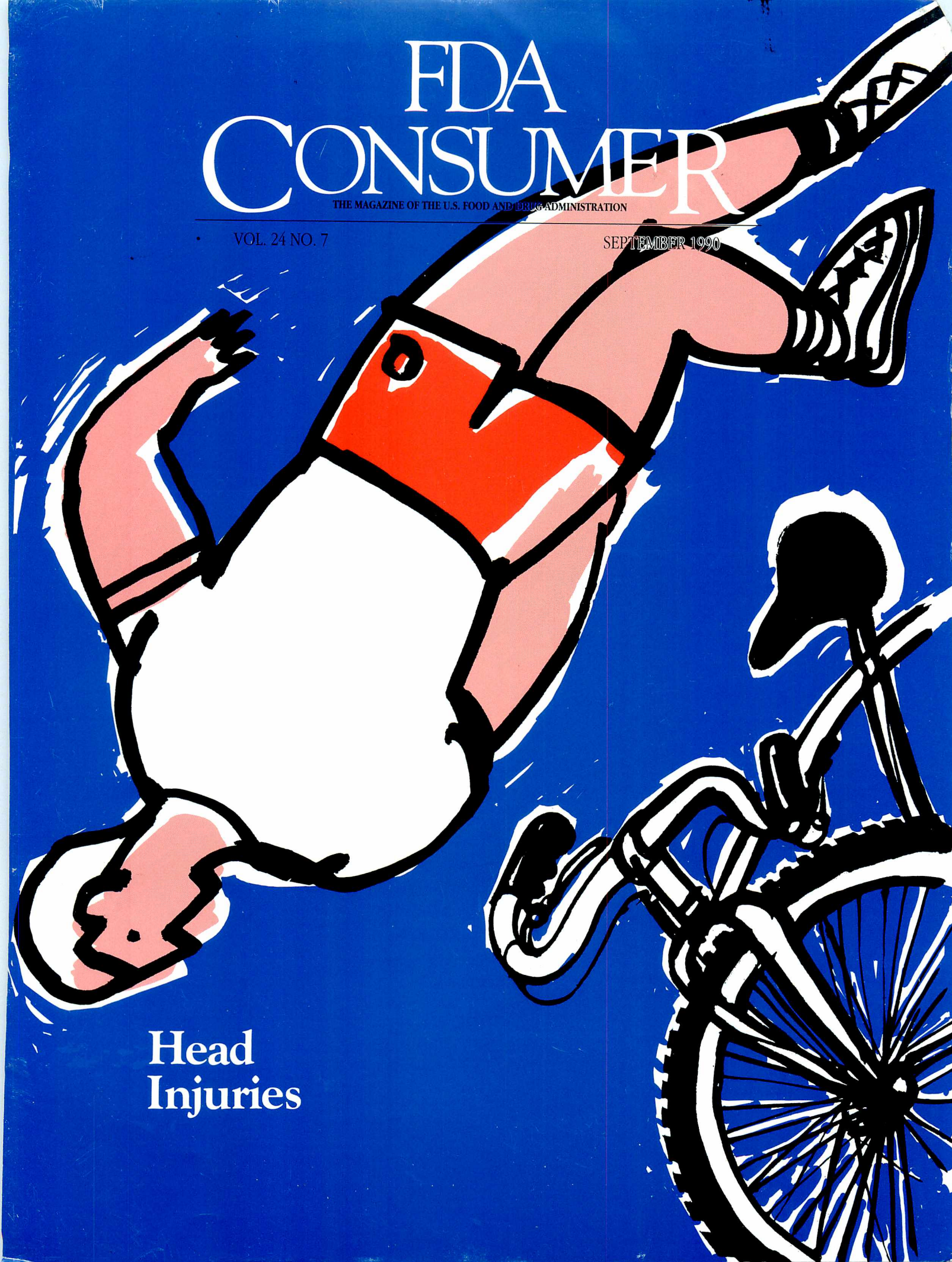
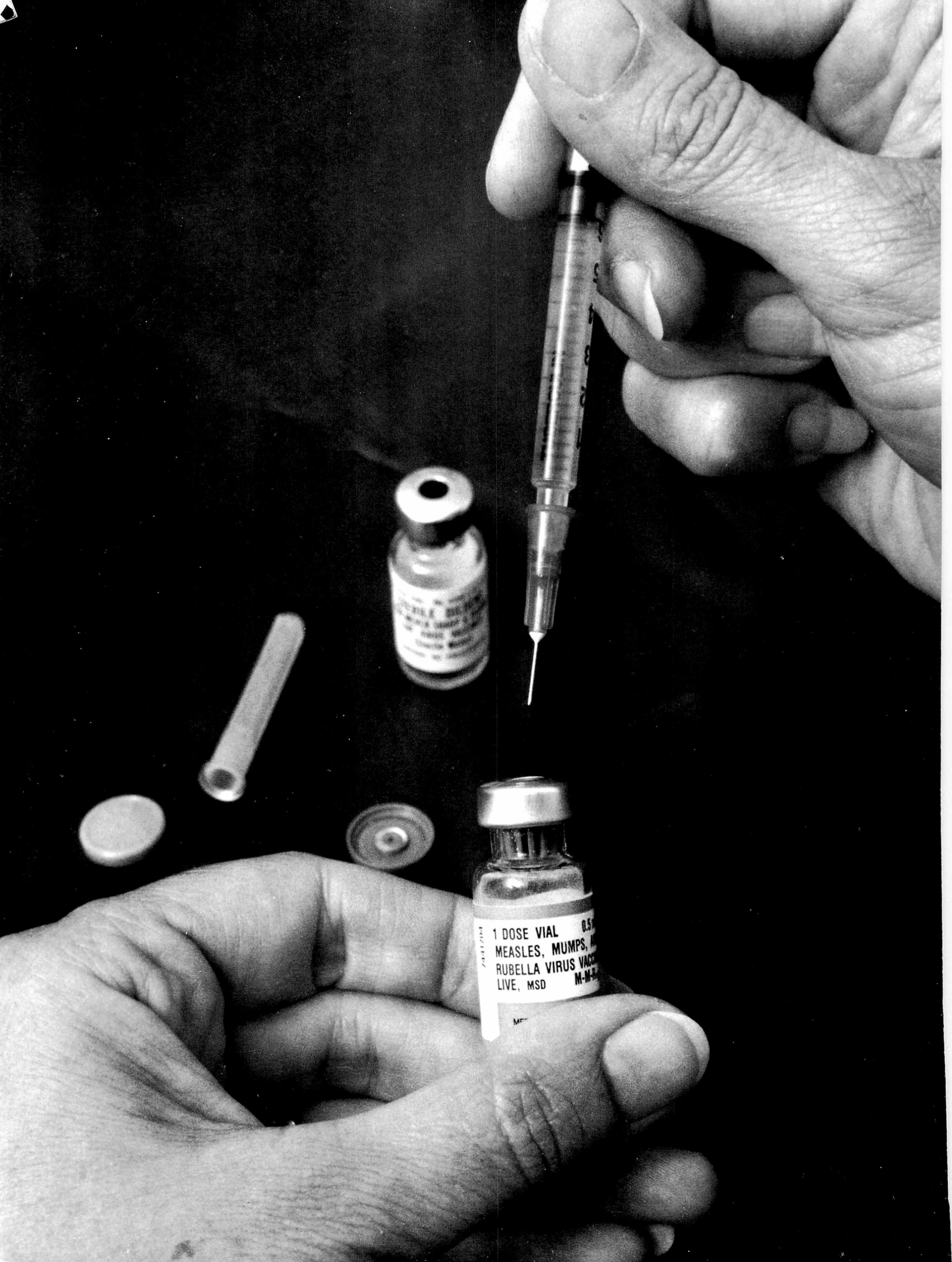
FDA CONSUMER

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

VOL. 24 NO. 7 SEPTEMBER 1990



Head Injuries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FDA CONSUMER

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

VOL. 24 NO. 7 **SEPTEMBER 1990**

Inside Front Cover Photo:

An injection of measles, mumps and rubella (MMR) vaccine—and other inoculations—may be just what the doctor oders in light of recent outbreaks of childhood diseases. For a look at the vaccines every child needs before entering school, see page 19.

New Pregnancy Warning on Aspirin

A statement warning pregnant women not to take aspirin during the last three months of pregnancy without a physician's advice will now be required on all oral and rectal nonprescription aspirin and drugs containing aspirin.

Aspirin use in late pregnancy may have adverse effects on fetal circulation and uterine contractions, causing harm to the baby and problems during delivery.

The warning will read: "It is especially important not to use aspirin during the last three months of pregnancy unless specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery."

A similar warning is already required on nonprescription products containing ibuprofen, another pain reliever that has effects similar to aspirin.

The new warning statement must immediately follow the general pregnancy-nursing warning now on aspirin labeling (as well as many other nonprescription drugs) that reads: "As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product."

FDA's decision to require the expanded label warning was based on a recommendation by the agency's Advisory Review Panel on OTC (over-the-counter) Internal Analgesic and Antirheumatic Drug Products, a group of non-government experts that evaluates data on active ingredients in these drug classes.

The regulation, published in the July 5 *Federal Register*, gives manufacturers 12 months to change their labels.

Laser for Gum Disease

U.S. dentists have access to the world's first YAG laser designed for general dentistry, following FDA's permission last May for the American Dental Laser to be marketed to treat gum disease.

In clinical trials at the University of California in San Francisco and in countries where the device is already approved, treatments in which the laser was used as a scalpel to cut soft tissue such as the gingiva and gums led to substantial reduction in bleeding and in use of anesthesia.

The laser pulses its energy in short bursts through a flexible fiber optic (an ultra-thin tube that carries a light). This design overcomes problems of destructive heat levels and inability to reach the recesses of the mouth, which confronted earlier laser inventors.

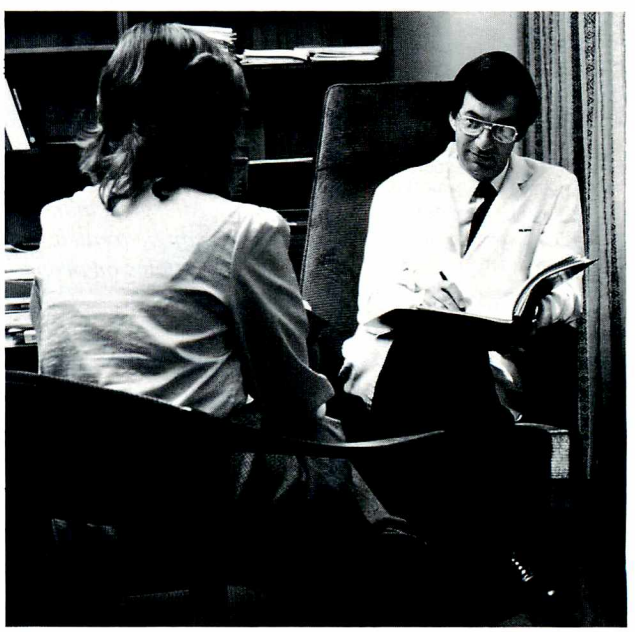
Sunrise Technologies Incorporated of Sunnyvale, Calif., developed and manufactures the instrument for American Dental Laser Incorporated, Birmingham, Mich., which owns the patents and markets it. The firms said they expect to expand the indications for the American Dental Laser to introduce new methods of treatment to dentistry and to make current procedures easier, faster, and less invasive.

(See also *FDA Consumer*: "Light for Sight: Lasers Beginning to Solve Vision Problems," July-August 1990; "Brushing Up on Gum Disease," May 1990; and "Laser Treatment to Go: Outpatient Uses of Healing Light Abound," October 1987.)

Additional Use for Tamoxifen

A drug widely used to treat breast cancer that has spread to the lymph nodes was recently approved for an additional use—to help prevent recurrence of the disease in patients in whom the cancer was confined to the breast.

FDA approved last June the use of tamoxifen citrate to help prevent recurrence of breast cancer in "node-



negative" patients—that is, those in whom the cancerous cells have not spread from the breast area to the lymph nodes under the arm.

Originally approved in 1977, tamoxifen is thought to work by blocking the effects of the hormone estrogen on tumor growth. In node-negative patients, the drug is indicated for use after lumpectomy or modified radical mastectomy. (For more information on breast cancer diagnosis and treatment, see "Progress Against Breast Cancer" in the May 1986 *FDA Consumer*.)

Breast cancer strikes 1 out of 10 American women. More than 44,000 women will die from this disease in 1990 alone, making it the second greatest cause of death from cancer in women.

Tamoxifen citrate is sold under the trade name Nolvadex by ICI Pharmaceuticals of Wilmington, Del.

New Therapy for Colon Cancer

A combination drug therapy to treat some cases of advanced, postoperative colon cancer has been approved by FDA.

Levamisole, a drug used to eliminate intestinal parasites in animals, was approved for use in combination with the cancer drug fluorouracil for patients who have undergone surgery for stage III colon cancer.

This type of cancer, also called Dukes' C colon cancer, is an advanced colon cancer that has spread to nearby lymph nodes. It is second only to lung cancer as a cause of cancer deaths.

About 21,000 of the 110,000 Americans diagnosed each year with colon cancer have stage III colon cancer. Only about 40 percent survive five years after surgery.

Scientists do not yet understand what makes the levamisole-fluorouracil combination work. But in two large clinical trials sponsored by the National Cancer Institute, use of the combination drug treatment following surgery reduced the death rate by about one-third and reduced the rate of tumor recurrence by about 40 percent. The therapy has not yet been shown effective for treating other stages of colon cancer.

The most common side effects are nausea, occasional vomiting, headache, diarrhea, sores in the mouth, and lowered blood count.

A blood disorder, agranulocytosis, also has been associated with the treatment and has caused one death among the more than 1,000 patients who received it in the NCI trials. Therefore, patients given this therapy must have regular blood tests.

Fluorouracil has been approved to treat cancer of the colon, rectum, breast, stomach, and pancreas. Levamisole has been used to treat intestinal worms in domestic animals and, until now, has been available in the United States only for veterinary use.

Levamisole was synthesized in 1966 and developed as a treatment for parasites by Janssen Pharmaceutica of Beerse, Belgium. It works by paralyzing worms so they are eliminated through the intestines.

The drug began to be studied as a cancer treatment after scientists noted interesting changes in the treated animals.

Levamisole as a treatment for advanced, postoperative colon cancer has been available since May 1989 under FDA's Treatment IND Program (through which promising but still-experimental drugs are released to certain patients under specified conditions) and through NCI's Group C cancer treatment program. More than 4,000 patients with stage III colon cancer have received the combination treatment through these programs.

An NCI-supported clinical trial is being conducted for patients with cancer of the rectum to determine if the benefits seen with the new therapy extend to rectal cancer as well.

Levamisole is manufactured by Janssen Research Foundation of Piscataway, N.J. It will be marketed under the trade name Ergamisol.

New Treatment for Bladder Cancer

A new product to treat bladder cancer was recently approved by FDA. It is for use in carcinoma *in situ* (CIS) of the bladder, a cancer that involves the cells lining the inner surface of the bladder.

The product, Bacillus Calmette Guerin Live (intravesical), or BCG Live, is made from live, weakened bacteria. It is administered in high doses directly into the bladder through a catheter.

The bacteria cause an inflammatory reaction that eliminates many of the cancer cells. The procedure is repeated once a week for six weeks and then monthly for six to 12 months. The treatment may be used alone or following surgical scraping to remove any visible tumor.

CIS of the bladder is found in 20 to 30 percent of the 45,000 cases of bladder cancer detected each year in the United States. Studies sponsored by the National Cancer Institute found that 74 percent of the patients with CIS

of the bladder improved with BCG Live treatment. The median time for recurrence of the cancer in treated patients was four years.

Flu-like symptoms such as fever, chills and nausea and discomfort related to inflammation of the bladder are the most common side effects of BCG Live therapy. However, the product labeling warns physicians to watch for and treat any spread of BCG organisms through the body; spread of the bacteria has been associated with two deaths.

BCG Live, manufactured by Connaught Laboratories Inc., of Swiftwater, Pa., will be distributed by that firm under the trade name Theracys.

Drug for Gaucher's Disease Under Treatment IND

People with Gaucher's disease, a rare inherited enzyme deficiency for which there is no cure, now have access to an experimental drug that can replace the missing enzyme. The drug, Ceredase, will be distributed under FDA's Treatment IND regulations, which allow seriously ill patients to receive promising experimental therapies before they are approved for marketing.

Gaucher's disease affects approximately 5,000 people in the United States. It occurs when the body is deficient in the enzyme that breaks down glycolipid, a chemical in the body, and increased amounts of the chemical cause the spleen and liver to enlarge. The enlarged spleen begins to destroy red blood cells, causing bleeding and anemia, as well as severe bone and joint pain and bone abnormalities and fractures. The only other treatment for Gaucher's disease is to remove the spleen. This can increase the supply of red blood cells, but it worsens the problem of metabolizing glycolipid, which, ultimately, can be fatal.

Ceredase, which will be produced by Genzyme Corporation in Boston, is prepared using human placenta. The product is difficult and expensive to produce, and supplies will be very limited the first year, costing $20,000 to $60,000 per patient annually. Additional information is available from Genzyme at 616-451-1923.

Shiley C-C Heart Valve Alert

People with Bjork-Shiley 60° C-C (Convexo-Concave) heart valves and those in their households should be aware of the symptoms of valve failure, according to a letter Shiley Inc. sent last March to physicians and emergency room workers.

The letter was based on a report in the May 1988 *Journal of the American College of Cardiology* by Loren Hiratzka, M.D., and others—an independent panel Shiley had convened to evaluate its C-C valves. As a result of strut fractures, Shiley took its larger C-C valves off the market in October 1985 and withdrew the smaller sizes in November 1986. (See "Shiley Ends Sale of Heart Valve" in the Updates section of the February 1987 *FDA Consumer*.)

Although strut fractures are quite rare, they can occur without warning and are life-threatening. Patients may notice a change or absence of valve sound. Signs and symptoms may be similar to those of congestive heart failure, heart attack, and other cardiac conditions: shock, low blood pressure, sudden and rapidly progressive breathing difficulty due to severe fluid accumulation in the lungs, chest pain, irregular heartbeat, and impaired or loss of consciousness.

Patients and household members should know which hospitals can perform emergency valve replacement. Patients are advised to carry their implant card in wallet or purse and to wear a medical alert bracelet or similar article containing implant information.

Shiley told physicians that chest x-rays can help diagnose problems but that echocardiography or fluoroscopy may also be needed. A malfunctioning valve should be immediately replaced. However, removal of a valve in the absence of signs of malfunction is not advised because the risk posed by replacement surgery is far greater than the risk of strut fracture. According to the letter, the annual risk of fracture ranges from about 2 valves per 10,000 to about 29 per 10,000, depending on the size and date of manufacture. The risk of death from elective reoperation is likely greater than 5 out of 100.

(For information about other heart valves, see "Cardiovascular Spare Parts" in the May 1990 *FDA Consumer*.)

Alar Vanishing

Alar, the growth regulator that stirred a controversy last year among consumers, has been practically eliminated from the food supply. In a February 1990 issue paper, FDA stated that residues of daminozide (the chemical name for Alar) are "substantially below tolerance when present, and are decreasing rapidly."

The results of FDA's continued surveillance of daminozide, once widely used on apples, confirm a June 20 report from Consumers Union that tests showed no detectable daminozide in three-quarters of apples analyzed and only faint traces ("too low to cause concern") in the remainder of apples sampled from around the country.

In September 1989, EPA proposed phasing out permissible levels of daminozide in apple products over a two-year period, culminating with a ban taking effect in June 1991. Uniroyal, the sole manufacturer of daminozide products registered for food use, withdrew the chemical from the market in June 1989.

Alar became an urgent consumer concern following 1989 media coverage that represented the growth regulator as a severe cancer threat to children. EPA had been reviewing the safety of daminozide for years before the media coverage and had reduced the tolerance level on apples in 1987. The consensus was that using daminozide at the reduced levels until scientific studies were completed did not pose a health risk.

FDA monitoring continued to show throughout the 1980s that daminozide residue levels were much lower than the tolerance permitted.

Agency Reviews Comments On OTC Ingredient Ban

Public comments on FDA's proposal to ban 258 ingredients in 21 classes of nonprescription drugs are being reviewed by the agency.

The ingredients, used to treat a variety of conditions from acne to warts, have not been proven effective, the agency said.

Although still considering public comments, FDA has closed the book on scientific data. The agency said it has given manufacturers numerous opportunities to prove the ingredients are effective, but has not received any significant comments.

Many of the products containing the ingredients in question have already been voluntarily removed from the market by their manufacturers or reformulated with other ingredients.

FDA is also planning to propose by the end of the year a similar ban on more than 100 ingredients used in nonprescription diet or appetite-suppressing drug products.

Although the ban on the 258 ingredients would not go into effect until six months after the final rule is published in the *Federal Register*, the agency said it will urge manufacturers who are still marketing these ingredients to comply with it voluntarily as soon as possible.

Ingredients affected by the proposed ban include some used for allergies, boils, colds, corns and calluses, dandruff, digestive problems, ingrown toenails, constipation, oral health problems, pain, psoriasis and other skin problems, nail-biting, thumb-sucking, smoking addiction, and swimmer's ear.

Some of the ingredients have been banned for some uses, but not for others in which they are safe and effective. For example, under the proposal, aspirin would be banned as an external (topical) analgesic ingredient, yet could continue to be sold in the more familiar oral dosage form for pain relief.

The current action was taken to speed up FDA's massive review of all ingredients in some 300,000 nonprescription drug products, begun in 1972.

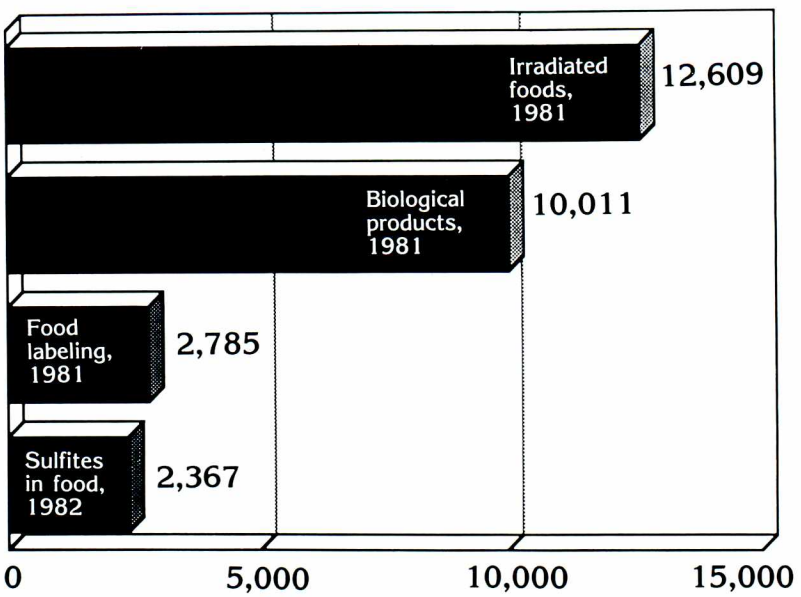
Since that review was initiated, FDA has proposed or finalized the labeling and acceptable ingredients for 66 drug groups. Ingredients identified as potentially harmful have been removed from the market.

Comment on Proposed FDA Regulations* in the 1980s

Proposals come and proposals go, but few have sparked the level of interest that these four did when issued in the early 1980s.

The irradiated foods proposal set up specific regulations for irradiating foods. The biological products proposal offered new procedures for reviewing the safety and effectiveness of biological products, such as vaccines and allergenic extracts. However, consumers feared the procedures would be used to remove many allergy tests and injections from the market. The food labeling proposal set up guidelines for listing sodium and potassium content and for defining sodium-related terms on food labels.

None of these topics, however, came close to equaling the all-time comment-getter, the 1978 proposed saccharin ban, which drew over 80,000 comments.



Starting with year of introduction.

Consumer Forum

Ambiguity Clarified

I am writing in response to the note by Stewart M. Brooks, "Ambiguity in Anesthesia Article" in the May 1990 issue of *FDA Consumer*.

Mr. Brooks' interesting letter, while illuminating in terms of Priestley's contribution to both chemistry and medical (pharmacologic) practice, did not clarify the ambiguity to which he referred.

