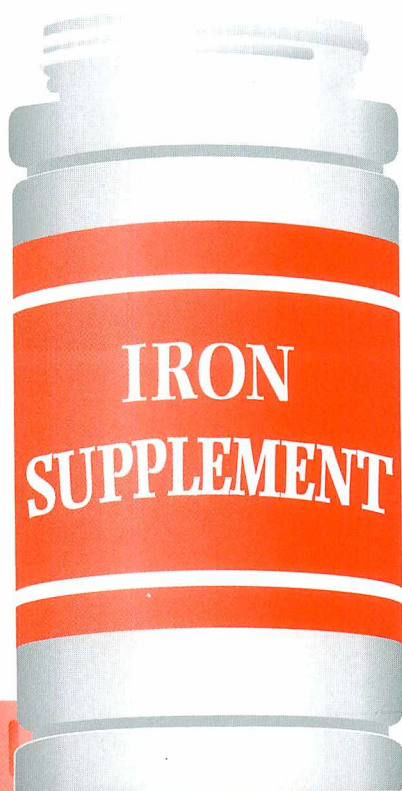
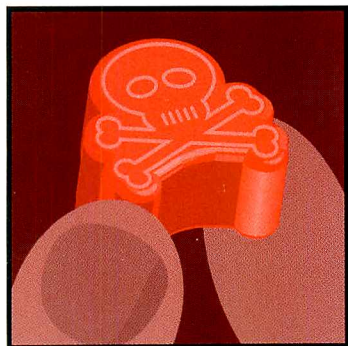


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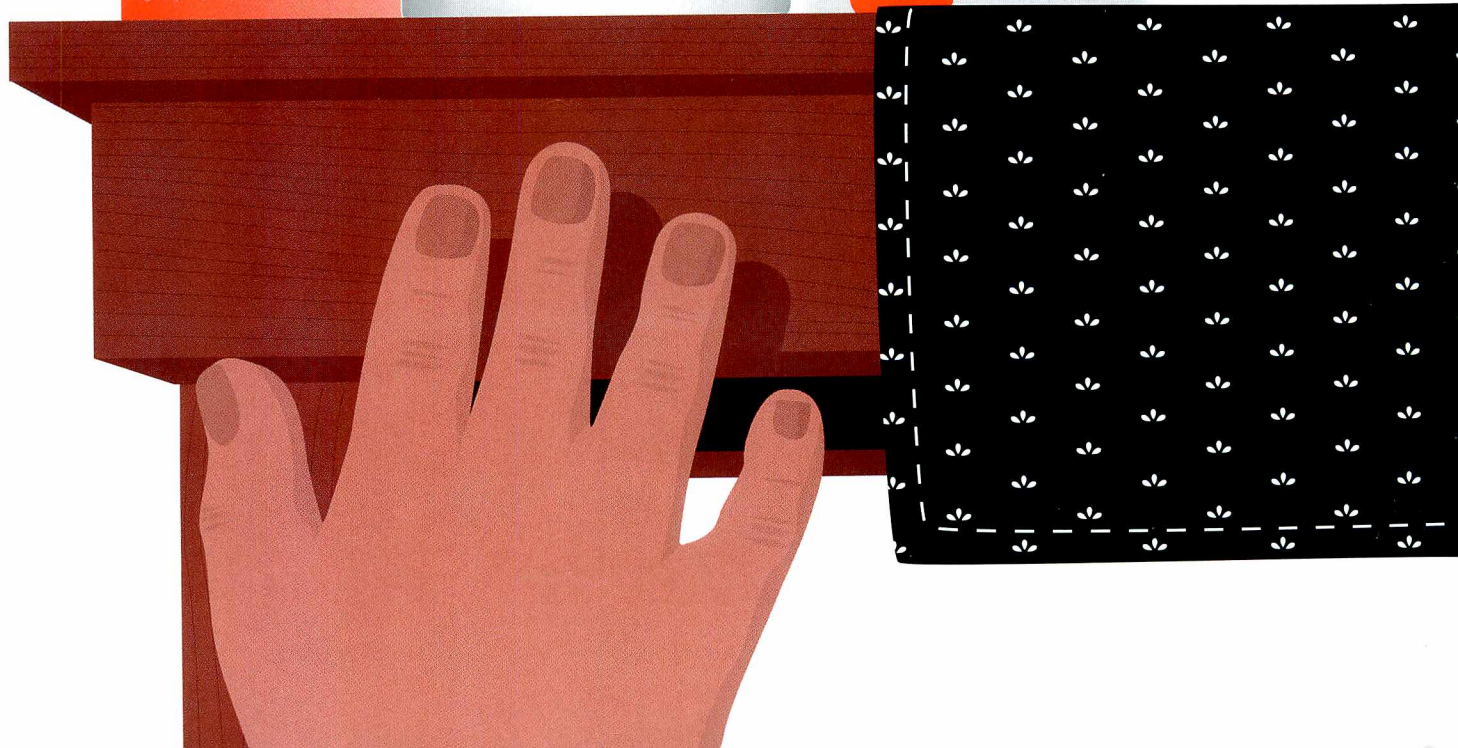
THE MAGAZINE OF THE U.S. FOOD AND DRUG ADMINISTRATION

• VOL. 30 NO. 2

MARCH 1996 •



Preventing Childhood Poisoning





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Inside Front Cover Photo:

Having meals delivered to the home by a local agency is one way older Americans can maintain good nutrition and social contact. For other ideas, see page 12.

FDA CONSUMER

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Home can be a dangerous place when it comes to childhood poisoning. It's not only prescription drugs that need to be kept out of little hands' reach: Today the biggest concern is iron supplements.

Growing Older, Eating Better 12
Many older Americans, especially those who live alone, have been unable to get proper nutrition due to problems that often accompany aging. But food programs and other types of assistance are now helping elders to a better diet.

Coping with Arthritis in Its Many Forms 17
One in seven Americans has some form of arthritis. Medications—some of them nonprescription—and some kinds of exercise can provide relief. But consumers need to avoid fraudulent products that seem to proliferate in this profitable market.

Tea: A Story of Serendipity 22
Happy coincidence has played a part in making tea second only to water in worldwide consumption. Americans drink their fair share—2.24 gallons per person in 1994—much of it iced and most of it black rather than green or oolong.

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FDA has formal cooperative programs with the states in four areas. The public benefits from the expertise each partner brings to these collaborations.

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Deadline for Supplement Comments

March 13, 1996, is the last day FDA will accept comments on its proposals to standardize the labeling of dietary supplements. The proposals appear in the Dec. 28, 1995, *Federal Register*.

The address for submitting comments is: FDA Dockets Management Branch (HFA-305), Rockville, MD 20857-0001.

Under one proposal, labeling for dietary supplements would follow the same format as that used in the labeling of packaged foods. It, too, would give nutrition information about certain vitamins and minerals, as well as other dietary ingredients. Instead of "Nutrition Facts," the information would be presented under the heading "Supplement Facts."

Another proposal would set definitions for the terms "antioxidant" and "high potency" as used in the labeling of dietary supplements.

The term "dietary supplements" refers to products containing vitamins, minerals, herbs, amino acids, and other nutri-



ents and ingredients intended to supplement the diet.

The proposals would implement major provisions of the Dietary Supplement Health and Education Act of 1994. Under that law, labeling rules for dietary supplements must be final and in effect by Jan. 1, 1997.

New Regulations for Seafood

A revolutionary way of protecting the U.S. food supply from contaminants could begin this year under new regulations for seafood safety that take effect Dec. 18, 1997.

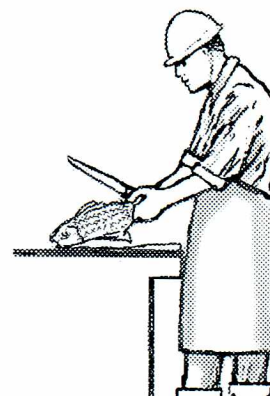
The regulations, announced by FDA last December, call for seafood processors to adopt food safety practices based on the Hazard Analysis Critical Control Point (HACCP) system. This system uses preventive controls to keep unsafe foods off the market, instead of addressing safety problems after the fact, which has been the approach since the early 1900s.

FDA estimates its HACCP seafood safety regulations will prevent 20,000 to 60,000 seafood poisonings a year, which cost consumers as much as \$116 million annually.

Next year, the U.S. Department of Agriculture will issue HACCP rules for meat and poultry, and in future years, FDA plans to issue regulations covering other foods.

Under the seafood regulations, processors must identify hazards that, without preventive controls, are reasonably likely to affect product safety. Examples of food hazards are chemicals, toxins, bacteria, parasites, and physical objects.

If a hazard is identified, the firm must implement an appropriate HACCP plan.



For example, a highly mechanized processing line would be checked regularly for metal fragments in the food and records kept of those checks. With the HACCP recordkeeping, FDA inspectors can monitor product safety more closely and on a more continuous basis than with the older "spot-checking" method.

The HACCP seafood regulations have special provisions for certain fish. For example, processors of raw molluscan shellfish, such as oysters, clams and mussels, must specify in their HACCP plans that they will accept only molluscan shellfish harvested from approved waters. For smoked fish, processors must implement procedures to ensure that the product remains safe from *Clostridium botulinum* toxin through the shelf life of the product.

The HACCP rules do not apply to fishing vessels and transporters. However, processors must take responsibility for their seafood materials, whether imported or domestic. The rules also do not apply to retail seafood operations, which are regulated by state and local authorities who have received training and

other technical assistance from FDA.

FDA published the rules in the Dec. 18, 1995, *Federal Register*.

(For more information, see "HACCP: Patrolling for Food Hazards" in the January-February 1995 *FDA Consumer*.)

Device Reporting Rule Final

Beginning April 11, hospitals, nursing homes, and other health-care facilities must report medical device-related deaths and serious injuries or illnesses, according to an FDA final rule that also spells out manufacturers' reporting requirements.

The rule requires that medical facilities:

- within 10 days, report deaths to FDA and to the manufacturer
- within 10 days, report serious injuries or illnesses to the manufacturer, or to FDA if the firm's identity is not known
- every six months, send FDA a summary of these reports.

The new criteria, published in the Dec. 11, 1995, *Federal Register*, are part of a universal "alert system," required by the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992.

The rule requires that manufacturers:

- within five days, report to FDA any device-related incident requiring immediate action to protect the public health, as well as any incident for which the agency requests a report
- within 30 days, report other device-related deaths, serious injuries, or illnesses, as well as device malfunctions likely to cause or contribute to death, serious injury, or illness

- annually, submit a statement certifying the number of reports filed, or that no reports were filed during the previous 12 months

- report incidents related even to products no longer marketed.

The rule helps lower costs by reducing paperwork. Reports can be submitted on the same FDA MEDWATCH form used for reporting drug- and biologics-related adverse events. Procedures are under way at FDA to allow electronic filing of reports.

Doublechecking Pap Smears

Two new computer-based Pap smear screening systems will help increase the detection of cervical cancer.

Laboratories can use the Autopap 300 QC System or the Papnet system to doublecheck all or a selected portion of Pap smears initially found to be normal.

Pap smears, samples of cervical cells quickly pressed on a glass slide and "fixed" to prevent them from drying and changing appearance, can detect cancer and precancerous cell changes in the cervix. About 50 million Pap smears are done annually in the United States.

Cytotechnologists, specially trained in identifying defective cells, examine the slides under a microscope to look for signs of abnormalities. Although cytotechnologists routinely rescreen 10 percent of all negative (normal) smears, some abnormal smears may go undetected. The error rate for Pap smears varies from lab to lab but is estimated to be from 5 to 25 percent.

The Autopap system makes it possible to rescreen all normal Pap smears. Using image processing and pattern recognition techniques, the device picks out

10 to 20 percent of the most suspicious smears for a second examination.

In the clinical studies conducted at seven laboratories in the United States, the device screened 11,751 Pap smears initially thought to be normal and found 297 that were actually abnormal.

The Papnet system also rescreens normal Pap smears. It selects the 128 most abnormal looking cells or cell clusters from each Pap smear. The cells are recorded on a high-resolution color video monitor for a cytotechnologist to evaluate.

In a clinical trial using Pap smears from 10 different labs, rescreening with Papnet detected 464 abnormal smears out of 9,666 originally diagnosed as normal.

Even with the Autopap and Papnet, however, false negatives may still occur, due to reading errors, sampling and technical errors in handling the smears, or rapidly progressing cancer that cannot be identified during routine screening.

FDA approved the Autopap, manufactured by Neopath Inc. of Redmond, Wash., on Sept. 29, 1995, and Papnet, manufactured by Neuromedical Systems of Suffern, N.Y., on Nov. 8, 1995.

(For more about Pap smears, see "The Controversial Pap Test," in the September 1989 *FDA Consumer*.)

Faster TB Test

A sputum test for tuberculosis recently approved by FDA gives results in only four to five hours, instead of the one to eight weeks required by conventional sputum culture tests. All tests

must be done by qualified laboratories.

The Amplified Mycobacterium TB Direct Test was approved last Dec. 18 for use only on specimens of sputum that an acid fast stain has already shown are likely to be positive for the TB bacteria. Because the new test gives results more quickly, patients can receive antibiotic treatment earlier, and isolation facilities can be used more efficiently. In addition, others who have been in contact with the patients can be tested earlier and given appropriate treatment if necessary. However, a follow-up culture test must also be done to confirm the presence of TB.

The manufacturer, Gen-Probe Inc., of San Diego, studied 6,079 specimens, finding 198 likely to be positive by the acid fast stain and confirmed with culture. The new test detected TB bacteria in 95.5 percent of specimens that had the bacteria.

Recent Drug Approvals

Drugs to treat AIDS, a form of leukemia, Lou Gehrig's disease, and skin damage were among those approved as 1995 drew to a close and this issue of *FDA Consumer* was being prepared.

Invirase (saquinavir) and Epivir (lamivudine, or 3TC) were both approved to treat HIV infection, including AIDS, under FDA's accelerated approval process, which allows the agency to grant early marketing to products while clinical studies continue.

Invirase is the first approved protease inhibitor, one of a new class of drugs for the treatment of advanced HIV infection. Invirase is approved for use in combination with drugs from the class known as nucleoside analogs, to which

five other drugs approved to treat AIDS, including Retrovir (zidovudine, or AZT) and Epivir, belong. The agency approved Invirase only three months after receiving its marketing application. Clinical trials compared three drug combinations in more than 900 HIV-infected patients. Over 16 weeks of treatment, CD4 counts increased an average of 30 to 40 cells in patients taking Invirase in combination with Retrovir or Hivid (zalcitabine, or ddC), or with a combination of Retrovir and Hivid. Invirase is manufactured by Roche Laboratories.

Epivir (lamivudine, or 3TC) is approved for use in combination with Retrovir in treating AIDS and HIV infection. Trials show that patients treated with the combination sustained higher increases of CD4 cells than patients receiving Epivir or Retrovir alone, or Retrovir with Hivid. Epivir and Retrovir are manufactured by Glaxo-Wellcome Inc.

Vesanoid (all trans retinoic acid, or ATRA) is approved to reverse the progression of promyelocytic leukemia in patients who are resistant to or cannot use standard cancer treatment. About 2,500 people in the United States have promyelocytic leukemia, a life-threatening disease associated with a genetic abnormality that causes excessive production of white blood cells. In clinical studies sponsored by the National Cancer Institute, 50 percent of patients who had relapsed following standard chemotherapy had complete remission of the disease when treated with the drug. Vesanoid is distributed by Hoffmann-La Roche.

Rilutek (riluzole) is the first drug shown to prolong the survival of patients with amyotrophic lateral sclerosis

(ALS), also known as Lou Gehrig's disease. FDA approved the drug 5½ months after receiving the application for approval. ALS is a disease with no known cure that causes progressive muscular weakness and paralysis. It is usually fatal within five years after diagnosis. In clinical tests, Rilutek prolonged the survival of ALS patients by about three months. The drug is manufactured by Rhône-Poulenc Rorer Inc.

Renova (0.05% tretinoin emollient cream) is approved to assist in treating certain kinds of skin damage, such as fine wrinkles, spotty discoloration, and rough skin. Renova is to be used as part of a comprehensive skin care and sun-avoidance program. In studies, after 24 weeks of treatment, about 30 percent of patients had moderate improvement, 35 percent had slight improvement, and 35 percent had no improvement. Renova does not eliminate wrinkles or repair sun damage that can lead to skin cancer. Nor is there evidence that Renova treats coarse skin, deep wrinkles, skin yellowing, or other skin problems. Renova has not been studied in people 50 or older or in those with moderately or darkly pigmented skin. Renova is related to the topical acne medication Retin-A. Both medications are manufactured by Ortho Pharmaceutical Corp.

Sensor Pad Helps Find Breast Lumps

A plastic pad that women, with proper training, can use to examine their breasts for lumps was recently cleared for marketing by FDA.

The Sensor Pad will be available through health-care providers, clinics,

and other institutions where women can receive instructions for its use. To ensure early detection of breast cancer, women should continue doing bare hand self-examination and having exams by a doctor and yearly mammograms.

The manufacturer, Inventive Products Inc., of Decatur, Ill., submitted two clinical studies to FDA last November: a U.S. study of the impact of different educational strategies on the skill and frequency of self-exams, and a Japanese study that was part of a self-exam screening program.

The Japanese study of the 832 women showed that women who had been properly instructed in the pad's use detected their own breast lumps almost as frequently as the lumps were found by trained nurses also using the pad. Nurses were able to detect lumps in each of the 72 women identified with breast cancer. Of the same 72, only one missed her breast lump when self-examining with the pad.

FDA cleared the Sensor Pad for marketing last Dec. 22.

FDA Consumer Wins 4 Awards

FDA Consumer won four awards in important publication competitions recently.

The magazine was awarded first place among magazines for general audiences in the 1995 National Association of Government Communicators' "Blue Pencil" Competition. NAGC also awarded the magazine second place for visual design, and a second-place writing award for the feature "Stalking the Wild Mushroom" by Marian Segal in the October 1994 issue.

In addition, *FDA Consumer* received a Silver Award (second place) in the 1995 International Mercury Awards Competition, sponsored by MerComm Inc., a New York-based organization. Magazines competing for the awards include those from many sources, including industry and nonprofit associations.

Food Label Info Wins Prizes

Several of FDA's efforts to inform the public about the new food label have garnered recent awards.

