the penis. The other is activated by psychological stimuli such as erotic thoughts, the right kind of music, or the proximity of an attractive female.

The physical mechanism that makes an erection possible includes the corpora-cavernosa, two unique blood vessels that are filled with spongy matter. These cigar-shaped vessels flank the underside of the penis. They begin just behind the

Where to Get Help

Impotent men are understandably sensitive about their affliction. Clinical studies of impotence show that many men are reluctant to tell their doctors they have a problem. To offer understanding and information, an organization called Impotents Anonymous was formed in 1983 by Bruce and Eileen MacKenzie of Chevy Chase, Md. Chapters have been formed in many parts of the United States. Besides help for impotent men, the organization offers support and guidance to their partners. For further information, contact:

Impotents Anonymous
National Headquarters
5119 Bradley Blvd.
Chevy Chase, Md. 20815

Depending on the nature of the problem, impotent men can also seek help from physicians, clergymen, family counselors and sex therapists.

But beware of charlatans. Anyone can call himself or herself a sex therapist. This fact often makes it difficult to find a well-trained and competent specialist. Local universities or teaching hospitals are usually good places to start looking for qualified help.

There are two professional organizations that accredit sex therapists: The American Association of Sex Educators, Counselors and Therapists (a list of its members is available for \$5 by writing to: 1 East Wacker Dr., Suite 2700, Chicago, Il. 60601) and the American Society for Sex Therapy and Research (a list of its members is available for \$3 by writing c/o Dr. Robert Dickes, Department of Psychiatry, Box 1203, Downstate Medical Center, 450 Clarkson Ave., Brooklyn, N.Y. 11203).

For those who seek more detailed information on the subject of impotence, one source is a new paperback, "The Lifelong Lover" by Marvin B. Brooks, M.D., and Sally West Brooks, R.N., available from Doubleday. ■



pubic bone, where the penis is attached to the trunk, and run along the length of the shaft to the head.

Two sets of valves regulate the flow of blood to the corpora-cavernosa. One allows blood to be pumped into the vessels, changing the penis from flaccid and pendulous to hard and erect. An erection can increase the size of the penis from 20 to 200 percent. The other set of valves allows blood to drain off, returning the penis to its pre-aroused state.

Also important in the erectile process is the corpus spongiosum tissue surrounding the urethra (the tube that runs from the bladder through the center of the penis to its end). The male hormone testosterone also is essential to normal sexual functioning. It acts not only on the penis, but also on the prostate gland, the testicles, and the sex centers of the brain.

The brain can help bring about an erection and it can prevent one. The upper portion of the brain known as the cerebral cortex can be involved in blocking the reflex action that causes an erection. By this means, thoughts or emotions can inhibit the erectile mechanism and cause so-called psychogenic impotence. Psychogenic impotence seems to feed on itself because its number one cause is fear of the possibility of failure to perform.

Impotence can be caused by a variety of physical problems, and diabetes ranks high on the list. It's estimated that about half of the men who suffer from diabetes are impotent because the disease damages the nerve controlling the valves

of the corpora-cavernosa.

Medications also frequently cause impotence. Some of the drugs currently being used to treat high blood pressure and heart disease produce this unwanted side effect in many men. In the 1983 outpatient study in Minnesota, one of four cases of impotence among those examined was traced to medicines—largely those medicines used to treat disorders of the heart and circulatory system. Impotence can also be caused by depression, alcoholism, deficiencies of testosterone or thyroid hormones, elevated levels of prolactin—another hormone involved in sexual function—hardening of the arteries, and physical deformities of the penis.

With so many possible factors, even when it becomes clear that a particular case of impotence has a physical cause, finding exactly what is involved may not be easy.

Nevertheless, many men with impotence due to physical causes can be restored to normal sexual function. Heart patients often can be switched to other medications, hormonal deficiencies can be made up with medications, alcoholism can be treated, and many physical deformities can be corrected with surgery.

After all is said and done, an irreducible minimum of impotent men remain—those whose impotence is caused by diabetes, spinal cord injuries, brain damage, or other conditions that cannot be repaired—whose hope of being restored to normal sexual functioning is slim. However, even most of

***Many men with impotence
due to physical causes can be
restored to normal sexual
function.***

these men can be helped with a variety of prosthetic devices, which can enable them to simulate natural erections.

Penile prostheses provide an artificial means to make a flaccid, impotent penis rigid. They fall roughly into three major classes. All three varieties require an operation of one-half to three hours that can be performed under local anesthesia.

The first and simplest type of prosthesis is composed of a pair of semi-rigid silicone rods that come in various lengths to suit different anatomies. Some are designed to keep the penis constantly stiff. To avoid being embarrassed by bulging trousers, restrictive clothing can be worn to keep the penis

against the thigh or lower abdomen. An alternative design is hinged near the base so that the penis, while perpetually extended, will hang down naturally.

The second type of prosthesis is made of flexible, plastic-covered metal wire. While it also maintains the penis in a constant state of stiffness, it can be bent into either an erect or downward position.

Both of these types of penile prostheses are installed by means of an operation during which the surgeon inserts the rods into the corpora-cavernosa.

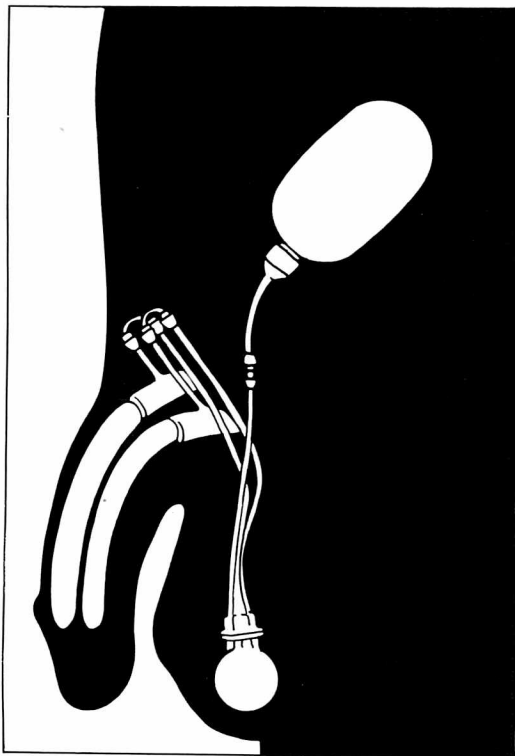
The third and most complex type of penile prosthesis mimics the natural erectile process. It works hydraulically to literally pump up the penis into an erect state.

This inflatable prosthesis consists of two expandable tubes, a tiny pump, and a small hydraulic reservoir. The tubes are implanted into the corpora-cavernosa. The reservoir is placed behind the muscles of the lower abdomen. The pump is placed in the scrotum. All three parts are connected by valves and tubes.

By squeezing the scrotum, the pump forces water from the reservoir into the inflatable tubes. The pressure of the water stretches the tubes, increasing the girth, length and rigidity of the penis much the same way blood pressure would in the case of a normal erection. By pressing a release valve, the water is returned to the reservoir and the penis returns to its flaccid state.

Each type of implant has advantages and disadvantages. These should be reviewed thoroughly with a specialist before making a choice. Among factors to be considered is cost of the device and the surgery, which can vary from \$2,500 for the simplest type of rigid-rod prosthesis to over \$10,000 for an inflatable type.

By making intercourse possible, penile prostheses can enable sexually impaired men to recapture the intimacy that goes with a shared sexual experience. They can father children, for impotence doesn't mean an inability to produce sperm or even to ejaculate. They can please their wives or sex partners. And, for a combination of complex psychological and emotional reasons, with the aid of prosthetic devices, many impotent men come to feel far better about themselves and they find that their self-confidence is restored. ■



An inflatable penile prosthesis employs a surgically implanted pump, hydraulic reservoir, and expandable tubes to mimic the natural erectile process.

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

Reacting to Sulfites

by Chris Lecos



Just a few years ago, Americans were heaping their plates at salad bars, munching on french fries, dipping into guacamole, and sipping beer and wine with little thought about sulfite preservatives or their possible adverse effects.

That is no longer the case.

Over the last three and a half years there have been extensive publicity and controversy surrounding the widespread use of sulfiting agents in the food supply. The controversy stems from sulfites' potential for triggering moderate to severe adverse reactions, including death, in certain sulfite-sensitive individuals. (However, sulfites are not considered hazardous to the general population.)

FDA is taking steps to help make consumers more aware of products that contain sulfites and to reduce public exposure to certain sulfite-treated foods that are believed to be responsible for many of the adverse reactions reported to the agency.

Sulfiting agents are primarily used to reduce or prevent spoilage and discoloration during the preparation, storage and distribution of many foods. They are used in many packaged potato products to preserve the vegetable's white appearance. Lettuce will not wilt or brown as quickly if treated with sulfites, thus extending its shelf life. Other produce and some types of seafood also will not discolor and will appear fresh, as a result of treatment with sulfites. These preservatives are also used in a number of drugs, as well as beer and wine.

Asthmatics are the primary population at risk. Some 10 million Americans suffer from asthma, and experts estimate that up to 1 million of them may have a particular sensitivity to sulfites. However, some reports of sulfite reactions indicate that an unknown number of non-asthmatic individuals also may be at risk. About one-fourth of the more than 500 com-

plaints of adverse reactions reported to FDA by last April involved individuals who had no known history of asthma.

Through mid-September of 1985, the number of complaints alleging adverse reactions reported to FDA had climbed to approximately 850, including reports of 20 deaths. Foods, beverages and, to a lesser extent, some drugs were implicated by the complainants. Agency investigations of the complaints, followed by analysis of the data by FDA epidemiologists, indicate that eight of the deaths were "probably" associated with the consumption of sulfites, while four others were classed as being "possibly" due to such consumption. Three others are not believed to be related to sulfites. The other five are still being investigated.

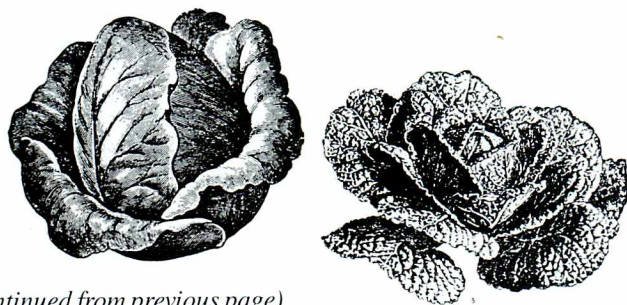
About 40 percent of the more than 500 complaints FDA had received by last April reported reactions after the consumption of raw fruits and vegetables in restaurants, and 4 percent attributed their reactions to produce bought in grocery stores. Another 15 percent blamed their reactions on wine and beer, and 14 percent mentioned various processed, packaged foods eaten at home. The remaining complaints were less specific about the types of foods and the place of purchase or consumption.

FDA currently is receiving an average of two consumer complaints a day. The agency, in investigating the reports it receives, gives priority to those involving deaths or other serious reactions, including those where hospitalization or emergency medical treatment is required.

The primary symptom reported by most consumers is difficulty breathing, although multiple symptoms are reported by many complainants. Other common symptoms include wheezing, vomiting, nausea, diarrhea, unconsciousness, abdominal pain, cramps, and hives.

(Continued on next page)

Consumers concerned about possible adverse reactions to sulfites should carefully read ingredient listings on food labels, such as those shown at right, to see if the products contain these preservatives.



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Direct evidence that sulfites are the cause of a person's reaction or death is often elusive. Medical histories, autopsy reports, a precise knowledge of what the person ate before suffering the reaction, and other pertinent information are usually needed to establish a strong circumstantial case that sulfite was the responsible agent.

And the variety of sulfite-containing foods that a person might eat at one sitting makes it even more difficult to pin the blame on a particular item.

"Sulfite" is actually a term that is applied to a variety of sulfur-based substances. They include sulfur dioxide, sodium sulfite, sodium and potassium bisulfite, and sodium and potassium metabisulfite.

Besides acting as preservatives or antioxidants, sulfites also have many other permitted uses. For example, sulfur dioxide is used as a bleaching agent for food starches; sodium metabisulfite and sodium sulfite are used with other ingredients to prevent rust and scaling in boiler water used in making steam that will contact food; sodium sulfite and sodium metabisulfite are used in the production of cellophane for food packing; potassium metabisulfite, sodium bisulfite, sodium metabisulfite, and sulfur dioxide are used as sterilizing agents in wine-making.

In effect, use of sulfiting agents is widespread and diverse, and suitable substitutes are not readily available to cover all uses. As FDA Commissioner Frank E. Young, M.D., testified before a Congressional subcommittee last March: "The problem is compounded by the fact that sulfites in foods have recognized benefits for which there are no good substitutes. . . . The extent to which suitable substitutes in foods are available is not entirely clear. The relevant industries have indicated, however, that it would be difficult, if not impossible, to replace the use of sulfites in shrimp, dried fruit, and corn syrup, for example."

Since November 1959, sulfites have been on FDA's list of substances regarded as "generally recognized as safe," or GRAS, for use in foods. However, FDA has always prohibited their use in foods that are important sources of thiamine (vitamin B₁), such as enriched flour and bread, because of sulfites' adverse effects on this nutrient. Sulfites also cannot be used on meats because of possible consumer deception:

CELERY, RED BELL PEPPERS, TOMATOES), MODIFIED FOOD STARCH, SALT, SUGAR, ONION POWDER, NATURAL FLAVORS, GARLIC POWDER, MONOSODIUM GLUTAMATE, SPICES, TRICALCIUM PHOSPHATE, CORN SYRUP, TORULA YEAST, TURMERIC, SODIUM SULFITE AND SODIUM BISULFITE ADDED AS PRESERVATIVES, DISODIUM INOSINATE, DISODIUM GUANYLATE.

Sulfites will restore red color to meat and thus give it a false appearance of freshness.

In the early 1970s, FDA began a review of all GRAS substances to determine if scientific evidence still supported their safety. Sulfites are among the many substances that are part of this ongoing review. In 1976, the Federation of American Societies for Experimental Biology (FASEB) issued a report under contract to FDA that essentially stated that sulfites posed no health hazard to the general population at the levels being used in food. FASEB based its conclusions on a review of the scientific literature up to 1975.