The original quote from Vern Modeland's "Modern Anesthesia: Going Under Safely," as quoted by Brooks as ". . . oxygen and nitrous oxide to support life . . .", was never really clarified by Brooks. To state the case clearly and simply: *oxygen supports life, nitrous oxide does not.*

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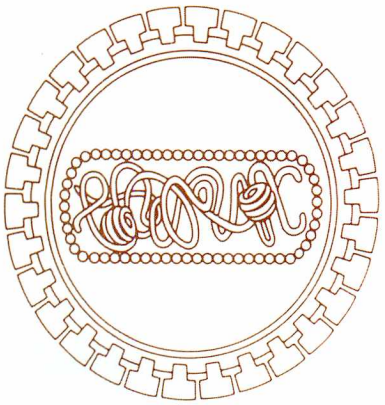
University of Kansas Medical Center
Kansas City, Kansas

Progress Reports in the Battle Against Acquired Immune Deficiency Syndrome



Parallel Track Proposed

The Public Health Service has proposed speeding the availability of investigational new drugs for people with AIDS and other HIV-related conditions by means of a "parallel track" mechanism.

Usually, new drugs are tested in a series of trials to determine their safety and effectiveness. These trials may take years to complete.

The new PHS plan would permit promising investigational drugs to be made available to selected patients at the same time that efficacy trials begin. Drugs approved for the parallel track would be made available through a special protocol for persons with HIV infection who:

- have no treatment alternatives
- have an immediately life-threatening disease
- cannot participate in the controlled clinical studies.

James O. Mason, M.D., Dr.PH., assistant secretary for health, pointed out that while the program has the potential to prolong and even save lives, it is not a substitute for controlled clinical trials. He said that sufficient safeguards are built into the mechanism "to ensure that it neither compromises the drug approval and clinical trials process nor delays the speedy delivery of promising investigational agents from the laboratory to the bedside."

Over the last several months, FDA has implemented other programs to speed up clinical trials and the approval process, especially for therapies for patients with life-threatening illnesses, including AIDS. Although the regulation proposed in May limits the parallel track mechanism to people with AIDS or HIV-related disease, PHS also asked for comments on whether the mechanism should be extended to include drugs for other life-threatening illnesses.

New Study for ddC

A new study to test the safety of the experimental anti-AIDS drug ddC (dideoxycytidine) has been sanctioned by FDA.

This protocol allows access to ddC for patients with AIDS or advanced ARC who can tolerate neither zidovudine (commonly called AZT), the standard treatment, nor dideoxyinosine (ddI), an experimental anti-viral drug currently available to certain patients through clinical testing and expanded access protocols. In addition, patients who have had progression of disease while on AZT and who were also ddI intolerant will be given ddC.

AZT can cause severe anemia and low white blood cell counts, while ddI may cause gastrointestinal problems, painful nerve damage to the feet (peripheral neuropathy), and, less commonly, severe and potentially fatal damage to the pancreas.

The new study will initially enroll approximately 25 patients, who will be given one of two doses of ddC in order to compare the relative safety of the dosage regimens and derive some information about effectiveness. The study is designed so that more patients can enroll as information about the safety of the drug accumulates.

Hoffmann-La Roche Inc. of Nutley, N.J., the manufacturer of ddC, will provide the drug free to physicians with enrolled patients.

Physicians wishing to enter a patient in this study may call toll-free, 1-800-ddC-2HIV, Monday through Friday, from 9 a.m. to 8 p.m., Eastern Standard Time.

Isoprinosine for HIV Needs More Study

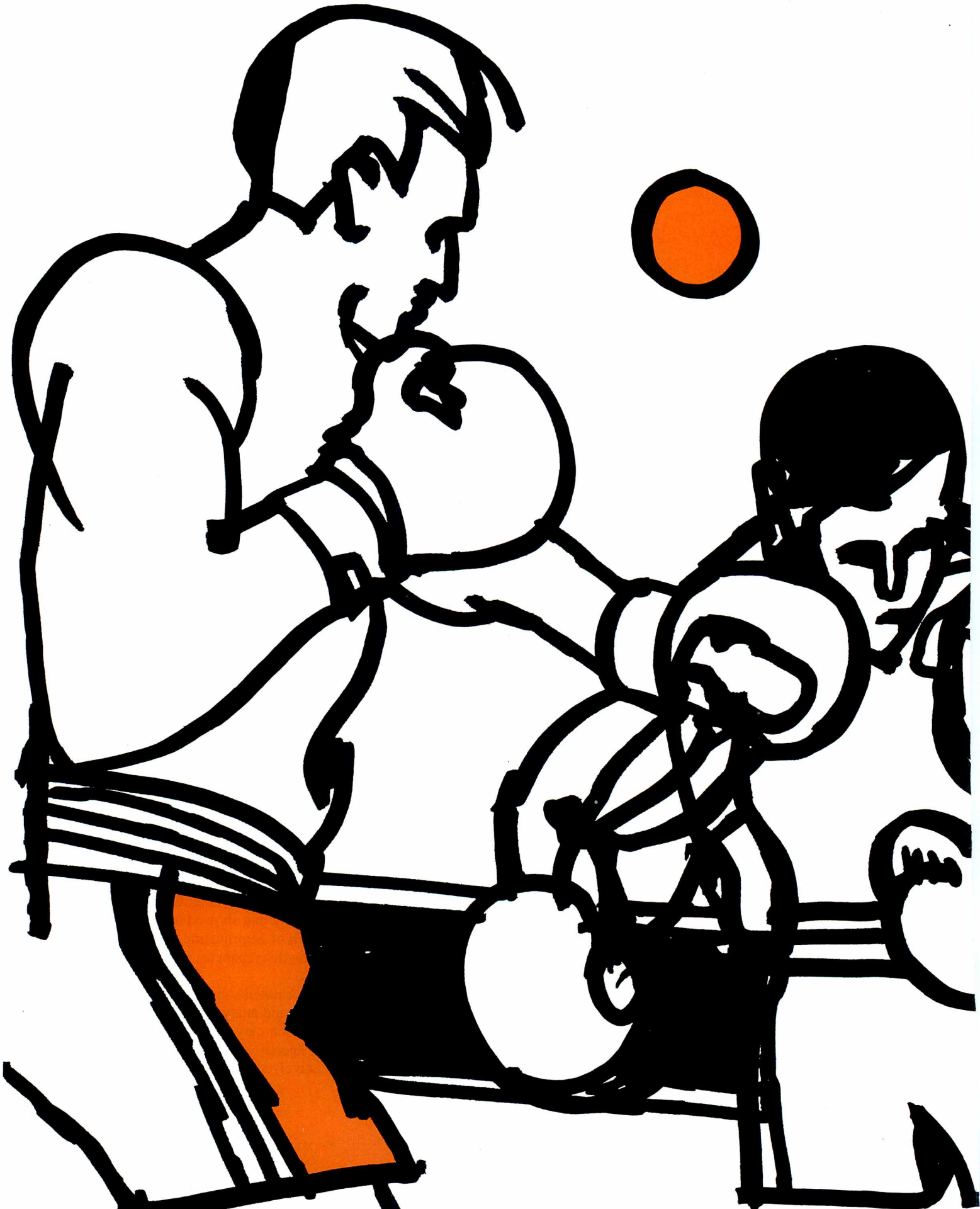
After reviewing a recent journal report describing use of the experimental drug isoprinosine to treat patients infected with the AIDS virus (HIV), FDA concluded that more studies are needed to determine its value to patients.

A Scandinavian study, reported in the June 21 *New England Journal of Medicine*, indicated that the immune system modulator isoprinosine significantly slowed disease progression. According to the report, of the 866 HIV-infected patients in the study, those given isoprinosine were significantly less likely to progress to AIDS than patients given the placebo. During the 24-week trial, 17 patients on placebo developed AIDS as opposed to two patients given isoprinosine.

Previous studies of isoprinosine for HIV-infected patients, however, showed no significant effect in slowing disease progression, and FDA's division of antiviral drug products believes additional clinical testing of the drug is needed. Recommended tests could incorporate approved therapies for preventing *Pneumocystis carinii* pneumonia and anti-viral treatments to determine how isoprinosine might be best used if proven effective.

The drug's sponsor, Newport Pharmaceuticals Inc. of Laguna Beach, Calif., is currently reanalyzing data from an earlier study that showed no significant benefit of isoprinosine in order to evaluate the discrepancies in results of the two trials.

FDA noted some concerns about the design and analysis of the Scandinavian study that may have affected the results. The agency also noted that 24 weeks is a relatively short study period.



Head Injuries Require Quick, Skilled Care

by Dixie Farley

American deaths from head injury since 1977 exceed the total of war dead from all U.S. battles, including the Revolutionary War. Yearly, head injury creates 5,000 cases of seizure disorders, leaves up to 90,000 victims permanently disabled, puts 2,000 humans into a vegetative existence, and claims as many as 100,000 lives, including 10 of every 100,000 children.

And, in the 15 seconds it took to read those statistics, another head injury occurred.

Most likely it was a young man, for his risk is more than twice that of a woman. Most likely it was from a motor vehicle accident, for mishaps involving cars, motorcycles and other vehicles account for half of all head injuries.

The annual tally of head injuries is conservatively estimated to be over 2 million, with 500,000 requiring hospital admission.

Emergency!

In a 1986 report published by the National Head Injury Foundation (a nonprofit advocacy group), Thomas Kay, Ph.D., of New York University Medical Center defines moderate to severe head trauma as clearly serious, often life-threatening, with obvious disability and need for specialized treatment. In other words, an emergency.

"Head trauma? We put a neck collar on. We always suspect spinal injury," says Burton Conway, emergency medical technician on weekends in rural Virginia and medical physicist during the week at the Food and Drug Administration's Center for Devices and Radiological Health (CDRH).

It's a good idea for anyone to learn first-aid, including cardiopulmonary resuscitation. The American Heart Association and the Red Cross offer classes.

To someone at the scene of an accident involving a potentially serious head injury, particularly if that person is untrained, Conway cautions:

- *Never risk spinal injury by moving the head-injured victim unless there's immediate danger, such as a fire.*
- *Never stem the flow of fluid from the nose or ears, which may be from the brain, as this can inflict damaging pressure on the brain.*
- *Never remove an object penetrating the skull, as this can cause massive bleeding.*

"Get professional help right away," he says.

Emergency protocols vary from state to state. In the unique state-wide Maryland Emergency Medical System, a 911 call reaches a "central alarm" communications center, one per county, that can dispatch ambulances from local fire departments and request a "medevac" helicopter. Maryland has eight helicopter bases and 11 trauma centers. Ambulances are staffed by emergency medical technicians, cardiac rescue technicians, or emergency medical technician paramedics, depending on the need. The helicopters carry paramedics able to provide the highest level of pre-hospital care.

Ameen Ramzy, M.D., who directs emergency medical services for Maryland, says the technicians arriving at the scene quickly assess injuries, determine where the patient should go, and begin radio communications with the receiving center. They start an intravenous line, administer fluids in case of shock, and may also apply medical anti-shock trousers to temporarily increase blood pressure.

"The emphasis," Ramzy says, "is rapid assessment, rapid evacuation, establishing and maintaining an airway—with a tube down the throat, if needed—and administering oxygen."

He stresses that severely injured patients should reach definitive care, not just the closest hospital, within an hour from injury—an interval some call the "golden hour."

The Trauma Center

"A young man we received today was injured in a car crash—an unbelted passenger," says Walker Robinson, M.D., acting chief of the University of Maryland's neurotrauma unit in Baltimore. "He's unconscious, unresponsive, and has rapid pulse. He's not moving his arms or legs and is gasping for breath. We've got shock, maybe from bleeding, problems with the chest, and a broken neck."

The first person who sees him, says Robinson, is a traumatologist, a surgeon experienced in treating accident injuries, who leads the trauma team in looking at the patient "to try to determine which bit and piece isn't working right."

Quickly, they measure vital signs such

Paramedics rush a head injury victim transported by helicopter to state-of-the-art trauma care at the R. Adams Cowley Shock Trauma Center in Baltimore. *(Photo courtesy of the Maryland Institute for Emergency Medical Services Systems)*

as heartbeat and blood pressure and place electrodes on the skin to attach lines to cardiac and other monitors. They set up life-support measures such as mechanical breathing (ventilation) and blood replacement to reduce the risk of imminent death. Seeing the young man has head injury, they consult the unit's neurosurgeon: Robinson.

A thorough physical examination follows. Systematic testing of reflexes determines the patient's level of consciousness—"the most important factor in evaluating a head-injured patient," says Robinson.

The computed axial tomography (CAT or CT) scan is the gold standard diagnostic radiological procedure (see also "What About Skull X-Rays?" on page 13) for head injury because it depicts the critical soft tissue of the brain so well.

(CT scans produce mathematically computed cross-sectional images of the brain's soft tissue. CT uses an x-ray tube but provides much more information than ordinary x-rays. CDRH regulates the instruments as medical devices and as radiological equipment. For more on imaging techniques, see "A Primer on Medical Imaging, Parts I and II" in the April and May 1989 issues of *FDA Consumer*.)

Robinson looks to CT scans and other diagnostic tests to explain why the brain isn't working right. There may be a blood clot (hematoma) or a depressed fracture pushing on the brain, which requires surgery. Quite commonly, he says, "we don't find anything to operate on but see evidence of damage, such as contusion, or bruise, on the brain."

Early Diagnosis Essential

Early recognition of the extent of damage is vital to survival and to immediate appropriate care. Indeed, the risk of dying increases tenfold when there's more than a four-hour delay of needed brain surgery. Some studies indicate any delay is harmful, for injured neuron cells in the patient's brain are easily killed by lack of oxygen, and the brain cannot long endure shifting fluid or tissue.

Once the diagnosis is made, critical care may go on for weeks or months to prevent further damage.

"When there's evidence that a patient has increased intracranial pressure—pressure in the skull—it is critical that the pressure be brought down," says Russell Katz, M.D., deputy director, neuropharmacological drug division at FDA's Center for Drug Evaluation and Research. "One way to do that is to place the patient on a respirator and artificially hyperventilate the patient."

This rapid breathing reduces the blood carbon dioxide content, he says, causing vessels in the brain to constrict and become smaller. The resultant decreased volume of tissue in the skull can help mitigate the effects of a major unsolved problem caused by head trauma: brain swelling.

"The swelling brain presses harder and harder against the rigid skull, which causes dysfunction of the nerve cells," he says. "In a worst case, the brain begins to herniate down to the brain stem, at the top of the spinal column. The brain stem controls the vital functions, so when the brain starts pushing on it, the person may stop breathing, go into cardiac arrest, lose consciousness, and, if the herniation goes unchecked, die."

Management of Brain Swelling

Modern management of brain swelling often requires continuous monitoring of pressure inside the skull, says Robert Munzner, Ph.D., who heads CDRH review of neurological devices such as electronic brain pressure sensors. The sensor is placed on the surface of the brain through a small hole drilled in the skull.

"But the physician needs to know the cause of increased pressure," he says. "For instance, a hole may be drilled in the skull to drain the blood from a large hematoma causing excessive pressure on the brain surface. Or, a catheter may be inserted into the interior of the brain to drain excess fluid, providing a connection for use also in measuring the pressure."

Other methods to reduce brain swelling include elevating the head to encourage blood to drain and giving diuretic drugs such as mannitol or Lasix (furosemide) through a vein.

If those measures fail, in a practice that is not uncommon Robinson may administer the barbiturate pentobarbitol to induce barbiturate coma. Though the physician labeling does not specifically list this use, it is a life-saving step that reduces pressure in about half the cases. It can cause liver damage and depress heart function, however, so it's only used in extreme cases, he says.

Early care includes follow-up CT scans as indicated to check for post-injury blood clots. Magnetic resonance imaging (MRI) may be used if it's available. MRI uses a large magnet and, like CT, produces computer-generated, cross-sectional pictures of the brain.

Anticonvulsant medication such as Dilantin (phenytoin) may be given to prevent seizures, and the body's chemical,

Causes of Head Injuries

Motor vehicle crashes **50%**

Assaults and violence **12%**

Falls **21%**

Sports and recreation **10%**

Other causes **7%**

fluid and nutritional balance is maintained. A plastic water-filled blanket can be temperature-regulated to heat or cool the patient, who may be left unclothed to provide total access and observation.

Thanks to increased knowledge about the brain, more accurate diagnosis, and earlier, aggressive care, 60 percent of head injury victims survive—compared with only 10 percent 25 years ago.

When patients become stable, they usually go to a regular bed in the hospital and then home or to a rehabilitation facility. About 1 percent require a chronic-care institution, says Robinson.

Coping with Coma

Rehabilitation should begin as early as possible to provide controlled stimulation and prevent further complications, even when the person is in coma, according to Beverly Whitlock, director of Head Injury Services in Gaithersburg, Md.

"There are many levels of coma, and nonresponsiveness is not always consistent and across the board," she says. "When impairment is primarily to the motor system, the person still mentally takes things in. Also, recovery from coma is a very slow process. It's not like on television where the hero wakes up before the end of the show and returns to his job as vice president of the firm. Rather, you may get nondirected motion, occasional response, some eye opening."

The survivors' cognitive (perceiving, thinking, remembering), behavioral, and physical disabilities can mean years of hopelessness and anguish, for neither medical science nor rehabilitation offers complete cure. The person is changed. Personality alteration, lack of inhibition, poor judgment, and impaired social perception can drive loved ones and their needed support from the patient, even to the point of family breakup—which is far more likely over a cognitive or behavioral handicap than a physical one. Financial ruin is not unusual.

Still, the brain continues healing for years, and medicine can support the body along the way while fine-tuned rehabilitation helps the person compensate for losses and accommodate the new self.

"The family should learn as much as possible about the problem," says Whitlock. "Otherwise they misunderstand some things that are going on and may begin to feel the person is having an emotional problem when it's really very organic."

She recommends getting in touch with the state head injury foundation or the National Head Injury Foundation for information and referral. Whitlock stresses that head injury rehabilitation requires professionals with special training in dealing with head injury patients. Since injuries vary, it's wise to keep close to the treatment team for specific advice, she says.

Head Injury Task Force

Responding to concern by Congress about head injury, the U.S. Department of Health and Human Services early in 1988 formed a federal task force of members from 13 agencies. Gordon Johnson, M.D., director of health affairs at CDRH, represents FDA.

"We were asked to identify gaps in all aspects of head injury," says Johnson, "and to make recommendations about how best to fill those gaps if funding were made available."

In February 1989, the group reported

(Continued)

Prevention: The Sure Cure

"In a very real sense, head injury is a social disease," says Russell Katz, M.D., deputy director of FDA's division of neuropharmacological drugs. "People drive drunk, don't use seat belts, shoot each other, or don't protect themselves with headgear in high-risk activities. If the social disease were 'treated,' then the head injury—the medical problem—would largely be prevented."

Common-sense measures to reduce head injuries are:

• Wear a helmet when:

Riding a motorcycle. Riders without helmets increase their risk of head injury two to four times and their risk of death three to nine times.

Riding a bicycle. Bicyclists are at greater risk of head injury than motorcyclists—in part, because they tend to land on the head while motorcyclists usually hit another part of the body first. Head injury causes 75 percent of the approximately 1,000 bike-related deaths that occur each year, according to the May 1990 *Consumer Reports*. The report evaluated various brands of bike helmets, noting that helmets can prevent 85 percent of bicyclists' head injuries.

Performing other high-risk activities, such as construction work, boxing, football, and rock climbing.

• Don't drink and drive.

• Use seat belts and approved infant and child restraint seats in automobiles.

• Keep infants and young children from open, unguarded windows.

• Don't leave youngsters unattended in highchairs, strollers, buggies, or walkers.

• Supervise children playing with projectile-type toys such as BB guns and archery sets.

• Pay close attention when using nailing machines and power staplers. The force can drive a nail or staple through a thin wall or board, making it a flying missile that could pierce the skull.

• Only use ladders in good condition. Match the length to the job, use stepladders opened, and prop straight or extension ladders against solid support. Face the ladder when using it.

• If you're an older person, make your environment as safe as possible. Remove scatter rugs, use a slip-proof tub mat, ensure stairways are well-lit, keep outdoor steps and walks safe from snow and ice, and hold onto handrails at stairways and in the tub or shower.

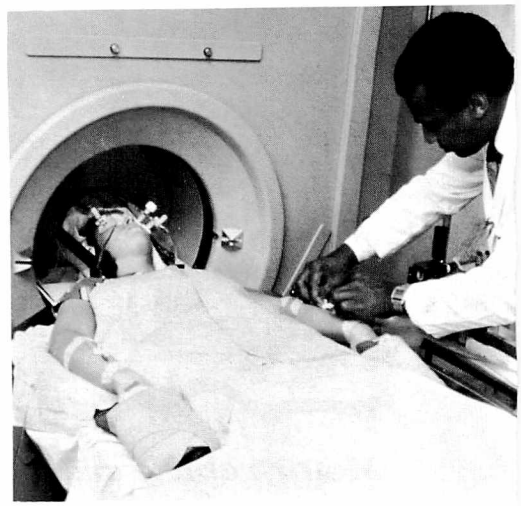
• Sidestep assault. If you jog in an isolated area, take along a partner. Keep the car doors locked. Instead of confronting a suspected burglar, leave the house and call the police from a neighbor's. ■

—D.F.

the need for research in every area: prevention, basic biology, treatment, rehabilitation, and community services. It recommended that the government institute a "traumatic brain injury" category in reporting systems, designate a lead federal agency and establish an advisory group, encourage state and local participation, create a national network of 15 head injury research centers, organize a treatment system tied into the centers, and study and document financial issues.

While the task force was developing its recommendations, the U.S. Department of Education's National Institute of Disability and Rehabilitation Research was setting up five model research and demonstration systems for brain injury at: Baylor College of Medicine in Houston, Medical College of Virginia in Richmond, Mount Sinai Medical Center in New York City, Santa Clara Valley Medical Center in San Jose, Calif., and Wayne State University Medical Center in Detroit.

"At an annual cost of $1.5 million, the programs are now fully operational and provide rehabilitation research and comprehensive services from emergency care, through long-term rehabilitation, to re-entry into the community," says J. Paul Thomas, Ph.D., the institute's director of medical sciences and task force member.



A researcher at the National Institute of Neurological Disorders and Stroke prepares a patient for a brain scan with positron emission tomography to find out how injury might affect brain function. The institute is the lead federal agency investigating brain trauma. *(Photo courtesy of National Institute of Neurological Disorders and Stroke)*

Minor Head Injury

Older people are particularly susceptible to head injury that may go unnoticed, says Mark Schapiro, M.D., chief of the brain aging and dementia section of the National Institute on Aging. Not only are falls more likely because of failing eyesight, reduced agility, and degenerative disorders such as Parkinson's disease, but also the chance of brain injury from a fall increases in the elderly because the brain shrinks with age.

"The shrinking stretches the tiny blood vessels between the brain and skull," Schapiro says. "If one tears, blood collects, pressing on the brain. This happens in anyone, but to a greater degree in older people, especially the very old, because the vessels are already strained." Tearing can occur from a fall or when the brain jars back and forth against the inside of the hard skull, as in whiplash in a car accident.

Twenty years ago, Schapiro says, many elderly people with minor head injury went undiagnosed, though they probably had headaches and might even have seemed senile.

"Today, if we suspect a blood clot because an older person complains about a

What About Skull X-Rays?

When it comes to diagnosing damage due to head injury, many physicians and most patients attach great importance to the detection of a skull fracture, says Philip M. McClean of FDA's Center for Devices and Radiological Health (CDRH).

"It's not unusual," he says, "for a physician to order an x-ray series because of pressure to do so by a parent or patient or because of fear of malpractice litigation."

But simple skull x-rays can't directly show intracranial injury because they don't depict the soft tissue. Further, McClean says, clinical studies show that without signs of nerve damage, discovery of a skull fracture usually doesn't affect treatment.

For these reasons, in 1979, CDRH convened a panel of experts representing family practice, pediatrics, neurological surgery, emergency medicine, and radiology to assess the value of skull x-rays following head injury and to develop a management strategy. McClean coordinated the study, which reviewed the records of more than 7,000 head injury patients. The findings were published in *The New England Journal of Medicine*, Jan. 8, 1987.

Among low-risk patients (those without symptoms or with only headache, dizziness, or a superficial scalp injury), the panel found that not a single intracranial injury had been discovered. They concluded that no such injury would have been missed by excluding skull x-rays for low-risk patients.