The video "The Food Label and You" received a gold award (first place) in the 1995 International Mercury Awards Competition sponsored by MerComm, Inc. Contestants in the competition include private, industry, nonprofit, and government groups.

A high school teachers' guide, "The New Nutrition Label: There's Something in It for Everyone," received The American Dietetic Association

Foundation's Presidents' Circle Award for Nutrition Education last Oct. 31. The guide was a joint effort of FDA and the International Food Information Council.

Two FDA public service announcements, "Check It Out" and the animated "The Fat that Jack Eats," each received a third place award in the 1995 National Association of Government Communicators' "Gold Screen" Competition. Both announcements give information about the new food label.

Free Publications Available

Three backgrounders and three *FDA Consumer* reprints are now available free from FDA. They are:

- Olestra and Other Fat Substitutes (Revised) (BG 95-18)
- HACCP: A State-of-the-Art Approach to Food Safety (BG 95-19)
- FDA Food Code (BG 96-1) (This replaces a January 1994 backgrounder.)
- Not a Cure-All: Eye Surgery Helps Some See Better (FDA 96-1227)
- On the Teen Scene: Food Label Makes Good Eating Easier (FDA 96-2294)
- Prostate Cancer: New Tests Create Treatment Dilemmas (FDA 95-1220).

To order single copies, write to FDA, HFE-88, Rockville, MD 20857. To order 2 to 100 copies, write to FDA, HFI-40, at the same address, or fax your order to (301) 443-9057. Include the publication number.

FDA Consumer welcomes comments from readers. Send letters to: Editor, *FDA Consumer*, HFI-40, 5600 Fishers Lane, Rockville, MD 20857.





Preventing *Childhood Poisoning*

by Audrey T. Hingley

Iron-containing
products remain
the biggest
problem by far
when it comes to
childhood
poisoning.

Most people regard their home as a safe haven, a calming oasis in an often stormy world.

But home can be a dangerous place when it comes to accidental poisoning, especially accidental poisoning of children. One tablet of some medicines can wreak havoc in or kill a child.

Childhood poisonings caused by accidental overdoses of iron-containing supplements are the biggest concern of poison control experts, consumer protection groups, and health-care providers. Iron-containing supplements are the leading cause of pediatric poisoning deaths for children under 6 in the United States. According to the American Association of Poison Control Centers, from 1986 to 1994, 38 children between the ages of 9 months and 3 years died from accidentally swallowing iron-containing products. The number of pills consumed by these children varied from as few as five to as many as 98.

FDA is taking steps to protect children from iron poisoning by proposing regulations that will make it harder for small children to gain access to high-potency iron products (30 milligrams of iron or more per tablet). FDA is also taking steps to ensure that health-care providers and consumers are alerted to the dangers associated with accidental overdoses of iron-containing products, including pediatric multivitamin supplements that contain iron.

Although iron poisoning is the biggest concern when it comes to childhood poisoning, there is also concern about other drugs.

"Over-the-counter diet pills have the potential to be lethal to children, as do OTC stimulants used to keep you awake and decongestant tablets," says George C. Rodgers, M.D., Ph.D., medical director of the Kentucky Regional Poisoning Center. "Tofranil [imipramine], an antidepressant drug also used for childhood

bedwetting, and Catapres [clonidine], a high blood pressure medicine, can be very hazardous because it takes very little to produce life-threatening problems in children. One tablet may do it.

"Antidepressant drugs have a high degree of toxicity," he continues. "They are cardiac and central nervous system toxins, and it doesn't take much of them to do harm, particularly in children. They are prescribed fairly ubiquitously. One of the things we look at when we get kids' poisonings is who had the medicine, and why."

Rodgers also urges extra caution when antidepressant drugs are prescribed for teenage patients who may have behavioral or emotional problems.

"Antidepressant drugs are commonly given to adolescents with behavioral problems, and often a month or two-month supply is prescribed. Teens should not be given more than a week's supply to begin with, and parents need to monitor their usage," he says.

The marketing of pediatric vitamins is also a cause of concern for Rodgers.

"Because they're marketed to look like candy or cartoon characters, it looks like candy and doesn't seem like medicine," he explains.

In addition, children frequently mimic the behavior of their parents. Children who watch their parents take pills may want to do it, too— with potentially fatal results.

Poison-Proofing Your Home

Poison-proofing your home is the key to preventing childhood poisonings. In the case of iron-containing pills or any medicine:

- Always close the container as soon as you've finished using it. Properly secure the child-resistant packaging, and put it away immediately in a place where children can't reach it.
- Keep pills in their original container.



- Keep iron-containing tablets, and all medicines, out of reach—and out of sight—of children.
- Never keep medicines on a countertop or bedside table.
- Follow medicine label directions carefully to avoid accidental overdoses or misdoses that could result in accidental poisoning.

For other substances, buy the least hazardous products that will serve your purposes. When buying art supplies, for example, look for products that are safe for children. For hazardous products such as gasoline, kerosene, and paint thinners that are often kept on hand indefinitely, buy only as much as you need and safely get rid of what you don't use. Never transfer these substances to other containers. People often use cups, soft-drink bottles, or milk cartons to store leftover paint thinner or turpentine. This is a bad idea because children associate cups and bottles with food and drink.

The kitchen and bathroom are the most likely unsafe areas. (Medicines should never be stored in the bathroom for another reason: a bathroom's warm, moist environment tends to cause changes or disintegration of the product in these rooms.) Any cabinet containing a potentially poisonous item should be locked.

"Bathrooms with medicines, kitchens

with cleaning products, even cigarette butts left out, can be toxic to kids," Rodgers explains. "And remember that child-resistant caps are child-resistant, not childproof. The legal definition is that it takes greater than five minutes for 80 percent of 5-year-olds to get into it: that means 20 percent can get in in less time! Kids are inventive, and can often figure it out. And leftover liquor in glasses on the counter after parties? Don't do it!"

Alcohol can cause drunkenness as well as serious poisoning leading to seizures, coma, and even death in young children. Children are more sensitive to the toxic effects of alcohol than are adults, and it doesn't take much alcohol to produce such effects. Alcohol-laced products, such as some mouthwashes, aftershaves or colognes, can cause the same problems.

Garages and utility rooms should also be checked for potential poison hazards. Antifreeze, windshield washing fluid, and other products should be stored out of children's reach in a locked cabinet. Childproof safety latches can be purchased at your local hardware store.

In the living room or family room, know your plants' names and their poison potential. Although most houseplants are not poisonous, some are. To be on the safe side, keep

houseplants out of the reach of young children. Although much has been made of problems with poinsettias (blamed for a death as early as 1919), recent studies indicate it is not as highly toxic as was once believed. Although ingesting it may cause some stomach irritation and burning in the mouth, it's unlikely to be fatal.

"Plants are mostly a problem for children, since it's a natural response for children to taste things. Few adults eat houseplants," Rodgers points out. "Plants have a high capacity for making you sick, but they are usually low-risk for producing life-threatening symptoms." After poison-proofing your home, prepare for emergencies. Post the numbers of your regional poison control center (which can be

found on the inside cover of the Yellow Pages or in the white pages of your phone directory) and your doctor by the phone. Keep syrup of ipecac on hand—safely locked away, of course. (See accompanying article, "Antidotes.") Never administer any antidote without first checking with your doctor or poison control center.

Lead Poisoning

Although lead levels in food and drink are the lowest in history, concern remains about lead leaching into food from ceramic ware. Improperly fired or formulated glazes on ceramic ware can allow lead to leach into food or drink.

Long recognized as a toxic substance, adverse health effects can result from exposure to lead over months or years.

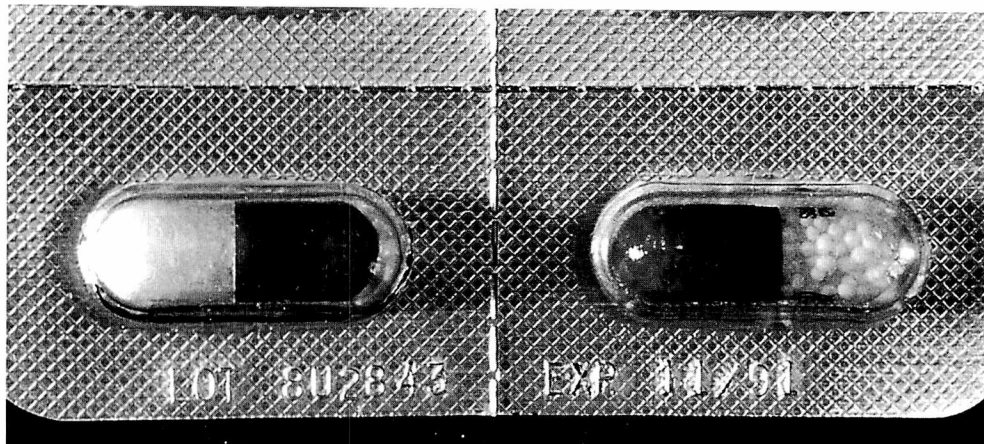
After a California family suffered acute lead poisoning in 1969 from drinking orange juice stored in a pitcher bought in Mexico, FDA established "action levels" for lead in ceramic ware used to serve food. Over the years, these original action levels have been revised as research has shown that exposure to even small amounts of lead can be hazardous. The last revision for ceramic foodware was in 1991. On Jan. 12, 1994, FDA published a regulation for decorative ceramic ware not intended for food use, requiring a permanently affixed

Protect Yourself Against Tampering

With FDA's new proposed regulations regarding packaging of high-dose, iron-containing pills in mind, it's important to remember that no packaging or warnings can protect without your involvement. Nonprescription OTC drugs sold in the United States are among the most safely packaged consumer products in the world, but "child-resistant" and "tamper-resistant" do not mean "childproof" and "tamperproof."

FDA adopted "tamper-resistant" packaging requirements after seven people in the Chicago area died from taking cyanide-laced Extra-Strength Tylenol capsules in 1982. Although the product met all FDA requirements at the time, it wasn't designed so tampering would leave visible evidence. FDA swiftly enacted new regulations requiring most OTC drug products to be packaged in "tamper-resistant" packaging, defined as "packaging having an indicator or barrier to entry that could reasonably be expected to provide visible evidence that tampering had occurred," and required OTC product labeling to alert consumers to tamper-resistant packaging. In 1989, FDA regulations were amended to require two-piece hard gelatin capsules to be packaged using at least two tamper-resistant features unless sealed with a tamper-resistant technology.

"Consumer vigilance is part of the equation," says Lana Ragazinsky, consumer safety officer with FDA's Center for Drug Evaluation and Research, division of drug quality evaluation, office of compliance. "The consumer is being led



Close visual examination can often expose tampering. In this blisterpack, the capsule on the left contains cyanide, a yellowish powder that does not resemble the larger white, time-release beads in the untouched Sudafed capsule on the right. These capsules are from the 1991 Sudafed tampering case in Washington state.

into a false sense of security because they see 'tamper-resistant.'... 'Tamper evident' means you, the consumer, need to look for evidence of tampering."

FDA has proposed changing the term "tamper-resistant" to "tamper-evident" to underscore the fact that no package design is tamperproof. The most important tool to detect tampering is you! Here are a few tips to help protect against tampering:

- Read the label. OTC medicines with tamper-evident packages tell you what seals and features to look for.
- Inspect the outer packaging before you buy.

- Inspect the medicine when you open the package, and look again before you take it. If it looks suspicious: be suspicious.
- Look for capsules or tablets different in any way from others in the package.
- Don't use any medicine from a package with cuts, tears, slices, or other imperfections.
- Never take medicine in the dark. Read the label and look at the medicine every time you take a dose. ■

— A.T.H.

label on high-lead-leaching products.

"Most lead toxicity comes from multiple exposure and is a slow accumulation over time," says Robert Mueller, a nurse and poison information specialist at the Virginia Poison Center, headquartered at The Medical College of Virginia Hospitals in Richmond. "Refusing to eat, vomiting, convulsions, and malaise can all be symptoms of lead poisoning." Because lead poisoning occurs over time, such symptoms may not show up

right away. A blood test is the surest way to determine that your child has not been exposed to significant amounts of lead.

"In general, if a consumer purchases ceramic ware in the U.S. marketplace today, it meets the new action levels," says Julia Hewgley, public affairs specialist with FDA's Center for Food Safety and Applied Nutrition. "But if you travel abroad and buy ceramic ware, be aware that each country has its own

safety regulations. Safety can be terribly variable depending on the type of quality control and whether the piece is made by a hobbyist." To guard against poisonings, Hewgley advises that ceramic ware not be used to store foods. Acidic foods—such as orange, tomato and other fruit juices, tomato sauces, vinegar, and wine—stored in improperly glazed containers are potentially the most dangerous. Frequently used products, like cups or pitchers, are also po-

Antidotes

If you suspect childhood poisoning, call the nearest poison control center or your physician first, and follow their instructions precisely.

To induce vomiting in case of accidental poisoning, experts recommend keeping on hand syrup of ipecac—safely stored away from children, of course! Syrup of ipecac induces vomiting, thus ridding the body of the swallowed poison. It usually works within a half-hour of ingestion.

Some medical experts also recommend that parents keep activated charcoal on hand as well: You may have to ask your druggist for it, because it may not be on store shelves. Although some poison control experts recommend having activated charcoal on hand, there is a difference of opinion on its use by consumers. The U.S. Consumer Product Safety Commission, for example, does not recommend that consumers use activated charcoal because it is less palatable to young children.

Activated charcoal (or charcoal treated with substances that increase its absorption abilities) absorbs poison, preventing it from spreading throughout the body. One advantage of activated

charcoal is that it can be effective for a considerable time after the poison is swallowed. But activated charcoal should never be used at the same time you administer syrup of ipecac: The charcoal will absorb the ipecac.

For children ages 1 to 12, give one tablespoon of syrup of ipecac followed by one or two glasses of water. Children ages 12 and over should get two tablespoons, followed by one or two glasses of water.

Activated charcoal is usually found in drugstores in liquid form in 30-gram doses. For children under 5, give one gram per every two pounds of body weight. Older children and adults may require much higher doses.

Both antidotes should only be used on conscious poison victims; an unconscious victim should always be treated by professionals.

"Remember to call your local poison control center first before giving your child any at-home antidote," says Robert Mueller, poison information specialist at the Virginia Poison Center in Richmond, Va. ■

—A.T.H.

by toddlers or infants, serious injury or death may result.

Children poisoned with iron face immediate and long-term problems. Within minutes or hours of swallowing iron tablets, nausea, vomiting, diarrhea, and gastrointestinal bleeding can occur. These problems can progress to shock, coma, seizures, and death. Even if a child appears to have no symptoms after accidentally swallowing iron, or appears to be recovering, medical evaluation should still be sought since successful treatment is difficult once iron is absorbed from the small intestine into the bloodstream. And children who survive iron poisoning can experience other problems, such as gastrointestinal obstruction and liver damage, up to four weeks after the ingested poisoning.

FDA regulates iron-containing products as either drugs or foods, depending on the product formulation and on intended use, as defined by labeling and other information sources. Iron products are regulated as drugs if they are intended to affect the structure or function of the body, or are used in the diagnosis, cure, treatment, or prevention of disease and are listed in the *U.S. Pharmacopeia*. All other products are regulated as foods.

Some iron-containing products have been regulated as prescription drugs because they included pharmacologic doses of folic acid and usually were prescribed to meet high nutritional requirements during pregnancy.

Between June 1992 and January 1993, five toddlers died after eating iron supplement tablets, according to the national Centers for Disease Control and Prevention's *Morbidity and Mortality Weekly Report* of Feb. 19, 1993. All tablets involved in the reported deaths were prenatal iron supplements. The incidents occurred in a variety of ways: Children ate tablets from uncapped or loosely capped bottles, swallowed tablets found spilled on the floor, and, in one case, a 2-year-old fed an 11-month-old sibling tablets from a box found on the floor.

Iron is always included in prenatal vitamins prescribed for pregnant women, and is sometimes included in multivitamin formulas. Often available without prescription, iron supplements can be found in grocery stores, drugstores, and

tentially dangerous, especially when used to hold hot, acidic foods.

"Stop using any item if the glaze shows a dusty or chalky gray residue after washing. Limit your use of antique or collectible housewares for food and beverages," she says.

"Buy one of the quick lead tests available at hardware stores and do a screening on inherited pieces."

Iron Poisoning

Iron-containing products remain the biggest problem by far when it comes to childhood poisoning. In October 1994 FDA proposed regulations for unit-dose packaging requirements for iron-containing products with 30 milligrams or more of iron per dosage unit. The agency also proposed requiring warning labels about the adverse effects of high-dose iron ingestion by children for all iron-containing products taken in solid

oral dosage forms. Because of the time and effort needed to open unit-dose products, FDA believes unit-dose packaging will discourage a youngster, or at least limit the number of tablets a child would swallow, reducing the potential for serious illness or death.

FDA's proposed requirements would be in addition to existing U.S. Consumer Product Safety Commission regulations, which require child-resistant packaging for most iron-containing products. FDA issued a supplementary proposed rule in February 1995. At press time, a final rule regarding iron-containing products was expected soon.

Iron is an essential nutrient sometimes lacking in people's diets, which is why iron is often recommended for people with conditions such as iron-deficiency anemia. Taken as indicated, iron is safe. But when tablets are taken beyond the proper dose in a short period, especially

health food stores in a wide variety of potencies, ranging from 18 milligrams (mg) to 150 mg per pill. For a small child, as little as 600 mg of iron can be fatal.

Because iron supplements are typically brightly colored and may look like candy, they are particularly attractive to children. In 1993, the Nonprescription Drug Manufacturers Association (NDMA), which manufactures about 95 percent of nonprescription OTC medicines available to Americans today, adopted formulation provisions for iron products containing 30 mg or more of elemental iron per solid dosage form. These provisions also stipulated that such products would not be made with sweet coatings. That same year, NDMA manufacturers also independently agreed to develop new voluntary warning labels for these products. The voluntary labels read: "Warning: Close tightly and keep out of reach of children. Contains iron, which can be harmful or fatal to children in large doses. In case of accidental overdose, seek professional assistance or contact a poison control center immediately."