In July 1982, FDA proposed a regulation to affirm the safety of the continued use of the various sulfiting agents in foods.

The public comment period that followed produced strong criticism, such as that from the Center for Science in the Public Interest, a Washington, D.C., based consumer advocacy group. The group's primary concerns focused on the potential health risks sulfites posed to certain individuals, mainly asthmatics, and on the widespread use of sulfites by the food service industry, especially in salad bars, which by then had become so popular in restaurants. Concern also was expressed that the presence of sulfites in many products was not indicated on the labels. FDA responded in 1984 by asking FASEB to reexamine sulfites, including a look at more recent data that had not been part of FASEB's earlier review.

In a report released in January 1985, FASEB again concluded that sulfites pose no hazard to most Americans. However, it also concluded that there was sufficient evidence "to demonstrate a hazard of unpredictable severity" to some consumers who were sensitive to sulfites. Stating that additional labeling requirements alone would not ensure adequate protection, FASEB recommended regulatory action by FDA on the use of sulfites in fresh fruits and vegetables and pre-cut potatoes.

Although two industry trade groups, the National Restaurant Association and the Produce Marketing Association, have been successful in recent years in getting many of their members to voluntarily curtail sulfite use, FDA concurred with FASEB that voluntary steps alone were not enough. That led to two regulations proposed by FDA in 1985.

On April 3, 1985, the agency proposed a regulation that would require the food industry to declare the presence of

LEMON JUICE EQUALS THE JUICE OF AN AVERAGE
SIZE LEMON, 1 CAPFUL EQUALS 1 TEASPOON.

CONTENTS: FILTERED WATER, LEMON CONCENTRATE,
PRESERVED WITH 1/10 OF 1% SODIUM BENZOATE AND
1/50 OF 1% SODIUM BISULFITE.

NUTRITIONAL INFORMATION PER SERVING

SERVING SIZE . . . 2 TABLESPOONS (1 FLUID OUNCE)
SERVINGS PER CONTAINER . . . 32
CALORIES . . . 6
PROTEIN . . . 0 GRAMS
CARBOHYDRATE . . . 2 GRAMS
FAT . . . 0 GRAMS
SODIUM . . . 10 MG PER SERVING
(25 MG PER 100 GRAMS)

PORTIONS PER ENVELOPE: 16 AND AS PREPARED

CALORIES . . .
PROTEIN . . .
CARBOHYDRATE . . .
FAT . . .
SODIUM . . .

CONTAINS LESS THAN 2% OF THE U.S. RECOMMENDED DAILY
ALLOWANCE (U.S. RDA) OF PROTEIN, VITAMIN A, VITAMIN C,
THIAMINE, RIBOFLAVIN, NIACIN, CALCIUM, AND IRON.

INGREDIENTS: SUGAR; MODIFIED CORNSTARCH; GARLIC; ONION;
CARROTS; SALT; GUAR GUM; SPICE; BLACK
PEPPER; XANTHAN GUM (THICKENER);
MINCED GREEN ONION; CITRIC ACID (FOR
TARTNESS); SODIUM BISULFITE AND BHA
(PRESERVATIVES); NATURAL FLAVOR;
APOCAROTENAL (FOR COLOR). 28 g

sulfites on product labels if the sulfite level in a finished food amounts to 10 or more parts per million. The regulation would greatly increase the number of food products required to have sulfite labeling.

The Food, Drug, and Cosmetic Act already requires that labels note if finished, packaged foods contain sulfites present as preservatives. Products so labeled include lemon juice, maraschino cherries, grape juice, some packaged fresh mushrooms, dried fruits and vegetables, and some canned soups. But because sulfites have uses in food processing other than as preservatives, the regulation proposed in April would extend labeling to cover those uses as well.

For example, sulfites used as dough conditioners in the making of cookies would dissipate in large part but could leave a small detectable residue in the finished product. If adopted, the regulation would help sulfite-sensitive people avoid *any* packaged food that contains a measurable level of sulfites.

If adopted in its present form, the April labeling proposal would require manufacturers to declare the presence of sulfites on the label of *any* food containing the substance at a level of at least 10 parts per million. Furthermore, if the sulfite was used specifically as a preservative (rather than for other purposes in processing), it would have to be listed on the label no matter what the amount in the finished product.

If it met either of those criteria, the sulfite would not be considered an "incidental additive" present at an "insignificant level," circumstances that would exempt it from labeling requirements.

But why 10 parts per million? FDA explained in its proposed regulation that it would consider that level as being significant because it was "unaware of any evidence that establishes a level below which these substances [sulfites] will not cause a reaction in sensitive individuals." FDA has to be in a position, as a law enforcement agency, to defend its enforcement actions, and the agency said that 10 parts per million was the lowest level possible at which sulfites could be measured accurately.

FDA stated in its proposal that various manufacturers "have incorrectly interpreted what constitutes an insignificant level of a sulfiting agent." In other words, even under existing requirements they should have been labeling their products, but weren't. During the past year, various producers of

dried fruits and vegetables and canned foods in which one or more of the principal ingredients had been treated with sulfites had to recall their products because their labels did not disclose the presence of sulfites. FDA officials said the April proposal clearly outlines the responsibilities of manufacturers for labeling products that contain sulfites.

The second regulation, proposed Aug. 14, 1985, would revoke the "generally recognized as safe" status of sulfites used on raw produce. It would, in effect, ban the use of sulfites on fruits and vegetables that are intended to be eaten raw. This regulation primarily would affect salads and salad bars in restaurants and other food service outlets and also would apply to raw produce sold in grocery stores and supermarkets.

FDA is not expected to take final action on the two proposals until 1986. Both proposals triggered a substantial response from industry, consumer groups and others, and neither will go into effect until after FDA reviews the comments received and publishes a final regulation. FDA also is considering a regulation dealing with the widespread use of sulfites in processed potato products.

Even with the adoption of the two proposed regulations, sulfite-sensitive consumers would still have to be alert to the possible presence of sulfites in the foods they eat at home or in restaurants. Foods served in restaurants generally are not packaged and therefore are not labeled. Most packaged potato products used by restaurants, for example, are treated with sulfites, as are other canned products used in cooking. Generally, foods and beverages that sulfite-sensitive consumers should be alert to when eating out are salads, potatoes, seafood, cooked vegetable dishes, wine, beer, and bakery products.

Pending a final regulation, FDA advises consumers concerned about sulfites in food to ask restaurant or supermarket personnel if they are used and to avoid restaurant foods, particularly salad bars, in which sulfites may be used.

Sulfites are also extensively used in various seafoods. Raw shrimp, for example, are often treated with the substance to prevent a condition known as "black-spotting." Early in 1985, FDA announced that shrimp with sulfite residues of more than 100 parts per million would be considered adulterated, subject to removal from the market. FDA also advised that packaged shrimp that did not declare the presence of sulfites

on the label would be considered misbranded, also subject to removal from sale.

FDA also is closely monitoring drug industry efforts to voluntarily disclose the use of sulfites as preservatives in more than 1,100 prescription and nonprescription drug products, including some medications used by asthma patients. The substances are used to prevent oxidation, which can affect the potency and stability of a drug. The majority of drugs containing sulfites are intravenous or spray-type products. Comparatively few are oral medications.

The types of medications that may contain sulfites include antiemetics (taken to prevent nausea), cardiovascular drugs, antibiotics, psychotropic drugs, intravenous muscle relaxants, analgesics (painkillers), anesthetics, steroids, and nebulized bronchodilator solutions (used for treatment of asthma). Metered-dose bronchodilator inhalers do not contain sulfites.

Except for drug products prescribed for oral use, FDA regulations require prescription drug labels to identify all active and inactive ingredients. (Inactive ingredients include flavors, binders, colors and preservatives, such as sulfites.) With nonprescription products, only the active ingredients must be declared on the label. FDA has the authority, however, to require inactive ingredients to be listed if they pose a potential health hazard. Fifteen people have told FDA they had adverse reactions from sulfites in various medications.

FDA Commissioner Young testified last March that the agency had met with various drug industry groups to determine the extent of sulfite use in drug products and to discuss the feasibility of switching to other antioxidants. Some manufacturers already are reducing the amount of sulfites or are seeking alternative antioxidants for their products.

The Proprietary Association, which represents 85 companies that account for more than 90 percent of all nonprescription drugs made in the United States, has approved a program under which its members voluntarily would list inactive ingredients in alphabetical order on the labels of the over-the-counter products packaged after Dec. 1, 1985. By the same date, the Pharmaceutical Manufacturers Association, which represents companies that produce the vast majority of prescription drugs, also will begin a voluntary program to list inactive ingredients for prescription drugs for oral use. The Generic Pharmaceutical Industry Association also approved a plan to voluntarily list, by Dec. 31, 1985, inactive ingredients on prescription drug labels. FDA officials expect the entire pharmaceutical industry to follow suit.

At present, FDA is not considering banning the use of sulfites in drugs. As Commissioner Young testified in March 1985: "Because the agency believes that sulfites serve a useful public health function by maintaining the potency of certain medications, some of which may be life-saving, prohibiting sulfite use in drug products could be justified only if acceptable alternatives were available. A general replacement has not yet been identified to our knowledge. Moreover, with the exception of ascorbic acid, alternative antioxidants have

not had wide exposure and could pose safety problems as severe or worse than with sulfites. Any substitutions will have to be based on the demonstrated ability of the substitute to maintain a stable and acceptable drug product." Young added that FDA also was considering a variety of other actions, including the possibility of requiring a warning statement "on those drug products likely to be used by patients at high risk," such as asthma patients.

Some products that contain sulfites do not come under FDA's jurisdiction—wine and beer, for example. In June 1985, the federal Bureau of Alcohol, Tobacco and Firearms proposed requiring sulfite labeling for wine, distilled spirits, and malt beverages if the sulfite levels were 10 or more parts per million. Final action is still pending. One of the sulfites, sulfur dioxide, is used as a fungicide on grapes, and such use comes under the authority of the U.S. Environmental Protection Agency. At this time, EPA has not taken any regulatory action against that use of sulfites. ■

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

Prevalent Preservatives

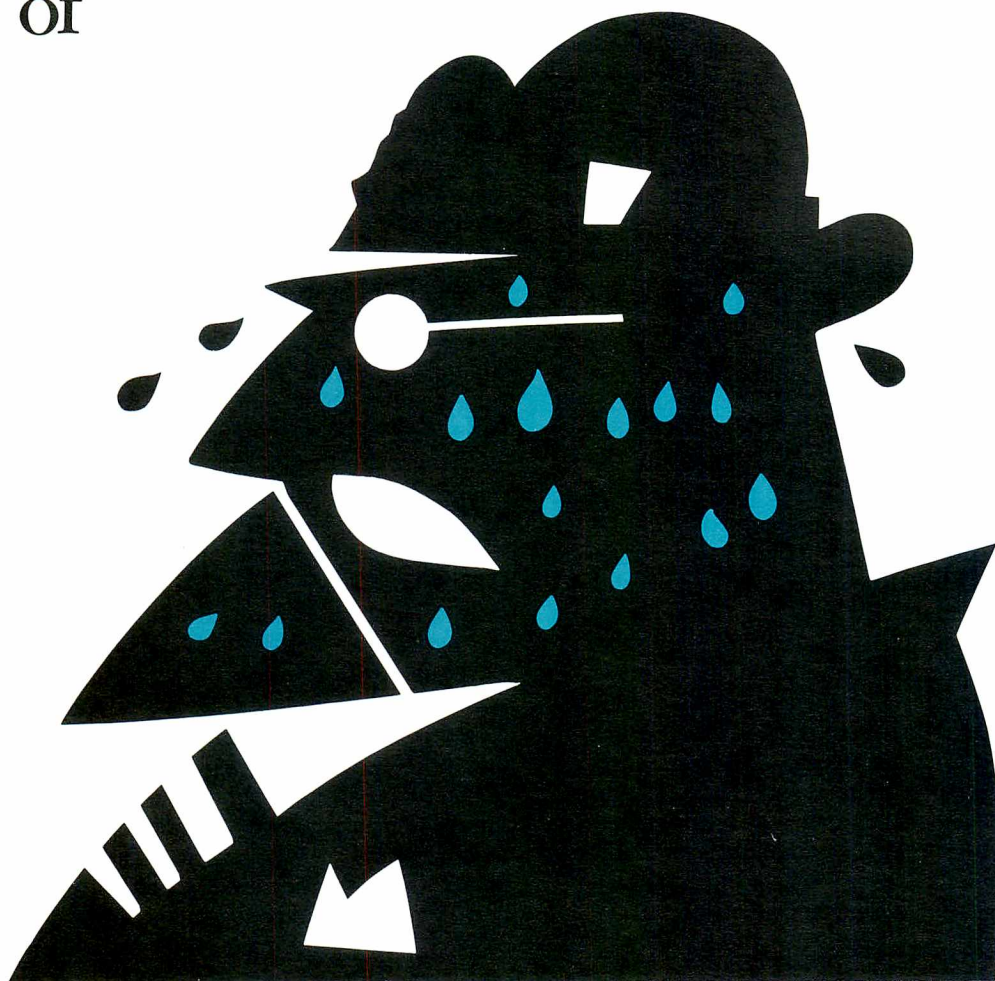
Sulfur dioxide and various forms of inorganic sulfites that release sulfur dioxide when used as food ingredients are known collectively as sulfiting agents. On food labels, their presence may be identified as sulfur dioxide, potassium bisulfite, potassium metabisulfite, sodium bisulfite, sodium metabisulfite or sodium sulfite. Some of the major food categories in which they are used include:

- Avocado dip and guacamole
- Beer
- Cider
- Cod (dried)
- Fruit (fresh peeled, dried, or maraschino-type)
- Fruit juices, purées and fillings
- Gelatin
- Potatoes (fresh peeled, frozen, dried or canned)
- Salad dressing (dry mix) and relishes
- Salads (particularly at salad bars)
- Sauces and gravies (canned or dried)
- Sauerkraut and cole slaw
- Shellfish (fresh, frozen, canned or dried), including clams, crab, lobster, scallops, and shrimp
- Soups (canned or dried)
- Vegetables (fresh peeled, frozen, canned or dried), including fresh mushrooms
- Wine vinegar
- Wine and wine coolers



Sweating It Out: The Problem of Profuse Perspiration

by Dixie Farley



In only 15 minutes, profuse perspiration drenches a woman's clothes. Sweat drips steadily onto machinery from the hands of a worker called "the rustier." Waterlogged socks steep a young man's feet until they're spongy, sore and foul-smelling.