The panel recommended that low-risk patients be discharged under 48-hour observation by someone at home, as explained in a take-home instruction sheet. Typically, a "head" sheet lists symptoms requiring the patient's immediate return to the hospital, such as unusual drowsiness, confusion, persistent vomiting, blurred vision, neck stiffness, unrelenting headache, bleeding or fluid leakage from ears or nose, leg or arm weakness, convulsions, or unequal size of pupils.

The recommended strategy calls for withholding radiographic imaging unless additional symptoms develop. Should the physician deem the injury to be more than trivial despite the presence of solely low-risk criteria, the panel agreed patients may be reassigned as moderate risk or high risk, usually warranting computed tomography radiological examination, consultation with a neurosurgeon, and possibly supportive skull x-rays.

CDRH has made these criteria available to emergency departments throughout the country. ■

—D.F.

persistent headache, we can look for it with the CT scan," he says. "A good example is when former President Ronald Reagan fell from a horse last year. During a later medical checkup, a CT scan showed a collection of blood, which they drained, and he recovered."

In minor head injury, patients often spend little or no time in the hospital, make quick medical recovery, and are discharged without a perceived need for formal rehabilitation, according to New York researcher Kay.

But even though there may not be obvious problems, there may nevertheless be injury, such as widely scattered stretching or tearing of the brain's nerve fibers. This diffuse injury doesn't cause specific deficits such as language problems but results in a general disruption of the overall speed, efficiency, execution and integration of mental processes, Kay wrote.

"I'm convinced that everybody who gets hit on the head has some brain damage," says CDRH's Johnson. "Repeated injuries, such as a boxer receives, add up over time to cause some damage to some cells. This is true even if he's never knocked unconscious. But usually the damage is so small, microscopic or submicroscopic, there's no simple way to detect it."

To assess various kinds of damage, including minute damage not indicated by CT scans or MR imaging, researchers are investigating regional brain blood flow with nuclear scanning techniques: single photon emission computed tomography (SPECT) and positron emission tomography (PET), Johnson says.

(A radionuclide drug is given and tracked in blood through the brain by a scanner, which produces a cross-section or 3-D image. SPECT and PET are regulated by both CDRH and the Center for Drug Evaluation and Research, the latter taking the lead since it regulates the drugs.)

"If brain blood flow is less in one person than another, we don't really know what that means," Johnson says. "But if we measure a person one year, and then measure again at a later date and identify changes, that may be significant."

According to New York researcher Kay, the most effective handling of minor head injury is to educate the injured person and the family before discharge. He urged that patients be carefully evaluated and informed of the likely scenarios, not only for physical symptoms and recovery but also for cognitive, emotional and behavioral symptoms and recovery.

Dr. Judith Middleton of Tadworth's Court Children's Hospital in Surrey, U.K., wrote recently in *Journal of Child Psychology and Psychiatry* that when problems arise—whether behavioral, emotional or mental—"it might be salutary to ask routinely whether children have had a past blow to the head."

The accompanying article "Prevention: The Sure Cure" gives practical tips to prevent head injury. ■

Dixie Farley is a staff writer for FDA Consumer.

For More Information

American Speech-Language-Hearing Association
10801 Rockville Pike
Rockville, Md. 20852
301-897-5700

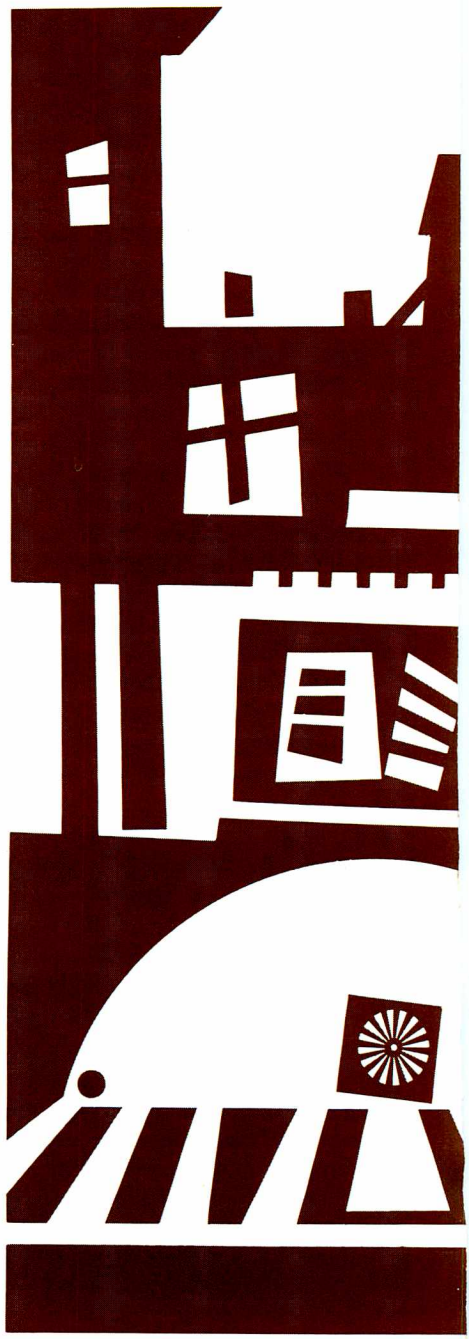
National Easter Seal Society
70 East Lake St.
Chicago, Ill. 60611
312-726-6200

National Head Injury Foundation
333 Turnpike Road
Southborough, Mass. 01772
1-800-444-NHIF

The Canning Process

Old Preservation Technique Goes Modern

by Dale Blumenthal



The steamboat Bertrand was heavily laden with provisions when it set out on the Missouri River in 1865, destined for the gold mining camps in Fort Benton, Mont. The boat snagged and swamped under the weight, sinking to the bottom of the river. It was found a century later, under 30 feet of silt a little north of Omaha, Neb.

Among the canned food items retrieved from the Bertrand in 1968 were brandied peaches, oysters, plum tomatoes, honey, and mixed vegetables. In 1974, chemists at the National Food Processors Association (NFPA) analyzed the products for bacterial contamination and nutrient value. Although the food had lost its fresh smell and appearance, the NFPA chemists detected no microbial growth and determined that the foods were as safe to eat as they had been when canned more than 100 years earlier.

(Continued on page 16)


HONEY
PEACHES

More than 1,500 different foods come in shelf-stable cans.
(Photo courtesy of the Canned Food Information Council)

The nutrient values varied depending upon the product and nutrient. NFPA chemists Janet Dudek and Edgar Elkins report that significant amounts of vitamins C and A were lost. But protein levels remained high, and all calcium values "were comparable to today's products."

NFPA chemists also analyzed a 40-year-old can of corn found in the basement of a home in California. Again, the canning process had kept the corn safe from contaminants and from much nutrient loss. In addition, Dudek says, the kernels looked and smelled like recently canned corn.

The canning process is a product of the Napoleonic wars. Malnutrition was rampant among the 18th century French armed forces. As Napoleon prepared for his Russian campaign, he searched for a new and better means of preserving food for his troops and offered a prize of 12,000 francs to anyone who could find one. Nicolas Appert, a Parisian candy maker, was awarded the prize in 1809.

Although the causes of food spoilage were unknown at the time, Appert was an astute experimenter and observer. For instance, after noting that storing wine in airtight bottles kept it from spoiling, he filled widemouth glass bottles with food, carefully corked them, and heated them in boiling water.

The durable tin can—and the use of pottery and other metals—followed shortly afterwards, a notion of Englishman Peter Durand. Soon, these "tinned" foods were used to feed the British army and navy.

21 Billion Cans a Year

Canned foods are more than a relic dug from the past. They make up 12 percent of grocery sales in the United States. More than 1,500 food products are canned—including many that aren't available fresh in most areas, such as elderberry, guava, mango, and about 75 different juice drinks. Consumers can buy at least 130 different canned vegetable products—from artichokes and asparagus to turnips and zucchini. More than a dozen kinds of beef are canned, including beef burgers and chopped, corned and barbecued beef.

According to a recent study cosponsored by the U.S. Department of Agriculture and NFPA, canned foods provide the same nutritional value as fresh grocery produce and their frozen counterparts when prepared for the table. NFPA researchers compared six vegetables in three forms: home-cooked fresh, warmed canned, and prepared frozen.

"Levels of 13 minerals, eight vitamins, and fiber in the foods were similar," says Dudek. In fact, in some cases the canned

product contained high levels of some vitamins that in fresh produce are destroyed by light or exposure to air.

The Canning Process

Food-spoiling bacteria, yeasts and molds are naturally present in foods. To grow, these microorganisms need moisture, a low-acid environment (acid prevents bacterial growth), nutrients, and an appropriate (usually room) temperature.

Dennis Dignan, Ph.D., chief of FDA's food processing section, explains that foods are preserved from food spoilage by controlling one or more of the above factors. For instance, frozen foods are stored at temperatures too low for microorganisms (bacteria, yeasts and molds) to grow. When foods are dried, sufficient moisture is not available to promote growth.

It is the preservation process that distinguishes canned from other packaged foods. During canning, the food is placed in an airtight (hermetically sealed) container and heated to destroy microorganisms. The hermetic seal is essential to ensure that microorganisms do not contaminate the product after it is sterilized through heating, says Dignan. Properly canned foods can be stored unrefrigerated indefinitely without fear of their spoiling or becoming toxic.

Canning for a New Age

Dignan also notes that foods packaged in materials other than metal cans are considered "canned" by food processing specialists if the food undergoes the canning preservation process. Thus, today a canned food may be packaged in a number of other types of containers, such as glass jars, paperboard cans, and plastics that can be formed into anything from pouches to soup bowls to serving trays.

For example, FDA consumer safety officer Tom Gardine, holding up a small, plastic container of half-and-half for his morning coffee, says, "This is a canned food." He explains that the coffee creamer was heated to destroy bacteria and sealed to prevent microorganisms from entering the sterile container. Until it is opened, the creamer is intended to be stored on the shelf, not in the refrigerator.

Meals for today's U.S. military come in plastic pouches—a new version of the heavier C-rations in metal cans. Such flexible pouches aren't as popular with American civilians as they are with Europeans. Many Americans, instead, are buying their canned foods in plastic containers that come with a peel-off metal top and plastic lid—ready for the microwave. Barriers (made of sophisticated synthetic materials) that provide an airtight seal are sandwiched in these plastic layered containers. They are used for applesauce, pudding, and other foods that can be stored on supermarket or home shelves for years.

Then there are containers made of new transparent plastic materials like polyethylene terephthalate—used for peanut butter and catsup. Packages made of paperboard layers have been designed in the shape of boxes to contain such foods as fruit juices, tomato sauce, and even milk.

Even the tin can is changing. For years, the three-piece can (made from a top, a bottom, and a body formed from a plate soldered into a cylinder) was the only can around. Now there are two-piece cans, which eliminate the side seam and one seamed end. These cans are made by feeding metal into a press that forms the can body and one end into a single piece.

In the traditional three-piece cans, a welded side seam has replaced the lead-soldered side seam in all but 3.7 percent of American cans, says NFPA official Roger Coleman. The welding process uses electrodes that apply pressure and electric current to overlapping edges at the side seam. These new seams eliminate concern about lead leaching into metal canned foods. In the 3.7 percent of U.S. cans where lead still is used, it is often for dry foods (such as coffee) packaged in cans, according to Coleman. Leaching is not a concern here.

Many imported cans, however, still bear lead-soldered side seams. To tell whether a can has been soldered with lead, first peel back the label to expose the seam. The edges along the joint of a lead-soldered seam will be folded over. Silver-gray metal will be smeared on the outside of the seam. A welded seam is flat, with a thin, dark, sharply defined line along the joint.

Turning Up the Heat

Foods with a naturally high acid content—such as tomatoes, citrus juices, pears, and other fruits—will not support the growth of food poisoning bacteria. In tests, when large numbers of food poisoning bacteria are added to these foods, the bacteria die within a day. (The exact amount of time depends upon the bacteria and amount of acidity.) Foods that have a high acid content, therefore, do not receive as extreme a heat treatment as low-acid foods. They are heated sufficiently to destroy bacteria, yeasts and molds that could cause food to spoil.

Canners and food safety regulators are most concerned about foods with low acid content, such as mushrooms, green beans, corn, and meats. The deadly *Clostridium botulinum* bacterium, which causes botulism poisoning, produces a toxin in these foods that is highly heat-resistant. The sterilization process that destroys this bacteria also kills other bacteria that may poison or spoil food.

Low-acid canned foods receive a high dose of heat—usually 107 degrees Celsius (250 degrees Farenheit) for at least three minutes. (The amount of time the food is heated, though, depends upon the size of the container and the product.) The canned food is heated in a retort, a kind of pressure cooker.

The coffee creamer on Gardine's desk, however, was packaged differently. Although both the half-and-half and plastic container were sterilized with heat, they were heated separately and then brought together in a sterile environment where the container was filled and sealed. The advantage of this "aseptic processing," a type of canning, is that higher temperatures with reduced heating times prevent deterioration in the quality of the food.

Aseptic processing is the "wave of the present and the future," says Gardine. It is now used for liquids, and scientists are on the way to perfecting the method for canning stews and chowders. However, says Gardine, because solid foods may be more difficult to keep sterile during the filling and sealing period, FDA is being especially cautious in approving uses for aseptic processing.

Finessing the Attack on Food Spoilers

Another critical element in the canned food process is sealing products in airtight containers. It is essential that air be removed from the container before sealing. Air could cause the can to expand during heating, perhaps damaging the seals or seams of the container.

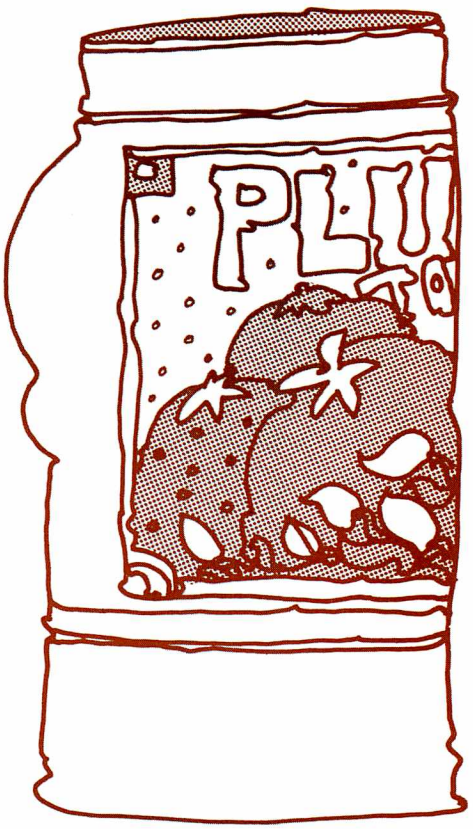
A telltale sign of loss of this vacuum—and a possibly contaminated product—is a can with bulging ends. (See accompanying article.) If a seal is not airtight, bacteria may enter the can, multiply, and

How to Recognize Can Defects

"Never eat food from a tin can with bulging ends" was a maxim many grew up with. Bulging was one of several clues that might indicate contamination of food packaged in metal cans. Guidelines have been adapted for recognizing defects in cans made of plastic and other materials, as well. The guidelines are:

Metal Cans
- an obvious opening underneath the double seam on the top or bottom of the can
- a can with bulging ends
- a fracture in the double seam
- a pinhole or puncture in the body of the can
- an unwelded portion of the side seam
- a leak from anywhere in the can

Plastic Cans
- any opening or non-bonding in the seal
- a break in the plastic
- a fractured lid
- a swollen package



Paperboard Cans
- a patch in the seal where bonding or adhesive is missing
- a slash or slice in the package
- a leak in a corner of the package
- a swollen package

Glass Jars
- a pop-top that does not pop when opened (indicating loss of the vacuum)
- a damaged seal
- a crack in the glass of the jar

Flexible Pouches
- a break in the adhesive across the width of the seal
- a slash or break in the package
- a leak at a manufactured notch used for easy opening
- a swollen package

(Taken from a chart for retailers developed by FDA and NFPA and published by the Association of Official Analytical Chemists.)

—D.B.

contaminate the product.

The hermetic seal finesses the canning process. The bacteria in a food and container are killed through heating, and at the same time new bacteria are kept from contaminating the food.

The distinction between the canning process and food handling before processing is an important one for food processors and regulators. Last February, 22 students at Mississippi State University became ill after eating omelets made with canned mushrooms imported from China. Similar outbreaks followed in New York and Pennsylvania, affecting more than 100 people. FDA identified the culprit as staphylococcal enterotoxin, a poison produced by the bacteria *Staphylococcus aureus*.

FDA's investigation suggests that poor sanitation caused the problem, and that the mushrooms were contaminated with staphylococcal enterotoxin even before they were canned. The canning process did not destroy the substance because food preservation processes are not normally designed to destroy staphylococcal enterotoxin, a highly heat-resistant toxin.

Since this incident, FDA and the Peoples Republic of China have been working together to determine the source of the contamination. However, FDA authorities still are preventing mushrooms canned in China from entering the United States. And, says Gardine, FDA is focusing attention on sanitation procedures in imported foods.

Surpassing Napoleon

The canned food principle that won Nicolas Appert his prize of 12,000 francs has endured over the years. What might surprise Appert, however, is how his discovery is making food shopping and storing easier for the 20th century consumer.

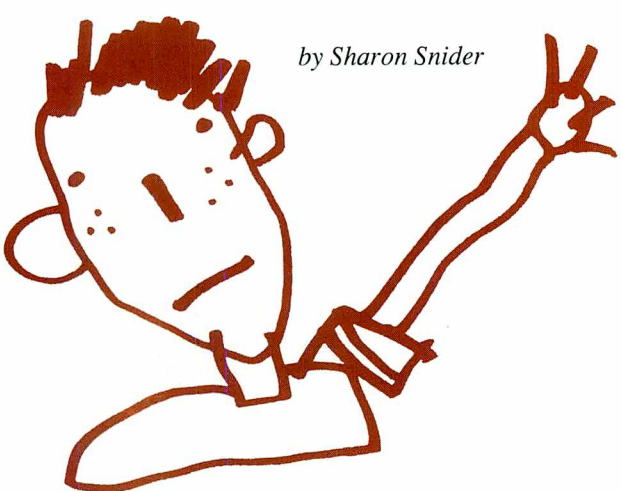
Those who order coffee at fast food restaurants now also are served canned half-and-half, which has been transported and stored without concern about refrigeration. Hikers can take flexible pouches of canned food on backpacking trips without having to worry about saving water to reconstitute freeze-dried meals. And, in this society of microwave owners, Americans who don't have time to prepare a well-balanced meal can pick up a plastic container filled with a canned, nutritious dinner. ■

Dale Blumenthal is a staff writer for FDA Consumer.

A Responsibility To Remember

Childhood Vaccines

by Sharon Snider



Though immunizations may seem to be routine, recent events have reminded the American public that protecting the population from childhood diseases is a responsibility that is foolhardy to forget.

The U.S. Centers for Disease Control estimates that in 1989 there were more than 17,000 cases of measles in the United States, an epidemic of great proportions that developed over the previous few years. Many victims were babies and toddlers who were not immunized. Others were teenagers and college students. Until recently, measles, like many other infectious childhood diseases, had been all but forgotten.

Public health officials fear that recent outbreaks of measles and mumps, and an increase of whooping cough in children under 5, could signal a return to a higher incidence of contagious childhood diseases once thought to be nearly eradicated.

According to CDC, an estimated 50 to 60 percent of all children under 2 have completed the recommended infant immunizations:

• four DTP shots (for diphtheria, tetanus and pertussis, commonly called whooping cough), plus a booster shot before school entry

(Continued on next page)

- three doses of oral polio vaccine
- one shot for measles, mumps and rubella (German measles), plus another shot before school entry
- one shot for *Haemophilus influenza* type b.

State laws vary in their immunization requirements for enrollment in school and state-licensed day-care centers. This means that immunizations are often delayed until age 5, and in some states certain immunizations are not required at all.

Measles

Measles is a highly contagious disease transmitted by coughing, sneezing—through microscopic droplets in the air—and by close contact with an infected individual. It causes a rash persisting several days, and high fever, cough, runny nose, and watery eyes, lasting one or two weeks. In more serious cases, it results in ear infection or pneumonia. In rare instances, it can cause encephalitis (inflammation of the brain) and lead to convulsions, deafness, mental retardation, or death. In pregnant women, measles can cause miscarriage or premature delivery. In very rare cases, measles virus may cause a fatal brain disease which doesn't appear until many years later.

In 1962, the year before the measles vaccine was developed, there were 500,000 reported cases of measles in the United States, of which more than 400 were fatal. After the vaccine was introduced in 1963, the incidence of the disease dropped dramatically, reaching a record low of 1,493 reported cases. Between 1984 and 1988 a yearly average of 3,700 cases were reported. According to CDC, the worst outbreaks in 1989—and continuing into 1990—were in the Los Angeles, Chicago and Dallas areas. The measles epidemic continues and has caused almost as many deaths in the first 20 weeks of 1990 as in all of 1989.

Most measles cases were among adolescents and young adults who weren't fully or effectively immunized as children. (See "And Measles Too" in the July-August 1989 *FDA Consumer*.)

The epidemic has public health officials worried. The California outbreak, for example, started in high schools and on college campuses but then took hold in a particularly fragile population—unimmunized children of poor and immigrant families in Southern California.

Vaccination confers immunity in about 95 of every 100 people vaccinated. Until this year, public health officials recommended that children receive a single injection at 15 months. However, due to the recent outbreaks, the Public Health Service now recommends that two doses of measles vaccine be given to all children, preferably as part of the measles-mumps-rubella (MMR) vaccine. In localities with no outbreaks, the first dose of vaccine is to be given at 15 months and the second at 4 to 6 years, when the child starts school. However, in counties where there have been recent cases or outbreaks, the first dose is often given at 12 months.

The Public Health Service also recommends that students entering college and medical personnel who work directly with patients receive a second measles vaccination.

Mumps

Before the advent of a vaccine to prevent it, mumps was common throughout the world, striking most children between ages 5 and 10. Vaccination for mumps was available in 1967 but not widely used in the United States until 1977. Priority at that time was being given to vaccination for measles, which was more common and more severe than mumps, and for rubella (German measles) because of its association with birth defects if contracted during pregnancy.

While mumps is now rare in elementary school children, many adolescents and young adults are still susceptible. A number of outbreaks in high schools, on college campuses, and in the work place have been reported in recent years. (See "Mumps Makes a Comeback" in the July-August 1989 *FDA Consumer*.) Approximately 4,000 mumps cases are reported annually, according to CDC.

Mumps is caused by a very contagious virus transmitted by coughing, sneezing, and close contact. It usually causes fever, headache, and inflammation of the salivary glands, making the jaw swell. Mumps can be a fairly minor illness, or it can have serious complications, such as meningitis (inflammation of the membranes of the brain or spinal cord), encephalitis, and, in rare cases, deafness. About 1 in 4 adolescent and adult males who gets mumps develops painful inflammation and swelling of the testicles (called orchitis), which leads to sterility. The pancreas may also become infected.

About 95 of 100 children who receive mumps vaccine develop immunity. The vaccine is given at 15 months, usually as part of the MMR vaccine.

Rubella (German Measles)

Rubella, also known as German measles and three-day measles, is usually a relatively harmless illness. However, according to CDC, a woman who contracts the disease during the first three months of pregnancy has at least a 20 to 25 percent increased risk of bearing a child with birth defects. Or she may suffer a miscarriage. The most common birth defects associated with rubella are deafness, blindness, heart and artery damage, abnormally small brain, and mental retardation.

Rubella is characterized by a rash that begins on the face and neck, preceded by a low-grade fever, swelling of the lymph glands, eye irritation, sneezing, coughing, and a sore throat. Adolescents may have temporary joint pains or inflammation. The disease usually lasts only a few days, and recovery is speedy and complete.

Rubella is a very contagious virus that can be transmitted by coughing, sneezing, and close contact. Although about 200 to 400 cases still occur in the United States each year, according to CDC, the last epidemic was in 1964, before the introduction of rubella vaccine in 1969. As a result of that epidemic, CDC estimates, 20,000 babies were born with severe birth defects.

About 95 of 100 people who receive rubella vaccine develop immunity. The vaccine is usually given at 15 months, usually as part of a measles-rubella (MR) or MMR vaccine. Health officials also recommend that adolescents and adults—especially women of childbearing age—who have no proof of vaccination or immunity to rubella be given the vaccine. However, women who are pregnant or might become pregnant within three months should not receive the rubella vaccine. According to CDC, persons should consider themselves immune only if they can document that they were immunized or if they had a blood test indicating they are immune.