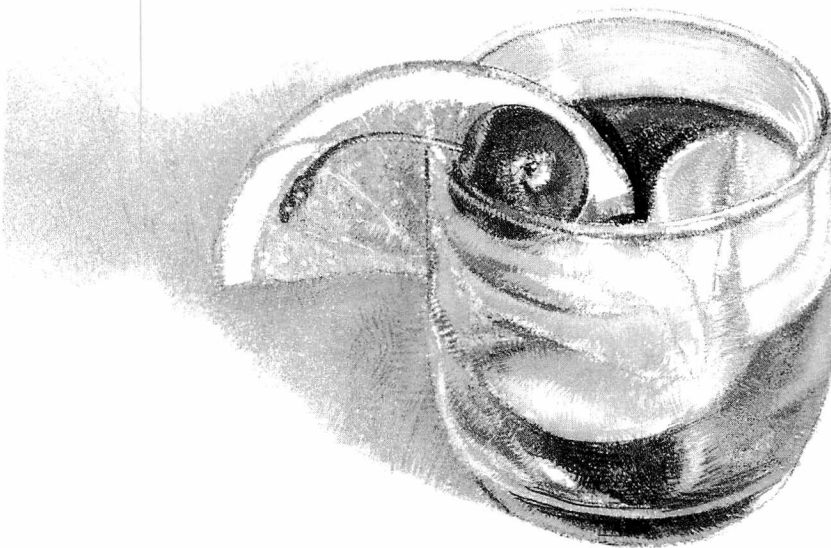
Signs of Poisoning

How can you tell if your child has ingested something poisonous? "Most poisons, with the exception of lead, work fairly quickly. A key is when the child was otherwise well and in a space of hours develops unusual symptoms: They can't follow you with their eyes, they're sleepy before it's their nap time, their eyes go around in circles. Any unusual or new symptoms should make you think of poisoning as a possibility," Rodgers advises. "Poisonings typically affect the stomach and central nervous system. If a child suddenly throws up, that can be more difficult to diagnose."

Other signs of poison ingestion can be burns around the lips or mouth, stains of the substance around the child's mouth, or the smell of a child's breath. Suspect a possible poisoning if you find an opened or spilled bottle of pills.

If you suspect poisoning, remain calm. For medicines, call the nearest poison control center or your physician. For household chemical ingestion, follow first-aid instructions on the label, and then call the poison control center

Alcohol can cause drunkenness as well as serious poisoning leading to seizures, coma, and even death in young children.



or your doctor. When you call, tell them your child's age, height and weight, existing health conditions, as much as you know about the substance involved, the exposure route (swallowed? inhaled? splashed in the eyes?), and if your child has vomited. If you know what substance the child has ingested, take the remaining solution or bottle with you to the phone when you call. Follow the instructions of the poison control center precisely.

Progress Against Poisonings

The nation's first poison control center opened in Chicago in 1953, after a study of accidental deaths in childhood reported a large number were due to poisoning. Since that time, a combination of public education, the use of child-resistant caps, help through poison control centers, and increased sophistication in medical care have lowered overall death rates.

Often, calling a poison center simply reassures parents that the product ingested is not poisonous. In other cases, following phone instructions prevents an emergency room trip.

Children are not the only victims of accidental poisonings: Older people in

particular are at risk because they generally take more medicines, may have problems reading labels correctly, or may take a friend's or spouse's medicine.

In June 1995, the U.S. Consumer Product Safety Commission voted unanimously to require that child-resistant caps be made so adults—especially senior citizens—will have a less frustrating time getting them off. Because many adults who had trouble with child-resistant caps left them off, or transferred their contents to less secure packaging that endangers children, officials say the new caps will be safer for children.

"Childhood poisoning will always be a focus, because children are so vulnerable, especially children under age 5," says Ken Giles, public affairs spokesman for the Consumer Product Safety Commission. "The first two or three years of a child's life are the highest-risk time for all kinds of injuries, so there is a special need to educate new parents. It's essential we keep raising these safety messages that medicines and chemicals can be poisonous." ■

Audrey T. Hingley is a writer in Mechanicsville, Va.

Growing Older,

Eating Better

by Paula Kurtzweil



Bernadette Harkins (left) and Laurett Abescrombia enjoy lunch, one of three meals served daily in the Raphael House, an assisted-living residence in Rockville, Md.

Whether it happens at age 65 or 85, older people eventually face one or more problems that interfere with their ability to eat well.

When Bernadette Harkins, 89, of Rockville, Md., could no longer feed herself properly, she moved to an assisted-living residence. Today, she can enjoy three meals a day served to her and about 30 other people in their home-like communal dining room.

When Harry, 85, of Moscow, Pa., could no longer feed himself properly, he moved in with his daughter and her family. Today, with her guidance, he's eating six times a day, snacking on high-calorie, high-protein foods, and maintaining a near-normal weight.

Harry, who asked that his last name not be used, and Harkins typify many of today's older generation. Living alone in most cases, they often are unable to meet their dietary needs and are forced to make compromises.

Harry didn't know how to cook. He developed cancer, which made it even

more important that he eat a well-balanced diet. Harkins knew how to cook but didn't take time to prepare adequate meals for herself.

"I would snack is what I'd do," she said. "I would think about getting a meal and then just have a cup of tea and toast. I knew I wasn't doing the right thing as far as nutrition was concerned."

Their eating problems stemmed from loneliness and lack of desire or skill to cook. Other older people may eat poorly for other reasons, ranging from financial difficulties to physical problems.

The solutions can be just as varied, from finding alternative living arrangements to accepting home-delivered meals to using the food label recently revised by the Food and Drug Administration and the U.S. Department of Agriculture. Physical activity also is important in maintaining a healthy lifestyle.

Why the Concern?

Nutrition remains important throughout life. Many chronic diseases that develop late in life, such as osteoporosis, can be influenced by earlier poor habits. Insufficient exercise and calcium intake, especially during adolescence and early adulthood, can significantly increase the risk of osteoporosis, a disease that causes bones to become brittle and crack or break.

But good nutrition in the later years still can help lessen the effects of diseases prevalent among older Americans or improve the quality of life in people who have such diseases. They include osteoporosis, obesity, high blood pressure, heart disease, certain cancers, gastrointestinal problems, and chronic undernutrition.

Studies show that a good diet in later years helps both in reducing the risk of these diseases and in managing the diseases' signs and symptoms. This contributes to a higher quality of life, enabling older people to maintain their independence by continuing to perform basic daily activities, such as bathing, dressing and eating.

Poor nutrition, on the other hand, can prolong recovery from illnesses, increase the costs and incidence of institutionalization, and lead to a poorer quality of life.



Montgomery County, Md., residents (from left) Alta Young Poole, Henrietta Singer, Song Soonok, and Rita Ford-Wheatley line up at the Waverly House in Bethesda for a chicken dinner.

The Single Life

Whether it happens at age 65 or 85, older people eventually face one or more problems that interfere with their ability to eat well.

Social isolation is a common one. Older people who find themselves single after many years of living with another person may find it difficult to be alone, especially at mealtimes. They may become depressed and lose interest in preparing or eating regular meals, or they may eat only sparingly.

In a study published in the July 1993 *Journals of Gerontology*, researchers found that newly widowed people, most of whom were women, were less likely to say they enjoy mealtimes, less likely to report good appetites, and less likely to report good eating behaviors than their married counterparts. Nearly 85 percent of widowed subjects reported a weight change during the two years following their spouse's death, as compared with 30 percent of married subjects. The widowed group was more likely to report an average weight loss of

7.6 pounds (17 kilograms).

According to the study, most of the women said they had enjoyed cooking and eating when they were married, but, as widows, they found those activities "a chore," especially since there was no one to appreciate their cooking efforts.

For many widowed men who may have left the cooking to their wives, the problem may extend even further: They may not know how to cook and prepare foods. Instead, they may snack or eat out a lot, both of which may lead people to eat too much fat and cholesterol and not get enough vitamins and minerals.

Special Diets

At the same time, many older people, because of chronic medical problems, may require special diets: for example, a low-fat, low-cholesterol diet for heart disease, a low-sodium diet for high blood pressure, or a low-calorie diet for weight reduction. Special diets often require extra effort, but older people may instead settle for foods that are quick and easy to prepare, such as frozen

For More Information

To learn more about the food label and nutrition for older people, write for these publications:

- *Using the New Food Label to Choose Healthier Foods.*

FDA, 5600 Fishers Lane (HFE-88), Rockville, MD 20857. Ask for publication number (FDA) 94-2276.

- *Food Facts for Older Adults: Information on How to Use the Dietary Guidelines.* Send check or money order for \$4 payable to "Superintendent of Documents" to Consumer Information Center, Pueblo, CO 81009. Ask for Home and Garden Bulletin Number 251.

- *Healthy Eating for a Healthy Life.* AARP (American Association of Retired

Persons) Fulfillment, 601 E. St., N.W., Washington, DC 20049.

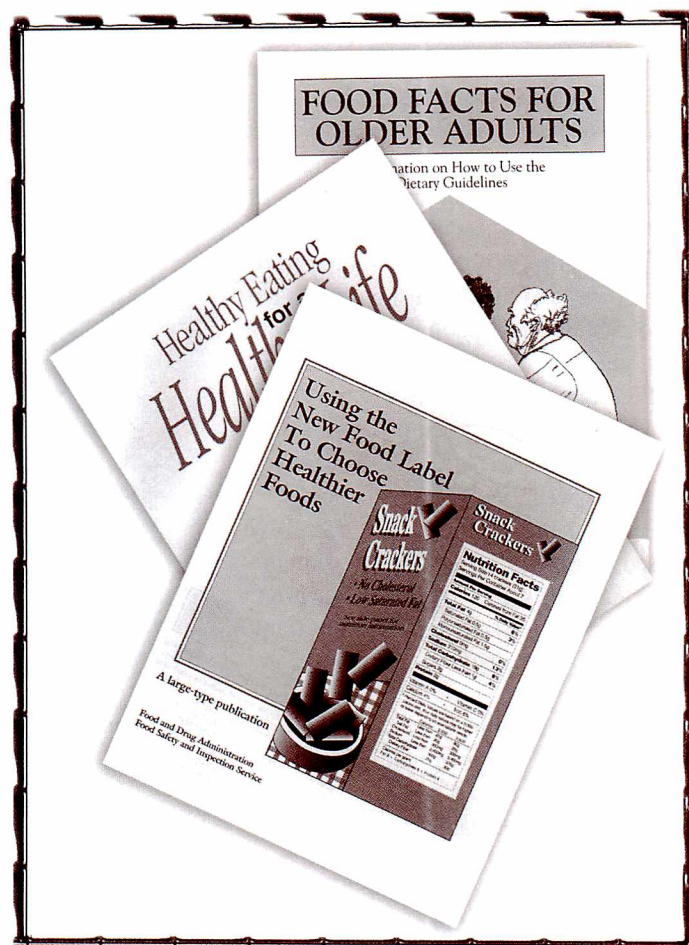
Ask for publication by title and stock number D15565.

To learn about meal programs for senior citizens in your area, call the Administration on Aging's Elder Care Locator, (1-800) 677-1116.

For information about food stamps, contact your county's food stamp office listed in the blue pages of the telephone book.

To find a registered dietitian in your area, call the National Center for Nutrition and Dietetics Consumer Nutrition Hotline, (1-800) 366-1655. ■

—P.K.



dinners, canned foods, lunch meats, and others that may provide too many calories, or contain too much fat and sodium for their needs.

On the other hand, Mona Sutnick, Ed.D., a registered dietitian in private practice in Philadelphia, pointed out that some people may go overboard on their special diets, overly restricting foods that may be more beneficial than detrimental to their health.

"My advice for a 60-year-old person might be 'watch your fat' but for an 80-year-old who's underweight, I'd say, 'eat the fat, get the calories,'" Sutnick said.

Physical Problems

Some older people may overly restrict foods important to good health because of *chewing* difficulties and gastrointestinal disturbances, such as constipation, diarrhea and heartburn. Because missing teeth and poorly fitting dentures make it hard to chew, older people may forego

fresh fruits and vegetables, which are important sources of vitamins, minerals and fiber. Or they may avoid dairy products, believing they cause gas or constipation. By doing so, they miss out on important sources of calcium, protein and some vitamins.

Adverse reactions from medications can cause older people to avoid certain foods. Some medications alter the sense of taste, which can adversely affect appetite. This adds to the problem of naturally diminishing senses of taste and smell, common as people age.

Other medical problems, such as arthritis, stroke or Alzheimer's disease, can interfere with good nutrition. It may be difficult, if not impossible, for example, for people with arthritis or who have had a stroke to cook, shop, or even lift a fork to eat. Dementia associated with Alzheimer's and other diseases may cause them to eat poorly or forget to eat altogether.

Money Matters

Lack of money is a particular problem among older Americans who may have no income other than Social Security. According to 1994 U.S. Census Bureau data, nearly 12 percent of people 65 and over are below the average poverty level for their age group. In 1994, the poverty level for a person 65 and over was \$7,108 a year.

According to the 1994 data, the mean annual income for people 65 and over was \$16,709, almost \$10,000 less than what they earned on average between ages 55 and 64.

Lack of money may lead older people to scrimp on important food purchases—for example, perishable items like fresh fruits, vegetables and meat—because of higher costs and fear of waste. They may avoid cooking or baking foods like meats, stews and casseroles because recipes for these foods usually yield large quantities.

Financial problems also may cause older people to delay medical and dental treatments that could correct problems that interfere with good nutrition.

Food Programs

Many older people may find help under the Older Americans Act, which provides nutrition and other services that target older people who are in greatest social and economic need, with particular attention on low-income minorities. According to the U.S. Administration on Aging, which administers the Older Americans Act, the nutrition programs were set up to address the dietary inadequacy and social isolation among older people.

Home-delivered meals and congregate nutrition services are the primary nutrition programs. The congregate meal program allows seniors to gather at a local site, often the local senior citizen center, school or other public building or a restaurant, for a meal and other activities, such as games and lectures on nutrition and other topics of interest to older people.

Available since 1972, these programs, funded by the federal, state and local governments, ensure that senior citizens get at least one nutritious meal five to seven days a week. Under current standards, that meal must comply with the Dietary Guidelines for Americans and provide at least one-third of the Recommended Dietary Allowances for an older person. Often, people receive foods that correspond with their special dietary needs, such as no-added-salt foods for those who need to restrict their sodium intake or ground meat for those who have trouble chewing.

Other nutrition services provided under the Older Americans Act are nutrition education, screening and counseling.

While these nutrition programs target poor people, they are available to other older people regardless of income, according to Jean Lloyd, a registered dietitian and nutrition officer with the Administration on Aging. Although no one is charged for the meals, older people can voluntarily and confidentially donate money, she said.

The meals provide not only good nutrition, but they also give older people a



Avis Taylor digs into a Waverly House meal. The site is one of 18 in Montgomery County where older people who live anywhere in the county can share a noon meal provided by the county's Area Agency on Aging.

chance to socialize—a key factor in preventing the adverse nutritional effects of social isolation.

For those who qualify, food stamps are another aid for improving nutrition. Under this program, a one-person household can receive up to \$115 a month in food stamps to buy most grocery items.

For the homebound, grocery-shopping assistance is available in many areas. Usually provided by non-government organizations, this service shops for and delivers groceries to people at their request. The recipient pays for the groceries and sometimes a service fee.

In some communities, private organizations also sell home-delivered meals.

Other Assistance

Family members and friends can help ensure that older people take advantage of food programs by putting them in touch with the appropriate agencies or organizations and helping them fill out

the necessary forms. Some other steps they can take include:

- looking in occasionally to ensure that the older person is eating adequately
- preparing foods for and making them available to the older person
- joining the older person for meals.

In some cases, they may help see that the older person is moved to an environment, such as their home, an assisted-living facility, or a nursing home, that can help ensure that the older person gets proper nutrition.

Whatever an older person's living situation, proper medical and dental treatment is important for treating medical problems, such as gastrointestinal distress and chewing difficulties, that interfere with good nutrition. If a medication seems to ruin an older person's taste and appetite, a switch to another drug may help.

A review of basic diet principles may help improve nutrition. Explaining to older people the importance of good nutrition in the later years may motivate

How to Use Nutrition Facts

The Nutrition Facts panel is the place to go for more complete nutrition information.

Start at the top with serving size information. Serving sizes are:

- given in both household and metric units
- uniform across product lines so you can more easily compare the nutritional qualities of similar foods
- close to the amounts people really eat (although they're not recommended amounts).

Be sure to look at %Daily Values on the right. They show how a serving of food fits in with current recommendations for a healthful diet. A high percentage means the food contains a lot of a nutrient. A low percentage means it contains a little. The goal is to choose foods that together give you about 100 percent a day.

Nutrition Facts

Serving Size ½ cup (114g)

Servings Per Container 4

Amount Per Serving

Calories 90 **Calories from Fat** 30

% Daily Value*

Total Fat 3g **5%**

Saturated Fat 0g **0%**

Cholesterol 0mg **0%**

Sodium 300mg **13%**

Total Carbohydrate 13g **4%**

Dietary Fiber 3g **12%**

Sugars 3g

Protein 3g

Vitamin A 80% • Vitamin C 60%

Calcium 4% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

		Calories: 2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

risk of high blood pressure, a disease associated with many factors."

More in-depth information is found on the "Nutrition Facts" panel on the side or back of the food label. This information is required on almost all food packages. Unlike before, this nutrition information is easier to read because it appears in bigger type and is usually on a white or other neutral contrasting background, when practical.

Some nutrition information also may be available for many raw meats, poultry and fish and fresh fruits and vegetables at the point of purchase. The information may appear in brochures or on posters or placards.

Physical Activity

Besides diet, physical activity is part of a healthy lifestyle at any age. It can help reduce and control weight by burning calories. Moderate exercise that places weight on bones, such as walking, helps maintain and possibly even increases bone strength in older people. A study published in the Dec. 28, 1994, *Journal of the American Medical Association* found that intensive strength training can help preserve bone density and improve muscle mass, strength and balance in postmenopausal women. In the study, subjects used weight machines for strength training.

Also, scientists looking into the benefits of exercise for older people agree that regular exercise can improve the functioning of the heart and lungs, increase strength and flexibility, and contribute to a feeling of well-being.

Any regular physical activity is good, from brisk walking to light gardening. Common sense is the key. But, before a vigorous exercise program is started or started after a long period of rest, a doctor should be consulted.