Those people are fictitious. But their condition—persistent, excessive sweating—is very real. Medically speaking, it's known as hyperhidrosis.

That many people are at least "annoyed" by underarm perspiration is evidenced by the millions of dollars spent each year on antiperspirants. (See accompanying article.) Unfortunately, for those suffering from hyperhidrosis, perspiration is far more than just annoying. Their excessive sweating often causes severe embarrassment, restricted social activity and, as with "the rustier," problems in performing their jobs.

An understanding of sweating, excessive and otherwise, begins with a look at the glands that produce sweat. There are two types: apocrine and eccrine.

Apocrine sweat glands appear in the areas of the groin, anus and nipples as well as in the underarms, where they are largest and most active. They are poorly developed in child-

hood and enlarge considerably near puberty. Apocrine sweat normally is scanty and is produced intermittently at a slow rate. It is a sticky, milky substance composed of proteins, carbohydrates and lipids (a group of water-insoluble organic materials with a greasy feel). Sterile and odorless upon arrival at the skin surface, apocrine sweat acquires its unpleasant odor from bacterial decomposition of its constituents.

It is generally accepted that apocrine sweat glands serve no useful physiological purpose, their only apparent outstanding capability being to foster the development of an embarrassing smell. But body odor works functionally for animals, so perhaps there's more to be said about human body odor. Among animals, for instance, it's been shown that odor-bearing secretions are an important means of communication. There is speculation that humans, too, might subconsciously send sexual signals through the odor of chemicals known as "pheromones." An FDA advisory panel evaluating nonprescription antiperspirants reported in 1978: "Axillary [underarm] sweating functions apart from the usual thermo-

(Continued on next page)

No Sweat

Shunning sweat is practically a national preoccupation. In fact, worry about wetness and so-called "offensive" underarm odor prompts Americans to spend more than \$750 million annually on over-the-counter (OTC) antiperspirants, deodorants, and deodorant soaps.

Rarely, however, is wetness totally controlled by an OTC product. And no deodorant can absolutely guarantee that a person's underarms won't waft that pungent, familiar scent.

Let one fact be clear: Although underarm wetness and odor are closely associated, they're not synonymous. Essentially, wetness is due to eccrine sweat-gland secretion. Underarm odor, however, is believed to be caused by the bacterial decomposition of apocrine sweat. A single product will not necessarily affect both of those quite distinct conditions.

Intended to reduce underarm odor, deodorants either mask the odor with fragrances of their own or use antibacterial agents to decrease the odor-causing bacteria. Some do both. Others use powder to absorb sweat. Because deodorants aren't intended to affect a bodily function, they are considered cosmetics by FDA and may not make antiperspirant "drug" claims.

The intended purpose of antiperspirants is to inhibit eccrine perspiration. But exactly how they do so isn't yet proven. In fact, different active ingredients may act in different ways. (No product can reduce apocrine sweat gland secretion.) Since antiperspirants are antibacterial, they're also effective deodorants. Therefore, antiperspirants may—and many do—make "cosmetic" deodorant claims.

Antiperspirants do affect a bodily function: sweating. Some are considered over-the-counter drugs and, thus, will be affected by an ongoing OTC drug rule-making review considering their safety, effectiveness and labeling. Tentative final regulations specifically addressing OTC antiperspirants were published in the Aug. 20, 1982, *Federal Register*. To be generally recognized as safe and effective and not misbranded, OTC antiperspirants will be required to meet the criteria established in the final monograph, when published. (Related *FDA Consumer* articles are "Aerosol Antiperspirants: Under a Cloud," November 1978, and "Underarm Safety," November 1982.)

The proposed FDA regulations call for specific information to be on the labeling of OTC antiperspirants. The product should be identified as an antiperspirant. Active ingredients should be

listed, so that a person experiencing irritation from one product can switch to a product with a different active ingredient. The labeling also should contain these precautions:

- Under the heading "Warnings": "Do not apply to broken skin. If rash or irritation develops, discontinue use" and "Avoid excessive inhalation." (For aerosol products.)
- Under the heading "Directions": "Apply to underarms only."

Here's some advice about using antiperspirants:

- Repeat applications regularly. Antiperspirants work for only a certain length of time.
- Dry the underarms thoroughly before applying an antiperspirant. Dryness enhances penetration of the active ingredient.
- To avoid irritation, don't apply an antiperspirant to freshly shaved skin.
- Try another product with a different active ingredient if one product doesn't work. What works for one person may not work for someone else.

FDA has seen no evidence that antiperspirants harm sweat glands, and normal sweating usually resumes within days after users discontinue antiperspirant applications. ■



(Continued from page 21)

regulatory [heat-controlling] sweating system. It is stimulated by emotional signals, not just heat. It becomes active only after puberty. The combination of a potentially odorous substrate; a hospitable, warm, moist environment for the requisite bacterial growth; a large volume of evaporate vehicle for odor dissemination; and a wicklike tuft of hair all point to an efficient system for broadcasting chemical signals."

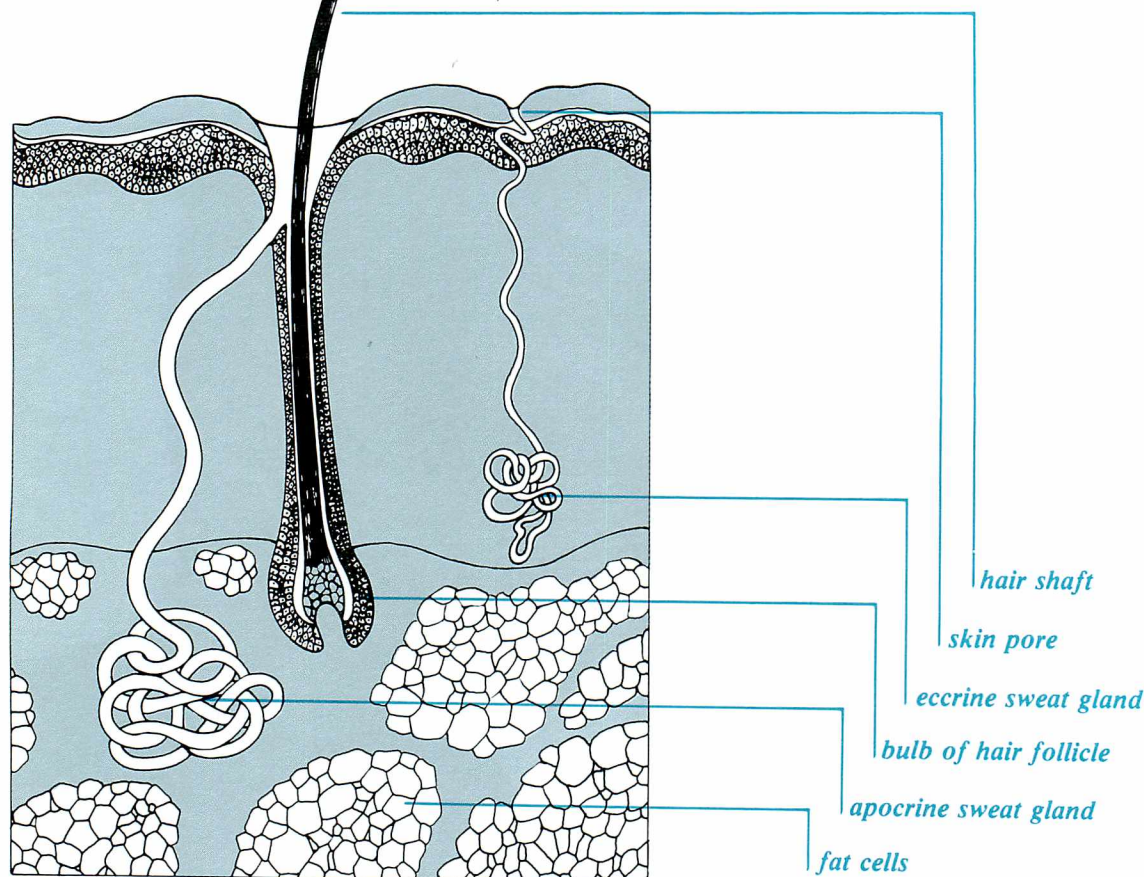
Pheromones haven't yet been detected in human sweat, so whether underarm perspiration plays a role as a sexual signal remains largely speculative. And in view of how much Americans spend on "sweatbusting," they evidently don't want Mother Nature's broadcast on the air anyway.

Unlike the seemingly useless apocrine sweat glands, eccrine sweat glands perform a vital function: They cool the body through evaporation of their secretion, which is mostly water. Eccrine sweat is clear and contains salt, potassium, urea, lactate, and traces of other compounds. Its composition varies with many factors, such as fluid intake, external temperature, and hormonal activity. And, although eccrine sweat contains such products as urea, the notion that sweat "purifies" the blood by excreting waste products in a manner

(Continued on page 24)



Eccrine and Apocrine Sweat Glands



(Continued from page 22)

similar to the kidneys is not scientifically supported. Like apocrine perspiration, eccrine sweat is sterile and generally odorless. But when certain foods, such as garlic, are eaten, the sweat may take on their odor.

Roughly 3 million eccrine glands cover almost every area of the body, save the lips and some of the genitalia. On the underarms, soles and palms, they gather in crowds—as many as 3,000 per square inch on the palms. While eccrine glands normally produce sweat in a daily amount ranging from negligible to about a quart, extreme circumstances can raise that amount to as much as 12 quarts in 24 hours. Most people have experienced excessive sweating from time to time as a result of heat, physical activity, or emotion. Such factors as race, age, sex, conditioning, and sensitivity to heat also can vary the amount a person sweats. Still, normal eccrine perspiration doesn't measure up to the great wetness of hyperhidrosis.

In "Diseases of the Apocrine and Eccrine Sweat Glands" in *Dermatology*, Dr. Harry J. Hurley lists more than 50 factors that cause, or are associated with, hyperhidrosis. As with normal perspiration, heat is a frequent cause of exaggerated sweating. That heat may be from sources outside the body, such as hot weather or a hot room. It may also be associated with factors within the body, such as malaria, diabetes mellitus, tumors, an overactive thyroid or pituitary gland, menopause, obesity, gout, and alcohol intoxication. Sweating in response to heat occurs primarily on the trunk and face, where sweat evaporates most readily in cooling the body.

Eating or drinking spicy foods and beverages also can bring on a hyperhidrotic cascade, on the face. Called gustatory hyperhidrosis, some cases are thought to reflect damage—as from a tumor, mumps or surgery—near the parotid salivary gland, with the result that impulses sent to sweat and salivary glands become mixed up. Thus, sweating rather than salivating occurs.

But the most common cause of persistent, troublesome hyperhidrosis is emotion. What is it that makes some people react so drenchingly to stressful situations that elicit only a mild reaction in others? No one seems to know for sure. Hurley writes that "a satisfactory explanation of the exaggerated sweating of emotional hyperhidrosis is still not available. A genetic factor . . . is apparently operative and predisposes the affected individual in some as yet unknown way."

The onset of emotional hyperhidrosis is usually in childhood or around puberty. Patients describe constant, heavy sweating on their palms and soles (palmar-plantar type) or on their underarms (axillary type). The affected skin may be pink or bluish white and may become cracked and scaling in severe cases, especially on the soles because of the lack of air circulation. Some patients have both palmar-plantar and axillary emotional hyperhidrosis, but one type usually predominates. According to Hurley, while both types have been seen in all races and both sexes, "women generally perspire less than men but tolerate it less."

In view of the great concentration of eccrine glands on the palms, it's no wonder that extreme palmar sweating can interfere with a career that often requires dry hands, as is the case for a jeweler, salesperson or industrial worker, to name a few. In hyperhidrosis, sweat constantly drips from the palms and fingertips.

For foot sweaters, close-fitting shoes can literally "stew" the soles in their own sweat, so it's important to get rid of as much moisture as possible. What's more, a bad odor may develop from bacterial decomposition of cellular debris caused by the scaling off of the outer layer of skin. Writing in the *Journal of the American Podiatry Association* (September 1983), William M. Jenkin, D.P.M., and Charles W. Craft offer these steps to help people dry out their over-perspiring soles:

- Wear shoes made only of leather or fabric, which "breathe."
- Choose footwear, such as sandals, that allows air circulation. Change shoes daily so they can dry thoroughly before they're worn again.
- Wear cotton socks. Change socks at midday (and shoes, too, if necessary).
- Use powder (no cornstarch) to absorb moisture.

In underarm emotional hyperhidrosis, sweating can be so profuse that a person's shirt and suitcoat become soaked within 15 to 30 minutes. Patients with underarm hyperhidrosis seldom have underarm odor, most likely because their profuse eccrine sweat washes away their apocrine sweat.

Emotional hyperhidrosis sometimes improves spontaneously around age 25. For persistent cases, however, dermatologists may prescribe topical agents—the first choice being a solution of aluminum chloride in absolute ethyl alcohol. To help prevent irritation and improve penetration of the active ingredient, the product should be applied to thoroughly dry skin, preferably at bedtime. After two or more applications, the heavy sweating may stop and, from then on, the product is usually applied once or twice a week, or as needed.

When all else fails in treating underarm hyperhidrosis, surgical removal of the sweat glands from the armpits has often proven successful. Several methods of reducing the mass of underarm sweat-gland tissue have been described;

they vary from selecting only the overactive glands to removing the skin layer containing sweat glands from the entire underarm area.

Scarring, of course, depends on which procedure is used, but it will not usually be visible when the arm is at the side. Whether decreased underarm sweating is worth the scars and, possibly, increased sweating on other areas of the body is an individual decision. Dr. C. Carnot Evans, a dermatologist with FDA's Center for Drugs and Biologics, adds, "Even if increased sweating occurs elsewhere to compensate for the absent armpit, patients nearly always prefer to deal with sweat in places other than the underarms."