Children in body-encompassing iron lungs, like the one on the right, were a common sight in hospital wards of the '50s. Today, polio has been virtually wiped out in the United States, and many young people have never seen one of these devices. *(Photo courtesy of the National Library of Medicine.)*

Side Effects: In most cases, the side effects of the MMR vaccine are relatively minor. Most children will not have any side effects at all, but, according to CDC, a few may experience:

- rash or slight fever a week or two after receiving the measles vaccine
- slight fever a week or two after receiving the mumps vaccine and occasionally some swelling of the salivary glands
- rash, fever, sore throat, headache, or some swelling in the lymph glands a week or two after receiving the rubella vaccine. Adults, especially women, may develop joint pains that last from one day to a few weeks. Very rarely, these joint symptoms may persist or recur.

Although CDC experts are not sure about the causal relationship, on very rare occasions, children who receive these vaccines may have a serious reaction, such as encephalitis. However, medical experts agree that the benefits of being immunized against measles, mumps and rubella far outweigh the risk of possible side effects from the vaccines.

Diphtheria

Diphtheria is a highly contagious, life-threatening disease that years ago was widespread and greatly feared. Through the 1920s, about 150,000 cases and 15,000 deaths were reported annually in the United States. The infection spreads most easily in socioeconomic conditions of poor personal hygiene, crowding, and limited access to medical care. A diphtheria vaccine has been widely used in the United States since the 1940s, and today the disease has been almost eradicated here.

Diphtheria usually starts with a sore throat, headache, slight fever, and chills. A grayish membrane often forms in the throat, and, if it continues to grow, can interfere with swallowing. If it extends to the windpipe, it can block air and cause suffocation. If untreated, the diphtheria bacteria produce a powerful poison that spreads throughout the body and can cause pneumonia, heart failure, paralysis, and, in 1 in 10 cases, death.

The diphtheria vaccine confers immunity in more than 90 percent of those vaccinated. Diphtheria vaccine is given along with immunizations for lockjaw and whooping cough, as part of a diphtheria-tetanus-pertussis (DTP) shot. Babies routinely receive shots at 2, 4, 6 and 18 months, with booster shots between 4 and 6 years, and every 10 years thereafter. Persons over 7 are usually given the Td vaccine, a combined tetanus-diphtheria vaccine for adults that contains less diphtheria toxoid than the DTP vaccine.

Tetanus (Lockjaw)

Tetanus was once commonly called lockjaw—and for good reason. The first signs are usually muscular stiffness in the jaw and neck, headache and irritability. As the condition worsens, the jaw, neck and limbs become locked in spasm, abdominal muscles grow rigid, and convulsions may occur. Complications include pneumonia, fractures, exhaustion from the muscle

Recommended Immunization Schedule

The following immunization schedule is recommended for infants and children who are being immunized for the first time. Different immunization schedules are followed for babies whose initial immunizations were delayed and for children and adults who have not been immunized. A physician should be consulted for these cases.

Recommended Age	Vaccines
2 months	DTP-1, polio-1
4 months	DTP-2, polio-2
6 months	DTP-3
15 months	DTP-4, polio-3, MMR-1, Hib
4-6 years	DTP-5, polio-4, MMR-2
14-16 years and every 10 years after	Td

spasms, and, in 20 to 30 percent of the cases, death.

Tetanus is caused by a bacterium found almost everywhere, but primarily in soil. The bacteria usually enter the body through deep puncture wounds and lacerations, but sometimes even through a pinprick or scratch.

In the United States, there are 50 to 100 tetanus cases annually, almost all among people who either have not been immunized or have been inadequately immunized, particularly the elderly. Many cases are caused by wounds incurred while gardening or handling animals.

Protection against tetanus can be achieved in more than 95 percent of all people by immunization. The injections are given beginning at 2 months as part of the DTP vaccine. However, to insure protection throughout adulthood, tetanus booster shots must be given every 10 years, from about age 15 on. Surveys show that 40 percent of people over 60 are not adequately immunized against tetanus. Tetanus booster shots are given in the Td vaccine.

Whooping Cough (Pertussis)

Whooping cough is a severe respiratory illness that affects primarily infants and young children. Its descriptive name comes from sharp spasms of coughing, followed by a prolonged gasping for breath ending with a "whoop." But the disease can also occur without the characteristic coughing, especially in babies and the elderly. Symptoms may be only those of a runny nose or mild cold.

Whooping cough is a very contagious disease caused by a bacterium found in the mouth, nose and throat of the infected individual. It is spread by coughing and sneezing. The coughing spells, which may be accompanied by vomiting, can occur as often as every half hour and can interfere with eating, drinking and breathing.

Complications from whooping cough are common. One in six children develops pneumonia; convulsions occur in 1 in 50; and encephalitis occurs in 1 in 200. An average of nine deaths a year result from whooping cough, most in infants under 6 months.

In the 1940s, approximately 200,000 cases of whooping cough were reported annually in the United States. As immunization of children became standard practice, the incidence began to drop. But whooping cough is on the rise once again. In the past few years, approximately 3,000 cases have been reported annually, according to CDC, and in 1989 there were an estimated 3,745 cases. Two-thirds were in children under 5.

The increased reported incidence of whooping cough can be attributed to several factors, according to Charles R. Manclark, Ph.D., chief of FDA's pertussis lab. Some doctors, he says, are reluctant to administer pertussis vaccine for fear of serious side effects. Some parents neglect to get their children the complete series of five DTP shots required for full immunization. In addition, he says, new diagnostic techniques have made it possible to detect the disease in cases where the characteristic cough is absent, thereby increasing the number of previously unreported cases.

Whooping cough can be prevented in at least 8 of 10 children by immunization with pertussis vaccine. Injections begin at age 2 months as part of the DTP vaccine. However, because the pertussis vaccine itself can cause severe reactions in a small proportion of children, doctors may advise deferring or omitting it in those children and immunizing them only against diphtheria and tetanus with the DT vaccine. Research is currently under way on new vaccines that would not have the side effects associated with the present DTP vaccine, but most scientists estimate it will be several years before one is available to completely replace the current vaccines.

Side Effects: Most commonly, children who receive the DTP vaccine experience minor side effects such as a slight fever and irritability for up to two days after the shot. Half develop some soreness and swelling at the site of injection. A few children, however, experience more serious side effects, such as a fever of 40.5 degrees Celsius (105 degrees Fahrenheit) or greater; continuous crying lasting three or more hours; unusual, high-pitched crying; or paleness and limpness.

In rare cases, children may experience seizures and long-lasting, even permanent, brain damage. Some parent groups,

(Continued on page 25)

Childhood Vaccine Injury Act

Although serious side effects from vaccination against childhood diseases are rare, they do occur.

The Childhood Vaccine Injury Act, passed in 1986, established the National Vaccine Injury Compensation Program to compensate individuals for injuries or death related to the DTP, MMR and polio vaccines.

To be eligible for compensation, the injured party need not prove negligence on the part of the physician who administered the vaccine or by the manufacturer, but must only show by a "preponderance of evidence" that the injury was vaccine-related.

This no-fault compensation program is designed to be easier, faster, and less costly for claimants than traditional legal remedies, and at the same time to provide doctors and manufacturers immunity from lawsuits.

In part because of an increasing number of lawsuits in the 1970s and early 1980s, 12 of the 16 American vaccine manufacturers dropped out of the market, threatening the stability of the supply of vaccines in the United States.

"The National Vaccine Injury Compensation Program provides a means of assisting seriously impaired children without the burden of lengthy and costly litigation, and at the same time, it helps stabilize the nation's vaccine supply," said Tullio F. Albertini, administrator of the program for the Health Resources and Services Administration.

Anyone who has incurred over $1,000 in expenses as a result of an injury or death associated with a vaccine may be eligible for compensation.

Compensation for injuries that occurred before Oct. 1, 1988, differs monetarily from injuries that occurred after that date.

Individuals alleging injury by vaccines before Oct. 1, 1988, are eligible for compensation for unreimbursed future medical, custodial or rehabilitation costs. Compensation for future lost wages, pain and suffering, attorney's fees, and other legal costs may not exceed a combined total of $30,000. Individuals are not compensated for past medical expenses and lost wages.

The deadline for filing claims for injuries that occurred before Oct. 1, 1988, is Oct. 1, 1990.

Individuals injured by vaccines after Oct. 1, 1988, are eligible for up to $250,000 for present and future pain and suffering. This includes past and future unreimbursed medical expenses, residential and custodial care and rehabilitation costs, and projected lost earnings from age 18. Attorneys' fees may also be awarded, even if the petition is denied.

Regardless of the date of injury, $250,000 is awarded in the event of death.

Before an individual can pursue civil legal action on a vaccine injury that occurred after Oct. 1, 1988, a claim must be filed under the Vaccine Injury Compensation Program. The case will be decided by the U.S. Claims Court, and the claimant can either accept or reject the court's judgment. A person who accepts the judgment cannot sue the physician or manufacturer. An individual who rejects the judgment can pursue civil legal action.

Claims for injuries after Oct. 1, 1988, must be filed within three years of the first symptom of injury and within two years of death.

All claims must be filed with the U.S. Claims Court in Washington, D.C., with two copies provided to the Secretary of Health and Human Services.

Eligibility for compensation is determined separately for each vaccine by a vaccine injury table that specifies the time frame for legally establishing a link between administration of the vaccine and injury. For example, to show that a child's seizure disorder was caused by the DTP vaccine, the child's first seizure must have occurred within three days of vaccination. To show that the MMR vaccine caused encephalitis, the injury must have occurred within 15 days of receiving the MMR vaccine. To establish that either the DTP or MMR vaccine caused a severe anaphylactic reaction or shock, the reaction must have taken place within 24 hours of immunization.

As of May 21, 1990, 296 vaccine-related claims had been filed. Of those, 194 were for injuries and 102 were for deaths, including many for sudden infant death syndrome. The vast majority of claims, 246, were related to the DTP vaccine.

As of the same date, 69 awards totaling $37 million had been made. Nineteen of the 296 claims were either dismissed or voluntarily withdrawn. ■

—*S.S.*

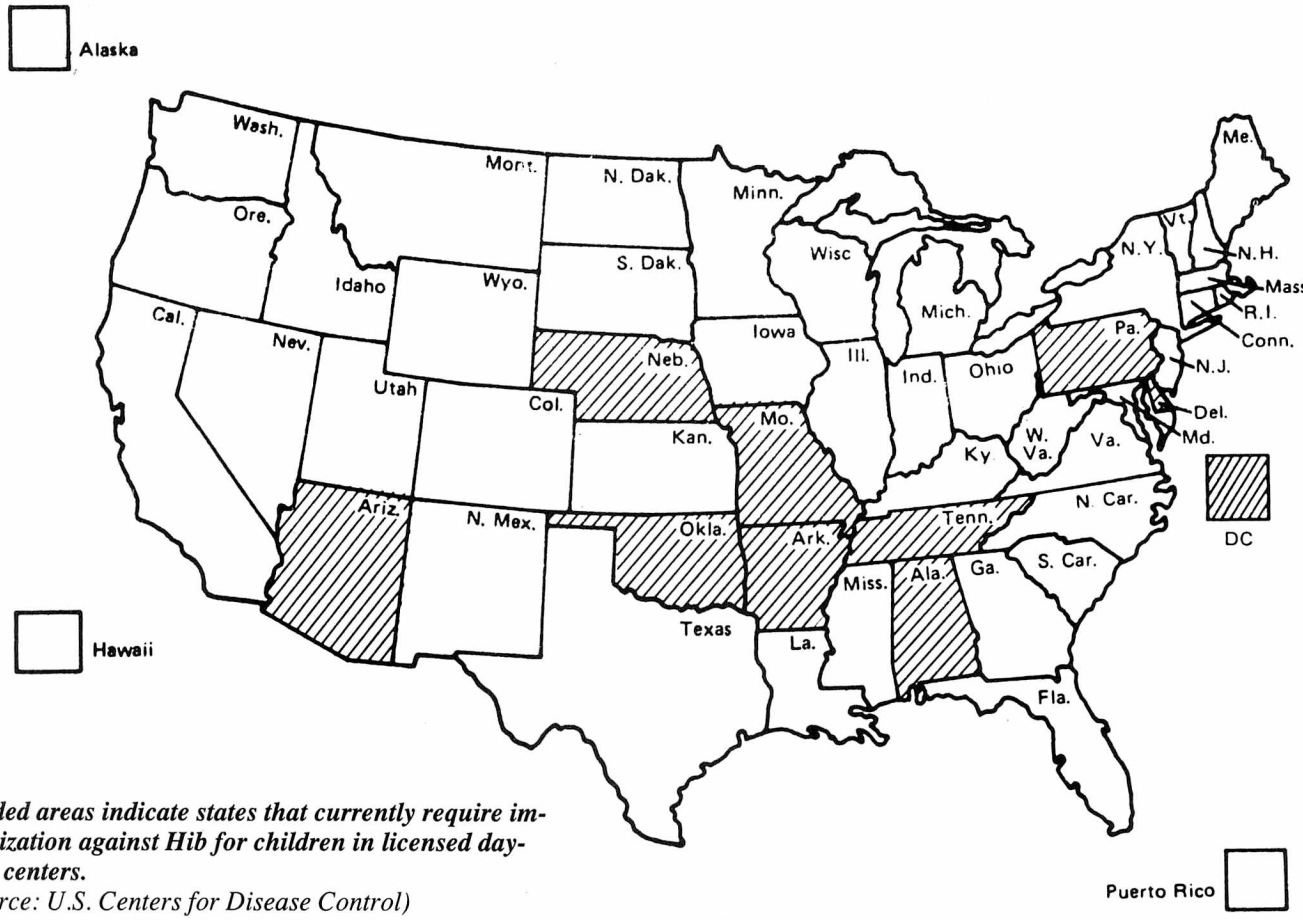
State Immunization Requirements
Grades K-12

State	Diphtheria	Tetanus	Pertussis	Measles	Mumps	Rubella	Polio
Alabama	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Alaska	K-12	K-12	K-6 yrs	K-12	Not Required	K-11 yrs	K-12
Arizona	K-12	Not Required	Not Required	K-12	Not Required	K-12	K-12
Arkansas	K-12	K-12	K-6 yrs	K-12	Not Required	K-12	K-12
California	K-12	K-12	K-6 yrs	K-12	K-6 yrs	K-12	K-12
Colorado	K-12	K-12	K-6 yrs	K-12	K	K-6	K-12
Connecticut	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Delaware	K-12	K-12	K-6 yrs	K-12	K-10	K-12	K-12
Dist. of Col.	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Florida	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Georgia	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Hawaii	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Idaho	K-5	K-5	Not Required	K-5	K-5	K-5	K-5
Illinois	K-12	K-12	K-5 yrs	K-12	K-12	K-12	K-12
Indiana	K-12	K-12	K-6 yrs	K-12	K-5	K-12	K-12
Iowa	K-12	K-12	K-6 yrs	K-12	Not Required	K-12	K-12
Kansas	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Kentucky	K-12	K-12	New Enterers	K-12	Not Required	K-12	K-12
Louisiana	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers
Maine	K-12	K-12	K-6 yrs	K-12	K-10	K-12	K-12
Maryland	K-12	K-12	K-6 yrs	K-12	Not Required	K-12	K-12
Massachusetts	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Michigan	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers
Minnesota	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Mississippi	K-12	K-12	K-6 yrs	K-12	New Enterers	K-12	K-12
Missouri	K-12	Not Required	Not Required	K-12	Not Required	K-12	K-12
Montana	K-12	K-12	K-6 yrs	K-12	New Enterers	K-12	K-12
Nebraska	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Nevada	K-12	K-12	K-6 yrs	K-12	New Enterers	K-12	K-12
New Hampshire	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
New Jersey	K-12	K-12	K-6 yrs	K-12	K-15 yrs	K-12	K-12
New Mexico	K-12	K-12	K-6 yrs	K-12	Not Required	K-12	K-12
New York	K-12	Not Required	Not Required	K-12	K-12	K-12	K-12
North Carolina	K-12	K-12	K-6 yrs	K-12	New Enterers	K-12	K-12
North Dakota	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Ohio	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Oklahoma	K-12	K-12	K-6 yrs	K-12	New Enterers	K-12	K-12
Oregon	K-12	K-12	Not Required	K-12	New Enterers	K-12	K-12
Pennsylvania	K-12	K-12	Not Required	K-12	K-12	K-12	K-12
Puerto Rico	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Rhode Island	K-12	K-12	Not Required	K-12	K-6 yrs	K-12	K-12
South Carolina	K-12	K-12	K-5 yrs	K-12	Not Required	K-12	K-12
South Dakota	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Tennessee	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Texas	K-12	K-12	Not Required	K-12	K-17 yrs	K-11 yrs	K-12
Utah	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Vermont	K-12	K-12	K-6 yrs	K-12	Not Required	K-12	K-12
Virginia	K-12	K-12	K-6 yrs	K-12	New Enterers	K-12	K-12
Washington	K-12	K-12	Not Required	K-12	K-1	K-12	K-12
West Virginia	New Enterers	New Enterers	New Enterers	New Enterers	Not Required	New Enterers	New Enterers
Wisconsin	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Wyoming	New Enterers	New Enterers	K-6 yrs	New Enterers	New Enterers	New Enterers	New Enterers

Chart shows immunization requirements by state for children in kindergarten through 12th grades.

(Source: U.S. Centers for Disease Control)

Haemophilus b Immunization Requirements (For Licensed Day-Care Centers)



Shaded areas indicate states that currently require immunization against Hib for children in licensed day-care centers.
(Source: U.S. Centers for Disease Control)

(Continued from page 22)

lawyers and physicians contend that these side effects are caused by the pertussis component of the vaccine and bolster their argument by saying that side effects are not common from the DT or Td vaccines alone and usually consist only of soreness and slight fever. (Partially as a result of their activism, the Vaccine Injury Compensation Act was passed four years ago. See accompanying article.)

Other experts, however, point out that there is no evidence that DTP causes seizures or other brain damage. "There are problems with the DTP vaccine," says FDA's Manclark, "but proof that it causes serious neurological problems just isn't there."

The most recent study, reported in the March 23-30, 1990, *Journal of the American Medical Association,* examined the records of more than 38,000 children who had received the DTP vaccine and found no evidence that it caused seizures or brain damage. This finding was supported by two earlier studies.

Some people have also questioned whether the DTP vaccine might cause sudden infant death syndrome (SIDS). However, according to CDC, the majority of evidence indicates that it does not.

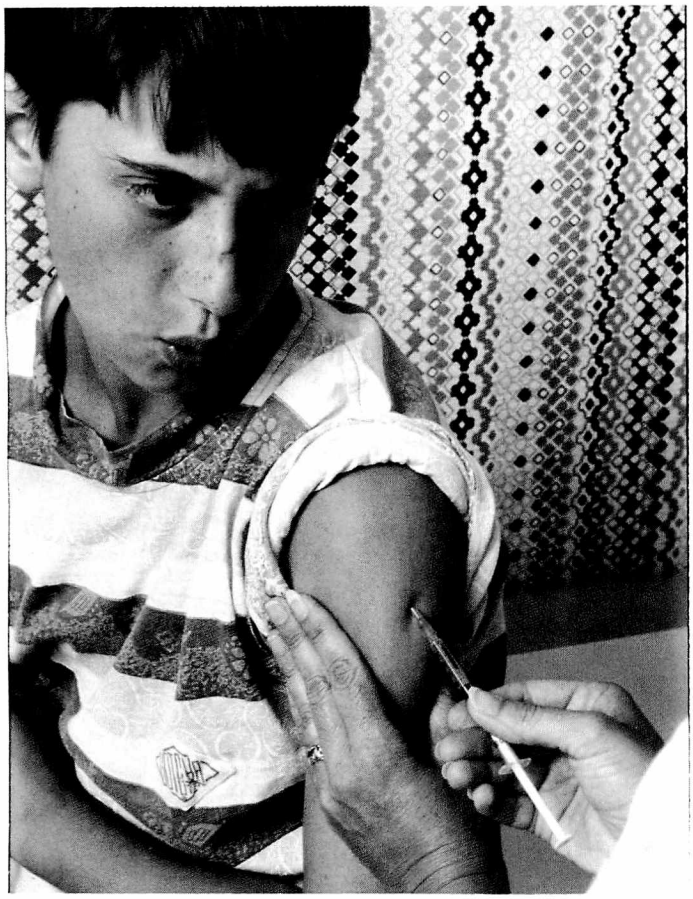
Because of the possibility of a serious reaction to the DTP vaccine, product labeling warns physicians not to continue with the pertussis component if the child exhibits any of the following symptoms:

- allergic reaction to any component of the vaccine
- fever of 40.5 C (105 F) or higher within 48 hours
- collapse or shock-like state within 48 hours
- persistent, inconsolable crying lasting three hours or longer within 48 hours
- an unusual, high-pitched cry within 48 hours
- convulsions within seven days
- neurologic problems, including severe alterations in consciousness.

Pertussis vaccine is not recommended for children past their seventh birthday.

Before having your child immunized with the DTP vaccine, CDC recommends that you check with the doctor if the child:

- is sick with something more serious than a cold
- has ever had a convulsion or is suspected of having a problem of the nervous system
- has had a serious reaction such as those listed above to a previous DTP, DT, or Td shot
- is undergoing treatment or taking a drug that lowers the body's immune response. Radiation treatment and drugs such as cortisone, prednisone, and certain anti-cancer drugs may decrease the degree of protection provided by DTP.



Polio

Until recently, polio was one of the most feared of all infectious diseases. Those who grew up in the 1950s and earlier remember well the thousands of cases of infantile paralysis each year in the United States. Photos of children wearing leg braces or lying enclosed in body-length "iron lungs" to enable them to breathe chilled warm summers when outbreaks would peak. The announcement in 1954 that Jonas Salk, M.D., had discovered a vaccine for polio brought rejoicing.

Today, polio has been virtually wiped out in the United States. Salk's injectable vaccine was supplanted by an oral vaccine developed by Albert Sabin, M.D., in 1961 and given to children on a sugar cube. The sugar cube has in turn been replaced by a liquid form of the Sabin vaccine that can be squirted into the child's mouth.

Last April, international health officials announced that, because of successful vaccination programs, polio probably would be eliminated from the Western hemisphere by the end of 1990. A campaign is under way to eradicate it from the entire world by the year 2000.

Polio is a contagious disease that is unapparent or mild in 90 to 95 percent of the cases, but in its severe form can cause permanent paralysis and, occasionally, death. It is caused by polio virus that multiplies in the nose, throat and, especially, the intestinal tract of the infected person.

Paralytic polio begins with symptoms that include fever, sore throat, nausea, headache, stomachache, and, sometimes, pain and stiffness in the neck, back and legs. These symptoms are followed by development of paralysis.

Polio can be prevented in at least 9 of 10 people by immunization. Live oral polio vaccine (OPV) is routinely given to children, beginning at 2 months. Inactivated polio vaccine (IPV) may be given to adults in some special cases.

The vaccine has been highly effective, and no new cases of polio were reported in the United States in 1989, according to CDC. However, on extremely rare occasions, OPV, like the polio virus itself, causes paralytic polio. In 1989, five cases of vaccine-associated polio were reported in the United States.

As the threat of paralyzing polio has diminished in the Western hemisphere, health officials note that the practice of immunization against it has relaxed. If this trend continues, they warn, there could be a resurgence of the disease.

Haemophilus Influenza

Haemophilus influenza type b (Hib) is certainly not a household phrase, but thousands of young, American children suffer its devastating effects. Every year, Hib causes an array of infectious diseases, mainly in youngsters between 6 months and 5 years, with the most serious cases occurring between 6 months and 1 year. Hib strikes about 1 in every 200 children in the United States before the fifth birthday.

Because Hib spreads among children in close, prolonged contact, babies and preschoolers who attend day-care centers are considered to run an especially high risk of infection.

Despite its name, Hib has nothing to do with influenza. It is a bacterium, not a virus, and was misnamed when it was mistakenly associated with the influenza epidemic of 1892. However, its effects in young children can be much more severe than the flu. In fact, its impact has been compared to the ravages of polio at its peak in the 1950s.