Taking time out for exercise, using the food label to help pick nutritious foods, taking advantage of the several assistance programs available, and getting needed medical attention can go a long way in helping older people avoid the nutritional pitfalls of aging and more fully enjoy their senior years. ■

Paula Kurtzweil is a member of FDA's public affairs staff.

them to make a greater effort to select nutritious foods.

Look to the Label

The food label can help older people select a good diet. Revamped in 1992, the label gives the nutritional content of most foods and enables consumers to see how a food fits in with daily dietary recommendations.

Some of the information appears as claims describing the food's nutritional benefits: for example, "low in cholesterol" or "high in potassium." Under strict government rules, these claims can be used only if the food meets certain criteria. This means that claims can be trusted. For example, a "low-choles-

terol" food can provide no more than 20 milligrams (mg) of cholesterol and no more than 2 grams of saturated fat per serving. A high-potassium food must provide at least 700 mg of potassium per serving.

Less common but also helpful are label claims linking a nutrient or food to the risk of a disease or health-related condition. So far, FDA allows only eight of these claims because they are the only ones supported by scientific evidence. One claim links sodium, a nutrient found in salt and used in many processed foods, to high blood pressure. On the food label, this claim would read something like this:

"Diets low in sodium may reduce the

Coping With **ARTHRITIS** In Its Many Forms

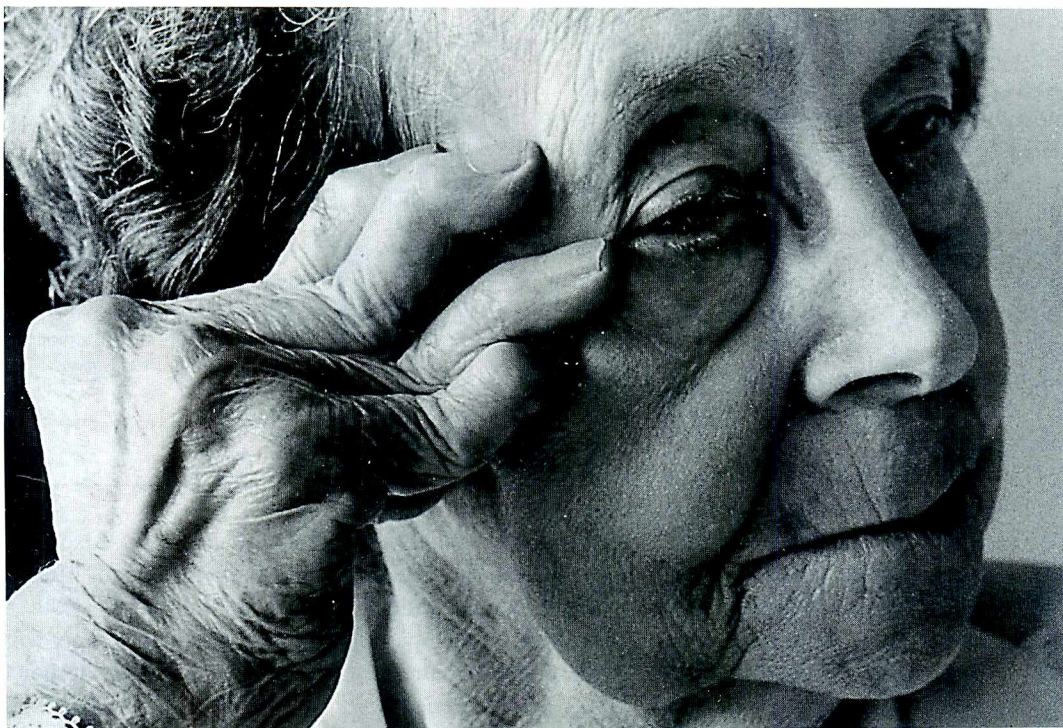
by Carolyn J. Strange

It may begin as a slight morning stiffness. For the lucky person with arthritis, that's as far as it goes. But for millions of others, arthritis can become a disabling, even crippling, disease. Roman Emperor Diocletian exempted citizens with severe arthritis from paying taxes, no doubt realizing that the disease itself can be taxing enough.

One in seven Americans—nearly 40 million—have some form of arthritis. That number will climb as the baby boomers age. By 2020, about 60 million Americans will have arthritis, according to The National Arthritis Data Workgroup of the National Institute of Arthritis and Musculoskeletal and Skin Diseases. The disease is physical, but also exacts a mental, emotional and economic toll.

“Chronic illness impacts a person's entire lifestyle—work, family and recreation,” says Gail Wright, Ph.D., a rehabilitation psychologist at the University of Missouri, Columbia. To improve quality of life, doctors and health educators increasingly advise combining drug treatment with education, social support, and moderate forms of exercise.

Arthritis means joint inflammation. In a normal joint, where two bones meet, the ends are coated with cartilage, a smooth, slippery cushion that protects the bone and reduces friction during movement. A tough capsule lined with synovial membrane seals the joint and produces a lubricating fluid. Ligaments surround and support each joint, connecting the bones and preventing excessive movement. Muscles attach to bone by tendons on each side of a joint. Inflammation can affect any of these tissues.



(Photo by Mary Lou Uttermohlen)

Inflammation is a complex process that causes swelling, redness, warmth, and pain. It's the body's natural response to injury and plays an important role in healing and fighting infection. Joint injury can be caused by trauma or by the wear and tear of aging. But in many forms of arthritis, injury is caused by the uncontrolled inflammation of autoimmune disease, in which the immune system attacks the body's own tissues. In severe cases, all joint tissues, even bone, can be damaged.

The general term arthritis includes over 100 kinds of rheumatic diseases, most of which last for life. (See accompanying article.) Rheumatic diseases are those affecting joints, muscle, and connective tissue, which makes up or supports various structures of the body, including tendons, cartilage, blood vessels, and internal organs. The Food and Drug Administration has approved a wide variety of drugs to treat the many forms of arthritis.

The most common type of arthritis is

A woman's hand swollen and deformed by arthritis.

osteoarthritis, affecting more than 16 million Americans. This degenerative joint disease is common in people over 65, but may appear decades earlier. It begins when cartilage breaks down, sometimes eroding entirely to leave a bone-on-bone joint in extreme cases. Any joint can be affected, but the feet, knees, hips, and fingers are most common. It may appear in one or two joints and spread no further. Painful and knobby bone growths in the fingers are common, but usually not crippling. The disease is often mild, but can be quite severe.

Second most common is rheumatoid arthritis, which affects 2.5 million Americans. It can strike at any age, but usually appears between ages 20 and 50. The hands are most commonly affected, but it can affect most joints of the body. Inflammation begins in the

Common Types of Arthritis

Of more than 100 different kinds of arthritis, these are the most common:

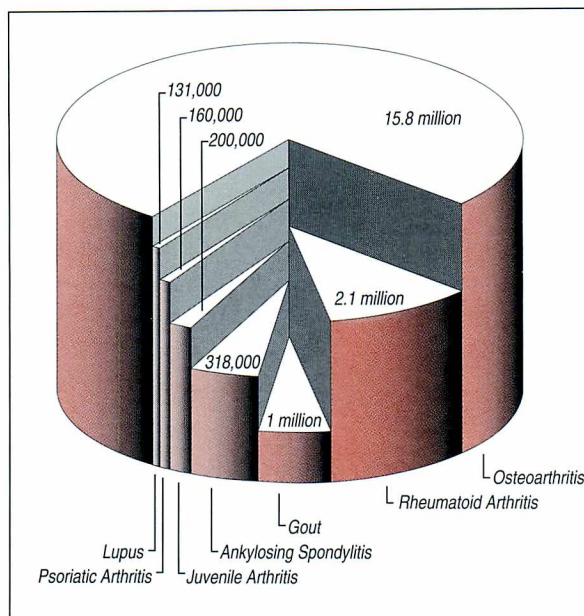
Osteoarthritis—Also called degenerative arthritis. Occurs when the cushioning cartilage in a joint breaks down. Commonly affects feet, knees, hips, and fingers. Affects 16 million Americans, mostly 45 and older. About half of those 65 and older have this form.

Rheumatoid Arthritis—Immune system attacks the lining, or synovial membrane, of the joints. Joint damage can become severe and deforming. Involves the whole body, and may also cause fatigue, weight loss and anemia, and affect the lungs, heart and eyes. Affects about 2.1 million Americans, three times more women than men.

Gout—Causes sudden, severe attacks, usually in the big toe, but any joint can be affected. A metabolic disorder in which uric acid builds up in the blood and crystals form in joints and other places. Drugs and attention to diet can control gout. Affects about 1 million Americans (70 to 80 percent men), with first attack starting between 40 and 50 years of age. (See "Getting to Know Gout," *FDA Consumer*, March 1995.)

Ankylosing Spondylitis—A chronic inflammatory disease of the spine that can result in fused vertebrae and rigid spine. Often milder and harder to diagnose in women. Most people with the disease also have a genetic marker known as HLA-B27. Affects about 318,000 Americans, usually men between the ages of 16 and 35.

Juvenile Arthritis—The most common form is juvenile rheumatoid arthritis,



Here are some of the more common of the 100 forms of arthritis and their approximate number of cases in the United States.

(Source: Arthritis Foundation)

tis. Arthritis diagnosis, treatment, and disease characteristics are different in children and adults. Some children recover completely; others remain affected throughout their lives. Affects about 200,000 Americans.

Psoriatic Arthritis—Bone and other joint tissues become inflamed, and, like rheumatoid arthritis, it can affect the whole body. Affects about 5 percent of people with psoriasis, a chronic skin disease. Likely to affect fingers or spine. Symptoms are mild in most people but can be quite severe. Affects about 160,000 Americans.

Systemic Lupus Erythematosus—Involves skin, joints, muscles, and sometimes internal organs. Symptoms usually appear in women of childbearing age but can occur in anyone at any age.

Also called lupus or SLE, it can be mild or life threatening. Affects at least 131,000 Americans, nine to ten times as many women as men.

Other forms—Arthritis can develop as a result of an infection. For example, bacteria that cause gonorrhea or Lyme disease can cause arthritis. Infectious arthritis can cause serious damage, but usually clears up completely with antibiotics. Scleroderma is a systemic disease that involves the skin, but may include problems with blood vessels, joints, and internal organs. Fibromyalgia syndrome is a soft-tissue rheumatism that doesn't lead to joint deformity, but affects an estimated 5 million Americans, mostly women. ■

—C.J.S.

synovial lining and can spread to the entire joint. Highly variable and difficult to control, the disease can severely deform joints. Some people become bedridden. Others continue to run marathons.

An autoimmune disease affecting the whole body, rheumatoid arthritis can also cause weakness, fatigue, loss of appetite, muscle pain, and weight loss. Blood tests may reveal anemia and the presence of an antibody called rheumatoid factor (RF). However, some people with RF never develop rheumatoid arthritis,

and some people with the disease never have RF. In about one in six, the disease becomes severe and can shorten life. Researchers hope to find ways to predict which patients should be treated more aggressively.

Ups and Downs

With so many kinds of arthritis, which can appear and progress unpredictably, diagnosis and treatment can be trying for both physician and patient. Diagnosis depends on integrating a host

of factors, including the possibility that a person may have two forms of the disease.

The normal ups and downs of chronic, painful disease further complicate matters. "Just about any painful condition will wax and wane on its own," says rheumatologist Dennis Boulware, M.D., University of Alabama, Birmingham.

A worsening or reappearance of the disease is called a flare. Remissions bring welcome relief, but can also obscure whether symptoms decreased on

their own or due to treatment.

Proper treatment depends on correct diagnosis of the specific disease, and varies with severity and location, as well as from person to person. But treatment need not wait for a final diagnosis because initial treatment options, such as anti-inflammatory drugs and exercise, are similar for many forms of the disease. Treatment should begin early to reduce joint damage.

The drugs used for treating most types of arthritis are drawn from many categories, but can be thought of in a few broad groups, such as anti-inflammatory drugs and disease-modifying drugs. For treating gout, there are also drugs that reduce the amount of uric acid in the blood. More than one medication may be required for treating arthritis.

Anti-inflammatory agents generally work by slowing the body's production of prostaglandins, substances that play a role in inflammation. Many have an analgesic, or painkilling, effect at low doses. Usually, higher, sustained doses are required to see sufficient anti-inflammatory activity for treating arthritis. The most familiar anti-inflammatory agent is aspirin, often a good arthritis treatment. Like aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs) fight pain and inflammation. More than a dozen NSAIDs are available, most by prescription only. At press time, FDA was considering whether labeling changes to prescription-strength NSAIDs are necessary, due to gastrointestinal side effects.

FDA has approved three NSAIDs for over-the-counter (OTC) marketing: ibuprofen (marketed as Advil, Nuprin, Motrin, and others), naproxen sodium (sold as Aleve), and ketoprofen (marketed as Actron and Orudis). Although these drugs are available OTC, a doctor should be consulted before taking any medication for arthritis symptoms.

"People shouldn't be mixing medications," says Linda Katz, M.D., of FDA's pilot drug evaluation staff, and anyone regularly taking NSAIDs should carefully read the labels of OTC products to make sure they don't contain similar drugs. For example, many cough and cold preparations contain analgesics such as aspirin, acetaminophen or ibuprofen.

The most potent anti-inflammatories

are corticosteroids, synthetic versions of the hormone cortisone. Like prednisone and dexamethasone, the generic names often end in "-one." They're usually reserved for short periods of use during intense flares or when other drugs don't control unrelenting disease. Relief can be dramatic, but long-term use causes side effects, such as weight gain, high blood pressure, and thinning of bones and skin. Usually given orally, they can also be injected directly into a joint to reduce side effects.

Disease modifiers slow the disease process in autoimmune diseases such as rheumatoid arthritis or systemic lupus erythematosus. Patients taking these drugs are closely monitored. It may take weeks or months to learn if a drug works. During that wait, it's important to keep taking other medications such as NSAIDs. Gold salts have been used to treat rheumatoid arthritis for 60 years, although nobody knows why this treatment works. Penicillamine, methotrexate, and antimalarials such as hydroxychloroquine are also used. Doctors usually reserve other powerful drugs that suppress the immune system for extremely serious disease.

Most people with arthritis never need surgery, but when all else fails, it can dramatically improve independence and quality of life by reducing pain and improving mobility. The surgeon may remove damaged or chronically inflamed tissue, or replace the joint entirely. Artificial replacements are available for all of the most commonly affected joints.

Use It or Lose It

In the past, doctors often advised arthritis patients to rest and avoid exercise. Rest remains important, especially during flares. But doing nothing results in weak muscles, stiff joints, reduced mobility, and lost vitality. Now, rheumatologists routinely advise a balance of physical activity and rest. Exercise offers physical and psychological benefits that include improved overall fitness and well-being, increased mobility, and better sleep.

For example, twice a week for three years, Elsie Sequeira, 81, of Concord, Calif., has attended a water-based exercise class sponsored by the Arthritis Foundation. "It's helped me a lot," she

says. Sequeira has rheumatoid arthritis in her shoulders and legs. She had also had a mild stroke and got to her first classes with the help of a walker and an attendant.

A few weeks passed before she saw any improvement, but within a few months she no longer needed either the walker or the attendant. "The warm water is very soothing and we can do things in the water that we couldn't do on land," Sequeira says. She enjoys the social contact, and feels better able to take care of herself. "I don't feel so hamstrung," she says.

Joints require motion to stay healthy. That's why doctors advise arthritis patients to do range-of-motion, or flexibility, exercises every day—even during flares. Painful or swollen joints should be moved gently, however.

Strengthening and endurance activities are also recommended, but should be limited or avoided during flares. Arthritis patients should consult their doctors before starting an exercise program, and begin gradually. Exercises must be individualized to work the right muscles while avoiding overstressing affected joints. Doctors or physical therapists can teach proper ways to move.

Muscle strength is especially important because strong muscles better support and protect joints. "Several studies show that if you improve muscle strength, you decrease pain," Boulware says. Joints will probably hurt during exercise, but shouldn't still hurt several hours later.

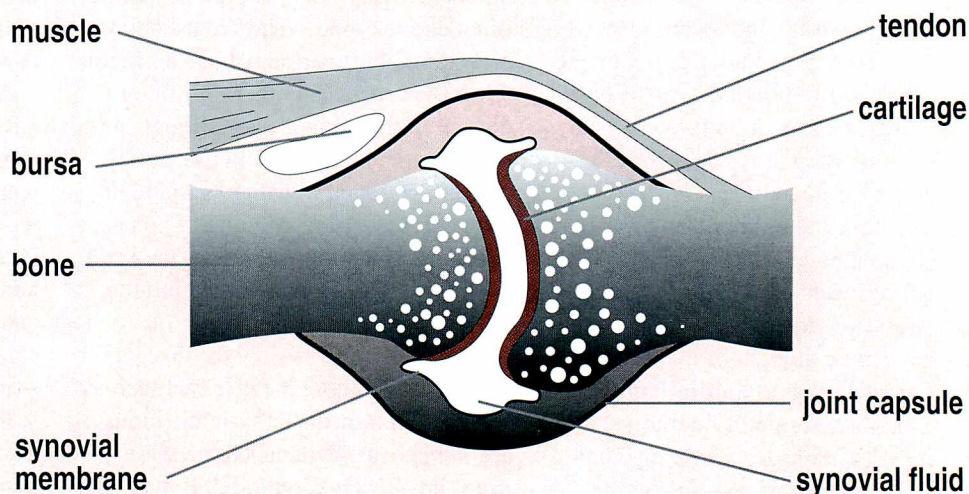
"There's a fine line between doing too much and too little," says rheumatologist William Ginsburg, M.D., of the Mayo Clinic, Jacksonville, Fla. "Sometimes people have to be reminded to slow down and listen to their disease."

Support groups and arthritis education can help people learn how to listen to their disease, and cope with it. "The psychological aspects are very important because that's what changes people's lives," Ginsburg says.