Another surgical procedure that is sometimes used is a "sympathectomy," in which the nerves that connect the sweat glands to the nervous system are severed. But according to Dr. R. Kenneth Landow, writing in the *Handbook of Dermatologic Treatment* (1983), while results may initially be good, "a fair number of patients develop recurrence of symptoms within 5 years." Also, it's possible that tissue damage may occur and cause a condition known as "Horner's syndrome," in which nerve paralysis results in drooping of the eyelids and other effects. Patients for whom *any* surgery has been recommended should thoroughly discuss the procedure with their physicians so that they clearly understand the risks and benefits.

Some physicians treat hyperhidrotic patients with prescription drugs known as anticholinergics. Although the drugs are marketed for uses other than hyperhidrosis therapy—reducing acid secretions in patients with peptic ulcers, for instance—Landow and other physicians have reported that hyperhidrotic patients also may benefit from short-term use of the drugs. Further, side effects such as dry mouth, drowsiness, and constipation caused by the drugs may be as undesirable as the sweating. And, according to Hurley, "Systemic anticholinergic drugs, even in doses productive of unpleasant side effects, rarely satisfactorily suppress the sweating." FDA's Evans agrees that the reduced level of sweating may still be so great as to be uncomfortable. Topically applied anticholinergics are reported to be effective with minimal side effects. Hyperhidrosis therapy is not an FDA-approved indication for *any* form of an anticholinergic drug.

A device that uses iontophoresis, in which ions (charged atoms) are electrically driven into the skin, has been said to inhibit sweat on the palms, soles and underarms. But FDA's Center for Devices and Radiological Health, which regulates iontophoresis devices, has determined that existing information is insufficient to establish the device's safety and effectiveness for use in inhibiting sweat. The device is available only by prescription.

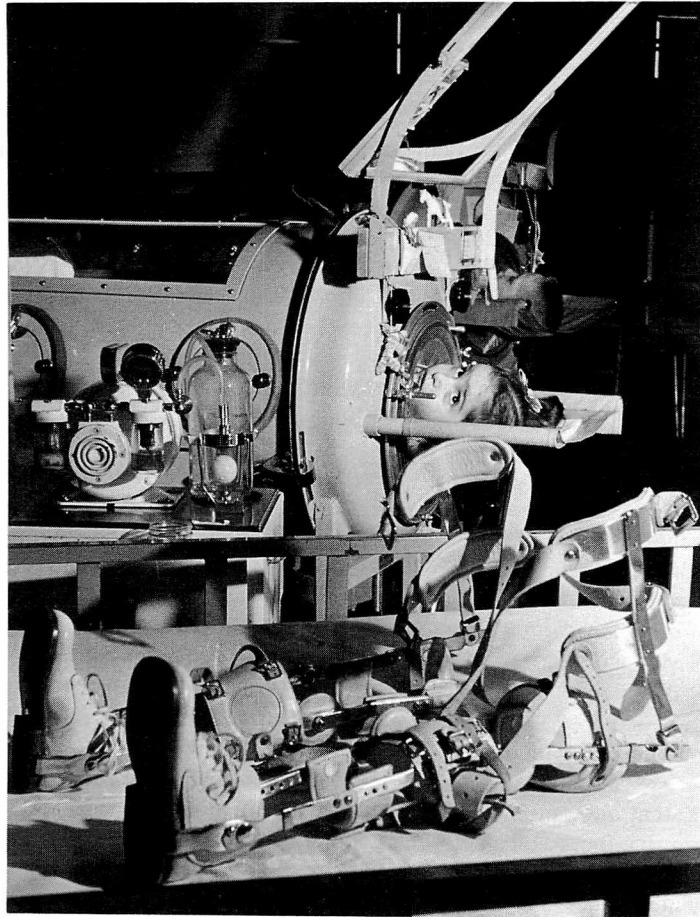
Other treatments for emotional hyperhidrosis with reported varying degrees of success include psychotherapeutic techniques such as biofeedback. (In biofeedback, the patient consciously tries to exert control over a bodily function, such as sweating, by using an instrument that monitors and records changes in that function.)

The treatments for hyperhidrosis may seem less than satisfactory, but perhaps a better, drier bottom line will yet be written. Meanwhile, the best source of advice for those seeking help is their physicians. ■

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

A Fearful Reminder Stalks Polio's Survivors

by Richard C. Thompson



A 1955 polio patient in the iron lung that became a virtual symbol of this dreaded affliction. In the foreground are braces typical of those worn by many polio victims. (Photo courtesy March of Dimes Birth Defects Foundation.)

In the first half of this century it was known as infantile paralysis, then poliomyelitis, appearing in dreaded summer epidemics that frightened parents as it struck down their children, killing many and leaving those who survived in wheelchairs and iron lungs and facing a lifetime of limited activity.

All that changed beginning in the 1950s. Mass inoculations of infants and children throughout the United States with Salk and Sabin vaccines made polio a sad memory. It was a classic public health triumph.

But now polio is back, not as a crippling and wasting scourge of children but as new

An estimated 40,000 polio survivors may be developing late post-poliomyelitis muscular atrophy.

symptoms for adults who once had the disease and—though handicapped—thought themselves partially or completely recovered.

For the 300,000 living survivors of polio, the threat of post-poliomyelitis muscular atrophy (PPMA) is a fearful reminder of the paralysis and suffering they experienced decades ago. An estimated 40,000 of these survivors may have or be developing late PPMA, which seems to occur about 30 years after the original illness.

The condition appears in its victims as extreme fatigue, often severe muscle pain, and a muscular weakness that may be slowly progressive over many years. Except for its association with childhood polio, the cause of late PPMA is not known and there is as yet no prevention, cure or treatment.

Dr. Marinos Dalakas, a neurologist at the National Institutes of Health who is studying PPMA, says it is a condition that affects perhaps 15 percent of the polio survivors. Why 85 percent are spared no one can say.

Although it is not life-threatening nor severely disabling, late PPMA can be very alarming to people who have already lost some of their muscle strength because of childhood polio. Some researchers believe it may even be affecting muscles that were not affected by the original polio.

Even if their recovery from polio left them without severe handicaps, the muscle weakness and fatigue brought on by PPMA can make it difficult for these patients to perform such simple tasks as opening jars or climbing stairs. Muscles may be sore or tender or actually painful. Sufferers also fear they are losing muscle mass, saying a particular set of muscles in their arms or legs appears thinner to them than it used to.

Dalakas stresses that late PPMA is not a new phenomenon; both patients and researchers have known about it in a general way for several years. "But now," he adds, "we have defined and classified the symptoms and are doing studies to see

what the causes and therapies might be."

There are several theories as to what may be producing these late post-polio symptoms. One is based on the fact that as people grow older they can be expected to lose nerve cells in the spinal cord. Ordinarily, the loss is not noticeable because other cells will compensate. But people who had polio have already lost some of the cells that control muscle movement; those are the cells the polio virus attacked. Now the remaining healthy cells, according to this theory, have become over-worked and are failing.

Some researchers have trouble with this reasoning. Although it helps explain the weakness that develops in muscles affected by the earlier polio, it does not explain such symptoms in muscles that were not originally affected. And a few researchers discount the aging factor altogether, saying that many late PPMA patients are still in their 30s and 40s, too young to be affected by the natural loss of nerve cells.

There is other speculation that late PPMA may be caused by a dormant polio virus that has reactivated, in much the same way that a dormant chicken pox virus can "reawaken" after many years to cause shingles. But this theory is not acceptable to many researchers. They point out that although the polio virus can persist in animals, there is no evidence that it persists in humans who have normal immune systems. Critics of this theory say emphatically that late PPMA is not recurrent polio attacking new muscle groups; it is instead, they believe, an increased weakness over time in the same muscles that were damaged years ago.

A variation of the reactivated virus theory holds that late PPMA may be related to a deficiency in the patients' immune systems. Researchers are looking at this possibility, but immune studies require long work before answers become available.

Whatever theories they espouse, researchers agree that late PPMA is not a form of amyotrophic lateral sclerosis, or

ALS. (See "Lou Gehrig's Disease Still Needs a Cure" in the December 1983–January 1984 *FDA Consumer*.) Although the same spinal cord cells are affected, late PPMA does not at all follow the course of ALS, and laboratory tests confirm that the two conditions are completely different. In particular, late PPMA is not life-threatening and its victims do not encounter the difficulty in breathing or swallowing that is symptomatic of ALS.

Late PPMA is enigmatic. Not only is it virtually impossible to predict which polio survivors will be afflicted with PPMA, it is also difficult to forecast the course of the symptoms once they occur.

The severity of fatigue, muscle weakness, and aching pain may level off and remain stable for several years. Or the symptoms may worsen every two or three years. But whatever the course, patients probably face some loss of muscle strength because PPMA seems to affect muscles that have already been weakened.

Dr. Lauro Halstead of the Institute of Rehabilitation and Research in Houston, himself a polio survivor, has studied over 200 post-polio cases. He found that almost all had experienced generalized, increased physical fatigue as well as renewed weakness in muscles that had been affected by their polio years earlier. He seems to see such fatigue and weakness as almost the expected and delayed consequences of polio. The symptoms appeared about 30 years after the original illness.

Most of his patients have also experienced severe joint and muscle pain as well as new weakness in muscles not affected by the earlier polio. Some who had been getting around on crutches reported they had to go back to wheelchairs, some even to motorized chairs.

Medication such as aspirin to control joint and muscle pain has worked for many of Halstead's patients. Beyond that, he suggests that good nutrition, good health practices, and especially no overexertion may be the best therapy.

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What Is Polio?

Poliomyelitis is an acute, infectious, communicable disease of humans that dates back to the ancient Egyptians. It is found throughout the world, especially in the temperate zones. It most often affects children, occurring as individual cases and as large and small epidemics.

One reference says that polio worldwide may be as prevalent as measles but in its milder forms it often goes unrecognized. Patients can have few symptoms and no complications and not know it is polio. From this, however, they could have immunity to further

polio infections.

Polio is caused by a virus that—in the more damaging infections—can affect the central nervous system, the brain, and spinal cord. Muscles no longer receive strong signals from the brain telling them how and when to move. The result is paralysis that, for such functions as breathing and swallowing, can be life-threatening. There are also painful muscle spasms in arms and legs from erratic nerve signals. Recovery from a serious bout with polio is slow, and residual effects such as limb and body weakness and paralysis can last a lifetime.

The virus seems most active in hot,

dry weather, which is why the summer months in the United States were traditionally known as the “polio season” and why children’s activities were so often restricted then.

The Salk and Sabin vaccines, introduced in the 1950s and 1960s, have virtually eliminated polio in the United States and have greatly reduced its incidence throughout the world.

Until the vaccines were developed, there were each year some 20,000 cases of paralytic polio in the United States, almost all among children and perhaps 5 percent of them resulting in death. There are now fewer than 10 cases of polio a year in this country. ■

Dr. Jonas Salk, developer of the first polio vaccine, administers a polio shot during clinical trials in Pittsburgh in 1954.

(Photo courtesy March of Dimes Birth Defects Foundation.)



ers also see the patients’ immune systems as perhaps playing a role in late PPMA. They accept the possibility that aging and a diminished reserve of strength in older polio patients may be a factor. Again, they strongly rule out Lou Gehrig’s disease as well as myasthenia gravis, a chronic, progressive muscular paralysis, as explanations for PPMA.

The NIH researchers are now going beyond the initial group of 17 to do a study of 2,500 patients who survived polio. They are investigating how many now have late PPMA; to what degree; how it is affecting them; what seems to be the cause; and how it might be treated.

Whatever the cause and course of late PPMA, persons who have recovered from polio and who now—years later—discover new muscle weakness and pain should get immediate medical attention. It must first be determined whether the affliction is due to another cause and not related to their earlier polio. If the condition is diagnosed as late PPMA, medication may be helpful in relieving painful symptoms, and the changes in life style suggested by Dr. Halstead, such as maintaining good health and avoiding overexertion, may be useful.

Once past their initial fears and misgivings, post-polio patients should understand that—whatever the theories being offered—the experts agree that this new complication is not life-threatening. Accepting that it is an added burden to an already burdened body, post-polio patients should still be able to adjust to these changed conditions and to continue to live productive lives. ■

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The NIH team headed by Dr. Dalakas reported last year on an initial study of 17 persons, aged 31 to 65, who had had polio and had recovered to various degrees. All 17 were experiencing recent neuromuscular symptoms.

The team found that the patients fit into two distinct groups. The first, a group of seven patients, had had generally severe paralytic and other symptoms at the time of their original illness. In their immediate recovery they tended to have little endurance, experienced joint pain, and were prone to falling and injuries. They had substantial disability and required corrective devices and braces. Over the years, their condition would remain stable for long periods, then deteriorate, requiring that adjustments be made to their braces and that their work demands be reduced.

This group was not experiencing muscular weakness or wasting in the late

PPMA sense. In effect, their basic condition had been defined as they recovered from their original illness, and that condition could be stabilized with minor adjustments to their corrective devices and in their life styles.

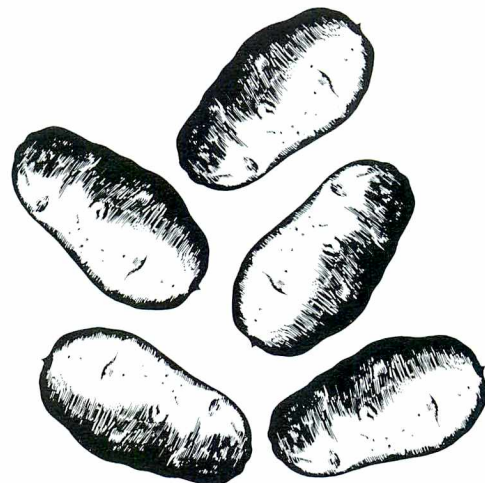
The second group of 10 patients had had less severe symptoms during their original illnesses. They were now experiencing late PPMA symptoms of a slowly progressive muscle weakness and wasting. One woman in this group, for example, had been functioning well with only mild, left-side weakness from her earlier (1950) polio. Some 30 years later she began developing focused pain and weakness in her right arm, which had not been affected in her original illness.