Hib causes a variety of diseases, including meningitis, severe croup, pneumonia, and infections of the blood, joints, bones, soft tissues, and membrane of the heart. Sixty percent of the children who get Hib come down with meningitis. Of these, approximately 1 in 4 suffers permanent brain damage, and 1 in 20 dies.

At the beginning of an Hib infection, a child may seem to have only a cold or earache. As the infection worsens, irritability, loss of appetite, vomiting, and fever may occur. If Hib bacteria enter the bloodstream, they may spread rapidly to the central nervous system and other parts of the body, causing life-threatening illnesses.

Years ago, doctors could do little to fight Hib infections, and mortality rates were high. The advent of antibiotics made it possible to treat many of the serious diseases caused by Hib—but not to prevent the infection itself. Today, thanks to new types of conjugate vaccines, the first of which was introduced in 1987, Hib infection can be prevented in many children. However, babies must be at least 15 months old for the currently recommended single dose of these vaccines to be effective. As yet, no vaccine is available for infants, in whom the majority of Hib diseases occur. Scientists are currently evaluating these vaccines to see if they could confer immunity at a younger age if given at a different dosage schedule.

The Immunization Practices Advisory Committee of the Public Health Service recommends that babies be routinely vaccinated with Hib vaccine at 15 months, but the vaccine may also be given to children up to 5 years. Health officials do not consider it necessary to vaccinate children over 5, the upper age limit for Hib. ■

Sharon Snider is a staff writer for FDA Consumer.

Feeding Baby
Nature and Nurture

by Dori Stehlin

Parents of a new baby have a million things to do, but menu-planning isn't one of them. Until a baby is 4 to 6 months old, for breakfast, lunch and dinner—and, of course, the infamous middle-of-the-night feeding—the only items on the menu are either breast milk or infant formula.

Breast Milk Is Best

Usually a manufacturer won't announce that the competition's product is a better choice. But when the competition is breast milk, infant formula manufacturers concede—right on the label—that breast milk is best.

Human breast milk is the ideal nourishment for human babies. Its protein content is particularly suited to a baby's metabolism, and the fat content is more easily absorbed and digested than the fats in cow's milk.

Breast milk also may protect the infant against certain diseases, infections and allergies. A mother's milk contains cells from her immune system and antibodies against diseases to which she has been exposed. Antibodies she develops after the baby is born are also passed to the baby through the breast milk.

For example, if Mom catches the flu, she develops antibodies to that strain of flu virus. Richard Schanler, M.D., associate professor of pediatrics at Baylor College of Medicine, Houston, explains, "The baby will get some protection. [The baby] might not get the flu at all, or the case may be milder . . . than if he or she wasn't breast-fed to begin with."

However, risks of breast milk may outweigh advantages if a nursing mother takes certain medications or abuses drugs. The quality and quantity of the mother's diet may affect the quality and quantity of breast milk. (See "Good Nutrition for Breast-Feeding Mothers" in

the December 1986-January 1987 *FDA Consumer.*)

Breast-Feeding Success

"Learn about breast-feeding before the baby is born," says Julie Stock of the La Leche League, an international breast-feeding support and educational organization. "If you know a lot beforehand, you start to build a sense of confidence. Many attempts at breast-feeding fail because of wrong information."

Once the baby is born, breast-feeding as soon as possible after delivery and often is the first of three essential keys for success, says Stock.

The second key is no artificial nipples—that includes pacifiers as well as bottles of water or formula—during the first few weeks. Stock explains that some babies can become very confused by the different feel and the different way of sucking needed with a bottle or pacifier, and they may not be able to switch back to the breast.

Finally, it is important to make sure that the baby "latches on" to the mother's nipple correctly. "If [a mother] has those three things going for her, in general that will eliminate about 90 percent of the common problems that mothers have," says Stock.

The La Leche League has local chapter meetings throughout the country where expectant and new mothers can learn about breast-feeding, nutrition, and other aspects of child care. For the number of your local chapter, call the La Leche League at 1-708-455-7730 or write to La Leche League International, 9616 Minneapolis Ave., P.O. Box 1209, Franklin Park, Ill. 60131-8209.

Second Best

The composition of infant formula is similar to breast milk, but it isn't a perfect match. Further, the exact chemical makeup of breast milk is still unknown.

"We're always discovering things in human milk that are there in small quantities that hadn't been looked at before," says John C. Wallingford, Ph.D., an infant nutrition specialist with FDA's Center for Food Safety and Applied Nutrition. "But [infant formula] is increasingly close to breast milk, especially in the area of fatty acids and lipids."

More than half the calories in breast milk come from fat, and the same is true for today's infant formulas. This may be alarming to many American adults watching their intake of fat and cholesterol, especially when high saturated fats, such as coconut oil are used in formulas. (High saturated fats tend to increase blood cholesterol levels more than other fats or oils.) But the low-fat diet recommended for adults doesn't apply to infants.

"Infants have a very high energy requirement, and they have a restricted volume of food that they can digest," says Wallingford. "The only way to get the energy density of a food up is to increase the amount of fat."

Homemade Isn't Best

Homemade formulas should not be used, says Nick Duy, assistant to the director in FDA's division of regulatory guidance. Homemade formulas based on whole cows' milk don't meet all of an infant's vitamin and mineral needs. In addition, the high protein content of cow's milk makes it difficult for an infant to digest and may put a strain on the baby's immature kidneys. Substituting evaporated milk for whole milk may make the formula easier to digest, but it is still nutritionally inadequate when compared to commercially prepared formula. Use of soy drinks as an infant formula can actually be life-threatening (see accompanying article).

Commercially prepared formulas are regulated by the Food and Drug Administration as a food for special dietary use. "Infant formulas are the most heavily regulated food that there is," says Wallingford.

FDA regulations specify exact nutrient level requirements for infant formulas, based on recommendations by the American Academy of Pediatrics Committee on Nutrition. The following must be included in all formulas:

- protein
- fat
- linoleic acid
- vitamin A
- vitamin D
- vitamin E
- vitamin K
- thiamine (vitamin B_1)
- riboflavin (vitamin B_2)
- vitamin B_6
- vitamin B_{12}
- niacin
- folic acid
- pantothenic acid
- vitamin C
- calcium
- phosphorus
- magnesium
- iron
- zinc
- manganese
- copper
- iodine
- sodium
- potassium
- chloride

In addition, formulas not made with cow's milk must include biotin, choline and inositol.

The safety of commercially prepared formula is also enhanced by strict quality control procedures that require manufacturers to analyze each batch of formula for required nutrients, to test representative samples for stability over the shelf life of the product, to code containers to identify the batch, and to make all records available to FDA investigators.

Formula Choices

The most common sources of protein in infant formulas are either cow's milk or soybeans. "For term infants, soy formulas appear to be as nutritionally sound as milk-based formulas, and their use is unlikely to expose infants to nutritional risk," wrote pediatrician Samuel J. Foman in 1987 in the *American Journal of Clinical Nutrition.* Baylor's Schanler agrees, but says that there is some question about whether the minerals in soy-based formulas can be used by the infant's body as well as those from cow's milk formula.

For a healthy, full-term infant, "cow's milk formula would be the first choice," Schanler says. "The only indication that I see for soy formula is for babies with lactose intolerance."

Lactose, also known as milk sugar, is the main carbohydrate in milk. Infants who don't have enough of the enzyme lactase to digest the lactose may suffer from abdominal pain, diarrhea, gas, bloating, or cramps. There is no lactose in soy formula.

Schanler does not think soy formula is a good choice for infants with milk allergies, however. "If there is a real history of [milk] allergy in the family, the baby might be allergic to soy, too," he says. Instead of soy, Schanler recommends special cow's milk formulas known as protein hydrolysates, which won't cause

Soy Beverages Not Complete Formulas

A severely malnourished 5-month-old infant was admitted to Arkansas Children's Hospital, Little Rock, Ark., last February with symptoms including heart failure, rickets, vasculitis (blood vessel inflammation), and possible neurological damage. According to the hospital, the baby girl had been fed nothing but Soy Moo since she was 3 days old. Soy Moo is a soy beverage sold in health food stores.

This kind of soy beverage, sometimes improperly called "soy milk," should not be confused with soy-based infant formulas. Unlike true infant formulas, which are nutritionally complete and appropriate for infants, soy beverages are lacking some of the nutrients infants need. Analysis of Soy Moo by the Arkansas Children's Hospital revealed deficiencies in calcium, niacin, and vitamins D, E and C.

Labels on Soy Moo cartons and literature about the drink do not suggest that Soy Moo be used as an infant formula. In addition, an FDA investigation found no evidence that the infant's parents were explicitly told that Soy Moo could be used as a baby's sole nourishment. Nevertheless, Soy Moo's distributor, Health Valley Foods, Irwindale, Calif., has voluntarily stopped distribution until new labels stating "Do Not Use As Infant Formula" can be printed.

FDA learned of a similar incident that occurred last April when a California couple questioned a physician about their 2-month-old daughter's failure to gain weight. The physician discovered that the baby had been exclusively fed Edensoy, another brand of soy beverage. A midwife had recommended Edensoy to the parents, according to the FDA investigator assigned to the case.

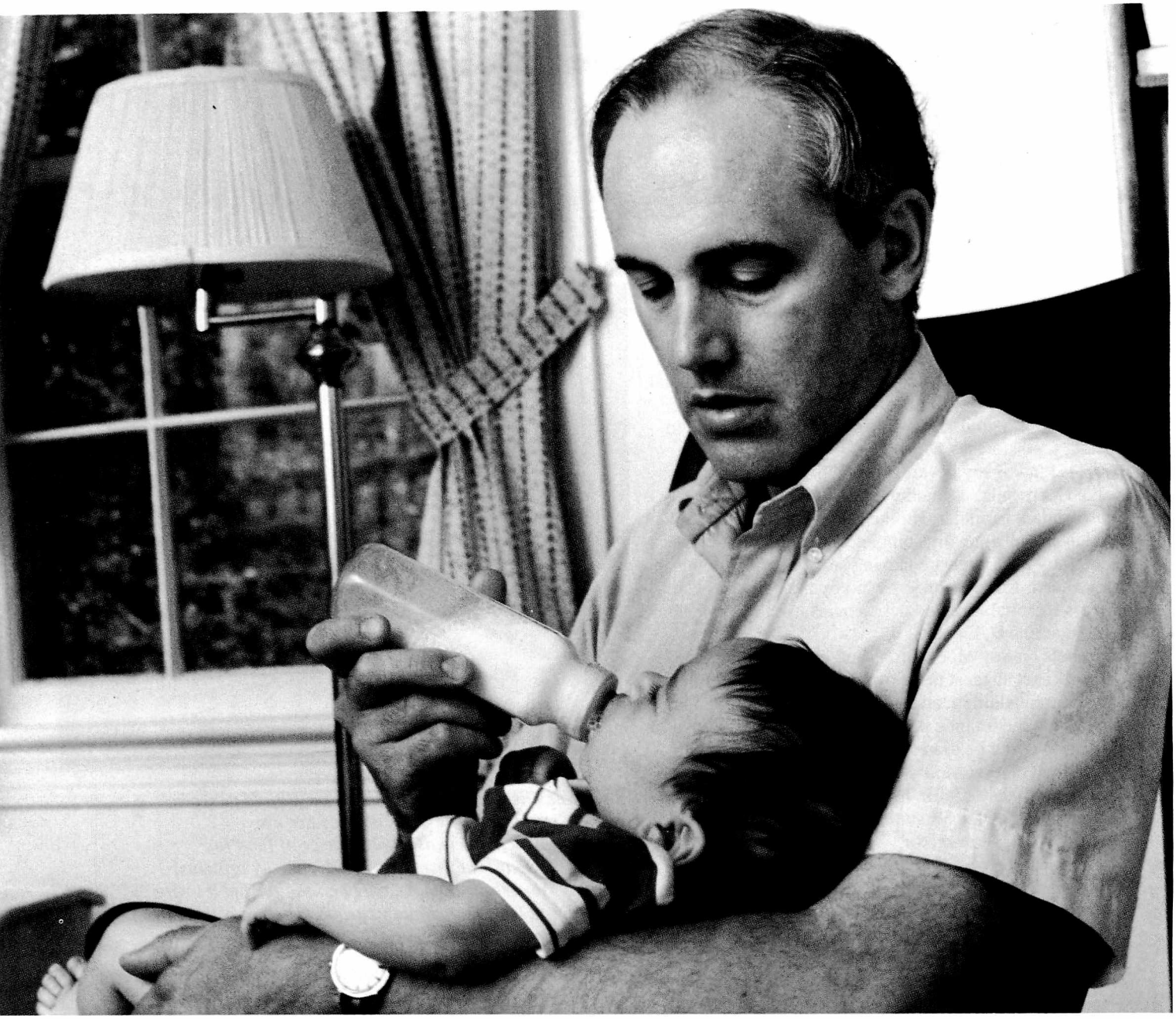
In response to this incident, Edensoy's manufacturer, Eden Foods, Clinton, Mich., wrote all its retailers in the United States and Canada to remind them that Edensoy is not an infant formula. In addition, the letter said, "Please make sure that no store personnel suggest or imply that Edensoy or other soy beverages are suitable for use as infant formula."

In an effort to prevent this problem with similar soy beverages, FDA asked all 68 known manufacturers, importers, and private label distributors of these products to include a warning against using the beverages as infant formula. The agency does not, however, have the regulatory authority to require this warning.

At press time, 16 firms, including Eden Foods and Health Valley Foods, had agreed to provide such a warning. (Four firms told FDA they no longer make these drinks.) If the other firms do not respond, the agency plans to send a second letter that includes a deadline for a response. ■

—D.S.

Soy drinks like the ones shown above should never be used as infant formula because they are not nutritionally complete as a sole source of food for infants. True infant formulas made with soy proteins, such as those shown below, may be used for babies who can't digest lactose, the main carbohydrate in cow's milk formulas.



During the first four to six months, babies not only require the breast or bottle, they also need Mom—or Dad—to help out. But as the little guy to the right proves, eating solids can be done independently as long as spoons aren't required.

allergic reactions because the proteins are already broken down. "That way the chance of a cross reaction with the soy protein is eliminated," he explains.

Both milk and soy formulas are available in powder, liquid concentrate, or ready-to-feed forms. The choice should depend on "whatever the parents find convenient and can afford," says Schanler.

Whatever form is chosen, proper preparation and refrigeration are essential. Opened cans of ready-to-feed and liquid concentrate must be refrigerated and used within the time specified on the can. Once the powder is mixed with water it should also be refrigerated, if it is not used right away. The exact amounts of water recommended on the label must be used. Under-diluted formula can cause problems for the infant's organs and digestive system. Over-diluted formula will not provide adequate nutrition, and the baby may fail to thrive and grow.

Warming the formula isn't necessary for proper nutrition, says William MacLean, M.D., a pediatrician at infant formula manufacturer Ross Laboratories. "There is nothing magical about having [the formula] warmed up to body temperature," he says. "But if it's cold, some babies may refuse it. It's the baby's preference."

Bottles should not be heated in microwave ovens because the ovens don't heat evenly, MacLean warns. "The drop a mother tests on her wrist could be fine," he says. But, he explains, undetected "hot spots" in the formula could seriously burn the baby.

The best way to warm a bottle of formula is by placing the bottle in a pot of water and heating the pot on the stove, according to Christine Watson, a nurse who specializes in maternal and newborn care at the Shady Grove Adventist Hospital in Gaithersburg, Md. "You can also run hot tap water over the bottle, but that isn't very quick," she says.

Vitamin Supplements—Yes or No?

The American Academy of Pediatrics says "the normal breast-fed infant of the well-nourished mother has not been shown *conclusively* to need any specific vitamin and mineral supplement. Similarly, there is no evidence that supplementation is necessary for the full-term, formula-fed infant and for the properly nourished normal child."

Many physicians recommend supplements, nevertheless—especially for breast-fed infants. "There is definitely some controversy here," says Wallingford.

The controversy on supplements usually revolves around the following:

• **Iron**—Although the amount of iron in breast milk is very low (0.3 milligrams of iron per liter), the infant absorbs almost half. In contrast, while iron-fortified formulas contain 10 to 12 mg per liter, babies absorb only about 4 percent, amounting to about 0.4 mg per liter to 0.5 mg per liter. In either case, those amounts of iron are adequate for the first 4 to 6 months, according to the American Academy of Pediatrics.

In the past, there was concern that iron-fortified formulas could cause gastrointestinal problems such as colic, constipation, diarrhea, or vomiting. But, based on several studies over the last 10 years, the American Academy of Pediatrics does not believe there is any evidence connecting these problems to iron and recommends that iron-fortified formula be used for all formula-fed infants.

• **Vitamin D**—Insufficient vitamin D can cause rickets, a disease that results in softening and bending of the bones. Although the amounts of vitamin D in breast milk are small, rickets is uncommon in the breast-fed term infant. This may be because, like the iron in breast milk, the vitamin D in breast milk is easily absorbed by the baby.

Sunlight is important for the formation of vitamin D, but probably as little as a few minutes exposure a day is all the baby needs, says Schanler, and exposure to the whole body isn't necessary—just the arms and face are enough.

• **Fluoride**—No one knows for sure if giving fluoride during the first six months of life will result in fewer cavities. Reflecting the uncertainty surrounding fluoride supplements, the American Academy of Pediatrics recommends starting fluoride supplements shortly after birth in breast-fed infants, but also says that waiting up to six months is acceptable. Because there is no fluoride in infant formula, that twofold recommendation also applies when ready-to-feed formula is used or when the water used for powdered or concentrated formula has less than 0.3 parts per million of fluoride.

Solid Evidence

Sometime between a baby's 4-month and 6-month birthdays solid food can be introduced. Exactly when depends on several factors.

One factor involves the disappearance of the involuntary action called the extrusion reflex. Before this reflex disappears, feeding solids usually involves putting a spoonful in the mouth and scraping most of it off the baby's face as he or she spits it back out.

Also, babies should be able to sit up and turn their heads away. That way, Schanler explains, they can communicate that they're not ready for the next spoonful or just not hungry anymore.

Usually, the first food recommended is a single-grain, iron-fortified infant cereal. Starting with single-grain cereals makes it easier to pinpoint any allergic reactions. (For more information on introducing solids, see "Good Nutrition for the Highchair Set" in the September 1985 *FDA Consumer*.)

The biggest concern with feeding solids too early is that the solids will replace breast milk or formula in the baby's diet. "Solids vary nutritionally depending on the food," says Schanler. "None of them is as complete as formula or breast milk. You don't want to rob [the baby] of milk."

Feeding babies exclusively with breast milk or formula during the first few months is not only the best thing for the babies' health, it can also be a blessing for busy, overtired parents. Now if only the baby would sleep through the night. ■

Dori Stehlin is a staff writer for FDA Consumer.

Latex Condoms Lessen Risks of STDs

With sexually transmitted diseases, infection is not always apparent. If you're not sure about yourself or your partner, the wisest course is not to have sex. But if you do, be sure to use a latex condom labeled for disease prevention from start to finish. And remember that the condom must cover the entire penis to reduce the risk of infection.

Condoms, one of the oldest forms of birth control, have for decades also been used to prevent sexually transmitted diseases (STDs) even though little scientific information to endorse this practice was then available. In this instance, "street smarts" turned out to be right.

With the discovery in the 1980s that the AIDS virus can be transmitted during sexual activity, the condom, which the Food and Drug Administration regulates as a medical device, was scrutinized more closely. Laboratory studies showed that condoms can block passage of the AIDS virus as well as agents responsible for other STDs.

The only sure ways to avoid sexual transmission of diseases (including AIDS, chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis) are not to have sex at all or to limit sex to one uninfected partner who is also monogamous. Short of this, condoms (also called rubbers, safes or prophylactics), though not 100 percent effective, may reduce the risk of STDs if properly used.

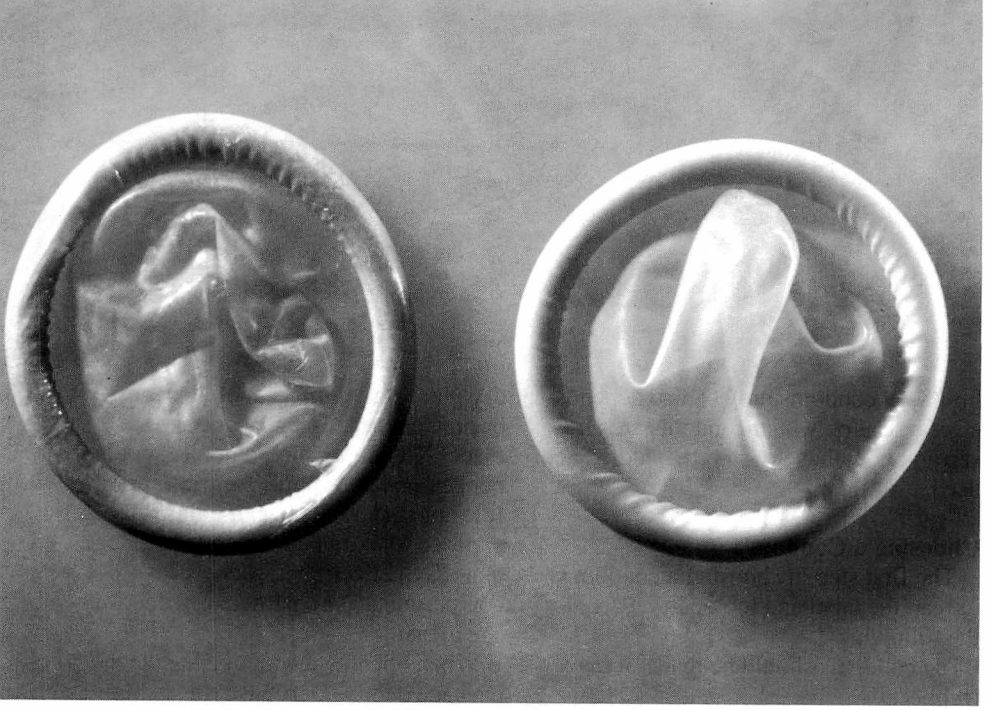
About two-thirds of people with AIDS in the United States got the disease through sexual intercourse with an infected partner. Experts believe that many of these people could have avoided the disease by using condoms.

The condom is a sheath that covers the entire penis. It protects against STDs by acting as a barrier, or wall, to keep semen, blood, and vaginal fluids from passing from one person to another. These fluids can harbor organisms such as HIV (human immunodeficiency virus), the virus that causes AIDS. If no condom is used, HIV or other disease-causing germs can pass easily from the infected partner to the uninfected partner.

Only Latex Effective Against STDs

Condoms currently marketed in the United States are made of either latex (rubber) or natural membrane (lambskin). Natural membrane condoms have different permeability characteristics and less uniformity than those made of latex and may allow HIV, which is tinier than sperm or bacteria, to pass through. For this reason, lambskin condoms are not considered as effective as latex condoms in reducing the risk of STDs, including AIDS.