Participants learn practical things, such as how to: get up off the floor after a fall, protect joints with careful use and assistive devices, drive a car, get comfortable sleep, use heat and cold treatments, talk with their doctors, and cope with emotional aspects of pain and

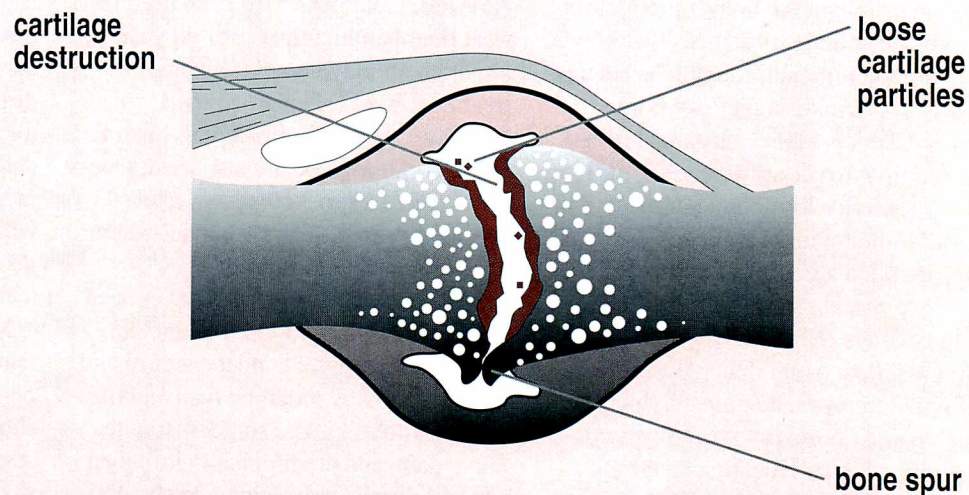
Normal Joint

In a normal joint (where two bones come together), the muscle, bursa and tendon support the bone and aid movement. The synovial membrane (an inner lining) releases a slippery fluid into the joint space. Cartilage covers the bone ends, absorbing shocks and keeping the bones from rubbing together when the joint moves.



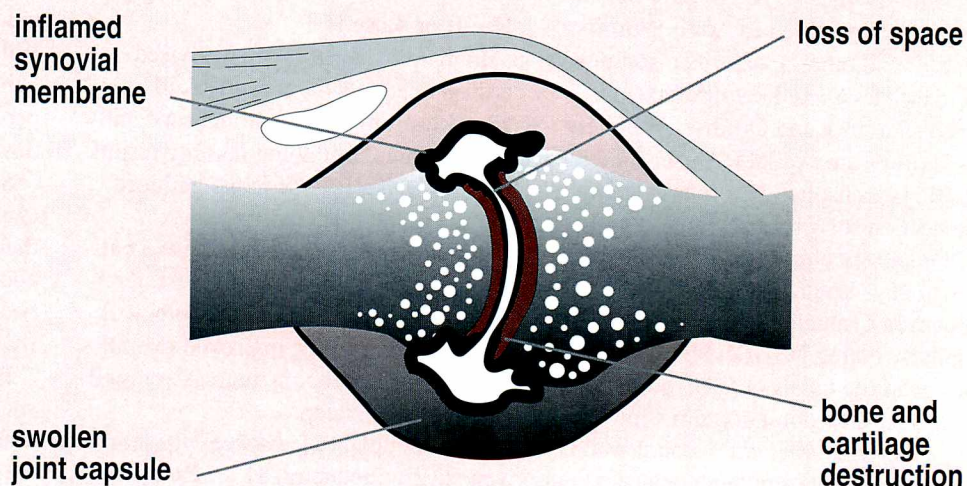
Osteoarthritis

In osteoarthritis, cartilage breaks down and the bones rub together. The joint then loses shape and alignment. Bone ends thicken, forming spurs (bony growths). Bits of cartilage or bone float in the joint space.



Rheumatoid Arthritis

In rheumatoid arthritis, inflammation accompanies thickening of the synovial membrane or joint lining, causing the whole joint to look swollen due to swelling in the joint capsule. The inflamed joint lining enters and damages bone and cartilage, and inflammatory cells release an enzyme that gradually digests bone and cartilage. Space between joints diminishes, and the joint loses shape and alignment.



(Source: Arthritis Foundation)

disability. They may also learn to acquire and maintain what health experts have long touted—a positive attitude.

Health education not only improves quality of life, but also lowers health-care costs, and the benefits are lasting, according to studies at Stanford University, Palo Alto, Calif. Four years after a short Arthritis Self-Management Program, participants still reported significantly less pain and made fewer physician visits, even though disability increased. The benefits came, not from the specifics taught, but from improved ability to cope with the consequences of arthritis—in other words, confidence. “It’s the same thing that any good coach tries to instill,” says Halsted R. Holman, M.D., Stanford University.

Avoiding Fraud

Learning to understand their disease can also help make people less likely to fall victim to fraud. Because they have a painful, incurable condition, people with arthritis are among the prime targets for fraud and spend nearly a billion dollars annually on unproved remedies, largely diets and supplements.

A claim describing the relationship between a nutrient or dietary ingredient and a disease, such as arthritis, cannot be made on the label or in labeling of a dietary supplement unless the claim is authorized by FDA. In order for FDA to consider authorizing the use of a health claim, there must be significant agreement among qualified experts that the health claim is scientifically valid. Frequently, however, dietary supplements are found on the market labeled in violation of these requirements.

“If the claim sounds too good to be true, it probably is. Talk to your doctor or other health professional,” says Peggy Binzer, a consumer safety officer in FDA’s Center for Food Safety and Applied Nutrition.

Consumers who have questions or who wish to report a company for falsely labeling its products should call FDA’s Office of Consumer Affairs at



Water exercise classes help some arthritis patients.

(Photo by Sylvia Rittweger)

(301) 443-3170 from 1 p.m. to 3:30 p.m. Eastern time. Consumers who have suffered from a serious adverse effect associated with the use of a dietary supplement should report the effect to their health-care professional or to MEDWATCH at (1-800) FDA-1088.

Some remedies, such as vinegar and honey or copper bracelets, seem harmless. But they can become harmful if they cause people to abandon conventional therapy. Others, such as the solvent dimethyl sulfoxide (DMSO), can be outright dangerous. (See “An FDA Guide to Choosing Medical Treatments,” *FDA Consumer*, June 1995.)

It’s tempting to conclude that arthritis pain gets better or worse because of what was added or eliminated from the diet the day or week before. However, gout is the only rheumatic disease known to be helped by avoiding certain foods. The unpredictable ups and downs of arthritis make it hard to establish a relationship between diet and disease. Scientists have only recently begun to study nutritional therapy for arthritis, and the American College of Rheumatology (ACR) urges continued research.

The ACR Position Statement on Diet and Arthritis advises, “Until more data are available, patients should continue to follow balanced and healthy diets, be skeptical of ‘miraculous’ claims and avoid elimination diets and fad nutritional practices.”

Research Under Way

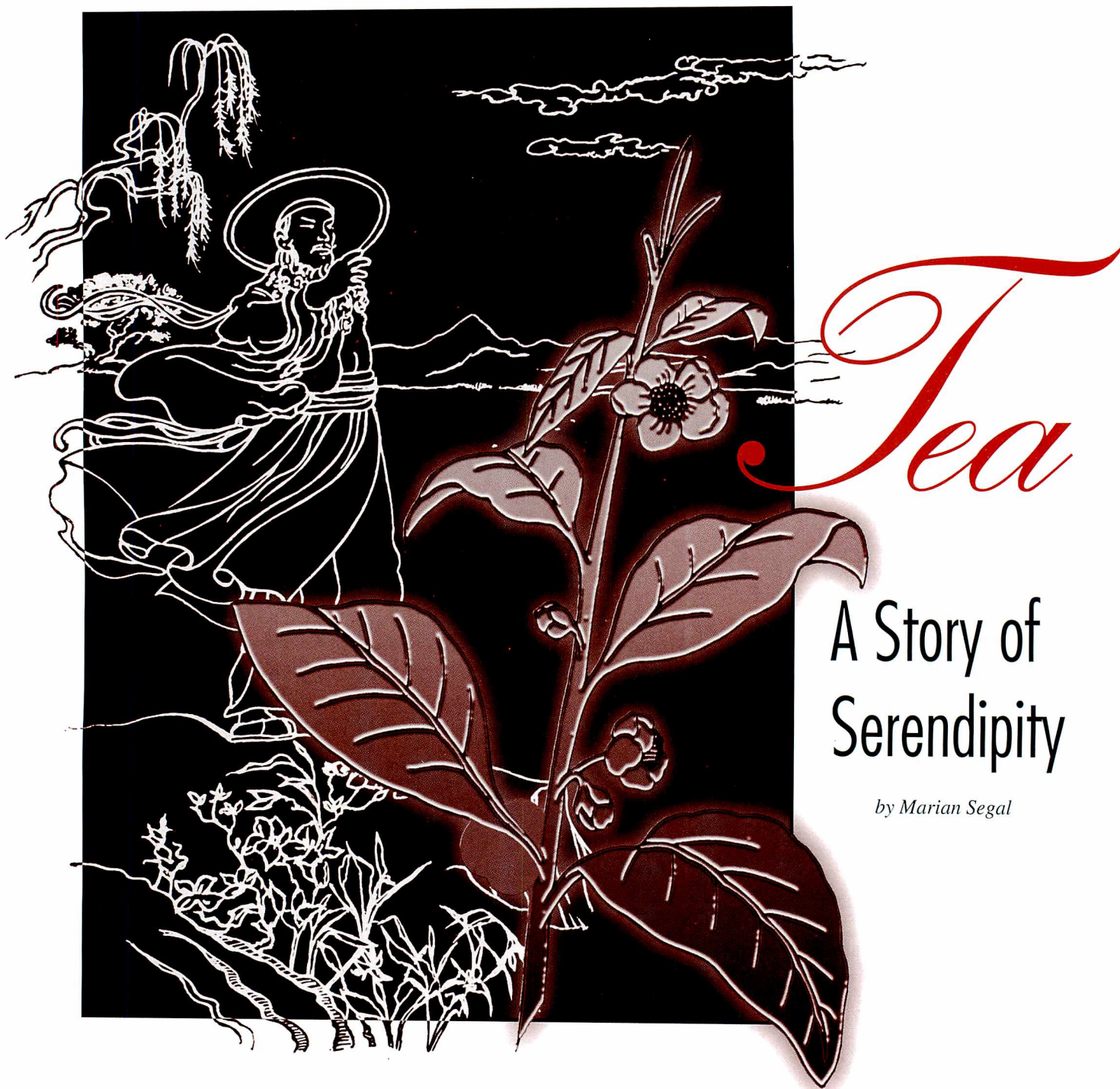
New treatments are likely to stem from better understanding of the underlying causes and destructive processes of the disease. Overuse, injury and obesity are contributing factors in osteoarthritis, and researchers have implicated a faulty gene in the breakdown of cartilage. Heredity plays a role in other forms of arthritis, too, increasing susceptibility in some people. Potential genetic therapy approaches are still far off, however.

Increased knowledge of immunology and the inflammatory process offers more immediate promise. Researchers have developed a drug that blocks the effects of TNF-alpha, an inflammatory protein responsible for reactions resulting in joint damage. In short-term preliminary trials, the drug significantly reduced symptoms in rheumatoid arthritis patients.

Such results are encouraging, but the ultimate goal is to understand what starts the immune response in the first place. “Until you know the real cause, you’re not going to have the right drug,” Ginsburg says.

That quest continues and offers hope. But short of a cure, enlightened coping may be the most promising avenue to a less taxing life for people with arthritis. Emperor Diocletian would be pleased. ■

Carolyn J. Strange is a science and medical writer in Saratoga, Calif.



A Story of Serendipity

by Marian Segal

As legend has it, one day in 2737 B.C. the Chinese Emperor Shen Nung was boiling drinking water over an open fire, believing that those who drank boiled water were healthier. Some leaves from a nearby *Camellia sinensis* plant floated into the pot. The emperor drank the mixture and declared it gave one “vigor of body, contentment of mind, and determination of purpose.”

Perhaps as testament to the emperor’s assessment, tea—the potion he unwittingly brewed that day—today is second only to water in worldwide consumption. The U.S. population is drinking its fair share of the brew; in 1994, Americans drank 2.25 billion gallons of tea in one form or another—hot, iced, spiced, flavored, with or without sugar, honey, milk, cream, or lemon.

A serving of tea generally contains about 40 milligrams of caffeine (less than half as much caffeine as in coffee), but the actual levels vary depending on the specific blend and the strength of the brew. Decaffeinated tea is also available.

Many tea drinkers find the beverage soothing, and folk medicine has long valued it as a remedy for sore throats and unsettled stomachs. Recent studies have shown that certain chemicals in tea called polyphenols may help reduce the risk of far more serious illnesses, including atherosclerosis and some cancers, although the data are not conclusive. (See accompanying article.)

Black, Green and Oolong

Tea comes in black, green and oolong varieties, all produced from the leaves of *Camellia sinensis*, a white-flowered evergreen. The method of processing the leaf distinguishes the three types. (Herbal teas are made from leaves of other plants. FDA requires that herbal tea labels carry the name of the plant the product derives from, such as chamomile. For more on herbal teas, see "Herbal Teas and Toxicity" in the May 1991 *FDA Consumer*.)

The traditional method of producing black tea begins with withering. The plucked leaves are placed on shelves called withering racks, where excess moisture is removed. They are then rolled in special machines that release the leaves' enzymes and juices, which give tea its aroma and taste. Next, the leaves ferment in a room with controlled temperature and humidity; finally they are dried in ovens. More recently some processors have forsaken the traditional method to speed production by using machines that finely chop the leaves, thereby cutting the time for withering and fermenting.

Green tea is made by steaming or otherwise heating the leaves immediately after plucking to prevent the fermentation that makes black tea. Then the leaves are rolled and dried.

Oolong tea is fermented only partially—to a point between black and green. While the leaves wilt naturally, enzymes begin to ferment them. Processors interrupt the fermentation by stirring the leaves in heated pans, then rolling and drying them.



Two leaves and a bud at a time—This is the secret of fine tea picking. The work is done chiefly by women, who carry light bamboo baskets strapped to their backs.

Debugging the Dispenser

After a restaurant patron in Cincinnati complained last summer that his iced tea smelled like sewage, the city's health department sampled iced tea from several area restaurants. The study revealed high levels of coliform bacteria (from fecal matter), prompting the state of Kentucky to launch a similar survey of its restaurants. That study, too, found contaminated tea in many restaurants. Although no illnesses were reported, both jurisdictions last fall issued advisories to retail food establishments on how to properly prepare brewed iced tea.

"There was a similar situation in Texas back in 1987," says Thomas L. Schwarz, director of the division of cooperative programs in FDA's Center for Food Safety and Applied Nutrition, "and the problem was the same—the tea dispensers were not being properly cleaned and sanitized."

After the tea leaves are brewed, the hot tea is transferred from the brewer to a reservoir-type unit with a spigot for dispensing the tea. This unit has at its base a short section of tubing that goes from the reservoir to the spigot.

"What was found in 1987 and again recently," Schwarz says, "is that the dispenser is not being cleaned properly. Over time, the tubing and the spigot build up a heavy bacteria-laden residue, accounting for the high bacterial counts in some of the tea samples."

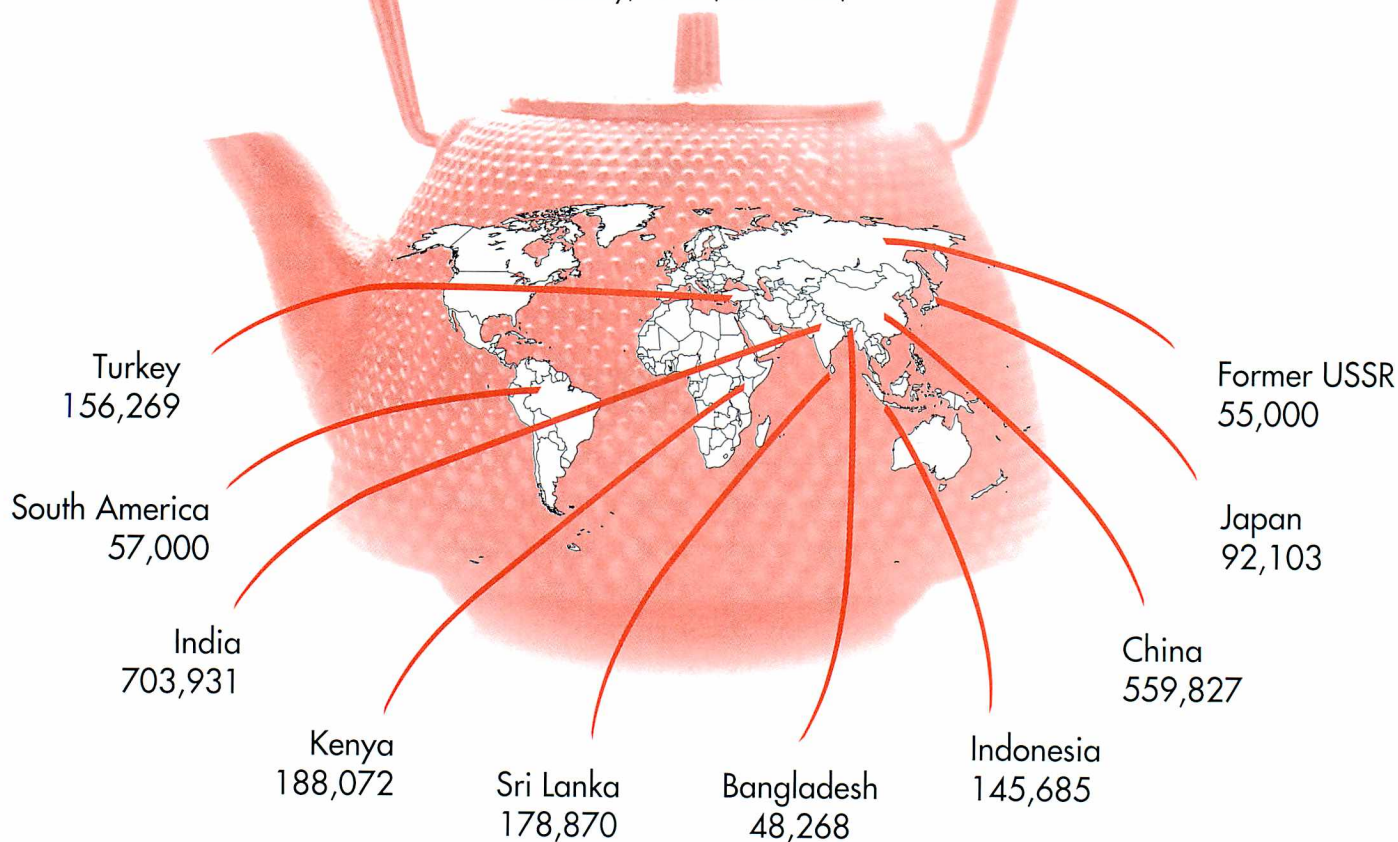
The solution to the problem is simple, Schwarz says. It requires disassembling, cleaning and sanitizing the dispenser, hoses, spigot, and other components. "If they dismantle the dispenser and clean and sanitize it at least once a day, as is recommended by FDA for retail food establishments, they shouldn't have any problems," he says, adding that no extra precautions need to be taken for home-brewed iced tea. ■

—M.S.