Laboratory tests and biopsies with this second group suggest to the NIH researchers that “late PPMA is a benign form of motor-neuron (nerve cell) disease” that may be slowly progressive. The research-

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

The Curious Compulsion Called Pica

by Evelyn Zamula



In TV sitcoms, when a pregnant woman has a sudden yen for pickles and sends her husband out for some in the middle of the night, it's a cue for the audience to erupt into laughter. Pickles are OK, but when pregnant ladies crave dirt, clay, starch, and a host of other unbelievable non-foods, it's no laughing matter.

The craving for unnatural or non-nutritious substances is called pica—pronounced pye'kuh—named after the magpie (pica pica), a bird with a reputation for poking its beak into all kinds of things to satisfy its hunger or curiosity. The term pica refers to the compulsive behavior, not to the substance or substances that the person craves. Some experts on pica, such as Dr. William H. Crosby, former professor of clinical medicine at George Washington University, stretch the meaning of the word to include the compulsive eating of anything, even ordinary foods. For example, eating abnormally large amounts of Life Savers or raw potatoes also qualifies as pica, according to Crosby.

Pica doesn't only happen among pregnant women. It occurs in both sexes, in all races, in all parts of the world, and in animals as well as humans. It was reported as early as 40 B.C. and is still with us today. Both children and adults can be pica victims, and what they eat may range from the absurd to the disgusting. In many cases, when toxic substances, like lead, are consumed, the results can be tragic—brain damage, epilepsy, even death.

Though pica is widespread, it's not easy to ferret out. Many mothers are aware that their children eat dirt or sand regularly, but don't report it to the doctor because they expect the children to outgrow the habit, which is usually the case. Children often try to conceal pica—especially if it involves eating something particularly nasty—for fear they'll be punished. And it might not occur to most doctors to ask about pica in taking a child's medical history, except when they suspect lead poisoning. Medical help is usually sought only when the pica amounts to an addiction that is disrupting the family, or because the habit has caused the child to become destructive, or ill, or to walk unsteadily or cry too much.

Out of shame, adults also try to keep their strange cravings

hidden. Pica is sometimes discovered when a victim complains to the doctor of abdominal pain, vomiting, or some other problem, or an X-ray shows an unexplained mass in the stomach.

Although a blood test can be a clue to pica—as many as 50 percent of pica victims have iron deficiencies—it takes an alert doctor to put the pieces of the puzzle together. When a nurse confessed to a hematologist (blood specialist) that she was trying to lose weight by eating 10 bunches of celery a day, he suspected she had pica and was anemic. He was right on both counts.

Physicians throughout history have speculated that emotions, magic spells, fantasies, hysteria, nervous conditions, or hereditary factors played a part in the disorder. In some cultures, though, it was taken for granted that pregnant women would have pica, and the condition was viewed as acceptable.

Other doctors regarded pica as a form of insanity and urged physical restraints or prison to keep the victims from eating what they wanted, since the pica frequently killed them. One clever 17th century physician recommended mixing an emetic with the desired substance so that it became associated in the patient's mind with the resulting nausea and vomiting—a sort of Pavlovian response two centuries before Pavlov.

From time to time, some astute physicians realized that pica in some people was caused by something lacking in their diet. Avicenna, who lived about 1000 A.D., was the first to recommend treating pica with iron. So did Boezo in 1638. But the pica-diet connection obviously didn't filter down to all. In 1835 a British doctor observed that dirt-eating blacks working on sugar plantations in the West Indies had symptoms of a disease that resembled chlorosis, a form of iron deficiency anemia. Since many dirt-eaters pursued their addiction relentlessly, until they wasted away and died, plantation owners were anxious to know how to prevent the habit. However, instead of recommending a better diet, the doctor's solution was to muzzle the victims with a face mask or locked mouthpiece.

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Pica for dirt, clay, stones, chalk, limestone, and so on was reported in the United States as far back as Colonial times, especially among slaves and poor people. Only malaria killed more blacks during the slavery era than clay-eating. Before the Civil War, some enlightened physicians urged plantation owners to improve the slaves' diet—which usually consisted of cornmeal and fatback—and add iron sulfate to cut down on the dirt-eating habit. Many plantation owners followed these recommendations with success.

Pica is full of paradoxes. Though experts know there is a relationship between iron deficiency and pica, the substances the victims crave are rarely rich in iron. People who eat

tremendous quantities of ice—a pica called pagophagia—are often deficient in iron, but ice adds only water to their diet.

In many cases, the pica itself contributes to the deficiency. Some clays contain substances that chelate iron (and other elements)—that is, they bind with iron and cause it to leave the body without being absorbed. But does iron deficiency cause pica in the first place? The cause-and-effect-relationship has not yet been proven, states Dr. Darla Danford, a noted authority on pica. Dr. Crosby calls this the chicken-or-the-egg dilemma: Which comes first, the pica or the deficiency?

To muddy the waters further, not everyone with iron deficiency (or zinc deficiency, primarily associated with pica in

Pica takes some bizarre forms, and the substances consumed are limited only by the imagination.

Middle Eastern clay-eaters) has pica, nor does everyone with pica have iron (or zinc) deficiency. Of the multitudes of people with these deficiencies, why should only some of them go on to develop this strange perversion of the appetite?

Obviously, other factors enter in besides lack of certain nutrients. The etiology of pica—that is, what causes it—is not known completely. While some authorities believe that pica may be a learned pattern of behavior, others theorize it may also be due to other cultural, psychological and physiological factors, or a combination of them.

The most commonly reported pica in pregnant women in the United States involves the eating of dirt, clay, starch or ice. Eating of clay or dirt is especially common among southern black women and may be a holdover from Africa, where pregnant women were encouraged to eat clay, and lumps of clay were given to babies to suck or teethe on. This habit may have originated in times of famine, or in the belief that clay had medicinal or magical properties. Researchers have speculated that some black women have continued the practice in this country because it is part of their culture, but poverty and poor nutrition clearly aggravate the problem.

The clays preferred may be either white, yellow or red, may be eaten in lumps *au naturel*, or may be molded into different shapes and baked, sometimes with the addition of salt or vinegar. Some like white clays for their “creamy and sweet” flavor, while others prefer the gritty and tart red clays. The custom has followed the migration of the black population from the South, so that clays from a favorite “clay hole” are frequently mailed by relatives to those who’ve moved away.

Clay consumption varies from a few lumps a day to a quart or more. When small amounts are eaten, often there are no ill effects, or relatively minor ones, such as constipation or injury to the teeth. With larger amounts, more serious effects occur, including (besides anemia) intestinal obstruction, bowel perforation, and infection with parasites present in the clay. In addition, zinc deficiency—common in Turkey and Iran—is linked with enlargement of the liver and spleen, delayed sexual development, loss of sense of smell and taste, and dwarfism.

Since the preferred clay is not often available in big cities, the craving is often transferred to laundry starch (cornstarch). Starch-eating, like clay-eating, interferes with iron absorption and adds a great many calories to the diet—there are 1,600 calories in a pound of starch. The average ingestion of laundry starch in one study was well over a pound a day per person. Eating that much starch makes the person feel full, and many starch-eaters have neither the desire nor the room to eat the nutritious foods they need.

Among adult males, non-pregnant females, and children,

pica takes some bizarre forms and the substances consumed are limited only by the imagination. Toilet bowl fresheners, mothballs, charcoal, inner tubes, cigarette butts, tomato seeds, refrigerator frost, hair, match heads, toilet paper and ashes are some of them. Retarded adults who are confined to institutions may have pica for pieces of cloth, plastic sheets or string. Several cases have required surgery to repair perforated intestines. Some forms of vampirism, or a craving for blood, are said to be motivated by pica.

In childhood pica, many factors may be involved, among them parental neglect, inadequate diet, boredom, low socioeconomic status, poor family environment, loneliness, retardation and neurosis. Experts say that pica occurs in some children who don’t progress beyond that stage in late infancy or early childhood when they put everything and anything in their mouths. This “mouthing” behavior is normal in a child’s development, and usually ends by age 2 or 3. However, for unknown reasons, some children continue to mouth and swallow inedible objects for much longer. It becomes pica when they habitually seek out a specific substance or substances.

Pica can begin as early as age 1 and is usually outgrown by age 6 or 7, though some cases go on until puberty. Since a child’s world is limited, the pica is satisfied with something in the immediate surroundings—paper, or perhaps their own hair. Large hairballs—called trichobezoars—have been surgically removed from the stomachs of children with pica for hair. However, when pica involves eating lead paint or plaster, household poisons, matches, soil or feces containing roundworms or other parasites, it not only arouses disgust in the family and other children, it can be life-threatening.

The most serious problem connected with pica in children is lead poisoning from eating lead-based paint chips or lead-impregnated plaster from the walls of old, substandard housing or tenements. Children can also pick up significant quantities of lead from eating soil or newspapers. In several studies, 70 to 90 percent of children suffering from serious lead poisoning were reported to have a history of pica, according to Dr. Jane Lin-Fu, an international authority on lead poisoning. Lead poisoning from pica occurs most often among poor, black, central-city children, but it can be found among white children and in suburban areas as well.

The Lead-Based Paint Poisoning Act of 1971 made it unlawful for paint manufactured for residential buildings, toys and furniture to contain more than 0.06 percent lead, or 600 parts per million, a still not inconsiderable amount. But old paint with an even higher lead content remains on the walls and woodwork of at least 37 million homes in the United

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A Campaign to Counter the Craving

Back in the bad old days before permanent press, a woman usually ironed her husband's shirts. If the man of the house liked them crisp, she boiled up a batch of starch on the stove (remember, this was also before spray starch) and dunked the shirts in. The shirts were then dried, sprinkled with water, and finally ironed. Real fun and games.

Some stores don't even sell that old-time kind of starch anymore. But it was and is a big seller in many inner-city groceries, and it's not used to starch a thing. In fact, it's usually not even displayed in the laundry products area, but is right there next to the candy and popcorn. The starch is popular among millions of black women, both pregnant and non-pregnant, to satisfy their pica.

Many black women in the United States have to contend with a long list of adverse health factors—poor nutrition, low socioeconomic status, and hypertension, among others—that make them twice as likely as white women to deliver babies of low birth weight, an important factor in infant mortality. Pica only compounds this problem. As noted in the main story,

starch, like clay, both prevents iron from being absorbed by the intestinal tract, contributing to iron deficiency anemia, and displaces the consumption of more nutritious foods. Laundry starch is high in bacteria, too, because it is not manufactured under the sanitary conditions required for food products. Besides being bad for the mother, the habit may harm the developing fetus.

Worried about the many cases of iron deficiency he was seeing in his community back in the '70s, Dr. Gerald W. Deas, a black internist practicing in Queens, New York City, concluded that starch-eating was not being recognized for the public health problem it is. Some women were eating as much as two pounds daily and stopping only when they saw black spots before their eyes, Deas discovered. The practice was so common that every time he saw patients with iron deficiency anemia, instead of asking them if they ate starch, he just asked, "How much laundry starch do you eat?"

"It usually saved a \$2,000 to \$3,000 workup on the patient," said Deas. "Most white doctors—and many black doctors—weren't aware of the problem since few patients willingly disclose this dietary habit. I thought it was time that someone did something about it."

Speaking from church pulpits, at community meetings, and at social events, Deas began a one-man public education campaign seven years ago against the practice

of eating laundry starch (and dirt, clay and chalk, as well). He also wrote a brochure, published by the Eli Lilly & Co. pharmaceutical firm as a public service, describing the signs of iron deficiency anemia—weakness, dizziness, irritability, shortness of breath, and pale nails—and explaining how starch-eating and poor diet were contributing to it. The brochure received wide distribution by black doctors and the National Urban League.

About three years ago, his activities got a special boost from WNEW-TV reporter William McCreary of New York City. In 21 segments of "Black News," in which Deas was frequently interviewed and quoted, McCreary hammered away at his audience about the dangers of eating laundry starch.

Along with the public education campaign, Deas worked on the makers of Argo laundry starch. He succeeded in getting them to put "Not recommended for food use" on the product label several years ago. More recently, Deas persuaded the company to reformulate the starch into a powder that is not as appetizing to its fans as its former chunk form. As a result, many black women have given up the habit, says Deas.

For their successful battle to reduce the consumption of laundry starch, both Deas and McCreary were the personal choices of FDA Commissioner Frank E. Young, M.D., to receive the 1985 Commissioner's Special Citation. ■

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States today, says Dr. Lin-Fu.

Lead is most dangerous to children because they can absorb a greater proportion of it during a critical growth period, when their nervous systems and other tissues are developing. If their diets are low in iron and calcium, which is often the case in poor areas, lead may cause still greater damage. Even relatively low levels of lead in the blood may result in anemia, learning disabilities, and behavior problems; higher levels can cause mental retardation and irreversible neurological damage. Lead can cause a child to stagger, vomit forcefully, have convulsions, or go into a coma and die due to swelling of the brain.

Treatment of lead poisoning consists of chelating the lead out of the body by injecting the chemical CaEDTA (edetate calcium disodium). In more acute cases, doctors inject dimercaprol in addition to CaEDTA. When the poisoning is less severe, doctors may use oral D-penicillamine, approved for chelating copper out of the body in Wilson's disease (a hereditary disorder in which too much copper accumulates within the body tissues) but used on an investigational basis for lead poisoning. To prevent re-exposure, it's necessary to identify the sources of lead in the child's environment and get rid of them.

Because pica has historically occurred in times of famine,

or when an individual's diet lacks certain important nutrients, or when the demands on the body for proper nutrition are heavy (such as during growth and pregnancy), the first step in treating pica today is to determine if any dietary deficiencies exist and then treat them, if possible.

But good diet and iron supplements don't always do the trick. Even after treatment, the hankering lingers on in some cases. Though ice-eaters quickly drop the habit when iron is added to their diets—confirming that iron deficiency is the cause of this pica—clay- and starch-eaters whose iron levels are brought back to normal continue to eat a lump or two now and then. Experts have also observed that when some pica victims are absolutely prevented from eating whatever it is they like, they'll often switch to something else. All of which suggests that there is more to pica than meets the eye. When pica persists despite iron administration, there may be other problems at the root. Psychiatric counseling aimed at modifying behavior is often recommended.

Pica—when it's a pregnant wife's midnight craving for pickles—may be funny on television. But for certain groups, it's a significant public health problem that may best be solved through education, as the campaign described in the accompanying article demonstrates. ■

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

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.