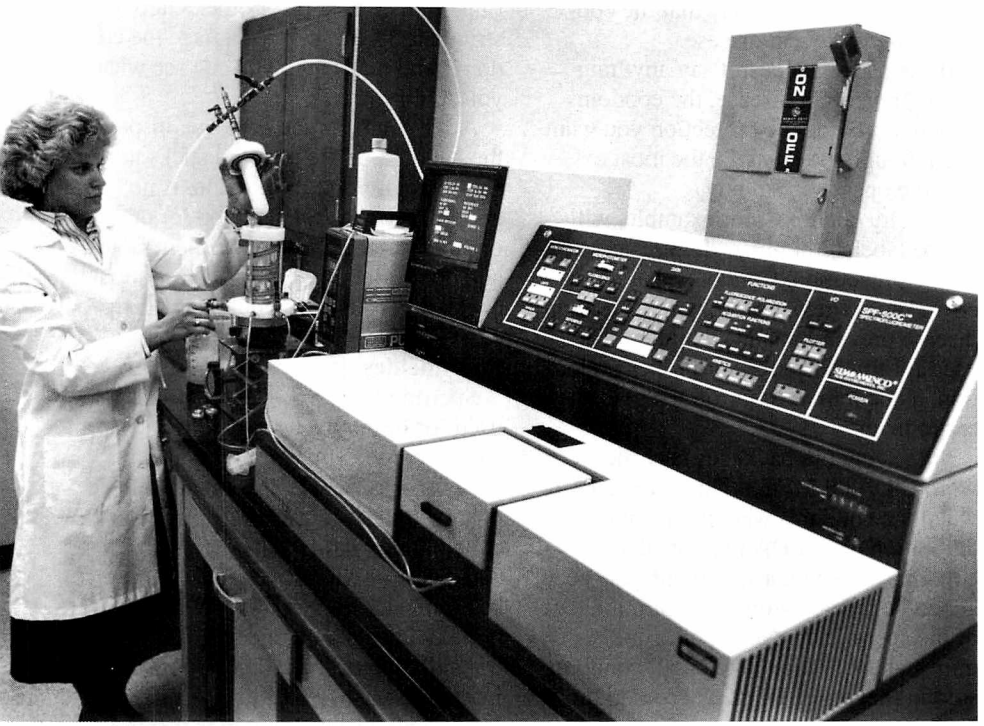
Only latex condoms labeled for protection against STDs should be used for disease protection. In the future, manufacturers may offer condoms of other materials and designs for disease prevention. As with all new products that make

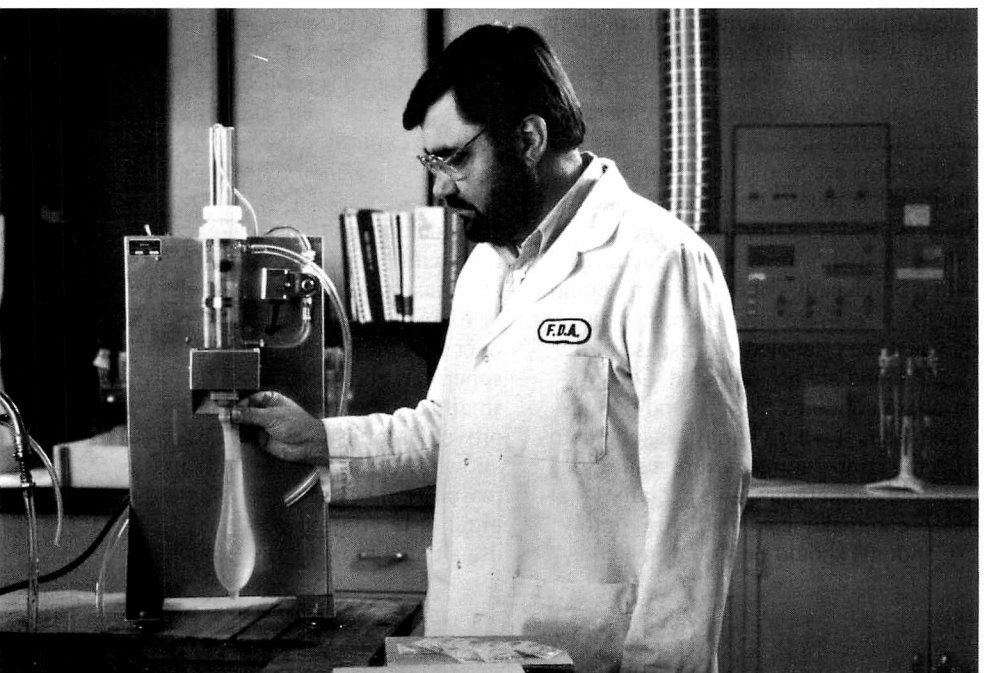


If a condom is sticking to itself, as is the one on the left, it's damaged and should not be used. Use condoms that look like the one on the right.

FDA's Jean Rinaldi, middle photo, demonstrates a test the agency developed for condoms that simulates actual use by incorporating such factors as body temperature and static pressure.

In the bottom photo, Tom Knott, a scientist in FDA's Baltimore district office, tests a condom using the "water-leak" test.





medical claims, these new condoms would have to be reviewed by FDA before they could be sold.

For many years, condoms have been labeled for the prevention of bacterially transmitted STDs, such as syphilis and gonorrhea. In 1987, however, FDA began allowing condom labeling to contain claims for the prevention of viral STDs such as HIV and herpes. The agency also reviewed the available medical literature showing that latex condoms offered some protection against the HIV virus, which is about 1/25th the size of sperm.

At that time, FDA revised its strategy for regulating condoms by stepping up its inspections of manufacturers and repackers, and its sampling and inspection of condoms in commercial distribution. It also made sure that imported condoms were tested before being allowed through U.S. Customs.

The agency also provided guidance on the labeling of condoms for use in disease prevention. In a letter to condom manufacturers, FDA suggested that the labeling language of condoms intended for disease protection include the following information, adapted by the manufacturer:

"When used properly, the latex condom may prevent the transmission of many sexually transmitted diseases (STDs) such as syphilis, gonorrhea, chlamydial infections, genital herpes,

Only latex condoms labeled for protection against STDs should be used for disease protection.

and AIDS. It cannot eliminate the risk. *For maximum protection, it is important to follow the accompanying instructions.* Failure to do so may result in loss of protection. During intimate contact, lesions and various body fluids can transmit STDs. Therefore, the condom should be applied before any such contact."

The agency also provided a sample set of instructions for using the condom, and requested that all condoms, whether or not they are labeled for STDs, include adequate instructions for use.

Leakage Standards

In strengthening its sampling and inspection of condoms, FDA adopted the voluntary standard established by the American Society for Testing Materials already being used by many manufacturers. Under this procedure, a sample of condoms is collected and then tested according to a statistically derived sample schedule. The standard requires that no more than an average of 4 condoms per 1,000 examined leak. If that level is exceeded, FDA can recommend recall or seizure of the substandard lots. In the instance of imported condoms, it can refuse entry to the United States.

The manufacturers and FDA inspectors determine condom leakage by filling the devices with water. *However, consumers should never use the "water test" on condoms they plan to use because filling a condom with any liquid weakens it.*

(FDA has recently developed an advanced system for testing condoms under conditions simulating actual use.)

All latex condoms sold in the United States, whether manufactured here or abroad, are subject to the same standards for leakage. At present, about 18 to 20 foreign manufacturers ship condoms to this country. FDA samples these condoms at ports of entry. The agency automatically detains condoms from companies whose products have previously failed entry criteria at a high rate. The condoms are not allowed into the United States until they are proven acceptable by results from an independent lab.

Although regulatory requirements and surveillance can go a long way towards ensuring the effectiveness of the product, how well condoms protect also depends a great deal on which condoms are chosen and how they are stored, handled and used.

Choosing a Condom

The first step in choosing a condom is to read the label and look particularly for the following:

- The condoms should be made of latex (rubber).
- The package should say that the condoms are to prevent disease.

If the package doesn't say anything about preventing disease, the condoms may not provide the protection you want even though they may be the most expensive ones you can buy.

Novelty condoms, for example, will not be labeled for either disease- or pregnancy-prevention. Condoms that don't cover the entire penis are not labeled for disease prevention and should not be used for this purpose. For proper protection, a condom *must* unroll to cover the entire penis.

Some condom packages bear the words "DATE MFG." This is the date when the condoms were made, not an expiration date. FDA requires that all condoms to which a spermicide has been added be labeled with the expiration date of the spermicide. New York state requires an expiration date on all condoms sold in that state. To gain access to the New York market, therefore, most of the five domestic manufacturers of condoms will now include this date on all their packages, usually abbreviated "EXP." The condom should not be purchased or used after that date.

Condoms are available in almost all pharmacies; many supermarkets and other stores also carry them. They are also available from vending machines. When purchasing condoms from vending machines, as from any source, be sure they are latex, labeled for disease prevention, and are not outdated. Do not purchase condoms from a vending machine located where it may be subject to extreme temperatures or direct sunlight. Extreme temperatures—especially heat—can make latex brittle or gummy.

Condoms should be stored in a cool, dry place out of direct sunlight. Closets or drawers usually make good storage places. Condoms should not be kept in a pocket, wallet or purse for more than a few hours at a time because they may be exposed to extreme temperatures. Places that may get very hot, such as car glove compartments, are particularly poor storage areas.

When opening a condom, handle the package gently. Don't use teeth, sharp fingernails, scissors, or other sharp instruments as these may damage the condom. And make sure you can see what you're doing!

After you open the package, inspect the condom. If the material sticks to itself or is gummy, the condom is no good. Check the condom top for other obvious damage such as brittleness, tears and holes, but don't unroll the condom to check it because this could damage it.

Spermicides

Spermicides, which kill sperm, are used for birth control either alone or with barrier contraceptives such as the diaphragm or cervical cap. Scientists have observed that, in test tubes, a spermicide called nonoxynol-9 kills organisms that cause STDs. Although it has not been scientifically proven, it is possible that nonoxynol-9 may reduce the risk of transmission of the AIDS virus during intercourse as well. Using a spermicide along with a latex condom is therefore advisable, and is an added precaution in case the condom breaks. Some condoms come with nonoxynol-9 already added. Their packages are required to be labeled with the expiration date of the spermicide, and they should not be used after that date.

Some experts think that even if a condom with spermicide is used, additional spermicide in the form of a jelly, cream or foam should be added. These are sold over the counter in pharmacies and some supermarkets. (Although swallowing small amounts of spermicide has not proven harmful in animal tests, it is not known if this is true for humans. For that reason, and because spermicides have a bitter taste, for oral sex it may be best to use a condom without spermicide.)

A pharmacist counsels a consumer about using condoms to prevent sexually transmitted diseases (STDs).

Spermicide should be added to the condom in the following way:
• Before placing it on the penis, put a small amount of spermicide inside the condom at its tip.
• After the condom is on the penis, apply more spermicide to the outside of the condom.
• Spermicide can also be placed inside the vagina. Directions for this are included in the spermicide package. Spermicides are required to carry expiration dates and should not be used after this date.

Lubricants

Lubricants may help prevent condoms from breaking during use and may prevent irritation that might increase the chance of infection. Some condoms already are lubricated with dry silicone, jelly or cream. If those you buy are not already lubricated, you can add water-based lubricants specifically made for this purpose (for example, K-Y Lubricating Jelly).

If you use a separate lubricant, never use a product that contains oils, fats or greases such as a petroleum-based jelly (for example, Vaseline), baby oil or lotion, hand or body lotions, cooking shortenings, or oily cosmetics such as cold creams. These can seriously weaken latex, causing a condom to tear easily. If you are not sure which product to use, ask your pharmacist.

If you use a spermicide, you do not need to use a lubricant because spermicide acts as a lubricant.

How to Use a Condom

The following guidelines are suggested to insure that the condom is used properly for disease protection:
• Use a new condom for every act of intercourse and oral sex.
• If the penis is uncircumcised, pull the foreskin back before putting on the condom.
• Put the condom on after the penis is erect and before *any* contact is made between the penis and any part of the partner's body.
• If using a spermicide, put some inside the condom tip.
• If the condom does not have a reservoir top, pinch the tip enough to leave a half-inch space for semen to collect.
• While pinching the half-inch tip, place the condom against the penis and unroll it all the way to the base. If you are using spermicide or lubricant, put more on the outside of the condom.
• If you feel the condom break during intercourse, stop immediately and withdraw. Do not continue until you put on a new condom and, if using spermicide, apply more.
• After ejaculation and before the penis gets soft, grip the rim of the condom and carefully withdraw.
• To remove the condom, gently pull it off the penis, being careful the semen doesn't spill out.
• Wrap the used condom in a tissue and throw it in the trash where others won't handle it. Because condoms may cause problems in sewers, don't flush them down the toilet. Afterwards, wash your hands with soap and water.
• Be aware that drugs and alcohol may affect your judgment and your ability to use a condom properly.

Although condoms afford good protection for vaginal and oral sex (where the penis is in contact with the mouth), the protection they give for anal sex is questionable. The Surgeon General of the Public Health Service has said, "Condoms provide some protection, but anal intercourse is simply too dangerous a practice."

Condoms may be more likely to break during anal intercourse than during other types of sex because of the greater amount of friction and other stresses involved. Even if the condom doesn't break, anal intercourse is very risky because it can cause rectal tissue to tear and bleed, allowing disease germs to pass more easily from one partner to another.

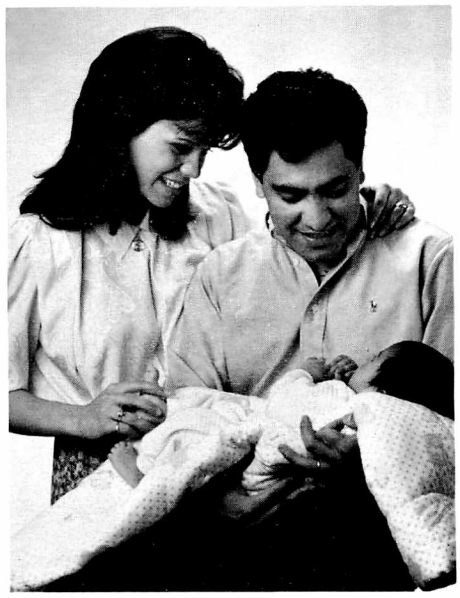
Because condoms are used for both birth control and reducing the risk of disease, some people think that other forms

Who Should Use a Condom?

To lessen the chance of being infected with AIDS or other STDs, people who take part in risky sexual behavior should *always* use a condom. High-risk behaviors include having sex—vaginal, anal or oral—with:

- a person who has an STD. This is the riskiest behavior. If you know your partner is infected, the best rule is to avoid intercourse (including oral sex). If you do decide to have sex with an infected person, always be sure to use a condom from start to finish, every time.
- someone who has shared needles to inject drugs with an infected person.
- someone whose past partner(s) was infected. Because the AIDS virus can be in the body a long time before a person gets sick, if your partner had intercourse with a person infected with HIV, he or she could pass it on to you even if the sexual contact was a long time ago—even as long as 10 years—and even if your partner seems perfectly healthy.

Use of a condom is also important for an uninfected pregnant woman because it can help protect her and her unborn child from STDs. ■



Condom use now can help protect any children you may have in the future from STDs that you might pass on to them.

STD Facts

- Sexually transmitted diseases affect more than 12 million men and women in the United States each year.
- Anyone can become infected through sexual intercourse with an infected person.
- Many of those infected are teenagers or young adults.
- Changing sexual partners adds to the risk of becoming infected.
- Sometimes, early in the infection, there may be no symptoms, or symptoms may be easily confused with other illnesses.

Sexually transmitted diseases can cause:

- tubal pregnancies, sometimes fatal to the mother and always fatal to the fetus
- death or severe damage to a baby born to an infected woman
- sterility
- cancer of the cervix in women
- damage to other parts of the body, including the heart, kidneys and brain
- death to infected individuals

See a doctor if you have any of these STD symptoms:

- discharge from the vagina, penis or rectum
- pain or burning during urination or intercourse
- pain in the abdomen (women), testicles (men), and buttocks and legs (both)
- blisters, open sores, warts, rash, or swelling in the genital area, sex organs, or mouth
- flu-like symptoms—including fever, headache, aching muscles, or swollen glands—which may accompany or precede STD symptoms. ■

of birth control will also protect them against disease. This is not true. Even if you use another form of birth control, you need a condom to reduce the risk of getting STDs.

Condoms do not make sex 100 percent safe, but, if properly used, they can reduce the chance of contracting STDs, including AIDS. This can mean protection not only for you and your partner, but also for any children you may have in the future. ■

—*Judith Levine Willis*

Some of the material in this article was taken from the FDA pamphlet *Condoms and Sexually Transmitted Diseases . . . Especially AIDS.* Copies of the pamphlet and other information about condoms and STDs are available from the National AIDS Hotline 24 hours a day. The phone numbers are:

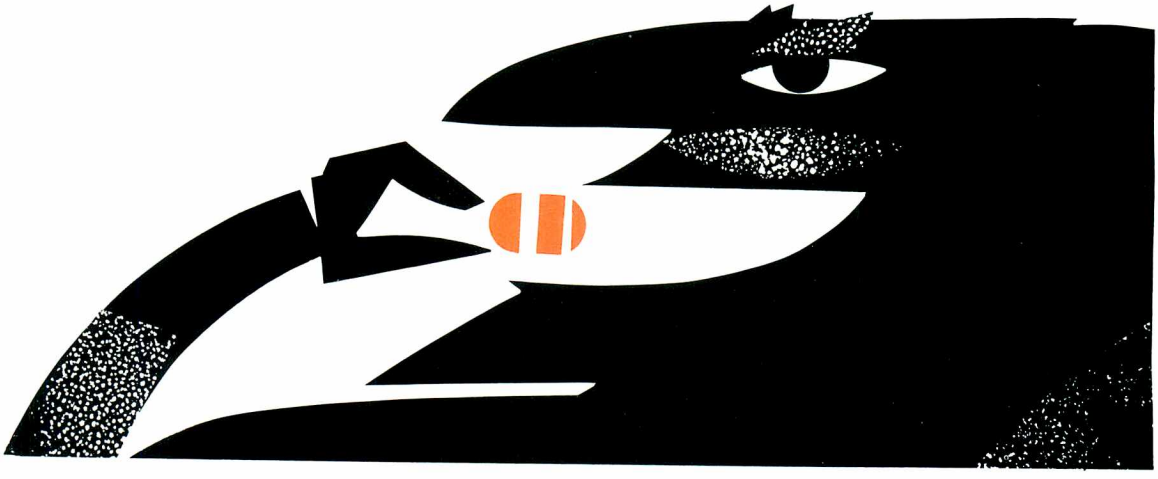
- 1-800-342-2437 (English)
- 1-800-344-7432 (Spanish)
- 1-800-2437-TTY (deaf access)

Information is also available from the National STD Hotline:

- 1-800-227-8922

How to Take Your Medicine

Antihistamines



How you take a medication makes a big difference in how well it works and how safe it will be for you. Sometimes it can be as important as what you take. Timing, what you eat and when you eat, proper dose, and many other factors can mean the difference between getting better, staying the same, or even getting worse. This drug information page is intended to help you make your medication work as effectively as possible. It is important to note, however, that this is only a guideline. You should talk to your doctor or pharmacist about how and when to take any prescribed drug.

This installment in a series of articles on commonly prescribed medications is about antihistamines. Some of these medications are available over-the-counter, or by prescription.

Antihistamines work by temporarily blocking the action of a substance produced by the body called histamine, which can cause itching, sneezing, runny nose and eyes, and other symptoms. Most of these drugs can have a drying effect on the nasal mucous. They are structurally related to local anesthetics and can produce sedation. The reason why some antihistamines are effective against motion sickness and some symptoms of Parkinson's disease is not known.

Generic Names

astemizole
azatadine
bromodiphenhydramine
*brompheniramine
carbinoxamine
*chlorpheniramine
clemastine
cyproheptadine
*dexbrompheniramine
*dexchlorpheniramine
*dimenhydrinate
*diphenhydramine
diphenylpyraline
*doxylamine
phenindamine
*pyrilamine
terfenadine
tripelennamine
*triprolidine

** Starred drugs are in over- the-counter products.*

Conditions These Drugs Treat

- hay fever and other allergies

A few antihistamines have special uses, such as for treating:

- cough due to colds or inhaled irritants
- motion sickness
- sleeplessness
- hives
- stiffness and tremors in patients with Parkinson's disease

How to Take

Extended-release tablets or capsules should be swallowed whole. The patient should follow directions on the container (or doctor's directions) on how often to take them.

Astemizole, one of the new relatively non-sedating antihistamines, is not absorbed well unless it is taken on an empty stomach, with no food one hour before and two hours after the medication.

Dimenhydrinate and diphenhydramine for motion sickness should be taken at least 30 minutes before travel and are most effective when taken one to two hours beforehand.

Missed Doses

These drugs are for symptomatic relief, and a missed dose does not have any

(Continued)

harmful consequences except for possible return of the symptoms. Too frequent dosing may cause increased sedation and other side effects.

Side Effects and Risks

Common side effects such as drowsiness may decrease somewhat as your body adjusts to the medicine.

Notify your doctor as soon as possible if you notice any of these symptoms after taking antihistamines:

- blurred vision
- painful or difficult urination
- unusual tiredness or severe drowsiness
- weakness, clumsiness or unsteadiness
- marked dryness of the mouth, nose or throat
- fainting, seizures, or other loss of consciousness
- hallucinations
- shortness of breath.

Some of these may be due to overdose, others to individual intolerance to the medication.

Precautions and Warnings

Most antihistamines cause some people to become drowsy. Make sure you know how you react to the drug you are taking before you drive or operate machinery. The elderly may be particularly susceptible to the sedative effect.

Do not give antihistamines to children under 6 years without consulting a doctor.

Antihistamines add to the effects of alcohol and other depressants. Therefore, avoid taking them close to the same time you drink alcohol or use drugs that slow down the nervous system, such as sedatives, tranquilizers, sleeping pills, narcotics, prescription pain medicines, seizure medications, muscle relaxants, or anesthetics.

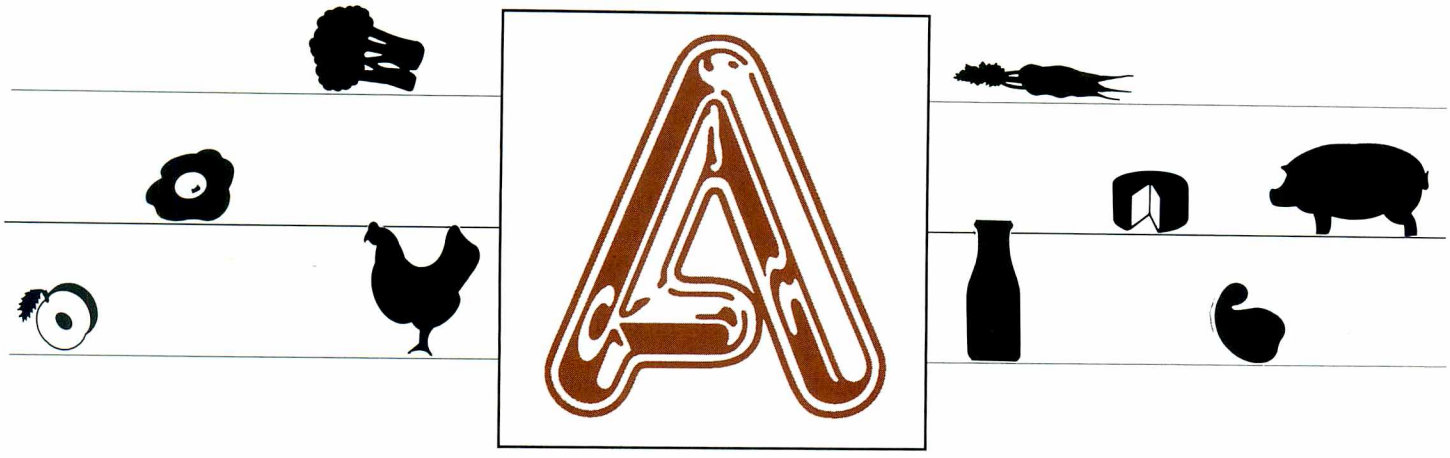
Antihistamines may also mask nausea associated with overdose from other medicines you are taking or from other medical conditions. If you suspect such effects while taking antihistamines, be sure to inform your doctor.

When buying over-the-counter products, be sure to read the ingredient labels to make certain you are not taking more than one product containing antihistamines. If you are already taking a sedative or tranquilizer, do not take antihistamines, including those sold over-the-counter as sleep aids, without checking with your doctor.

If you get skin tests for allergies or are receiving allergy injections, tell your doctor if you are taking antihistamines because these drugs can distort test results and mask reactions.

For relief of dry mouth, nose and throat caused by antihistamines, use sugarless candy or gum or melt pieces of ice in your mouth. If dryness continues for two weeks or more, it may increase the chance of dental disease. Check with your doctor or dentist if the symptom persists. ■

VITAMIN



This article is the first in a series giving essential facts and figures on different vitamins.

U. S. Recommended Daily Allowances

Infants (0-12 months)	Children (1-3 years)	Adults and Children 4 Years+	Pregnant or Nursing Women
1500 IU*	2500 IU	5000 IU	8000 IU

*International units

(The U.S. RDA amounts are sufficient to meet the needs of practically all healthy people.)

Vitamin A (retinoid) is a fat-soluble vitamin found mainly in animal foods in the vitamin form and in plant foods primarily as carotenes, substances that are formed into vitamin A chiefly in the small intestine.

Function: Essential for growth and for keeping skin and other tissues healthy; helps eyes to adapt to dim light and perceive colors; essential for normal tooth development.