Hot Spots in the Pot

Major Tea Producing Regions in the World

World Production of Tea by Country, 1992 (metric tons)



Source: Tea Association

Different varieties of *Camellia sinensis* grow in different geographic areas and produce leaves that vary from a very small China leaf, perhaps one-half to three-quarters of an inch long, to the Assam leaf, which may be 3 or 4 inches long. Certain varieties are better suited than others for a particular processing method. For example, the China leaf from China and Formosa produces the best oolongs.

Scented and spiced teas are made from black tea. "Scented teas look just like any other tea," says FDA chemist and tea expert Robert Dick, "because the scent is more or less sprayed on. They're

flavored with just about anything—peach, vanilla, cherry. The spiced teas, on the other hand, usually contain pieces of spices—cinnamon or nutmeg or orange or lemon peel—so you can see there's something in there."

What about orange pekoe? Orange pekoe refers to the size of the tea leaf. Processed tea leaves are sorted into sizes by passing them over screens with different size holes. The largest leaves are orange pekoe, pekoe, and pekoe souchong. The smaller or broken leaves are classified as broken orange pekoe, broken pekoe souchong, broken orange pekoe fannings, and fines (also called "dust").

In brewing, flavor and color come out of the larger leaves more slowly than out of the broken and fine grades. The broken grades, which make up about 80 percent of the total black tea crop, produce a stronger, darker tea. The grades have nothing to do with the quality or flavor of tea; they simply refer to leaf size.

"Technically, except for fannings and fines, the terms should apply only to black, or fermented, tea," Dick says, "but nowadays I often see oolongs labeled 'orange pekoe,' and even some green teas are labeled pekoe or flowery pekoe."

Tonic in a Teapot?

The first documented reference to tea, according to the Tea Council of the U.S.A., came in 350 A.D., when the Chinese scholar Kuo P'o described "k'u t'u" as a medicinal beverage "made from the leaves by boiling."

In his book *All About Tea*, William H. Ukers cites other references from China in the first millenium that ascribe to tea the healing powers of a virtual wonder drug:

The seventh century medical book, Pen ts'ao, proclaims that tea quenches thirst, lessens the desire for sleep, and "gladdens and cheers the heart." Even today, no one would take great exception to that, but the book goes on to pronounce the drink good for tumors or abscesses about the head, ailments of the bladder, inflammation of the chest, and dissipating heat caused by the phlegms. And the eighth century Ch'a Ching, or Tea Classic, written by the Chinese scholar Lu Yu, contains this prescription for children: "Bitter ch'a [tea] made with the rootlets of onions can cure children who are frightened and tumble without apparent causes."

Although these early claims have not been validated by 20th century science, recent studies do show some evidence that polyphenols—chemicals in tea with antioxidative and other biochemical properties—may, in fact, have value in protecting against some serious ailments.

Because they are processed differently, green and black tea have slightly different chemical makeups. Both contain polyphenols, however, and both have shown positive results in laboratory studies.

In a review article published in the July 7, 1993, issue of the *Journal of the National Cancer Institute*, Chung S. Yang, M.D., of Rutgers University in New Jersey reports that "many laboratory studies have demonstrated inhibitory effects of tea preparations and tea polyphenols against tumor formation and growth." The studies, though not conclusive, are intriguing.

Yang describes studies in which laboratory animals fed green tea had reduced formation or growth of skin tumors, esophageal tumors, gastrointestinal tract tumors, and tumors of the liver, lung and pancreas. Black tea also has shown activity against skin, lung, liver, and esophageal tumors.

Results of epidemiological studies are murkier. Some indicate a protective effect of tea against certain cancers, others show no relationship, and still others show a higher incidence of some cancers, particularly esophageal, in heavy tea drinkers.

Although higher rates of esophageal cancer are seen in some parts of China, Iran and Japan, where tea consumption is high, it's not clear why. According to FDA research chemist Joseph M. Betz, Ph.D., "It's been bounced back and forth as to whether the high incidence is due to tea polyphenols or to proliferation of esophageal cells in response to physical damage to those cells cause by habitual consumption of a very hot beverage, as has been proposed by Dr. Bruce Ames at the University of California at Berkeley."

Yang reports that several case-control studies showed no association between esophageal cancer and drinking tea at normal temperatures (35 to 47 degrees Celsius, or 95 to 117 degrees Fahrenheit), but that ingestion of very hot tea (55 to 67 degrees Celsius, or 131 to 153 degrees Fahrenheit) was associated with twofold to threefold increases in risk.

He concludes that tea may reduce cancer risk in certain populations, adding that, "Depending on the etiology [cause] of the disease, the protective effect may be observed in selected cancers in certain populations but not in other situations." He advocates more studies on the chemical properties and biologic activities of tea and tea components—particularly of black tea, which is the major kind of tea consumed in Western countries and whose properties, he says, are poorly understood.

Polyphenols in tea are being looked at

for a potential to lower heart disease risk also. Biochemist Joe Vinson, Ph.D., at the University of Scranton in Pennsylvania, found that hamsters fed green and black teas had lowered blood cholesterol levels and reduced LDL cholesterol oxidation. He also found that tea has an anti-clotting effect in rats, which could help prevent or reduce the severity of a heart attack.

Vinson is cautious about translating the results of his studies to humans, though, in part because the hamsters were given tea in amounts equivalent to two quarts a day for humans. And although he is encouraged by epidemiological studies in Japan and China that show less heart disease in people who drink lots of tea, he stresses that "the tea story has yet to be written as far as heart disease goes."

A. Richey Sharrett, M.D., Dr.P.H., at the National Heart, Lung, and Blood Institute in Bethesda, Md., agrees. Sharrett considers tea polyphenols potentially important in heart disease but is wary of epidemiological studies.

"People don't just live on tea," he points out, "and if you compare cultures, they differ in so many respects. To me, you have to fall back on the biochemistry—you want to know if polyphenols are antioxidants, if they are absorbed, and can you get direct evidence that they're effective against coronary disease."

"The Food and Drug Administration has not done any reviews of possible beneficial effects of tea," says John Vanderveen, Ph.D., director of FDA's Office of Plant and Dairy Foods and Beverages. "If we were to do it, it would be under the context of a health claim," he says, "and no one has submitted a request for a health claim."

Whether or not tea will ultimately prove of value in combating cancer, heart disease, or children's tumbling remains to be seen. In the meantime, cuppa tea, anyone? ■

—M.S.



Most of the tea Americans consume is grown on tea estates (or gardens) in Sri Lanka (Ceylon), India, and some of the East African countries. In mountainous regions, the tea plants are grown on terraces or long slopes to prevent soil erosion.

Tea tastes vary, and one aficionado who squirts lemon in his cup may cringe at the sight of another pouring milk or honey. But no matter how the tea may be doctored, in the United States the odds are overwhelming that it starts out black. Nearly 95 percent of all tea consumed here is black, according to the New York City-based Tea Council of the U.S.A.; 4 percent is green, 1 percent oolong, and 1 percent flavored.

That wasn't always the case, and our proclivity for drinking black tea over green or oolong may have been influenced by events in history. Sixty years ago and more, the amount of black and green tea Americans drank was split fairly evenly—each accounting for about 40 percent of the market—with oolong constituting the rest. During World War II, however, the major sources of green tea—China and Japan—were cut off from the United States, leaving us with tea almost exclusively from British-controlled India, which produces black tea. Americans came out of the war drinking nearly 99 percent black tea.

With the Korean War in the 1950s, uncertainties about tea supplies resurfaced, and the United States began to look for other suppliers.

"Argentina filled the bill," Dick says, "because tea could grow very fast there.

Although the country didn't produce an outstanding tea, it produced a good average tea."

Today, most of our tea comes from Argentina, China (which got back into the U.S. market in 1978), and Java. Thirty years ago most of it came from India and Ceylon (now Sri Lanka). Argentine black tea is the kind most used for iced tea, and that's another reason black tea dominates the U.S. market.

Some Like It Cold

America is unique in its tea consumption habits, the Tea Council says, in that approximately 40 billion of the 50 billion cups consumed here each year are over ice.

Iced tea debuted in 1904 at the Louisiana State Purchase Exposition in St. Louis, Mo. According to the Tea Council, "The temperature was soaring and the staff in the Far East Tea House couldn't get any fair-goers to even look their way, let alone sample their tea. So they poured the hot tea over ice cubes and the drink quickly became the exposition's most popular beverage."

The tea bag was born the same year as iced tea, and its arrival was equally serendipitous. A Boston tea merchant began sending samples of tea in small silk bags for customers to try. Eventually, the

convenient pre-measured sacks came to dominate the tea market. In 1994, according to the Tea Council, approximately 60 percent of tea brewed in the United States was prepared from tea bags; just over 1 percent was brewed from loose tea. Iced tea mixes accounted for another 25 percent of prepared tea, and the rest was made from instant tea.

These statistics attest to the importance of the "convenience factor" in tea's growing popularity in this country. The demand for convenience that led to the introduction of the tea bag and the creation of instant tea and iced tea mixes led also to the more recent packaging of ready-to-drink iced tea in cans, bottles, and plastic containers. Ready-to-drink teas are the fastest-growing tea products and the fastest-growing new product in the supermarket, according to the Tea Council.

The Tea Council estimates total U.S. tea sales for 1994 at \$3.75 billion, up from \$1.8 billion in 1990. On any given day, the council says, about half the population drinks tea, with the greatest concentration of drinkers in the South and Northeast.

Keeping teacups full in the United States and around the world takes a lot of tea. In 1993, 2,581,317 metric tons of tea were produced and 1,142,650 metric tons exported, according to the International Tea Committee's 1994 *Bulletin of Statistics*. This billion dollar business got its start centuries ago from a plant that once grew quietly undisturbed in a far corner of the world. William H. Ukers, in his comprehensive 1935 tome *All About Tea*, writes:

"Mother Nature's original tea garden was located in the monsoon district of southeastern Asia. Many other plants now grow there, but specimens of the original jungle, or wild, tea plant are still found in the forests of the Shan states of northern Siam, eastern Burma, Yunnan, Upper Indo-China, and British India. ... Before any thought was given to dividing this land into separate states, it consisted of one primeval tea garden where the conditions of soil, climate, and rainfall were happily combined to promote the natural propagation of tea." ■

Marian Segal is a member of FDA's public affairs staff.

FDA, States Collaborate For Safety's Sake

by John Henkel

When Congress passed a law in 1992 requiring federal certification of U.S. mammography facilities, regulators faced the daunting task of inspecting and accrediting the 10,000 mammogram providers scattered across the country.

If the Food and Drug Administration—responsible for enforcing the certification—had tried to tackle this alone, the task would have been nearly impossible because of limited resources. The agency gets the job done by drawing on a decades-long alliance with state departments.

Mammography facility inspection is part of a larger initiative to protect the public against adverse health effects of radiation exposure. It is one of four major FDA-state collaborations. Others involve retail food protection, shellfish sanitation, and milk safety.

"FDA does not have primary responsibility to enforce compliance for the commodities covered under the cooperative programs," says David Field, state programs director for FDA's Northeast Region. "The states do that. They have the police power."

In the case of mammography, FDA does enforce the law and does inspect some facilities itself, such as those in the military and in states without contracts with the agency. However, for thousands of other inspections, FDA trains, audits, and provides technical expertise to state inspectors under contract to FDA to do inspections.

The four FDA-state programs are unlike most others within the agency because they run by authority of the Public Health Service (PHS) Act, not the Federal Food, Drug, and Cosmetic Act, from which most of FDA's regulatory authority comes.

The PHS Act directs FDA to "assist



states ... in the prevention of communicable diseases" and to advise states "on matters relating to preservation and improvement of the public health."

More informal federal partnerships with states date back to the early part of this century. In the 1920s, the Industrial Revolution changed America's food habits. The shift away from an agricultural economy meant, for example, that "many people no longer had a cow in their backyard, so they were buying milk from the local store," says Field. But because the industry lacked standards and controls, outbreaks of food-

A Virginia state official and FDA inspector examine a catch of oysters from the Chesapeake Bay as part of the agency's Shellfish Sanitation Program.

A recent FDA-state review of mammography exams indicates a 34 percent improvement in image quality and a 20 percent decrease in radiation needed to produce a quality image.

train, and generally oversee shellfish sanitation programs.

FDA-state alliances nowadays are governed by memoranda of understanding with various national conferences, where federal and state officials, along with industry representatives and others, meet either yearly or biannually to review or revise procedures.

"The states come to the table, they have voting authority, and they examine ordinances, operational manuals, or pertinent issues to make sure everyone is going to be playing the same tune," says Field.

FDA uses its six administrative regions—Northeast, Mid-Atlantic, Southeast, Midwest, Southwest, and Pacific—as geographic sectors for cooperative programs, with each region responsible for a cluster of states. Working within these regions, state officials can readily consult with FDA experts about technical problems. The proximity also allows FDA regional personnel to audit state programs easily. And states in each region can arrange easily to have FDA conduct training for state inspectors.

Radiological Health

FDA's training role is crucial to the success of the cooperative programs because in many cases state inspectors—such as those who inspect mammography facilities—must be certified to perform a regulatory function. The train-

borne disease occurred from milk that had been contaminated somewhere along the processing route. Shellfish had similar tainting problems. In 1925, several states asked the surgeon general for help in stemming the rise of shellfish-related illnesses such as typhoid. In response, the surgeon general held a conference that created the framework for PHS programs that advise,

ing, much of it available only from FDA, is required for getting and maintaining certification.

Often, as in the radiological health program, states need a steady flow of trained inspectors. "If you're a state radiation control director, and you lose a seasoned member of the staff, it's tough," says Richard Gross, associate director for liaison in FDA's Center for Devices and Radiological Health. "You have to quickly bring someone else up to speed to keep up with the workload. That's where FDA really helps by offering the states specialized training [to individuals]."

Protecting the public from potentially harmful radiation effects is a duty shared by at least five federal agencies, including the Environmental Protection Agency, the Nuclear Regulatory Commission, the Department of Labor, and the Centers for Disease Control and Prevention, as well as FDA. But at the state level, these responsibilities typically are focused into a single division. This allows a more comprehensive approach to regulating local radiation sources, which include x-rays, radioactive materials, microwave devices, lasers, and even

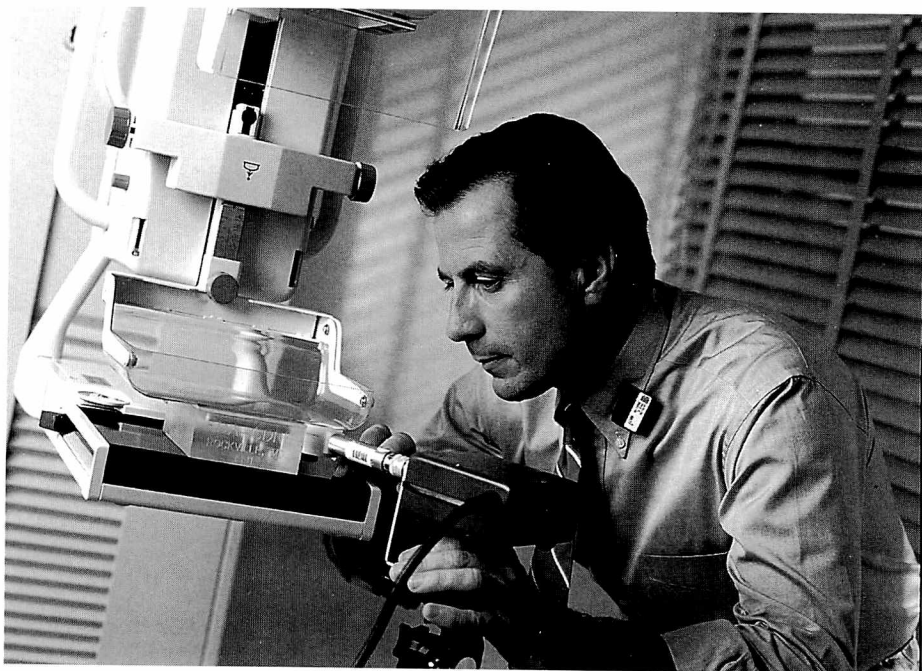
ultraviolet-source instruments.

The collaboration works well because federal agencies often have a greater concentration of technical expertise and scientific resources. But the states can respond to public health emergencies more quickly. States also have personnel resources close to the sources of problems and can act rapidly to resolve them.

The Conference of Radiation Control Program Directors guides FDA-state programs in radiological health. One of the conference's main activities is a yearly survey that gauges the quality of a specific x-ray—a dental bite-wing exam, for instance—from a random sampling of facilities nationwide. "The states voluntarily oversee data collection for these surveys," says Gross, "while FDA lends technical expertise and helps develop standard protocols [for gathering the data]."

The conference then distributes the data to trade groups (the American Dental Association, for example) and state health departments as a measure of radiological exposure nationwide to patients for the particular test studied.

These data also show trends. A review of survey data on mammography quality



Mammography quality is tested with an apparatus that attaches to the mammography device. It creates an "imaging phantom" that mimics a patient receiving a mammogram. In states under contract with FDA, the agency trains personnel to perform these inspections. In some other facilities, such as those in the military and in states not under contract, FDA conducts its own inspections.

from 1985, 1988 and 1992 indicates a 34 percent improvement in image quality and a 20 percent decrease in the “mean glandular dose” of radiation required to produce a quality image. This, Gross says, is consistent with the program’s goal of reducing unnecessary public radiation exposure.