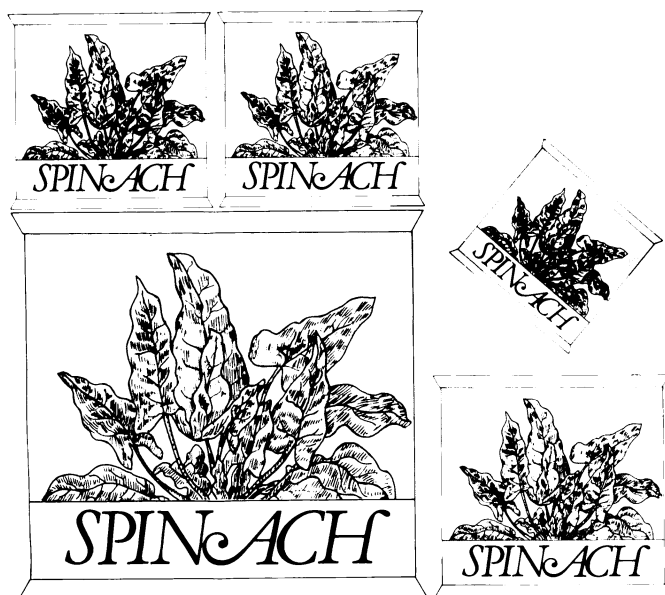
■ The World Health Organization has recommended international restrictions on 28 **stimulant/hallucinogenic drugs**, including cathine, fenproporex, morazone and MDMA. FDA has asked for comments to be considered in the U.S. response to the request (FR Sept. 6).

■ The Nuclear Regulatory Commission has amended its regulations to allow physicians to use **technetium-99m** labeled sulfur colloid and technetium-99m labeled pertechnetate for certain clinical procedures without prior permission (FR Sept. 10).

■ Amended performance **standards for sunlamp products** and UV lamps used in these products went into effect Sept. 8. FDA updated the standards to cover new products with different design concepts. The current standard dates back to 1980 (FR Sept. 6).

■ Approximately \$104,000 will be available from the U.S. Centers for Disease Control in Atlanta in fiscal year 1986 for continuation of the **hepatitis B vaccine** trial follow-up. Three awards will be made for a two-year period (FR Sept. 4).

■ The Larsen Co., a Wisconsin food processor, and the Continental Can Co. have been granted a 15-month temporary permit by FDA to test-market canned **spinach** that contains specified amounts of **zinc chloride**, added to retain the green color of the product (FR Sept. 13).



■ The Environmental Protection Agency has revoked tolerances for combined residues of the **herbicide nitrofen** and its metabolites containing diphenyl ether linkage on or in certain raw agricultural products. The compound may carry birth defects and cancer risks, and its use was canceled in 1982. FDA found only five food samples with detectable levels of the herbicide from 1981 through 1982 and none in 1983 (FR Sept. 18).

■ Boots Pharmaceuticals Inc. is requesting the sole right to market for two years the analgesic **ibuprofen** in dosages of 300, 400 and 600 milligrams. Ibuprofen is a prescription drug in those dosages. The Drug Price Competition and Patent Term Restoration Act of 1984 allows firms to ask for such exclusivity on certain products on which patent protection has expired (FR Sept. 27).

■ Temporary tolerances for combined residues of the **insecticide thiodicarb** and its metabolites on or in field corn grain and corn forage and fodder have been extended by the Environmental Protection Agency to July 8, 1986. The pesticide must be used in accordance with experimental use permits, and EPA must be notified by the petitioner, Union Carbide Agricultural Products, of any untoward findings (FR Sept. 18).

■ **Sodium metasilicate**, an alkali used for washing and peeling fruits, nuts and vegetables and for other food processing purposes, has been placed on the generally recognized as safe (GRAS) list as a direct food additive in a final ruling by FDA (FR Sept. 25).

■ Failure to promptly report information on **pesticide residues** in food, feed, water, and the environment by registered users of pesticides will be actionable violations of the law under a Final Interpretive Rule and Statement of Policy issued by the Environmental Protection Agency. The new rule updates and codifies previous policies dating back to 1978 (FR Sept. 20).

■ **Liquid grain fumigants** containing carbon disulfide, carbon tetrachloride, or ethylene dichloride may not be sold or distributed after Dec. 31, 1985, although existing stocks may be used through June 30, 1986. These were substitutes for ethylene dibromide, a fumigant banned in 1984 that had been used to control insects in stored grains and grain-milling machinery. Several other substitutes are available and may be used (FR Sept. 19).

■ A final rule has been issued by EPA that sets tolerances of 20 parts per million for residues of the **insecticide carbaryl** on or in pineapple bran, a livestock feed. The tolerance was derived from an FDA study that showed that carbaryl concentrates in the inedible bran and not in the pineapple pulp and juice consumed by humans (FR Sept. 18).



Investigators' Reports

N.Y. Sues Orachel Firm

Coronary bypass surgery is often effective in restoring adequate blood flow to a heart with cholesterol-clogged arteries. But because it is major surgery, many patients are understandably reluctant to undergo the procedure and would jump at a less drastic alternative.

Enter the latest form of health fraud: oral chelation, in which tablets and capsules are touted as a simple, painless and cheap alternative to bypass surgery.

Usually mixtures of vitamins, minerals and amino acids, these oral chelation products will do nothing to prevent or treat cardiovascular disease, says FDA. In fact, the agency has ordered the manufacturers to stop selling them. (See "Avoid 'Chelation Therapy' Pills" in Updates in the September 1985 *FDA Consumer*.)

Despite FDA's regulatory move, one of the oral chelating products, Orachel, was still being sold in some New York City stores in September. This was illegal, according to New York's attorney general and the New York Board of Pharmacy, because the safety and effectiveness of the product had not been substantiated and it had not been approved by FDA.

On Sept. 5, an investigator from the attorney general's office seized Orachel from nine retail outlets of two health food chains: seven branches of the Vitamin Shoppes, Inc., and two branches of L & H Vitamins.

The seizure was announced that day by Attorney General Robert Abrams and Dr. Albert Sica, executive secretary of the pharmacy board, who said there was "no reasonable scientific basis" to conclude that the drug was effective.

At the same time, Abrams and Sica announced the filing of a lawsuit against the stores and the distributor of Orachel, HRG Distributors, Huntington Beach, Calif., to prevent the sale and distribution of the product in New York state. The suit, filed in the New York Supreme Court in Manhattan, argues that the labeling and advertising for Orachel include unproven health claims describing it as "a scientifically com-

pounded and clinically proven formula that helps the body remove dangerous contaminants that may clog the arteries."

The name "Orachel" is misleading, the suit alleges, because it implies that the product is an oral chelating agent.

True chelating agents are substances that combine with metals and are used in an injectable form to combat poisoning from heavy metals, digitalis overdoses, and excess calcium.

The suit has not yet come to trial.

All for the Best?

Nature's Best Food Supplements, a firm that produces food supplements for body builders, did not have the best when it came to liquid protein supplements, nor when it came to following FDA regulations.

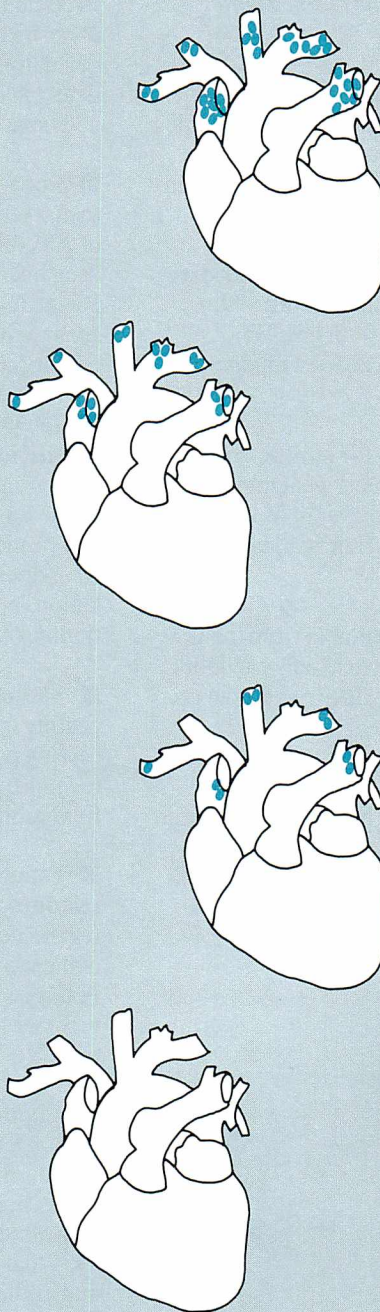
The company, located in Island Park, N.Y., manufactures and distributes products labeled as containing significant amounts of protein and amino acids. These food supplements are promoted for helping people gain weight and build muscles and are primarily geared toward body builders and weight lifters.

An investigator from FDA's Brooklyn district office inspected the firm after a competitor complained that Nature's Best liquid protein products did not contain the labeled amount of protein. Laboratory analysis of samples of the product by FDA confirmed the charge. The products were found to contain less than 8 percent of the protein declared on the label.

The district office sent the firm a letter requesting that the problem be corrected. The firm's president, George Statler Jr., wrote back that the product was being discontinued indefinitely and was being recalled.

However, the district office subsequently received reports, from the New York and New Jersey health departments and a consumer, that Nature's Best was continuing to market products that did not contain the labeled amount of protein. FDA investigators returned to the firm.

There they were puzzled by several things. One was that the manufacturing facilities at the firm did not seem capable of producing the amount of product involved. Another was that the products were labeled with names of other firms, firms unknown to the district office. The investigators asked Statler if he had any connection with



these firms. Statler said he was "seeking to do business" with one, Dynamic Nutrition Inc., but that he had no connection with other manufacturing facilities. Dynamic Nutrition, he said, was located on Brentwood Avenue in Brentwood, N.Y.

When the investigators tried to check out this firm, they discovered that there was no Brentwood Avenue in Brentwood and no Dynamic Nutrition there either. They then located a trucker used by Nature's Best and, through him, found Dynamic Nutrition. In fact, it was located in Island Park, just a mile from Nature's Best.

The FDA investigators were initially refused admittance to the plant. When they were allowed in, several days later,

it was by Statler, who admitted he was in charge of the firm. It had been in operation for over a month and was the source of the liquid protein products being shipped by Nature's Best. Samples collected by the investigators were analyzed and found also to be low in protein, most containing less than 10 percent of the labeled amounts.

Because of Nature's Best's persistent violations and evasive tactics, Brooklyn district staff took legal action. At the district's request, Nature's Best Food Supplements signed a consent decree of permanent injunction agreeing, among other things, that it would not ship its protein supplement products in interstate commerce without prior FDA approval. At the time the injunction was signed,

the firm was under new management.

Overinflated

Urinary catheterization is not exactly the average hospital patient's idea of fun, but it is a procedure that may be necessary to obtain a urine specimen, to prevent the bladder from blocking urine flow, or to monitor kidney function. Last May, the prompt recall by a manufacturer of some faulty catheters spared a lot of patients some pain and possible surgery.

Latex Industries, Inc., of Chippewa Lake, Ohio, manufactures Foley catheters, a type of thin plastic tube with a bulb, or balloon, on one end. After the catheter is inserted into the bladder, the balloon is inflated with air to keep the device in place.

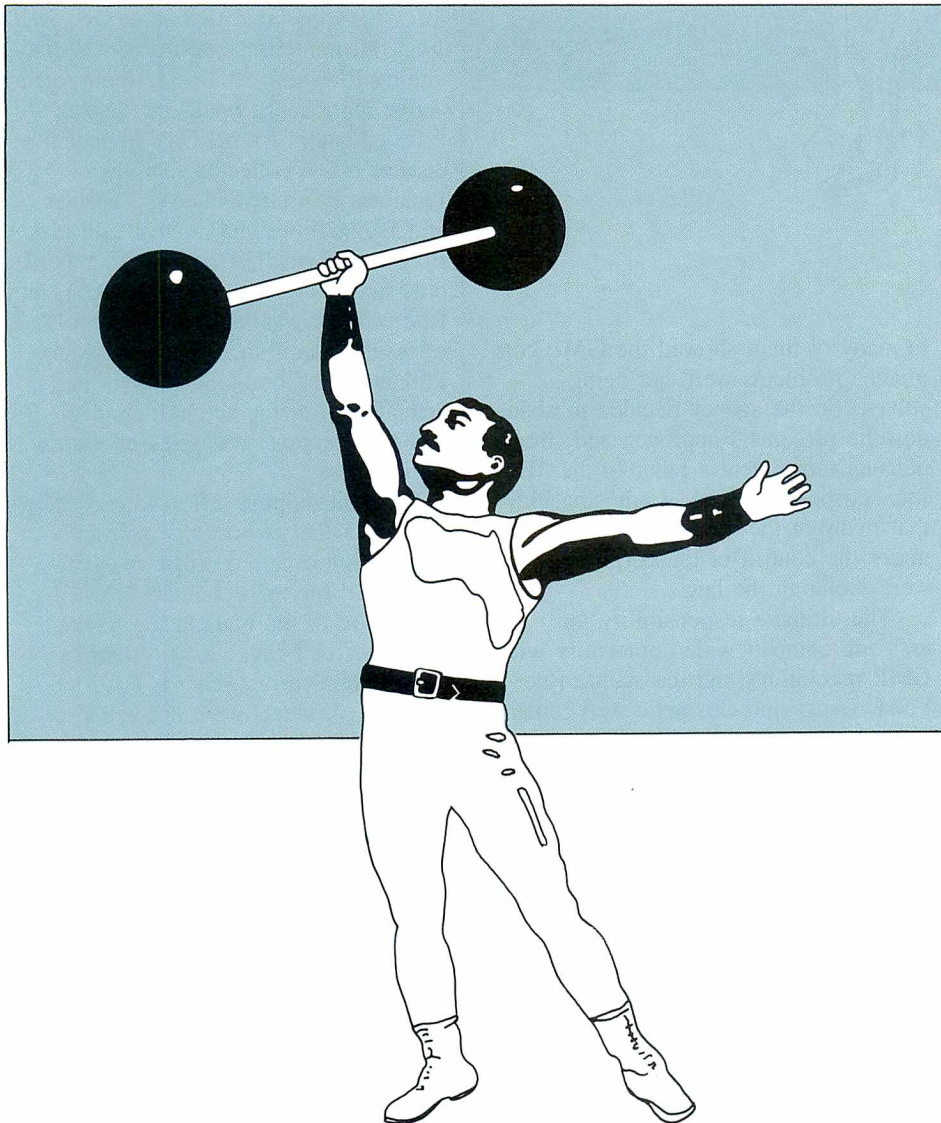
FDA learned from several nursing homes that sometimes the balloon would not deflate when the catheter was ready to be removed. Needless to say, manipulating the defective catheters to remove them would be painful. Had any broken apart, surgery would have been necessary. Fortunately, no cases of injury were reported.