Sources: Beef, chicken and pork livers; whole and vitamin A-fortified milk; cheddar cheese; butter; margarine; egg yolk; deep green, yellow or orange vegetables and fruits (including carrots, spinach, collards, broccoli, kale, nectarines, apricots, mangoes, cantaloupe, pumpkins, winter squash, turnip greens, sweet potatoes, and watermelon).

Deficiency: Vitamin A deficiency is rare in the United States; it mainly occurs among some people in developing countries. Some signs include skin changes, stunted growth, night blindness, and serious eye problems (such as drying, thickening, wrinkling, and muddy pigmentation of the mucous membrane lining the eyelid and eyeball, which eventually can destroy the eye). Inadequate intakes of foods containing vitamin A have been associated with some types of cancer, but the effect, if any, appears related to lack of carotene.

Excess: Because vitamin A is fat soluble, it is stored in the body. As a result, continued high doses (several times the U.S. RDA) have toxic effects. Signs of toxicity include dry and itching skin, headaches, and nausea and diarrhea. High vitamin A intake during pregnancy also may cause birth defects, but it is not known at what level this can occur. Excessive amounts of carotene are not known to be toxic, but will cause the skin to turn deep yellow. The color disappears when the amount of carotene in the diet is decreased. ■

Paula Kurtzweil, R.D., of FDA's Office of Public Affairs, and Theresa A. Young, of FDA's Philadelphia district office, contributed to this series.

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.*

■ **"Lite sour cream,"** a product of the T. Marzetti Co., will be test-marketed for 15 months. FDA issued the company a permit to temporarily sell the reduced-fat and reduced-calorie product as sour cream even though it deviates from the standards of identity for sour cream. For further information, contact Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFF-414), FDA, 200 C St., S.W., Washington, D.C. 20204, 202-485-0106. (*FR* May 2.)

■ **Estrogen drug products** will have revised patient package inserts, according to new FDA requirements. Changes in the inserts should reflect updated information about benefits and risks of estrogen drug use. For further information, contact Adele S. Seifried, Center for Drug Evaluation and Research (HFD-362), FDA, 5600 Fishers Lane, Rockville, Md. 20857, 301-295-8046. (*FR* May 4.)

■ **(Phthalocyaninato(2-))** copper may now be used to color nonabsorbable sutures used in general and ophthalmic surgery. This final rule responds to a petition filed by Davis & Geck. For further information, contact Sandra L. Varner, Center for Food Safety and Applied Nutrition (HFF-335), FDA, 200 C St., S.W., Washington, D.C. 20204, 202-472-5690. (*FR* May 10.)

■ **Hypophosphatemia** (low blood phosphate) may not be treated by an OTC product, according to a new final rule. Any OTC drug product labeled to treat this condition is misbranded. The final rule also states that aluminum phosphate may be used only in combination with other OTC antacid ingredients. For further information, contact William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), FDA, 5600 Fishers Lane, Rockville, Md. 20857, 301-295-8000. (*FR* May 11.)

■ **OTC deodorant drug products** for internal use may now be used only in ways outlined in a final FDA rule. The regulation applies to products taken internally to reduce odors from conditions such as colostomies, ileostomies, or fecal incontinence. For further information, contact William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), FDA, 5600 Fishers Lane, Rockville, Md. 20857, 301-295-8000. (*FR* May 11.)

■ **Action levels** for added harmful substances in food are defined as general statements of policy, according to a final FDA rule. The rule clarifies the legal status of action levels. Although they provide guidance to courts, action levels themselves do not have the "force of law." The rule also removes regulatory provisions for exemptions to action levels. For more information, contact John R. Wessel, Office of Regulatory Affairs (HFC-6), FDA, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-1815. (*FR* May 21.)

■ **Direct mail promotion by Health and Nutrition Laboratories, Inc.,** has been ended after an investigation by the Council of Better Business Bureaus. An ad by Health and Nutrition said its Berry Trim Weight Loss Product provided an "amazing weight-loss breakthrough," and the president offered an "iron-clad, legally binding personal and corporate" money-back guarantee for the product.

The National Advertising Division of the council noted that the product's principal active ingredient is not an accepted ingredient in weight-reduction products and questioned the absence of actual weight- and fat-loss data to support the claims. (*NAD Case Report*, May 21, 1990.)

■ **Contact lenses** may now be colored with D&C Red No. 17, according to an amendment in FDA's color additive regulations. The action was taken in response to a petition filed by Polymer Technology Corporation. Written objections should be sent to the Dockets Management Branch (HFA-305), FDA, Room 4-62, 5600 Fishers Lane, Rockville, Md. 20857. For more information, contact Andrew Laumbach, Center for Food Safety and Applied Nutrition (HFF-335), FDA, 200 C St., S.W., Washington, D.C. 20204, 202-472-5690. (*FR* June 5.)

■ **"Premarket Testing Guidelines** for Female Barrier Contraceptive Devices Also Intended to Prevent Sexually Transmitted Diseases," a draft document prepared to expedite pre-market study of the device, is now available. Send written requests for single copies to the Dockets Management Branch (HFA-305), Room 4-62, 5600 Fishers Lane, Rockville, Md. 20857. (*FR* June 7.) For more information, contact Lillian Yin, Center for Devices and Radiological Health (HFZ-470), FDA, 1390 Piccard Drive, Rockville, Md. 20850, 301-437-1180. (*FR* June 7.)

■ **A new seafood inspection program** is the subject of an advance notice of proposed rule-making issued by FDA and the National Marine Fisheries Service (NMFS). The voluntary, fee-for-service program would extend the use of Hazard Analysis Critical Control Point (HACCP) principles in the fish and seafood industries. For further information, contact George Hoskin, Center for Food Safety and Applied Nutrition (HFF-400), FDA, 200 C St., S.W., Washington, D.C. 20204, 202-245-1231, or Richard Cano, Office of Trade and Industry Services, NMFS, 1335 East-West Highway, Silver Spring, Md. 20910, 301-427-2355. (*FR* June 27.)

Drug Counterfeiter Sentenced

by Marian Segal

After months of international intrigue, the chase to bring a prescription drug counterfeiter to justice ended in a California courtroom last May 7, with sentencing of the defendant, Javid Naghdi, to 14 years in prison. This exceeded the term recommended under federal sentencing guidelines by nearly three years. In delivering the sentence, presiding Judge Judith N. Keep stated that an upward departure was justified in this case because "Naghdi's crime was one of the most callous, cruel and insensitive crimes I have ever seen." She characterized the defendant as "a serious threat to society."

The sentencing followed a four-week trial in the U.S. District Court for the Southern District of California, in which the 30-year-old Iranian national was convicted by a jury on nine counts of wire fraud. The indictment charged Naghdi with wire fraud based on a scheme to sell counterfeit Naprosyn, a nonsteroidal anti-inflammatory drug used primarily to treat arthritis; Tagamet, used to treat ulcers; and Anspor, an antibiotic used to treat various infections (see "Sting Operation Nabs Iranian Counterfeit Drug Dealer" in the April 1989 *FDA Consumer*).

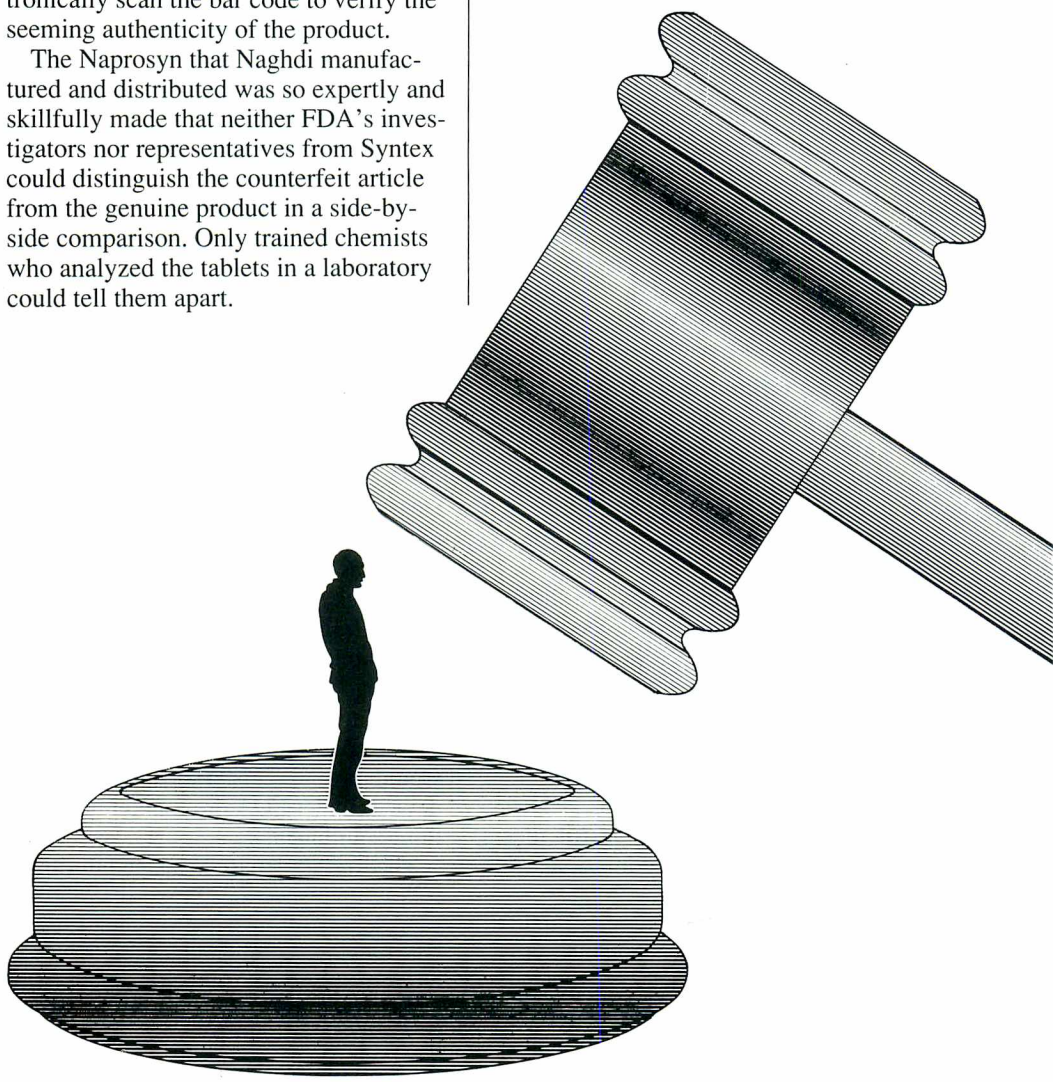
This was not Naghdi's first offense involving counterfeit drugs. On June 26, 1987, he had pleaded guilty in the U.S. District Court for the Central District of California to charges of conspiracy, manufacturing and distributing counterfeit Naprosyn and trafficking in goods bearing counterfeit trademarks.

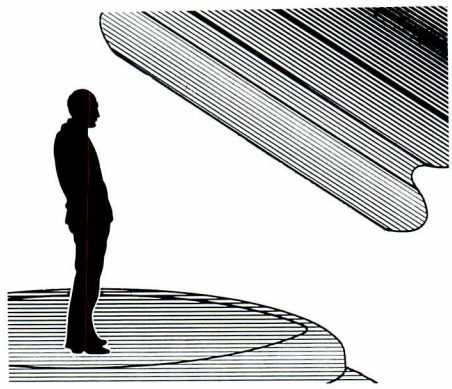
After Naghdi was apprehended on those charges, government agents learned that he had manufactured the counterfeit drug by obtaining tableting machines, bulk acetaminophen, bulk aspirin, bulk lactose, and coloring agents to manufacture the bogus Naprosyn. He also got tooling to imprint the trademark of the manufacturer (Syntex) on the tablets, bottles, bottle caps, bottle liners, package inserts, and art work to duplicate the Naprosyn carton and bottle label. In addition, Naghdi got a bar code for the counterfeit Naprosyn carton identical to that used by Syntex. Drug wholesalers and retail pharmacists could electronically scan the bar code to verify the seeming authenticity of the product.

The Naprosyn that Naghdi manufactured and distributed was so expertly and skillfully made that neither FDA's investigators nor representatives from Syntex could distinguish the counterfeit article from the genuine product in a side-by-side comparison. Only trained chemists who analyzed the tablets in a laboratory could tell them apart.

Sentencing in that case was set for Aug. 3, 1987, but Naghdi fled the United States for England before sentencing. From London, he continued his illegal activities. In October 1987, Naghdi began sending American drug wholesalers and commodities brokers offers to sell 8 million bottles of Tagamet and Anspor (both manufactured by SmithKline Beckman) and Naprosyn for approximately $485 million.

To convince prospective purchasers





that he had millions of bottles of Naprosyn, Tagamet and Anspor that had been sold to him by the drugs' manufacturers, Naghdi gave prospective purchasers fraudulent shipping documents, a forged financial statement, a phony insurance policy, and numerous forged documents on fake SmithKline and Syntex letterhead seeming to verify the authenticity of the drugs. Naghdi told the prospective buyers that the drugs had been shipped to him from Syntex's and SmithKline's manufacturing facilities and were being stored in a bonded warehouse in Tampico, Mexico.

A lengthy undercover investigation by the Justice Department, U.S. Customs Service, and FDA led to Naghdi's arrest Aug. 12, 1988, in London. Following extradition proceedings, he was returned to the United States to stand trial in San Diego and to be sentenced in the earlier counterfeiting case.

When arrested, Naghdi possessed numerous documents relating to a variety of frauds, including some that appeared to relate to the sale of arms to Iran. Before the trial began, Naghdi's lawyer tried to use these documents to prove that his client was acting as an operative for the Central Intelligence Agency and using the drug scam as a cover for his part in the Iran-Contra affair.

Naghdi attempted to subpoena corroborating documents from the Central Intelligence Agency, the Defense Intelligence Agency, and the National Security Administration. He also tried to subpoena 55 high-ranking government officials—including Oliver North, Caspar Weinberger, and Robert McFarland—to testify on his behalf. Almost all of these subpoena requests were denied because he could not show that the individuals he sought to subpoena had any relevant information to impart about him.

In FDA's history, there have been few known attempts to manufacture and distribute counterfeit prescription drugs on the legitimate market. Within the past five years, however, FDA has brought successful enforcement actions in cases involving counterfeiting of Ovulen 21 birth control pills and of two antibiotics, Ceclor and Pipracil.

Naghdi may have been the most cunning counterfeiter, however, according to Colleen Martin, the FDA attorney involved in his case. "Naghdi's counterfeiting skills," she says, "combined with his education and training in pharmaceutics and in-depth knowledge of the pharmaceutical industry, make him by far the most dangerous prescription drug counterfeiter known to the FDA."

Judge Keep agreed. During the sentencing, she said, "This was one of the most elaborate and extensive fraud schemes I've ever seen," and described Naghdi as "a master of innuendo—glib, quick and slippery."

The 14-year sentence will run consecutively with a five-year sentence imposed in the Central District of California July 7, 1989, for the earlier counterfeit scheme.

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

Pressure Chambers Destroyed

A five-year FDA investigation that sent the agency around the country in search of misbranded hyperbaric oxygen chambers led to the destruction of five of these illegal devices.

Frenco Laboratories, Inc., of Dallas, had been selling fiberglass hyperbaric oxygen chambers since 1982. The pressure chambers, which are filled with pure oxygen, were promoted to hospitals and clinics to treat numerous medical conditions, including acne, arthritis, cancer, atherosclerosis, decompression sickness, Parkinson's disease, lupus, gastric ulcers, leprosy, heart attacks, and multiple sclerosis.

Although FDA has recognized stainless steel chambers as acceptable in the treatment of some disorders—such as carbon monoxide poisoning, decompression sickness, embolisms, burns, and certain ulcers—the agency has not approved fiberglass ones for any uses.

FDA's Dallas district office first inspected Frenco in January 1984, about two years after company president Charles Thedford bought the medical device manufacturing firm (formerly known as Lamex, Inc.). During this routine check, Thedford told investigator Sandy Zeigler that his company intended to manufacture and sell new fiberglass hyperbaric oxygen chambers, in addition to leasing the Lamex chambers it had acquired. Zeigler told Thedford that he would have to register the new medical devices under FDA pre-market notification requirements.

Thedford failed to do so, and during follow-up inspections in April 1985, FDA learned from Thedford that Frenco was illegally selling and leasing the fiberglass chambers. FDA investigators located four of them in Texas and Oklahoma. Donald Healton, FDA southwest regional director, wrote Thedford on Nov. 25, 1985, warning him that the agency was prepared to seize the devices if Frenco did not comply with the law.

Thedford replied that he had recalled four chambers and would not sell additional ones. He also proposed to replace the unapproved fiberglass shells of four chambers he had sold with stainless steel shells. FDA rejected the proposal, and Thedford agreed to recall all Frenco fiberglass chambers by Feb. 24, 1986.

When FDA learned the next month that Frenco had not recalled the chambers, the agency launched its effort to remove them from distribution. At FDA's request, U.S. marshals seized the four chambers in Oklahoma and Texas, three of which were later destroyed.

Zeigler visited Frenco in January 1987 to close out the recall of the four chambers remaining in distribution.

Thedford refused to divulge their location, saying only that they were "in a warehouse." Zeigler informed Thedford that FDA required knowledge of the chambers and instructed him to write the agency detailing their location.

Thedford failed to submit a letter, and Zeigler returned two months later with another notice of inspection. Thedford then allowed him to visit the warehouse, where Zeigler found only two of the chambers. Thedford said another was at his home in Dallas, and the fiberglass shell of the fourth had been shipped to Joe Brown in LaQuey, Mo. Zeigler located Brown in Ida, Ark., and, at this writing, the agency is still investigating the location of this chamber.

In September 1988, Zeigler again contacted Thedford about the recall and learned that the company now had only one fiberglass chamber in its possession—the one stored at Thedford's residence.

The two at the warehouse had been repossessed by First City Bank in Richardson, Texas. (Thedford had used them as collateral for a loan.) One of the repossessed chambers had been sold to Brown. FDA is also searching for this chamber in Arkansas. The other repossessed chamber was destroyed under FDA supervision, with the bank's consent.

On Feb. 15, 1989, the U.S. District Court for the Northern District of Texas ordered seizure of the hyperbaric oxygen chamber in Thedford's possession. It was destroyed in October.

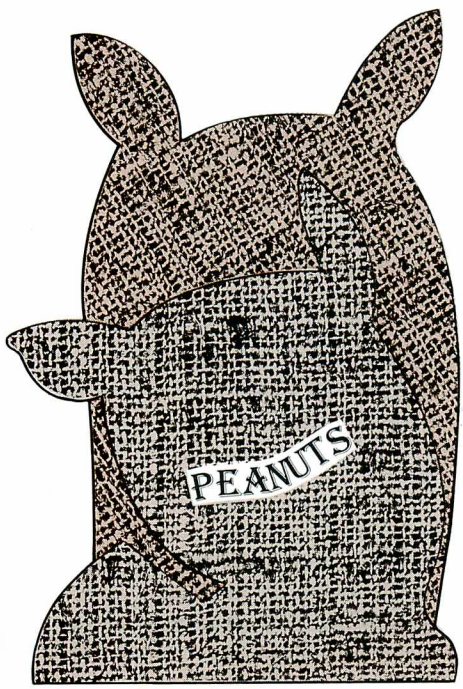
Fines and Probation For Peanut Problems

A Suffolk, Va., warehouse company and its president were ordered in March to pay thousands of dollars in fines, serve probation, and hire a sanitary engineer after FDA investigators found peanuts held in storage contaminated by human urine, mouse urine, and insects. The contamination by human urine is one of only two or three such incidences documented by FDA in the past 14 years, according to FDA's Center for Food Safety and Applied Nutrition.

The case revolves around Mar-Ja Inc., a company of nine warehouses—seven of which are cold storage units used to store bulk peanuts shelled and in the shell. The president of the company, James Pond Sr. of Suffolk, also is involved.

During a routine inspection of the company in May and June 1986, Charlotte Pacilio and Ed Creech, FDA investigators with the Norfolk, Va., resident post, discovered a number of sanitation violations. Chief among them were urine stains in cascading patterns. The stains, which had penetrated several burlap bags stored in three of the warehouses, were unlike the tiny dribbling pattern usually found with rodents. These stains showed up under black light inspection as clusters over a 30- to 41-centimeter area and had a cascading appearance.

Pacilio and Creech immediately suspected human urine and noted at that time that the rest room, which was in insanitary condition itself, was fairly distant from the warehouses, suggesting that an employee had opted to urinate in the warehouses. Subsequent laboratory analysis by FDA of several stain samples indicated a high probability that the urine was of human origin.



Pacilio and Creech also found numerous insects on or near peanut bags and rodent urine that had penetrated the burlap covering.

On Aug. 15, 1986, FDA initiated a seizure action in the U.S. District Court for the Eastern District of Virginia, Norfolk Division, that prohibited Mar-Ja from selling contaminated lots of peanuts until they had been reconditioned by destroying the urine-contaminated bags, fumigating the insect-infested ones, and then removing the dead insects.

On Sept. 23, 1986, Mar-Ja told FDA it was ready to begin reconditioning. However, when Pacilio went to oversee the process that same day, she found that conditions had actually worsened. Investigators Creech and Michael Verdi from the Richmond resident post were called in on Sept. 25 to continue the reinspection, which ran into October. They found that the warehouses had not yet been fumigated, that rodent and insect infestation had increased, and that there was still evidence of mouse urine.

Following the second inspection, FDA turned over its findings to the Justice Department for prosecution. On Oct. 19, 1989, a Norfolk, Va., grand jury returned a six-count misdemeanor indictment against Mar-Ja and Pond for allowing foodstuffs to be stored under insanitary conditions in which they might become contaminated by insects, rodents and human urine. Three counts also charged that the peanuts were adulterated by insects and insect parts.

Before trial, on Jan. 5, 1990, Pond pleaded guilty to one count of insect infestation and one count of contamination by both insects and rodent urine. The company pleaded guilty to all six counts on Jan. 8, 1990.

Sentencing, originally scheduled for Feb. 16, was postponed one month by U.S. District Judge Robert Doumar, who asked FDA to reinspect the warehouses and report back to him. That same day and continuing into the next week, Pacilio and Creech inspected Mar-Ja and

found that conditions had improved, although insect infestation persisted. The investigators also noted that improper storage of bags prevented adequate inspection.

At the same time, investigators Miriam Stuckey and Russ Davis of the Norfolk resident post also inspected Producers Peanut Co. Inc—a peanut butter manufacturing company of which Pond was also president. FDA was concerned about conditions at Producers Peanut because the company, located across a driveway from Mar-Ja, was storing peanuts at Mar-Ja. FDA had received prior permission from Judge Doumar to present its findings regarding Producers Peanut at sentencing.

Conditions were less than ideal at Producers Peanut, where investigators found insects in all life stages inside peanut butter production equipment. Company managers acknowledged that the equipment was not taken apart and fumigated regularly and said it had been nine months since it had last been done. They said they would clean up and fumigate the equipment that weekend; however, the following Monday, investigators found dead insects inside the equipment.

FDA presented these findings, along with those of the two 1986 inspections, during sentencing March 16. Judge Doumar fined Mar-Ja $23,000 with $10,000 suspended, placed the company on two years' probation, and ordered it to hire a sanitary engineer and comply with the Federal Food, Drug, and Cosmetic Act.

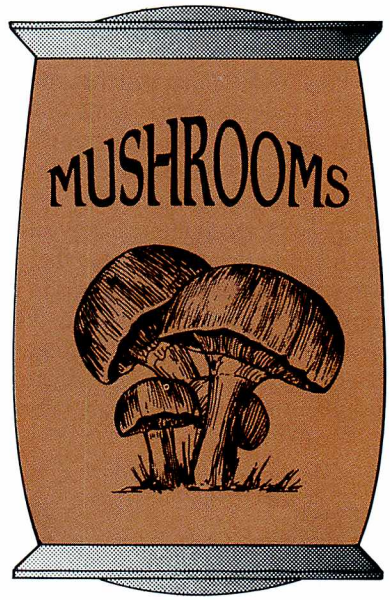
Pond was sentenced to a 90-day suspended jail term, fined $4,100, and ordered to perform 100 hours of community service. In addition, he was placed on two years' probation and ordered to hire a sanitary engineer, comply with the FD&C Act, and provide records to the probationary officer showing compliance with the judge's orders. He also was ordered not to sell or merge his business interests or acquire new companies without consent of the court.