Retail Food Protection

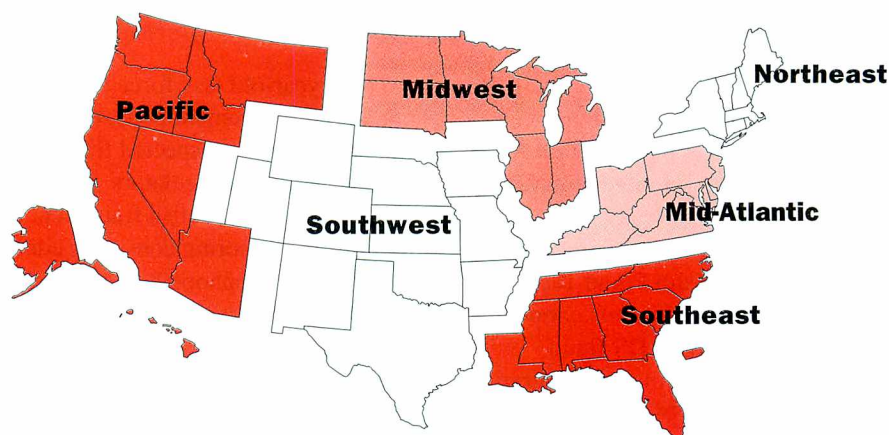
More than 3,000 state and local government agencies regulate the country’s retail food industry. They are responsible for over 1 million food establishments—restaurants and grocery stores, as well as vending machines, cafeterias, and other outlets in health-care facilities, schools, and correctional facilities. FDA’s regional food specialists provide training, program evaluation, and technical assistance to these agencies.

State health officials may request to be “standardized” in the Food Code before they inspect food establishments. The Food Code is a model of food safety standards FDA introduced in 1993 and updated in 1995. States are encouraged to adopt this code as a sound technical and legal basis for their own regulation of retail food establishments.

The standardization process, which tests an official’s performance in actual inspections, begins at FDA headquarters. A standardizing officer from the agency’s Center for Food Safety and Applied Nutrition and an FDA regional food specialist inspect numerous food establishments jointly, using a checklist that includes factors such as management knowledge, food employee health, hand cleanliness, and time and temperature management of potentially hazardous foods.

The regional specialist’s ratings must agree with at least 80 percent of the standardizing officer’s ratings of items on the inspection form. The regional standardized specialists then use the same method to standardize state officials, who, in turn, can standardize county and local inspectors.

FDA regional specialists also give the states technical assistance. For example, state officials recently asked FDA for help in responding to food-borne illness outbreaks, including incidents of contamination by the bacterium *E. coli* O157:H7 in Missouri, Washington,



Each administrative FDA region is responsible for maintaining cooperative programs in a cluster of states.

Oregon, and Texas, as well as a Texas botulism outbreak. Regional specialists provided states with information on the relevance to the problem of food additives, microbiology, ethnic foods, and plumbing.

In other instances, FDA regional specialists helped states ensure food safety after disasters such as floods and earthquakes. They are assisting with major food-service events such as the 1996 Olympics in Atlanta and the 1996 Boy Scout Jamboree in rural Virginia.

As in the radiation health program, training is critical in the food programs. Regional food specialists conduct many workshops for state health departments. For example, in 1994, FDA began offering training to familiarize state officials with the Food Code, and states now look to FDA for guidance in interpreting and applying the code.

The Food Code includes standards for such things as cooking times and temperatures, refrigeration temperatures, and storage requirements for many kinds of foods. In 1994, Rhode Island was the first state to implement the Food Code as law. But that was just a first step.

“After we got the code through, the high priority was training people on what the code is,” says Ernest Julian, Ph.D., chief of Rhode Island’s division of food protection. “FDA was of great assistance there, putting together a Food Code course for us. And now if we have questions about the code, we can go to FDA and have those answered.”

Shellfish Sanitation

The shellfish program is governed by the Interstate Shellfish Sanitation Conference, which was established in 1982 and meets each summer for seven days. In April each year, conference members—FDA, states, industry representatives, the Environmental Protection Agency, and the National Marine Fisheries Service—submit ideas and issues for consideration by the conference. One of three task forces, made up of conference members, examines each issue and makes a recommendation to the general assembly, which includes only state representatives who vote on the issue.

In 1994, FDA offered the conference an option for controlling the potentially hazardous *Vibrio vulnificus* bacterium in raw oysters. The option suggested a ban on harvesting oysters for raw consumption from Gulf of Mexico waters between April and October. The conference rejected that option but agreed to a year-long study of time and temperature factors that can reduce the risk of *Vibrio* infection in medically compromised individuals. In early summer 1995, the states, with FDA’s input, offered another option based on oyster refrigeration when the water reaches a certain temperature. For example, oysters taken from an affected site during a month with an average monthly maximum water temperature of more than 84 degrees Fahrenheit (29 degrees Celsius) would have to be chilled within six hours of harvesting. Oysters taken from cooler waters could be kept unchilled longer.

Battling AIDS Fraud

Recent years have seen a growth in fraudulent or scientifically unproven treatments aimed at patients with AIDS who are desperate for any help against this deadly disease.

FDA has joined with several states to form the AIDS Health Fraud Task Force Network, a grassroots cooperative striving to curb AIDS fraud through various information programs. So far, California, Colorado, Florida, Georgia, Illinois, Louisiana, Michigan, Minnesota, Ohio, and Texas have created task forces, each with its own programs tailored to the state's needs.

"Our hope is that eventually all 50 states will come aboard the program," says Richard Barnes, director of FDA's division of federal-state relations. Task forces include federal, state and local officials, along with members of AIDS service organizations, academia, businesses, and AIDS medication "buyers' clubs." FDA funds the task forces.

The 6-year-old task force network is not a law enforcement body, though it sometimes refers suspected fraud cases to state or federal regulators. Instead, the network seeks to abolish fraudulent activities by sponsoring consumer education through telephone hot lines, newsletters, public service announcements, exhibits, and videos. Because they regard AIDS fraud as common and costly for people with AIDS or infected with HIV (the virus that causes AIDS), task force members help patients steer clear of fraudulent operations. Patients can report suspected fraud to task forces (the phone numbers are listed in local directories under state services). Task forces also help patients make informed choices about legitimate treatments.

A clear advantage of the task forces is speed, says Lynne Isaacs, AIDS coordinator in FDA's Florida district office. "If suspected fraud is found, the task force can rapidly alert the news media, which gets the message to the public."

One recent Florida case involved a hand lotion the distributor claimed could block HIV and eliminate the need for health workers to wear protective gloves. The task force quickly spread the word about this unproven product, and FDA sent a warning letter to the company, which resulted in the company canceling its advertising.

Collaborating with states makes good sense, Barnes says, because "FDA cannot stop AIDS fraud alone. Fraud happens at the local level, and that's where exposure of the fraud should take place."

Barnes emphasizes that AIDS fraud is not an isolated problem affecting a small patient population. It is part of a much larger problem that has negative consequences for the country's economy. "Let's face it," Barnes says, "when someone is involved in health fraud, it ends up costing all of us." ■

—J.H.

This time, the conference's voting members approved the measure.

"Sometimes FDA is placed in a situation where it must compromise to get an issue approved by the conference," says Stan Ratcliffe, team leader for shellfish programs in FDA's Center for Food Safety and Applied Nutrition. "Other times the agency might have to accept defeat of its proposals."

Like the food safety program, FDA's Shellfish Sanitation Program has a regional staff that interacts with state officials to help bolster enforcement programs. These shellfish specialists audit state programs to ensure compliance with laws, regulations and requirements of the National Shellfish Sanitation Program (NSSP) and other criteria agreed on by the Interstate Shellfish Sanitation Conference. Their goal is to ensure that state officials comply with the NSSP in classifying harvesting waters, controlling illegal harvesting, as well as overseeing processing plant conditions and product labeling.

The shellfish program also provides states with training, technical assistance,

and results of scientific research. FDA shellfish specialists use a process similar to that of food specialists for standardizing state inspectors.

Milk Safety

FDA assists states in preventing disease transmitted through milk and helps enforce state milk regulations. It promotes and helps ensure compliance with the model Grade A Pasteurized Milk Ordinance, a document similar to the Food Code. FDA's regional milk specialists offer seminars to state officials to promote uniformity in interpreting the Pasteurized Milk Ordinance, as well as on other issues such as laboratory analysis methods.

The milk program has an auditing feature called check rating, which doublechecks state evaluations of milk sources. FDA produces a quarterly Interstate Milk Shippers list of ratings states have given to interstate milk plants and farms. "We then go in and check rate, or justify, the rating the state has given," says Field.

FDA regional milk specialists, like

their counterparts in retail food and shellfish programs, standardize state officials, after themselves being standardized by FDA headquarters. Milk specialists also track public health problems, such as those caused by bacterial contamination, to assess the impact of state control programs and the effects of FDA's activities on promoting public health.

The four FDA-state cooperative programs all have their own strategies, but their methods of helping states are similar. "For a state compliance officer with four or five programs to worry about, it can be difficult to know who's on first," says FDA's Richard Gross. "That's why there's been an effort to make these [cooperative] programs similar."

FDA officials also say the programs make good economic sense. Says FDA's David Field: "For a small amount of resources, FDA is able to influence and give good direction to four major industries across the country." ■

John Henkel is a staff writer for FDA Consumer.



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 public libraries.

■ **Oat bran and oatmeal products** would be able to carry a heart disease health claim under an FDA proposed rule. FDA has tentatively concluded that diets high in oat bran and oatmeal and low in saturated fat and cholesterol may reduce the risk of coronary heart disease. The public may submit written comments on the proposed rule by April 3 to FDA, Dockets Management Branch, HFA-305, Rockville, MD 20857. (FR Jan. 4)

■ **Biotechnology medication regulations** will be overhauled under measures FDA has proposed to reduce costs for manufacturers, increase agency efficiency, and continue to protect the public health. The measures were published last November in the pamphlet "Reinventing the Regulation of Drugs Made from Biotechnology." To date, FDA has published two *Federal Register* notices: "FDA Guidance Document Concerning Use of Pilot Manufacturing Facilities for the Development and Manufacture of Biotechnology Products" (FR July 11) and "Interim Definition and Elimination of Lot-by-Lot Release for Well-Characterized Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Biotechnology Products" (FR Dec. 8). Those interested may comment on either document at any time. For a free copy of the reinventing report, write to FDA, HFI-40, Rockville, MD 20857; telephone (301) 443-3220.

■ **User fee** revenues and rates for fiscal year 1996 were set by FDA under the Prescription Drug User Fee Act. The act authorizes FDA to collect fees on drug and biological product applications, on establishments where the products are made, and on the marketed products. The new fees took effect Oct. 1, 1995. (FR Dec. 1)

■ **A new antibiotic**, cefpodoxime proxetil, was recently approved, according to an FDA final rule effective last Dec. 27. In the rule, FDA published standards for the drug and its use both as tablets and as granules for oral suspension. (FR Nov. 27)

■ **The first generic albuterol** metered-dose inhaler (MDI) was approved by FDA last Dec. 29. The albuterol MDI is used to prevent bronchospasm in patients with asthma and was found equivalent to the brand-name product. (FDA Talk Paper, Dec. 29)

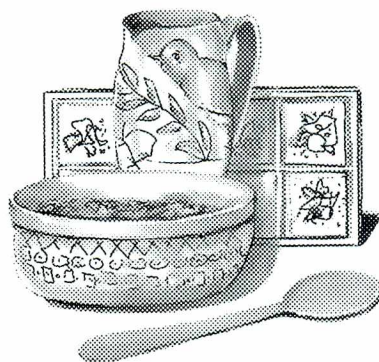
■ **Cadmium and lead contamination** of pottery compliance policy guides have been revised by FDA. For free single copies of "Pottery (Ceramics); Imported and Domestic—Cadmium Contamination" and "Pottery (Ceramics);

Imported and Domestic—Lead Contamination," send two self-addressed labels to FDA, Division of Compliance Policy, HFC-230, Rockville, MD 20857. Request Docket No. 95D-0370. (FR Dec. 12)

■ **Animal drug** and other veterinary information is now available through FDA's Center for Veterinary Medicine World Wide Web home page. The site includes general center information, some guidelines, and information on center research activities. The Internet address is <http://www.cvm.fda.gov/>. (FDA *Veterinarian*, November-December 1995)

■ **U.S. grade standards** and other selected regulations have been lifted for various agricultural products, according to an Agriculture Department final rule effective last Dec. 4. Dairy products, tobacco, wool, mohair, fresh and processed fruits and vegetables, livestock, meats and meat products, eggs, and poultry and rabbit products will now be regulated under voluntary standards set by USDA's Agricultural Marketing Service. (FR Dec. 4)

■ **Dietary fat and cancer** will be the topic of the American Institute for Cancer Research's annual conference at Loews L'Enfant Plaza Hotel in Washington, D.C., Aug. 29 and 30. For more information, telephone AICR's research department at (202) 328-7744 or (1-800) 843-8114; e-mail jcohn@capcon.net.





Pharmaceutical Executives Convicted

by Isadora B. Stehlin

False statements to federal officials, false records, and unapproved manufacturing procedures led to the conviction of two executives of a Pennsylvania generic drug manufacturing firm. In addition, the firm pleaded guilty to similar charges and was ordered to pay a \$3,250,000 fine.

On March 31, a jury in the U.S. district court for the district of Maryland found Suhas V. Sardesai guilty of seven felony counts of lying to FDA and violating the Food, Drug, and Cosmetic Act. Sardesai was senior vice president of operations for Mutual Pharmaceutical Co., Inc., Philadelphia. The jury also found Edmund J. Striefsky, director of quality control for Mutual, guilty of six counts.

The charges included conspiracy to defraud FDA, preparing and maintaining false production records that failed to reflect reprocessing, batch number switches, intermingling of several batches, failing to file supplemental new drug applications before making changes in manufacturing processes, and false statements in annual reports to FDA.

The illegal activities first came to the government's attention in May 1992, when a former production manager at Mutual contacted the U.S. Attorney's Office in Baltimore. According to the informant, Mutual had problems in manufacturing several of its generic drug products according to the formulas and methods it had submitted to FDA in its abbreviated new drug applications. The agency had approved the firm's applications, and rather than seek supplemental approvals from FDA as required by law, Mutual routinely reprocessed some products by illegally using unapproved ingredients and manufacturing procedures. Mutual concealed these actions

from FDA by creating and maintaining false records, and by filing false reports.

During an FDA inspection of the firm in July 1989, Sardesai told an investigator that Mutual had never reprocessed any batches, and if the firm decided to do so in the future, it would get FDA approval before beginning.

FDA employees with the agency's generic drug task force began interviewing current and former Mutual employees during the summer and fall of 1992. All of those interviewed corroborated the original informant's allegations.

According to these employees, Mutual routinely had problems with low tablet hardness and with tablets splitting and sticking to the equipment. At the direction of Sardesai and Striefsky, Mutual employees returned these batches to the blending department for remilling and remixing, and sometimes added extra lubricants such as magnesium stearate. Remilling tablets or adding additional lubricant can affect the bioavailability of a drug. The batch numbers of these reworked batches were often switched



with other batches of the same product in order to maintain a sequential batch numbering system so that the additional processing would not be detected by FDA.

Subsequently, the reworked batches would either be intermingled with other batches of the same product, resulting in a loss of batch purity and identity, or sent back to the tableting department for recompression. Among the products Mutual reworked were acetazolamide 250-mg tablets, a prescription medication used to treat congestive heart failure and glaucoma, and sulfasalazine 500-mg tablets, a prescription antibiotic.

Some Mutual production employees gave the task force handwritten notes of the reworking and intermingling of drug batches, and photocopies of internal Mutual records, which also corroborated the allegations.

In September 1993, FDA asked the Justice Department to initiate a grand jury investigation. In April 1994, the grand jury for the District of Maryland indicted four of the firm's executives.

Mutual pleaded guilty to seven counts of criminal violations involving interstate shipments of adulterated prescription medications on July 22, 1994. At that point, the court imposed the fine.

On March 31, 1995, after a seven-week trial, a jury convicted Sardesai and Striefsky. At press time, sentencing had not been scheduled.

Production employee Sunil C. Shah was found not guilty on all counts. The jury convicted quality assurance manager Kirit R. Patel on one count, but was not able to reach a verdict on the other counts. The government has not decided whether to retry Patel on those counts.

Isadora B. Stehlin is a member of FDA's public affairs staff.

Correction

In the July-August 1995 issue of *FDA Consumer*, an article about the criminal prosecution of New England Shrimp Company and Robert Randazzo contained errors. In April 1994, when that issue went to press, Randazzo had not gone to jail. His three-year sentence was stayed by the district court judge pending his appeal to the U.S. Court of Appeals for the First Circuit. The statement in the article that an employee of the company had been "fired because he failed to go along with New England Shrimp's illegal activities" should have been attributed to the employee.

Finally, the statement that "because STP was used in levels exceeding the limits allowed under good manufacturing practices the product was regarded as unsafe for human consumption" was also incorrect. Although Randazzo was convicted of using STP in shrimp products in which STP was prohibited, there is no evidence that New England Shrimp Company's product was unsafe due to the use of STP. Rather, the harm caused by the STP abuse was economic fraud.

Hair Relaxers Destroyed After Consumers Complain

Two types of hair relaxers, valued at almost \$2 million, were destroyed last fall after thousands of consumers reported problems with them. It was the largest number of complaints FDA had ever received about a cosmetic product.

The destruction was one of several measures the hair products' distributor, World Rio Corp. of Los Angeles, agreed to take in a consent decree entered in the U.S. District Court for the Central District of California on Sept. 1, 1995. The company also agreed not to sell another product like the two destroyed and to use FDA's Cosmetic Product Experience Report to report to the agency any adverse reactions from any hair straighteners it markets.

In 1994 and early 1995, more than 3,000 people reported to FDA that their scalp itched or burned and that their hair broke off or fell out—and, in some cases, turned green—after using the hair relaxers Rio Hair Naturalizer System and Rio Hair Naturalizer System with Color Enhancer.

Based on the complaints and an FDA investigation, the agency alleged that the hair products were being illegally sold in the United States because:

- Adverse effects experienced by consumers were consistent with those seen with harmful substances.
- Their labeling was false. The products' labeling listed an acid pH level of 3.4, but FDA analysis revealed that the pH was significantly less than 3.0. In addition, FDA alleged the labeling falsely described the products as "chemical free," even though the ingredient labels listed substances commonly recognized as chemicals.
- Ingredients, such as mineral salts, were not listed by their common or usual name, as required.