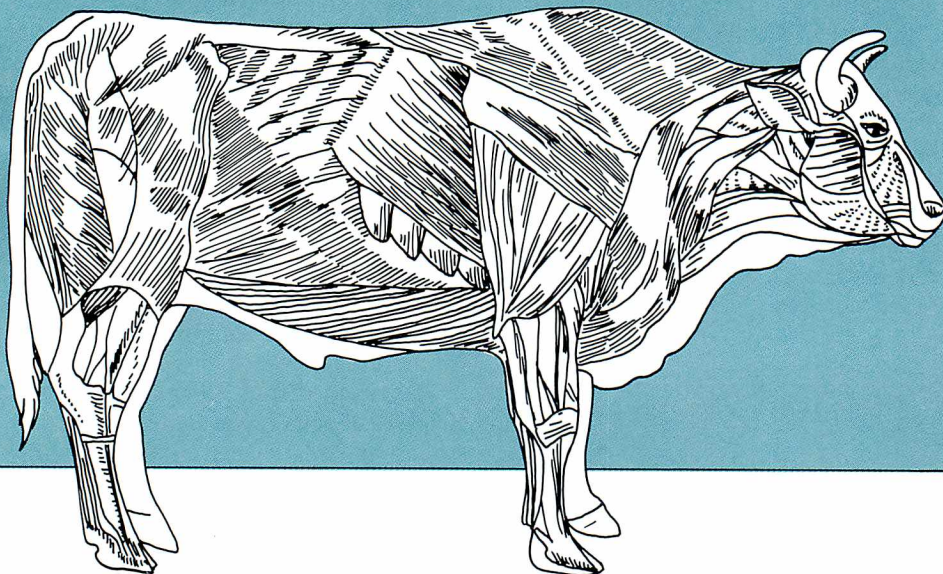
FDA notified Latex Industries, Inc., of the problem. The firm identified the cause of the defect and initiated an immediate recall of 1,200 catheters that had been distributed nationwide. Wholesalers and pharmacies were asked to return the defective products, which the firm planned to destroy. Investigators from FDA's Cincinnati office inspected the plant and confirmed that the recall had taken place.

Going Topside at the Feed Mill

There's no better way to get cooperation than going straight to the top. That's what FDA's Kansas City district office did when dealing with medicated feed problems at feed mills owned by MFA, Inc., a farm cooperative based in Columbia, Mo.

MFA is reportedly the 14th largest farm cooperative in the nation, with about 89,000 members. The firm sells feed, seed, fertilizer and farm supplies through a network of 75 retail centers and also buys and sells grain through a system of terminal elevators. Within MFA's vast corporate structure are a number of feed mills—called in the trade grind-and-mix operations—that manufacture and market medicated





feeds. Medicated feeds contain drugs to prevent or cure diseases or make the animals grow faster.

During routine inspections of 61 of these facilities over a two- to three-year period, inspectors from FDA's St. Louis office noted that many of these mills were having problems complying with FDA's Good Manufacturing Practice (GMP) regulations for making medicated feeds. One problem was that the mills were not analyzing enough samples of the feeds to determine that the active drug ingredients were present in the right proportions. Also, custom-mixed feeds did not have information for the farmer on proper withdrawal times—the number of days before slaughter that use of the medicated feeds should be stopped. If proper withdrawal times are not followed, potentially hazardous residues of the drugs can end up in meat, milk and other food products made from the animals. And drug inventory records were poorly kept, which could result in the firm's underusing or overusing drugs.

At first, FDA tried to get the problems corrected by dealing with the feed mills individually. But follow-up visits

to many of them showed the GMP compliance problems were not being solved. So the agency decided to abandon the piecemeal approach and, in an unusual move, sent a letter to the MFA, Inc., corporate president advising him that many of the medicated feed mills under the control of the corporation were violating the law.

"The ultimate responsibility for assuring companywide conformity with GMP regulations and the statute [the Food, Drug, and Cosmetic Act] remains at your direction . . ." the letter said.

As a result of the letter, a meeting was held between MFA, Inc., and FDA at which the firm acknowledged the deficiencies in its operations and promised correction.

The direct approach clearly has paid off. Follow-up inspections of a number of the feed mills has shown that almost all are following the GMP regulations to the letter.

E-Z Off, E-Z Out

There was one major problem with two weight-loss products distributed by Lancon Vitamins, Bethlehem, Pa. They

contained a combination of ingredients FDA had recently taken off the market.

The ingredients were phenylpropanolamine (PPA) and caffeine. Both are central nervous system stimulants that had been sold legally as diet aids and "stay-awake" products. But tablets containing these ingredients began to be peddled "on the street" with implications that they were controlled substances such as amphetamines. This flood of cheap and less potent imitations obstructed the efforts of federal and state officials to deal with actual controlled substance abuse. It also caused many people who used the drugs to misjudge the potency and danger of the real controlled drugs. Therefore, FDA declared that as of Oct. 29, 1984, all nonprescription products containing PPA and caffeine as their sole active ingredients would be illegal.

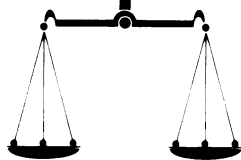
Investigators from FDA's Philadelphia district office collected samples of Lancon's E-Z Off Diet Aid Capsules and E-Z Off Weight Control Capsules. Both contained PPA and caffeine as the only active ingredients. In addition, the first product was labeled as a time-release preparation, but testing by the Philadelphia laboratory showed that virtually all of the active ingredient (over 93 percent) was released within 30 minutes.

The Philadelphia office notified FDA's Brooklyn district office, which had jurisdiction over the drugs' manufacturer, JSP Inc. of Bohemia, N.Y. Inspection of the manufacturer found violations of FDA's Good Manufacturing Practice regulations. For instance, products were not being tested for the rate of release of the active ingredient; in fact, there were not even any written procedures for doing so.

The investigators also found several other drugs in which caffeine or PPA or both were the only active ingredients. Under supervision of the FDA investigator, the firm destroyed five lots of unapproved drugs. In addition, a U.S. marshal seized 137,000 capsules of E-Z Off Weight Control Capsules and 36,000 E-Z Off Diet Aid Capsules at Lancon Vitamins.

—This small sample of reports from the field was prepared by Annabel Hecht, Carol Ballentine and Herman Janiger.

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/Poisonous and Deleterious Substances

PRODUCT: Corn, shelled, in bulk, at Pantego, E. Dist. N.C.; Civil No. 84-122-CIV-4.

CHARGED 11-20-84: When returned to the dealer from Chesapeake, Va., the article contained the added poisonous and deleterious substance aflatoxin—402(a)(1).

DISPOSITION: Consent—authorized release to the dealer, Bell Farms, Inc. (Bell Land Co.), Pantego, N.C., for salvaging. (F.D.C. No. 64417; S. No. 85-398-653 et al.; S.J. No. 1)

Foods/Contamination, Spoilage, Insanitary Handling

PRODUCT: Bulgur, lentils, macaroni, and other food stocks, at Houston, S. Dist. Texas; Civil No. H-84-26.

CHARGED 1-4-84: While held by Antone's Import Co., Houston, Texas, some of the articles contained rodent or insect filth, and all of the articles had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: The articles were claimed by the dealer who, to avoid expense and time, consented to a decree of condemnation authorizing release for salvaging. (F.D.C. No. 64167; S. No. 84-292-362; S.J. No. 2)

PRODUCT: Flour, corn flour, and rice, at Woburn, Dist. Mass.; Civil No. 82-0274-MA.

CHARGED on or about 2-15-82: While held by Bay State Food Co. Inc., Woburn, Mass., one lot of flour contained rodent filth, and all of the articles had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63636; S. No. 82-254-358 et al.; S.J. No. 3)

PRODUCT: Popcorn in bulk, packaged popped popcorn (flavored and unflavored), and other food stocks, at Cincinnati, S. Dist. Ohio; Civil No. C-1-85-0680.

CHARGED 3-8-85: While held by Concession Specialties, Cincinnati, Ohio, who was manufacturing popped popcorn from bulk popcorn, the articles had been prepared, packed and held under insanitary conditions—402(a)(4).

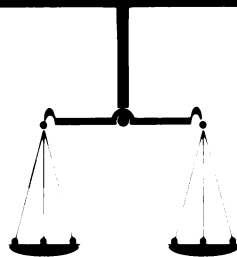
DISPOSITION: Consent—authorized release to Sumage Inc. (t/a Concession Specialties), Cincinnati, Ohio, for salvaging. (F.D.C. No. 64527; S. No. 85-357-656; S.J. No. 4)

PRODUCT: Rice, dog food, and grocery stocks, at Birmingham, N. Dist. Ala.; Civil No. C-84-627-S.

CHARGED 3-12-84: While held by J.T. Massey Mercantile Co., Birmingham, Ala., all of the articles had been held under insanitary conditions—402(a)(4).

DISPOSITION: The articles were claimed by the dealer. The claimant served written interrogatories on the government. The claimant moved for a temporary restraining order against the government and for a partial summary judgment. The court denied the claimant's motions. Ultimately, by way of compromise, a consent decree was entered which authorized release to the claimant for salvaging. (F.D.C. No. 64221; S. No. 84-376-213 et al.; S.J. No. 5)

PRODUCT: Sardines in mustard sauce, and sardines in soy-



bean oil, canned, Beach Cliff Brand, at Alexandria, W. Dist. La.; Civil No. CV-85-0379.
CHARGED 2-8-85: When shipped by Stinson Canning Co., Belfast, Maine, the articles had been packed and held under insanitary conditions whereby they might have been rendered injurious to health (due to an excessive number of critical and major can-seam defects)—402(a)(4).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64507; S. Nos. 85-313-642/3; S.J. No. 6)

PRODUCT: Soy sauce, thick, canned, at Tampa, M. Dist. Fla.; Civil No. 85-75-Civ-T-13.
CHARGED 1-15-85: When shipped by Taroco Food Corp., New York, N.Y., the article (labeled “Thick Soy Sauce . . . Manufactured & Packed by Koon Chun Hing Kee Soy & Sauce Fty . . . Yuen Long, Hong Kong”) was unfit for food due to being held in swollen cans—402(a)(3).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64462; S. No. 85-374-246; S.J. No. 7)
PRODUCT: Whey, dried, bagged, and in bulk, at Monticello, N. Dist. Iowa; Civil No. C-85-11.
CHARGED 1-17-85: While held by Dried Whey Inc., Monticello, Iowa, the 70,000-pound bulk lot contained rodent and bird filth—402(a)(3); and all of the article had been prepared, packed or held under insanitary conditions—402(a)(4).
DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 64481; S. Nos. 85-354-178/9; S.J. No. 8)

Foods/Economic and Labeling Violations

PRODUCT: Table syrups, Clark's Farm, at Riverside, C. Dist. Calif.; Civil No. CV 85-2110-TJH(Kx).
CHARGED 3-27-85: When shipped by Dewey Clark, Philadelphia, Miss., the articles labeled “Pure Pioneer . . . Maple Syrup,” “Clark's Farm Maple Table Syrup,” and “Clark's Farm Pure Sorghum” had had corn syrup substituted wholly or in part for maple syrup and sorghum syrup—402(b)(2); and the articles labeled “Clark's Farm Strawberry Flavored Syrup” and “Blackberry Table Syrup” had had the artificial color FD&C Red No. 40 added to them to make them appear better or of greater value than they were—402(b)(4). The labeling of the “maple” and “sorghum” syrups was false and misleading for products that contained little or no maple syrup or sorghum syrup and were in fact largely corn syrup—403(b); the “maple” and “sorghum” syrups were syrups offered for sale under the name of other foods—403(b); the “maple” and “sorghum” syrups failed to conform to the definition and standard of identity for maple syrup and sorghum syrup because they were largely corn syrup—403(g)(1); and the blackberry and strawberry syrups contained the artificial coloring FD&C Red No. 40 and their labeling failed to state that fact—403(g)(1).
DISPOSITION: Default—ordered destruction. (F.D.C. No. 64546; S. No. 85-354-947; S.J. No. 9)

Food Additives

PRODUCT: Chubs, smoked, frozen, at Miami, S. Dist. Fla.; Civil No. 84-3050-CIV-HASTINGS.
CHARGED 12-31-84: When shipped by St. Pierre Fisheries, Inc., Chicago, Ill., the article contained the nonconforming food additive dieldrin (approx. 0.33–0.38 ppm)—402(a)(2)(C).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64442; S. No. 85-271-252; S.J. No. 10)

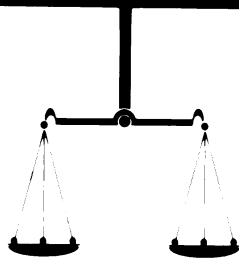
Drugs/Human Use

PRODUCT: Homatropine-pentobarbital combination suppositories, at Arlington, N. Dist. Texas; Civil No. 4-80-282-K.
CHARGED 9-4-80: When shipped by G&W Laboratories, Inc., South Plainfield, N.J., the articles (labeled “Matropinal Inserts [or “Matropinal Forte Inserts”] . . . Comatic Laboratories, Inc., Houston, Texas”) were new drugs without effective approved New Drug Applications—505(a); and while held for sale, the labeling of the articles lacked adequate directions for use and were not exempted due to their new drug status—502(f)(1).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63107; S. No. 80-211-857; S.J. No. 11)

PRODUCT: Liquid for the disorders of children, at Bronx, S. Dist. N.Y.; Civil No. 84-Civ. 7854.
CHARGED 10-30-84: When imported, the article (labeled “Woodward's Gripe Water For . . . Gripes, Flatulence and other complaints . . . Sodium Bicarbonate . . . Concentrated Dill Water . . . Ginger Tincture . . . Alcohol . . . Prepared in Canada for W. Woodward Ltd., London, England Distributors: Julius Schmid of Canada, Ltd., Scarborough, Ontario”) was a new drug without an effective approved New Drug Application—505(a).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64351; S. No. 84-400-510; S.J. No. 12)

PRODUCT: Oxygen, U.S.P., at Memphis, W. Dist. Tenn.; Civil No. 84-0185(MA).
CHARGED 12-6-84: While held by American Air Products, Inc., Memphis, W. Dist. Tenn., the circumstances used for the manufacture, processing, packing and holding of the article failed to conform with current good manufacturing practice—501(a)(2)(B).
DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 64430; S. No. 84-344-530; S.J. No. 13)

PRODUCT: Phaseolamin special legume concentrate (starch-blocker) tablets, at Las Vegas, Dist. Nev.; Civil No. LV-82-814 HEC.
CHARGED 12-9-82: When shipped by Paragon Laboratories, Torrance, Calif., the article, which was labeled “Phaseolamin . . . Manufactured to the specifications of Vita Plus, Inc., Las Vegas, NV” and which was accompanied by specified promotional brochures and other labeling, was a new drug without an effective approved New Drug Application—505(a).



DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63795; S. No. 82-247-501; S.J. No. 14)

Medical Devices

PRODUCT: **Adhesive patches with magnets, Acu-Dot**, at Cleveland, N. Dist. Ohio; Civil No. C-79-2041.

CHARGED 11-30-79: The article, which was labeled “Acu-Dot Magnetic Analgesic Patch, Acu-Dot Corp. . . . Akron, Ohio” and which had been prepared and packaged at Huntington Beach, Calif., for Acu-Dot Corp., Akron, Ohio, had false and misleading labeling claims for temporary relief of occasional minor aches and pains of muscles and joints—502(a); and the article’s labeling lacked adequate directions for lay use for its intended purposes—502(f)(1).

DISPOSITION: The article was claimed by the distributor (Acu-Dot Corp.), who denied the charges, demanded a jury trial, and sought a declaratory judgment and an injunction against the government. The government moved to dismiss the claimant’s counter-suit or, in the alternative, moved for summary judgment. The claimant served requests for admissions on the government and moved for a consolidation of hearing on interlocutory matters with the final hearing on the merits, and waiving trial. The claimant moved for a protective order as to trade secrets and commercial costs. The government served requests for admissions.

The court set the case for trial with two earlier seizure actions. Meanwhile, the government served written interrogatories on the claimant who objected to all of the interrogatories.

After trial, the court found that the seized devices were misbranded and subject to seizure and condemnation (even though the claims were not technically false), because the claims were inherently misleading. In making such a finding, the court resisted “the impulse to allow claimant to market a product that works only by means of a placebo effect,” because the device was not inherently effective and the results achieved by the devices were attributable to the psychosomatic effect produced by the advertising and marketing of the device. The court said, “A kiss from mother on the affected area would serve just as well to relieve pain, if mother’s kisses were marketed as effectively as the Acu-Dot device.”

In ruling for the government, the court also found that FDA gave the claimant sufficient notice that the labeling was not satisfactory, and that the existence of a patent covering the devices and creating a “presumption of validity” was not conclusive but merely gave the grant substance and value; and, even if such presumption were applicable in this case, the government’s evidence was sufficient to overcome that presumption. Because of the existence of uses to which the devices or its components might be put, the court authorized release of the devices to the claimant (upon the filing of a bond) for destruction or other FDA-authorized disposition. Such disposition was actively litigated by the claimant until the claimant became involved in bankruptcy proceedings. (F.D.C. No. 62654; S. No. 79-114-039; S.J. No. 15)

PRODUCT: **Diapulse electromagnetic energy generators**, at Norfolk, E. Dist. Va.; Civil No. 77-532N.

CHARGED 8-11-77: The labeling of the article, which had been shipped by Diapulse Corp. of America, New York, N.Y., failed to bear adequate directions for use for the articles’ intended purposes, and neither adequate directions for lay use nor adequate information for use by licensed practitioners could be furnished—502(f)(1).

DISPOSITION: The article was claimed by Lord Cecil Rhodes, D.D.S., Norfolk, Va., who denied the charge. The claimant served written interrogatories and requests for the production of documents on the government. The government litigated the claimant’s failure to produce medical histories and other items. The action came on for trial before the court.

At the trial, the government argued that the claimant had violated an injunction issued by the Eastern District Court and affirmed upon appeal, and that a previous seizure (also affirmed upon appeal) of the device in Connecticut operated as *res judicata* or collateral estoppel. Although the injunction enjoined the Diapulse Corp. of America and anyone in active concert with that corporation, although Dr. Rhodes probably received actual notice of the injunction, and although Dr. Rhodes had participated as a witness at the previous trials, the court found that the government had not offered adequate proof of Dr. Rhodes’ acts, assistance, or privity with Diapulse Corp., and that the government was mistaken as to the binding effect of the previous actions upon Dr. Rhodes.

The court found that Dr. Rhodes was not estopped from relitigating the factual issue of whether his device was misbranded and that the issue in this case boiled down to whether Dr. Rhodes’ device had all the information required by the regulations on prescription devices. However, because Dr. Rhodes never even attempted to rebut the proof that the device was ineffective for many of the claims made for it by the Diapulse Corp., the court found that the device was clearly misbranded. In addition, because Dr. Rhodes did not present sufficient scientific proof that the device was effective as an adjunct in treating bone and soft-tissue inflammation, the court reluctantly agreed with FDA that Dr. Rhodes could not relabel his device for such uses. Accordingly, the court ordered the device destroyed. The claimant filed an appeal, but the appeal was never perfected. (F.D.C. No. 61325; S. No. 77-19-794; S.J. No. 16)

PRODUCT: **Radiopaque clamps, eye spears, Surgi-Brushes, and mini fragment blades**, at Fairport, Rochester, and Spencerport, W. Dist. N.Y.; Civil No. 84-740-T.

CHARGED 6-29-84: The quality of the articles—which were labeled (clamp) “Radiopaque Clamp . . . Sterile Contents are sterile unless package has been opened or damaged . . . Healthmed Corp. . . . Fairport, N.Y.”—and other articles, similarly labeled, packaged (clamps and spears) by Lifetime Assistance, Inc., Spencerport, N.Y., and (brushes and blades) by Continuing Development Services, Inc., Fairport, N.Y., which, in part, were



sterilized by another firm and which, in part, had been delivered to a distribution warehouse at Rochester, N.Y., fell below the articles' purported sterile quality, since their packaging contained openings (i.e., approximately 49 percent of the examined packages had defective package seals)—501(b); the articles' labeling was false and misleading in representing that the articles were sterile when the packaging contained openings compromising the sterility—502(a); and the articles were processed in unregistered establishments—502(o).

DISPOSITION: Consent—authorized release to Healthmed Corp., Fairport, N.Y., for bringing into compliance. (F.D.C. No. 64285; S. No. 84-369-986; S.J. No. 17)

Cosmetics

PRODUCT: **Toilet water in self-pressurized spray bottles, Caleche**, at North Miami, S. Dist. Fla.; Civil No. 84-0930-Civ-NCR.

CHARGED 4-13-84: When shipped by Parfumerie Royal-Opera Paris, France, the article—labeled (bottle) "Caleche Eau De Toilette Hermes Paris . . . 25 ml. .8 fl. oz."—contained a poisonous and deleterious substance, a chlorofluorocarbon propellant that was prohibited—601(a); the labeling of the article was misleading in failing to reveal material facts concerning conditions of use, since required warning statements were lacking—602(a); and the article was also in violation of the Fair Packaging and Labeling Act, as follows: the outer carton labels of the article lacked a quantity of contents declaration in terms of U.S. measure—15 U.S.C. 1453(a)(3)(A)(i); and the label of the outer container of the article failed to declare the propellant ingredient—15 U.S.C. 1454(c)(3)(B).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64243; S. No. 84-373-709; S.J. No. 18)

PRODUCT: **Toilet water in self-pressurized spray bottles, Climat, Caleche, and Je Reviens**, at Miami, S. Dist. Fla.; Civil No. 84-0927-Civ-JE.

CHARGED 4-13-84: When shipped by Parfumerie Royal-Opera, Paris, France, and other shippers in Paris, France, the articles—labeled (cartons) "Climat Eau De Toilette Atomiseur Lancome Paris," "Eau De Toilette Atomiseur Caleche . . . Parfums Hermes Paris," and "Je Reviens Eau De Cologne Atomizer . . . Worth Paris"—contained a poisonous and deleterious substance, a chlorofluorocarbon propellant that was prohibited—601(a); the labels of the immediate containers and their outer cartons were misleading in failing to reveal material facts concerning conditions of use, since required warning statements were lacking—602(a); and the articles were also in violation of the Fair Packaging and Labeling Act, as follows: the outer carton and immediate container labels of the Je Reviens and Climat lacked quantity of contents declarations in terms of U.S. measure of fluid ounces; and the outer carton labels of Caleche lacked a quantity of contents declaration in terms of U.S. measure of fluid ounces—15 U.S.C. 1453(a)(3)(A)(i); the labels of the outer con-

tainers of the Climat and Je Reviens failed to declare the propellant ingredients; and the outer container label of the Caleche failed to declare the article's ingredients in descending order of predominance—15 U.S.C. 1454(c)(3)(B).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64241; S. No. 84-373-704 et al.; S.J. No. 19)

CRIMINAL ACTIONS

DEFENDANT: **Commodity Sales, Inc.**, and **Steven M. Forman**, president and treasurer, and **Melvin Bendixon**, division manager, at Framingham, Dist. Mass.; Criminal No. 83-2.

CHARGED 1-4-83 by grand jury: While held for sale, Greenland turbot (counts 1, 2, and 3) was repackaged with the label "I.Q.F. Sole Fillets Product of Holland," when the article was neither sole nor from Holland, and when the repackaged label lacked the common or usual name of the food and lacked name and place of business of the manufacturer, packer and distributor—403(a)(1), 403(b), 403(e)(1), 403(i)(1); and (counts 4 and 5) Greenland turbot, labeled as above, was shipped to Denver, Colo., and New York, N.Y.—403(a)(1), 403(b), 403(e)(1), 403(i)(1).

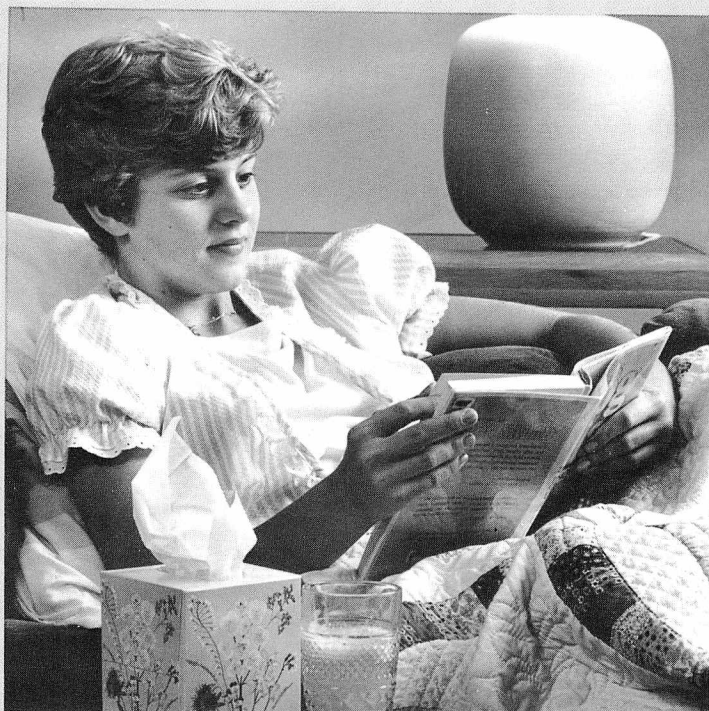
DISPOSITION: The charges against the division manager were **dismissed**. The corporation pleaded guilty to all counts and was fined \$5,000; and the president pleaded guilty to counts 1, 2 and 5 and was fined \$3,000. (F.D.C. No. 62281; S. No. 78-118-455 et al.; S.J. No. 20)

INJUNCTION ACTIONS

DEFENDANT: **Wendell Elevator Co.**, **Charlotte L. Kroll**, president, **Egon H. Kroll**, vice president, and **Lloyd M. Little**, manager, Wendell, Dist. Idaho; Civil No. 84-1349.

CHARGED 8-23-84: That the defendants, at their warehouse facility (which included a lower bean warehouse, an upper bean warehouse, an animal feed warehouse, and a grain elevator) at Wendell, Idaho, prepared, packed and held beans, grains and animal feed; that the defendants distributed the beans in interstate commerce; that, when shipped by the defendants, the beans contained rodent filth, and the beans had been held under insanitary conditions; that FDA inspections of the warehouse facility disclosed a number of specified insanitary conditions; and that the defendants, on a number of occasions, had been notified of the violative conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent decree of permanent injunction enjoined the complained-of violations and enjoined interstate shipment of any food from the defendants' facility unless and until a number of specified conditions had been met, including the following: the cleaning and renovation of the defendants' facility, the examination of the facility by a qualified person and his certification that sanitary requirements had been met, and the examination of all foods on hand and the destruction or bringing into compliance of any food on hand found to be contaminated. (Inj. No. 1077; S. No. 84-355-859 et al.; S.J. No. 21)



R_x for Flu or Chicken Pox: Kindness

Be good to yourself when you've got the flu or chicken pox. Take it easy. Get plenty of rest.

Viral illnesses such as these are usually self-limiting. Time will cure them.

Check with your doctor about using medications to treat flu or chicken pox. For children—including teenagers—medications such as aspirin and aspirin-containing products may not be a good idea. A rare but dangerous condition called Reye syndrome may develop in young people just when they appear to be recovering. Studies suggest a link between the development of Reye and the use of aspirin to treat the flu or chicken pox.

So, treat yourself right when you've got the flu!

—A message from the
Food and Drug
Administration