As for the human urine contamination, Mar-Ja has since built a new rest room closer to the warehouses.

Chinese Mushrooms Detained

Contaminated mushrooms from China were seized from a U.S. importer to keep the product from consumers here and abroad. Some of the cans of mushrooms were swollen and leaking, but many others gave no clue that they contained a toxin, produced by *Staphylococcus aureus* bacteria, that can cause severe food poisoning.

Chemists in FDA's Los Angeles district laboratory detected the toxin in a sample collected by FDA investigators



during a routine inspection of imported goods at the Los Angeles warehouse of S.E. Rykoff & Company in June 1989. Rykoff was distributing the mushrooms for the importer, Princeton International, Inc., Los Angeles. FDA's Center for Food Safety and Applied Nutrition in Washington, D.C., confirmed the findings.

Although no illnesses were associated with these mushrooms, several outbreaks of staphylococcal food poisoning had been linked to previous shipments of Chinese mushrooms in 1989, and FDA concluded that the contamination was probably widespread throughout the mushroom industry in China.

On Oct. 23, 1989, the agency announced that all mushrooms imported from the Peoples Republic of China would automatically be detained until the Chinese government identified the causes of the contamination and corrected the problems. At this writing, most mushrooms from China are still under automatic detention.

Bacteria produce gases that cause the cans to swell. Heat treatment during the canning process kills the bacteria, but does not affect toxins produced before the bacteria are destroyed. Analyzing the mushrooms from Rykoff, FDA determined that the non-swollen cans could not be assumed safe from toxin because they may have been contaminated before heat treatment, whereas the swollen cans were contaminated after treatment.

When FDA informed Princeton International of its findings, the company voluntarily recalled all mushrooms from a lot that had already been distributed. Of 800 cartons in the lot, Princeton was able to recover 628 by November. At that time, the firm's president, George Lin, requested that FDA issue a Notice of Refusal of Admission and let him ship the mushrooms back to China.

FDA refused, according to compliance officer Mary LoVetere, because "we didn't want [the contaminated mushrooms] going to another country." She added that it was possible that the mushrooms might be reshipped to the United States.

To make sure that the recalled mushrooms would not reach consumers, FDA asked the U.S. District Court for the Central District of California to seize the lot. U.S. marshals seized the 628 cartons, valued at $31,600, on Feb. 1, 1990.

Because Princeton did not file a claim for the mushrooms after the seizure, the court issued a default judgment on Feb. 23. However, shortly after it was issued, Lin requested that the default be set aside and again asked that he be allowed to return the mushrooms to China. The court denied Lin's request on May 17. FDA has asked U.S. marshals to destroy the mushrooms.

—This small sample of reports from the field was compiled by Dale Blumenthal, Paula Kurtzweil, and Dori Stehlin.

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

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

SEIZURE ACTIONS

Food/Contamination, Decomposition, Insanitary Handling

PRODUCT: **Peanuts, shelled, peanut pieces, cashew pieces, and filberts,** at Boykins, E. Dist. Va.; Civil No. 89-573-N.
CHARGED 8-8-89: While held by Aster Nut Products, Inc., Boykins, Va., the articles had been held under insanitary conditions—402(a)(4).
DISPOSITION: Consent—authorized release to dealer for salvaging. (F.D.C. No. 65689; S. No. 89-585-205 et al.; S.J. No. 1)

PRODUCT: **Scallops, frozen, and other seafood stocks,** at Elk Grove Village, N. Dist. Ill.; Civil No. 88 C 8741.
CHARGED 10-13-88: While held by Impex Shrimp & Fish Co., Inc., Elk Grove Village, Ill., the articles had been held under insanitary conditions, and the scallops contained rodent filth or decomposed seafood—402(a)(3), 402(a)(4).
DISPOSITION: The articles were claimed by the dealer. The dealer moved for a consent decree of partial condemnation and destruction, because the freezers where the articles were stored were crowded and approximately 150 pallets of miscellaneous seafood needed to be removed to allow for cleaning and maintenance operations. A consent decree ordering the destruction of 150 pallets of such articles was entered. Subsequently, pursuant to stipulation, a lot known as "Royal Bengal Brand—Raw, Peeled, Bangladesh Shrimp" that was held under U.S. Customs Office entry E180003505-0 was released for exportation. Ultimately, a consent decree of condemnation authorized release of the remaining articles for salvaging. (F.D.C. No. 65554; S. No. 89-507-087 et al.; S.J. No. 2)

Food/Economic and Labeling Violations

PRODUCT: **Cereal flakes, bottled drinking water, farina, and pre-cooked rice,** at New Bedford, Dist. Mass.; Civil No. 89-1136-2.
CHARGED 5-23-89: When imported, the labeling of the bottled drinking water bore nutritional information that was not in the prescribed format, and the other articles contained added vitamins and minerals but their labels lacked nutritional information in the prescribed format—403(a)(1), 201(h); required words and other label information were not prominently placed on the labels with such conspicuousness and in such terms as to be read and understood since (except for the water) the common or usual name of the foods was in Portuguese rather than English, since the name and place of business of the manufacturer, packer and distributor did not appear in prescribed locations on the drinking water and farina and (in the case of the drinking water) was partially obscured by a sticker label, since the labels of the cereal flakes, farina and pre-cooked rice lacked the name of their ingredients in English, and since nutrition information failed to appear as prescribed on the labels of the drinking water, the cereal flakes, and the pre-cooked rice—403(f); and the articles were also in violation of the Fair Packaging and Labeling Act, since the quantity of contents statement of the drinking water was not separately stated as required and the quantity of contents statements of the other articles were not in the established type size and (for all of the articles) was not expressed in the required terms—15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i), 1453(a)(3)(A)(i).
DISPOSITION: Default—ordered constructive destruction by donation to a bona fide charitable organization. (F.D.C. No. 65598; S. No. 89-531-824 et al.; S.J. No. 3)

Food Additives

PRODUCT: **Germanium complex capsules, in bulk carton and in retail bottles,** at Hauppauge, E. Dist. N.Y.; Civil No. 89-1227.
CHARGED 4-18-89: While held for sale by Consac Industries, Inc., Hauppauge, N.Y., the article labeled (retail bottle) "Super Potency Germanium Complex . . . Germanium Sesquioxide GeOxy 132 . . . Country Life, Hauppauge, N.Y." and (bulk carton) "Consac Industries, Inc. . . . Hauppauge, N.Y. . . . GE-132 (Germanium Sesquioxide) . . . garden state nutrition" contained the nonconforming food additive germanium sesquioxide—402(a)(2)(C).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65610; S. No. 89-521-094; S.J. No. 4)

PRODUCT: **Crab meat chunks, canned,** at Port Royal, Dist. S.C.; Civil No. 87-0076-8.
CHARGED 1-13-87 and amended 6-10-87: While held for sale, the article contained a nonconforming food additive—a sulfiting agent calculated as sulfur dioxide—402(a)(2)(C); and the labeling of the article failed to declare the presence of such sulfiting agent (sodium sulfite)—403(k).
DISPOSITION: The article was claimed by Blue Channel Corp., Port Royal, S.C., who denied the original 402(a)(2)(C) charge and asserted as a defense that sulfur dioxide was authorized to be used as a preservative if the food was not recognized as a source of a nutrient and that canned crab meat was not a food containing significant sources of nutrient. The government subsequently informed the claimant that it did not intend to further pursue the 402(a)(2)(C) adulteration charge and amended the complaint to add the charge that the article was misbranded under 403(k).

The claimant filed an answer to the amended complaint and shortly thereafter filed an amended answer. As a defense and by way of a counterclaim, the claimant alleged that the article was not

adulterated at the time of seizure, that adulteration was the only ground initially given for the seizure, and that the article was wrongfully seized. The parties served written interrogatories on each other.

The claimant moved for a stay of the action, or in the alternative for a stay of all discovery on the grounds that there was an impending criminal action involving some of the same parties and their agents. However, before the court ruled on the motion, the impending action was resolved in favor of the claimant, thereby mooting the motion. After additional discovery, the government moved for summary judgment.

Ultimately, without admitting or denying allegations of wrongdoing, the claimant entered into a consent decree of condemnation that adjudged that the article did not declare the presence of the food additive sulfiting agent and authorized the article to be released to the claimant for relabeling. (F.D.C. No. 65083; S. No. 87-435-076/8; S.J. No. 5)

Drugs/Human Use

PRODUCT: **Appetite control kit for weight reduction (bottle of homeopathic formula drops with adhesive patches),** at Lynwood and Sylmar, C. Dist. Calif.; Civil No. 88-3245 RSWL (Tx).
CHARGED 6-8-88: While held by BECO Chemical Co., Inc., Lynwood, Calif. (who manufactured the drops and assembled finished kits), and Jerica Packaging (who also packaged finished kits), the kits (labeled "Appetoff Appetite Control Program Distributed By: Meditrend International . . . San Diego, CA") were new drugs without effective approved new drug applications—505(a); the labeling of the kits was false and misleading in claiming that the kits were effective for appetite control—502(a); and adequate directions for use could not be written for lay use of the kits for their intended use—502(f)(1).
DISPOSITION: Default—ordered destroyed. (F.D.C. Nos. 65486/7; S. Nos. 88-259-754 et al.; S.J. No. 6)

PRODUCT: **Clarins skin treatment product,** at Oakland, Dist. N.J.; Civil No. 89-2936.
CHARGED 7-14-89: When imported from France by Clarins USA, Inc., Oakland, N.J., the article, labeled "Clarins Paris Double Serum Multi-Regenerant 'Anti-Aging' Total Skin Supplement Hydro Serum . . . Lipo Serum," and accompanied by package insert reading "Clarins 'Double Serum'—'Anti-Aging' . . . to combat all signs of aging of the skin" and by literature reading "Clarins . . . Reference Guide for a Youthful Face, a Firm Bust, or Toned Body . . . III Preventative Aging Treatments" and "Clarins . . . Guia y Consejos para la Juventud del Rosto, la Belleza del Busto, la Estetica del Cuerpo . . . III Tratamientos Anti-Evejecimiento," was a new drug without an effective approved New Drug Application—505(a); and, when shipped and while held for sale, the article's labeling lacked adequate directions for use, and the article was not exempt due to its new drug status—502(f)(1).
DISPOSITION: Consent—authorized release to importer for return to original foreign supplier in France. (F.D.C. No. 65665; S. No. 89-545-663; S.J. No. 7)

Medical Devices

PRODUCT: **Condoms,** at Los Angeles, C. Dist. Calif.; Civil No. 89-4936 JMI(Sx).
CHARGED 8-17-89: The article, which had been imported from Hong Kong, China, and was labeled "Lubricated Olympus Latex Prophylactics Made in Korea," failed to bear a label containing the name and place of business of the manufacturer, packer or distributor—502(b)(1); and the quality of the article fell below the article's purported quality due to excessive holes—501(c).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65698-A; S. No. 89-378-214; S.J. No. 8)

PRODUCT: **Gloves, latex, for examination**, at Compton, C. Dist. Calif.; Civil No. 88-7245FFF(Kx).
CHARGED 12-8-88: The quality of the articles, some that were unlabeled and some labeled "Examination M2 Gloves . . . Made In China . . . Distributed By: Kensington Industries, Inc. . . . North Miami, Florida," fell below their purported quality—501(c).
DISPOSITION: The articles were claimed by Kensington Industries, Inc. (Marc Sporn), N. Miami, Fla., who denied the charge and who asserted as an affirmative defense that the alleged violation of the article did not occur after the articles had been imported, that previously the claimant had no cause for believing that the articles were in alleged violation, and that, accordingly, the goods should be re-exported to the manufacturer for credit.

The government filed a motion for summary judgment, arguing that the government needed only to establish that the articles were adulterated and that the government's evidence (demonstrating that the gloves were defective) could not reasonably be controverted. The matter was set for a hearing, but the claimant failed to file an opposition to the motion. Accordingly, the court took the summary judgment motion under submission without oral argument and subsequently ordered summary judgment in the government's favor.

The claimant and U.S. Surgical Supply Corp. (Marc Sporn) proposed that they should be permitted to re-export the condemned gloves. FDA reviewed the re-export proposal and determined that the claimant had not met the statutory burden required for re-export. Accordingly, the government moved for an order of destruction, which was granted by the court. (F.D.C. No. 65568; S. No. 89-567-401 et al.; S.J. No. 9)

PRODUCT: **Jupiter Electronic Acupuncture device,** at Birmingham, N. Dist. Ala.; Civil No. 89L1247S.
CHARGED 7-20-89: The article, labeled "Electronic Acupuncture Model 707 Made In Taiwan," was accompanied by promotional materials containing false and misleading claims for convulsions, shock, diabetes, hypertension, bronchitis, asthma, cystitis, deafness, tinnitis, paralysis, dysentery, enuresis, liver and kidney ailments, edema, toothache, and other conditions—502(a); the article's labeling lacked adequate directions for its intended

use—502(f)(1); the article's labeling lacked adequate warnings for safe use—502(f)(2); pre-market notification had not been submitted—502(o); and the article (a device classified in class III) lacked an effective approved application for pre-market approval—501(f)(1)(B).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65691; S. No. 89-504-296; S.J. No. 10)

CRIMINAL ACTIONS

DEFENDANTS: **Eden Foods, Inc., and Michael J. Potter,** president, Clinton, E. Dist. Mich.; Criminal No. 88-80489.
CHARGED 7-14-88: While the soy-food product Edensoy was being held for sale after being imported from Japan, the defendants labeled and caused the labeling of 13 specified shipments of the article (counts 1–13) with a pamphlet entitled "Edensoy," which read in part "GOOD FOR BABIES Nothing can surpass mother's milk . . . but . . . Edensoy is a quality substitute. It may be used with confidence for bottle fed babies. Infants formula . . . because babies under the age of one year cannot tolerate (digest) cow's milk. Vegetable quality babies cry less." Such food product was an infant formula within the meaning of 321(aa) because of the above pamphlet and because of published advertisements reading "Easily-digested EDENSOY is a preferred milk substitute for children who cannot tolerate dairy milk or liquid or powdered formulas"; and the product's required valuable constituents (i.e., vitamins A, D, E, C, B_1, B_{12}, pantothenic acid, calcium, and iodine) had been omitted and abstracted from the article—402(b)(1); that when such 13 specified shipment of the Edensoy food product were subsequently shipped (counts 14–26) to specified interstate consignees, the food product's labeling was false and misleading, because the food product, contrary to the product's claims, was neither an appropriate substitute for mother's milk nor a substitute for infant formula since the product lacked ingredients essential to the health of babies and contained other ingredients in excess of the amounts appropriate for babies—403(a). In addition, three other interstate shipments of a soy-food product labeled in part "Natural Edensoy Eden Foods, Inc. Clinton, Michigan Product of Japan" were charged to be adulterated (counts 27–29) and misbranded (counts 30–32) because they lacked the required minimum levels of vitamins A, D, E, C, B_1, B_{12}, pantothenic acid, calcium, and iodine, and the food exceeded the maximum permitted levels of sodium, potassium and protein—402(b)(1), 500a(a)(1)(A), and because their labeling was false and misleading—403(a).
DISPOSITION: The defendants moved to dismiss and/or compel an election on the basis that the adulteration and misbranding counts were multiplicitous and that the 301(a) and 301(k) counts were similarly multiplicitous. The defendants moved to dismiss the charges on the grounds that the charges all hinged on the allegation that five sentences caused an adult beverage/cooking agent to metamorphize into an infant formula and that the statute's definition of infant formula as a food "for special dietary use and solely as a food for infants" did not include their product, which was not a food solely for infants, and that the magazine advertisement was not "labeling" and was therefore not within FDA's jurisdiction. After the court denied such motion, the individual pleaded guilty to count 12; and he was sentenced to one year imprisonment (of which all but 30 days imprisonment were suspended), was fined $25,000, and was placed on probation for two years. The corporation pleaded guilty to counts 1, 3, 5, 7, 11, 12, 15, 17, 19, and 21; and it was fined $111,000. (F.D.C. No. 64575; S. No. 85-308-809, et al.; S.J. No. 11)

DEFENDANTS: **Wesley A. Jacobs, D.V.M., and Santokh Singh Takhar, D.V.M.,** owners of an animal hospital, Hilmar, E. Dist. Calif.; Criminal No. 86-108.
CHARGED 6-23-86 by grand jury: (count 1) that, while held for sale, chloramphenicol had omitted from its labeling the statement that the product was not to be used in animals that are raised for food production, which resulted in the chloramphenicol labeling being false and misleading—502(a); (count 2) that, while held for sale, chloramphenicol was sold for use in animals raised for food production, a use for which no approved New Animal Drug Application was in effect—501(a)(5); and (count 3) that Jacobs knowingly made to an FDA investigator during an FDA inspection certain false statements of material fact (i.e., that Jacobs' animal hospital had no chloramphenicol powder and no finished chloramphenicol solution on hand and was no longer dispensing chloramphenicol except for dogs and cats), when Jacobs knew such statements were untrue—18 U.S.C. 1001.
DISPOSITION: *District Court*—The defendants moved to dismiss the indictment, primarily on the following grounds: that FDA's "extra label drug use" policy (a policy of refraining from action against veterinary use of any approved new animal drug regardless of label indications for use) had been withheld from the grand jury; and that, with the disclosure of such exculpatory evidence, the evidence presented to the grand jury would not have supported the indictment. The defendants also argued that the defendants did not have sufficient notice of FDA's policies regarding the prohibition against prescribing chloramphenicol in food-producing animals. The defendants also moved for a bill of particulars, sought to view the grand jury testimony, and amended and renewed their motion to dismiss. After additional litigation, including a government motion *in limine* to exclude the defendants from introducing evidence at trial concerning whether chloramphenicol was hazardous and other matters, the case came on for trial before the court and a jury.

On the second day of the trial, a government witness mistakenly testified that a government document was incomplete, and the court dismissed the indictment for prosecutorial misconduct because the court believed that the government had not complied with court orders of complete discovery production. In fact, the government had complied fully; and the government prosecutor had corrected the testimony after a two-minute delay. Later that same day, the government filed a motion for reconsideration, which the court denied. Subsequently, the government appealed.

Court of Appeals for the Ninth Circuit—The Court of Appeals reversed and remanded the case for trial before another judge. In reversing the District Court, the Court of Appeals agreed with the

government that the District Court erred when it dismissed the indictment for prosecutorial misconduct. Since the only possible prosecutorial misconduct was a two-minute delay in correcting a witness' mistake as to the completeness of a document (an act that neither amounted to a flagrant act of misconduct nor resulted in prejudice to the defendants), the sanction imposed was disproportionately harsh and was an abuse of discretion. The Court of Appeals also noted the following facts: that the motion for reconsideration had been denied after no misconduct had been proven, that the defendants had been permitted to file an untimely motion to dismiss, that the government's handling of the case had been criticized by the trial judge in the jury's presence and that the trial judge had offered strategic advice to a defendant's counsel on how to win his case. On such facts, the Court of Appeals found that the gains made for the appearance of justice by reassignment to another judge would outweigh the duplication of time and effort.

Upon Remand to District Court—After additional litigation, including a third motion to dismiss the indictment, a motion to disqualify or recuse government attorneys, motions for severance and motions for additional discovery, the government moved to strike the third motion to dismiss. Subsequently, the court rendered a 37-page decision and order regarding the defendants' motion to dismiss counts 1 and 2 of the indictment. The court denied the government's motion to strike the defendants' motion to dismiss and, because this was a criminal case, felt constrained to give the defendants the benefit of the doubt. However, on the merits, the court also denied the defendants' motion to dismiss.

The court ruled as follows: that the exemption from labeling of section 503(b)(2) was not intended and did not apply to veterinary drugs and that veterinarians, as licensed practitioners, were not exempt from the labeling provisions of 502(a); that licensed veterinarians, although exempt from registering as drug manufacturing establishments, were not exempt from other provisions of the law; and that, regardless of whether FDA's "extra-label drug use" policy was subject to the notice and comment policy of the Administrative Procedure Act, the statute expressly prohibited the charged conduct, and the "extra-label drug use" policy expressly stated that it was inapplicable to chloramphenicol in food-producing animals. The court also declined to dismiss the indictment on the ground of selective prosecution.

Ultimately, pursuant to a plea agreement, Jacobs pleaded guilty to counts 1 and 2; imposition of sentence as to imprisonment was suspended; he was placed on probation for three years and was to complete 300 hours of volunteer community service; and he was fined $2,000. Takhar pleaded guilty to count 1; imposition of sentence as to imprisonment was suspended; he was placed on probation for three years and was to complete 300 hours of volunteer community service; and he was fined $1,000. (F.D.C. No. 64557; S. No. 84-312-718, et al.; S.J. No. 12)

DEFENDANT: **Julio Klepach,** operator of a pharmaceutical importing and distributing corporation, Miami, S. Dist. Fla.; Criminal No. 90-9-CR-Alkins.
CHARGED on or about 2-26-90: That, with intent to defraud and mislead, the antibiotic prescription drug "Pipril" (packaged for shipment and marketing in Latin America with Spanish language labeling) was diverted in Miami, repackaged and relabeled as "Pipracil," and distributed throughout the United States with labeling that was false and misleading as to the drug's original trade name, true control numbers, and secondary processor—502(a).
DISPOSITION: Guilty plea; $25,000 fine and probation for three years. (F.D.C. No. 64759; S. No. 86-340-808 et al.; S.J. No. 13)

DEFENDANTS: **Sun Shine Trading & Transportation, Inc., of Norfolk, and Richard I. Lu, president,** Norfolk, E. Dist. Va.; Criminal No. 89-128-N.
CHARGED 10-11-89 by grand jury: That, while held for sale, scented jasmine rice and dried red chilies were held under insanitary conditions in a building accessible to rodents and insects and were exposed to contaminators by rodents and insects—402(a)(4).
DISPOSITION: Pursuant to a plea agreement, the corporation pleaded guilty to one count involving scented jasmine rice and was fined $4,000. The individual pleaded guilty to one count involving dried red chilies; imposition of sentence was suspended, he was placed on probation for 18 months, and he was fined $1,000. (F.D.C. No. 65316; S. No. 87-516-148; S.J. No. 14)

INJUNCTION ACTIONS

DEFENDANTS: **Nature-All Corp., S.T.F., Inc. (t/a Spinal Touch Formulas, Inc., and Makes The Difference Formulas), and Nature-All Formulas, Inc., and Gary A. Barnes,** president of corporations, **W. Lamar Rosquist,** D.C., member of corporations' boards of directors, and **Gary Whitley,** D.C., vice president, Orem, Dist. Utah; Civil No. 88C -0602W.
CHARGED 7-7-88 in a complaint for injunction: That the defendants, at their Orem, Utah, facility, were packaging, labeling and distributing, in interstate commerce, a number of products (approximately 28 specified products) that were drugs because of their intended uses; that the promotional literature and other labeling distributed by the defendants in connection with their products established uses for various human diseases (e.g., Arthro-All for arthritis, Fiber-Lax as a laxative and to lessen probability of colitis and other forms of cancer, Vascu-All for cardiovascular problems, Pain-Relief-Plus for chronic pain, Worm-All for internal parasites, and Fem-Plex Pak of products for female disorders); that such products were new drugs without effective approved New Drug Applications—505(a); that the labeling of such products lacked adequate directions for their intended uses—502(f)(1); and that, despite the defendants having been told by FDA that their distribution of such products violated the law, the defendants continued to manufacture and distribute such unapproved new drug products.
DISPOSITION: A consent decree of permanent injunction perpetually enjoined the defendants from promoting, labeling, advertising, or representing that any of the specified products was safe or effective for any human body function or structure, or disease, unless and until an approved New Drug Application was in effect for such product for such use. The decree also perpetually enjoined the manufacture, processing, packing, labeling, or distributing of any such products unless and until: (1) there was an effective approved New Drug Application for the product or (2) FDA had given specific prior acceptance for proposed product names, labeling, and promotional material of any kind for a product, in accordance with specified procedures. The decree also required the defendants to demand (in a letter sent by certified mail to each of their agents, distributors and known customers) the return for destruction of all the specified old products, labeling, and promotional material. (Inj. No. 1179; S. No. 87-370-706 et al.; S.J. No. 15)

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[1] FDA survey, "Patient Receipt of Rx Drug Information", 1983

[2] A Study of Attitudes, Concerns, and Information Needs for Rx Drugs and Related Illnesses, CBS Television Network Consumer Model Survey, 1983