The products were destroyed in Nevada in June 1995 and in California in October 1995.

FDA and state government offices around the country began receiving complaints about the Rio hair products in mid-1994. Many complainants said they had bought the hair relaxers by mail after viewing a 30-minute TV infomercial targeted to African Americans.

Some complainants reported that their hair began falling out immediately after applying the products, while others said they had problems after multiple applications. Some said they had seen doctors for treatment of scalp irritation. Many women said they had to cut their hair short to deal with bald spots.

FDA collected samples of the hair relaxers on Nov. 6 and 8, 1994, at a Los Angeles-based affiliate, Pantron I Corp., of World Rio. Most of the products, which were imported from Brazil, were

in the possession of Product Packaging West, also known as Pic 'N' Pac West, of North Hollywood, Calif.

On Nov. 23, the California Department of Health embargoed the products held in Los Angeles and North Hollywood, essentially blocking their sale in the United States. On Dec. 21, FDA advised against use of the products after laboratory findings identified the low pH and the number of consumer complaints indicated that the hair relaxers were causing adverse reactions.

About the same time, World Rio stated it would stop all sales of the products. But, FDA received reports from consumers that the company may still have been taking orders and billing customers through a mail-order company, Addressing and Mailing Inc., in North Las Vegas, Nev.

On Jan. 23, 1995, at FDA's request, U.S. marshals seized the entire lot of products at Product Packaging West in California.

On Jan. 24, an investigator with FDA's San Francisco district office went to Addressing and Mailing to inspect the firm and found more than 8,000 cases of the Rio hair relaxers, worth about \$500,000 in retail value. FDA notified the State of Nevada Division of Health, which, in turn, embargoed the products, thus preventing their sale.

On June 14, World Rio voluntarily destroyed the 8,000 cases of Rio hair relaxers held at Addressing and Mailing in Nevada.

Under the terms of the consent decree between the United States and World Rio, the company agreed to destroy the product kits seized at Product Packaging West, although it was allowed to retain some of the kits for use in product liability litigation and for laboratory analysis. These kits must be held by a custodian and be destroyed at the end of the litigation. The company faces about 200 individual lawsuits.

Under the consent decree, World Rio agreed, among other things, not to sell a

reformulated hair relaxer or similar product until the product is tested for safety, the results of those tests are shared with FDA, and World Rio notifies FDA of the date on which it will begin marketing the new product.

—Paula Kurtzweil

Dairy Farm Enjoined For Illegal Drug Residues

An Oregon dairy farmer signed that state's first consent decree of permanent injunction involving illegal drug residues found in animal tissues. The order enjoined him from selling calves intended to be slaughtered for food until he established a system of identifying drug-treated animals and keeping treatment records on them.

David L. Hogan, owner and operator of Hogan's Misty Meadow Dairy in Tillamook, Ore., signed the order July 5, 1995, in the U.S. District Court for the District of Oregon after an FDA investigation documented illegal drug residues in calves he sold at market.

A follow-up inspection by FDA Aug. 17 found the dairy to be in compliance with the terms of the injunction.

Hogan's dairy is primarily a milk farm. At the time of the investigation, it had a milk-producing herd of 700 cows out of a total herd of 850 adult animals. It also had about 850 replacement calves in different stages of growth, and it sold approximately 450 bull calves each year for veal.

A calf that is given a drug or that has nursed from a drug-treated cow must be withheld from the market until the drug withdrawal time is complete. Residues in animals sold for food can present public health risks both directly from the meat (for example, to someone who is allergic to the drug) and by contributing to the development of resistance to antibiotics.

"To keep cows milking, they have to be impregnated periodically," explains FDA Seattle district compliance officer Tom Piekarski. "They dry up eventually, but when they deliver a calf, the milk starts flowing again. Female

calves are kept as replacements. Bull calves go straight to market, within hours to days of birth," he says.

When calves go to market, the U.S. Department of Agriculture samples portions of tissue—the liver, kidney, and sometimes muscle—from virtually every calf right at the slaughterhouse, Piekarski says. If illegal drug residues are found, the carcass is condemned and USDA notifies the producer and FDA. FDA then inspects the producer.

An FDA inspection of Hogan's dairy on Aug. 17, 1994, found that a calf that had tested positive for drug residues in USDA's sampling program had been slaughtered at Hogan's dairy June 15. The USDA analysis showed illegal residues of the antibiotic neomycin in the calf's kidney. This was not the first violative residue found in calves from Hogan's dairy. FDA inspections and USDA sampling dating from March 1990 documented 16 illegal residues of streptomycin, neomycin, gentamicin, and oxytetracycline in his animals.

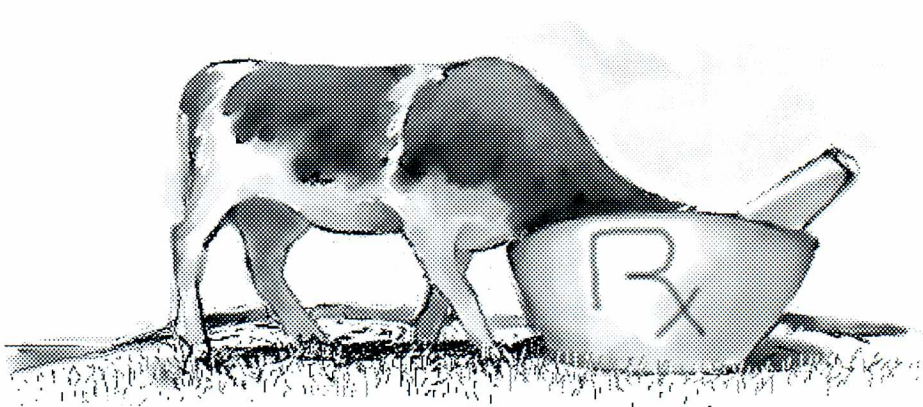
"Tissue residues in calves can come either from treatment right around birth or from the mother if the cow was treated," Piekarski says, "so that records must be maintained on both the adult animals and the calves." Hogan admitted he fed calves milk from treated cows and did not keep medication or treatment records. Despite the lack of records, investigators located at the dairy sources of the residues found in the animals: gentamicin and a stress formula containing neo-terramycin.

FDA had issued a warning letter to Hogan March 27, 1992, regarding the

violations, but he continued to ship calves with residues. After USDA notified the agency of the most recent violation, FDA inspected again in June and August 1994. Because the violations persisted, in November FDA asked the Department of Justice to file a complaint for injunction, which it did July 20, 1995, after negotiating with Hogan. The resulting consent decree prohibited Hogan from selling veal calves for slaughter until he complied with the terms of the decree, which include the following:

- Medicated bulls and cows must have a band affixed with the date of banding or the date of medication, whichever is later.
- Medication for the bulls and calves must be used in accordance with the labeling, and tissues from these animals cannot be sold until the withdrawal period for the medication is passed.
- Calves intended for sale must be segregated in separate pens from those not intended for sale.
- If a calf is medicated or fed milk from a medicated cow, the medication for the calf or cow must be used in accordance with its labeling; the calf must be marked for identification; and written records must be kept showing the identity and date of medication, the amount and method of administration, the withdrawal period for the medication, the date the withdrawal period expires, the date the calf was sold, and the name and address of the purchaser.
- Such a calf cannot be sold until the withdrawal period has lapsed.

—Marian Segal



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 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.

SEIZURE ACTIONS

Food/Contamination, Spoilage, Insanitary Handling

PRODUCT: **Betel Nuts, dried and sliced**, at Chicago, Ill. (N.D.Ill.); Civil No. 95-C-4903.

CHARGED 8-25-95: While held for sale after shipment in interstate commerce at Lien Hoa Food Corp., in Chicago, Ill., the articles were adulterated in that they contained a poisonous and deleterious substance—402(a)(1).

DISPOSITION: A default decree of condemnation, forfeiture and destruction ordered the articles destroyed. (F.D.C. No. 67100; S. No. 95-741-549; S.J. No. 1)

PRODUCT: **Lobster Tails, frozen**, at Miami, Fla. (S.D.Fla.); Civil No. 95-616-CIV-Ungaro-Benages.

CHARGED 3-27-95: While held for sale after shipment in interstate commerce at Preferred Freezer Services, Inc., in Miami, Fla., the articles were adulterated in that they consisted of decomposed lobster tails—402(a)(3).

DISPOSITION: A consent decree for reexport authorized the release of the goods for reexportation. (F.D.C. No. 67075; S. No. 95-711-238; S.J. No. 2)

PRODUCT: **Mushrooms, canned**, at Jacksonville, Fla. (M.D.Fla.); Civil No. 95-106-CIV-J-20.

CHARGED 2-3-95: While held for sale after shipment in interstate commerce at Grimes Distribution Services, in Jacksonville, Fla., the articles were misbranded in that their labeling falsely represented that the articles were packed and grown in Taiwan—403(a)(1).

DISPOSITION: A default decree of condemnation and destruction ordered the articles destroyed. (F.D.C. No. 67042; S. No. 93-682-700; S.J. No. 3)

PRODUCT: **Prune Culls**, at Cheektowaga, N.Y. (W.D.N.Y.); Civil No. 94-CV-0144.

CHARGED 2-25-94: While held for sale after shipment in interstate commerce at Allied Frozen Storage, Inc., in Cheektowaga, N.Y., the articles were adulterated in that they consisted of insects, insect parts, insect pupae, insect larvae, insect webbing, and insect excreta—402(a)(3).

DISPOSITION: A consent decree of condemnation, forfeiture and destruction ordered the articles destroyed. (F.D.C. No. 66908; S. No. 93-673-113; S.J. No. 4)

PRODUCT: **Scallops**, at Gretna, La. (E.D.La.); Civil No. 95-0604 Sect. SMAG.5.

CHARGED 2-21-95: While held for sale after shipment in interstate commerce at Gulf Atlantic Cold Storage, Inc., in Gretna, La., the articles were adulterated in that they consisted of a decomposed substance—402(a)(3).

DISPOSITION: A default decree ordered the articles destroyed. (F.D.C. No. 67065; S. No. 95-745-218; S.J. No. 5)

Drugs/Human Use

PRODUCT: **Oxygen USP**, at Tulsa, Okla. (N.D.Okla.); Civil No. 93-C 840B.

CHARGED 9-16-93: While held for sale after shipment in interstate commerce at American Respiratory, Inc., in Tulsa, Okla., the article was adulterated in that the methods used in, and the facilities and controls used for, its manufacture, processing, packing, and holding did not conform to and were not operated and administered in conformity with current good manufacturing practice requirements—501(a)(2)(B). The article was misbranded in that its labeling failed to bear the name and place of business of the manufacturer, packer or distributor—502(b)(1). The article was also misbranded in that its labeling failed to contain a statement of the quantity of contents and adequate directions for its intended use—502(b)(2) and 502(f)(1).

DISPOSITION: A consent decree of condemnation and reconditioning was filed. The articles were reconditioned and brought into compliance. (F.D.C. No. 66758; S. No. 93-687-401; S.J. No. 6)

Medical Devices

PRODUCT: **Bandages, conforming stretch gauze**, at Mundelein, Ill. (N.D.Ill.); Civil No. 94C-4505.

CHARGED 7-25-95: While held for sale after shipment in interstate commerce at Medline Industries, Inc., in Mundelein, Ill., the articles were adulterated in that they were contaminated with mold, yeast and bacteria—501(c). The articles were misbranded in that their labeling falsely represented them as sterile—502(a).

DISPOSITION: A consent decree of condemnation was filed.

The articles were reexported to Germany under agency supervision. (F.D.C. No. 66999; S. No. 94-710-913; S.J. No. 7)

PRODUCT: Eye Cleaners and Disinfectants, at San Jose, Calif. (N.D.Calif.); Civil No. C-94-20711.

CHARGED 10-7-94: While held for sale after shipment in interstate commerce at Lobob Laboratories, in San Jose, Calif., the articles were adulterated in that the methods used in, and the facilities and controls used for, their manufacturing, packing and storage were not in conformity with current good manufacturing practice requirements—501(h).

DISPOSITION: A default decree of condemnation, forfeiture and destruction ordered the articles destroyed. (F.D.C. No. 67008; S. No. 94-705-815; S.J. No. 8)

PRODUCT: Frequency Generators and Cosmic and Magnetic Polarizers, at San Diego, Calif. (S.D.Calif.); Civil No. 93-0230S.

CHARGED 2-12-93: While held for sale after shipment in interstate commerce at Crane Foundation, in San Diego, Calif., the articles were adulterated in that they were class III devices without an application for premarket approval—501(f)(1)(B). The articles were misbranded in that their labeling represented them as effective for treating cancer, AIDS, heart disease, arthritis, diabetes, infections, burns, and pain—502(a). The articles were also misbranded in that their labeling failed to bear adequate directions for use, and they were not manufactured in a duly registered establishment—502(f)(1) and 502(o).

DISPOSITION: An order of summary judgment, condemnation and destruction was filed, and the articles were destroyed. (F.D.C. No. 66496; S. No. 92-641-318; S.J. No. 9)

CRIMINAL ACTIONS

DEFENDANT: John Bushow, at St. Croix, U.S. Virgin Islands (D.Md.); Criminal No. HAR-91-0330.

CHARGED 9-6-91: The defendant, with the intent to mislead, failed to establish and maintain accurate batch production records—301(e). The defendant also failed to comply with current good manufacturing practice requirements in that he directed employees to manufacture a drug product following production procedures different from the process approved by FDA—301(e). He also directed employees to prepare and maintain production batch records which falsely stated that the approved mixing procedures were utilized—333(a)(2).

DISPOSITION: Guilty plea; sentenced to four months of prison, four months of parole, and ordered to pay a \$50 special assessment. (F.D.C. No. 66528; S.J. No. 10)

DEFENDANT: Steve Colton, at Springfield, N.Y. (D.Md.); Criminal No. HAR-91-0125-R.

CHARGED 4-24-91: Counts 1-3: The defendant knowingly made a false statement to FDA in that he filed a bioequivalency study claiming it compared a generic drug product to the innovator product when the generic product was disguised as the innovator product—18 U.S.C. sections 2 and 1001.

DISPOSITION: Guilty plea; sentenced to 27 months of prison, fined \$150, and debarred from providing any services in any capacity to a person with an approved or pending drug product application. (F.D.C. No. 66529; S.J. No. 11)

DEFENDANTS: Cypress Seafood Processors and Bethel Dyson, at Abbeville, La. (W.D.La.); Criminal No. CR-95-60017-01-02.

CHARGED 4-10-95: Counts 1-3: The defendants introduced adulterated food into interstate commerce—402(a)(4). The food was adulterated in that it was prepared, packed and held under insanitary conditions whereby it might have been contaminated with filth or rendered injurious to health—301(a) and 402(a)(4).

DISPOSITION: Cypress Seafood Processors, Inc., was sentenced to three years of probation and fined \$2,500. Bethel Dyson, president of Cypress Seafood Processors, Inc., was sentenced to three years of probation and fined \$3,000. (F.D.C. No. 66824; S.J. No. 12)

INJUNCTION ACTIONS

DEFENDANT: Frank Lampley, at Glenmoore, Pa. (E.D.Pa.); Civil No. 91-8023.

CHARGED 12-31-91: The defendant distributed adulterated and misbranded animal drugs in interstate commerce—301(a). The animal drugs were adulterated in that they were new drugs without an approved new drug application—501(a)(5). Some of the animal drugs were misbranded in that their labels did not contain a list of active ingredients—501(e)(1)(A).

DISPOSITION: A permanent injunction was filed and granted. The defendant appealed the decision to the U.S. Court of Appeals for the Third Circuit, which affirmed the district court's decision. (Inj. No. 1274; S. No. 90-611-703/704; S.J. No. 13)

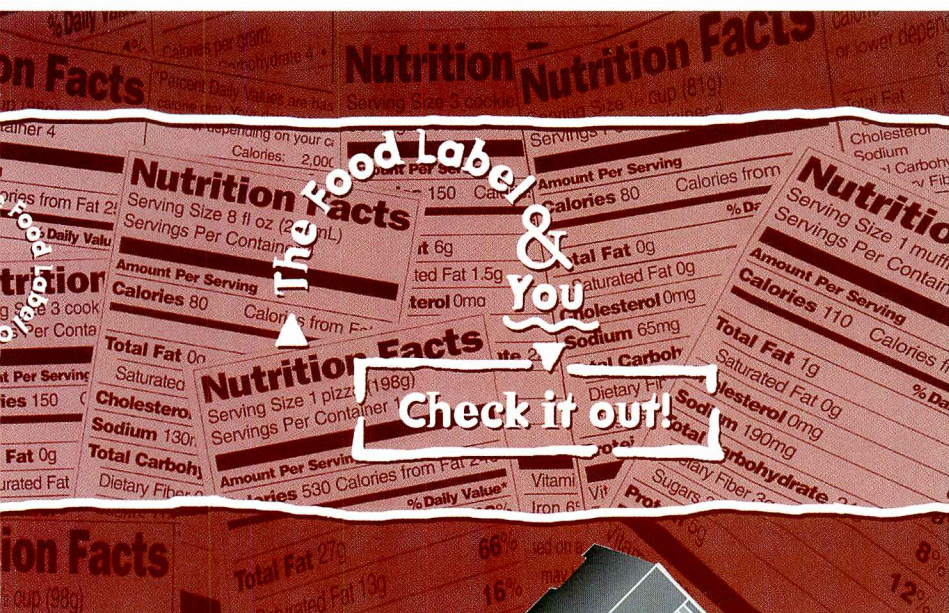
MISCELLANEOUS ACTIONS

ACTION: U.S. v. Floyd E. Weston, at Sacramento, Calif. (E.D.Calif.); Civil Action No. CR-S 93-517 GGH.

CHARGED 3-22-94: The defendant pleaded guilty to a misdemeanor count for introducing unapproved medical devices into interstate commerce. The plea agreement required the defendant to agree to a permanent injunction barring him from selling the device or homeopathic remedies—301(a).

DISPOSITION: A consent decree of permanent injunction was filed. (Misc. No. 1073; S.J. No. 14)

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