

# FDA CONSUMER

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

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MARCH 1997

## fighting phobias

the things  
that go bump  
in the mind









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#### ◀ Inside Front Cover Photo:

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

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## Big Steps Forward for Amputees

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Bioengineers using new materials and high technology are forging artificial limbs that are more and more lifelike—in appearance and function. Many amputees are now able to put aside their wheelchairs for an active lifestyle.

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Panic arising from an intense fear of everyday objects, events or feelings may seem irrational, but for the 18 percent of the U.S. adult population who suffer from phobias, the feeling is very real. One or more of several anti-anxiety medicines approved by FDA can help.

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First your mother told you to eat your fruits and vegetables; then the government chimed in with its 5-servings-a-day campaign. But you're still not following the advice? Here's some help to make eating right a little easier and, in the process, lower your risk of heart disease and cancer.

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Menopause is becoming a popular conversation piece. And for a major reason: By the end of this century, as the "baby boomers" reach their 50s, more women than ever will be experiencing menopause. Estrogen replacement therapy can help alleviate their symptoms, such as hot flashes, and also protect their bones. But it does carry some risks.

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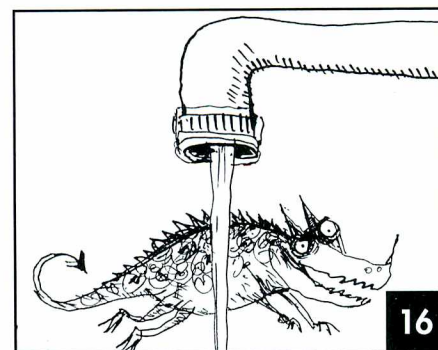
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Today's artificial limbs, made with cylinders, roller bearings, chassis, and other parts typical of modern machinery, give amputees greater mobility, flexibility and comfort. See page 6.

(Photo courtesy of Endolite North America Ltd.)

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## Second Alzheimer's Drug OK'd

The second drug for treating mild-to-moderate symptoms of Alzheimer's disease has received FDA approval.

Aricept (donepezil) is a "cholinesterase inhibitor" that increases levels of a neurotransmitter important to memory, judgment, ability to reason, and other cognitive functions. The drug was approved last Nov. 25. Tacrine (cognex) was approved in 1993 to treat the disease.

Alzheimer's disease affects an estimated 4 million Americans.

In a 30-week trial of 473 patients, those treated with Aricept improved on two assessment scales compared with those on a placebo. A second 15-week study confirmed these results. One scale gauged memory, attention, language, and reasoning. The other was a physician's interview-based evaluation to confirm treatment benefit.

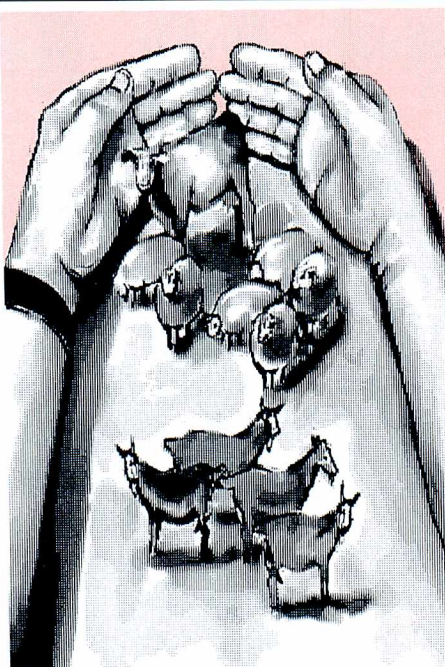
In the trials, most patients tolerated typical side effects of diarrhea and nausea. Other possible side effects include a slowed heartbeat and fainting spells.

Eisai America Inc., Teaneck, N.J., and Pfizer, New York City, market Aricept.

(For more on the disease, see "Despite New Clues, Alzheimer's Mystery Remains Unsolved" in the March 1992 *FDA Consumer*.)

## FDA Proposal Aims to Protect Animals, Humans from Diseases

To help protect animals from transmissible, fatal degenerative nerve diseases and to minimize the risk of the dis-



eases being transmitted to humans, FDA has proposed banning tissue from cows, sheep, goats, and other ruminant animals in ruminant feeds. Mink tissue would also be prohibited in such feeds.

These animal diseases are known as transmissible spongiform encephalopathies (TSEs), which are characterized by a long incubation period and a relatively short clinical course of neurological signs, leading to death. A major concern is that one type of animal TSE, bovine spongiform encephalopathy (BSE), could in the future be identified as the cause of a new TSE in humans.

In March 1996, the British government announced a possible link between BSE and 10 cases of a variant form of Creutzfeldt-Jakob disease, a degenerative nerve disorder in humans. That same month, U.S. national livestock organizations and professional health groups announced a voluntary moratorium on the use of ruminant protein in ruminant feed.

Although there has never been a reported case of BSE in the United States, FDA proposed the new rule as a precautionary measure. "It will add another level of safeguards to protect the U.S. against the potential risk from these diseases," said Donna E. Shalala, Secretary of Health and Human Services.

FDA's proposal would ban nearly all potential sources of ruminant and mink protein in feed for ruminants. Bovine blood and ruminant-derived milk and gelatin would be excepted, however, as FDA has no information suggesting these proteins are potential carriers of TSEs.

FDA published the proposal in the Jan. 3, 1997, *Federal Register*. The proposal is on the agency's World Wide Web site at <http://www.cvm.fda.gov/fda/infores/updates/bse/bsefr.html>.

The fact sheet "Bovine Spongiform Encephalopathy and Creutzfeldt-Jakob Disease, Public Health Service Actions to Ensure Against Health Risks" is also available on the web site at <http://www.cvm.fda.gov/fda/infores/updates/bse/bsefact.html>. Or, single copies can be ordered by writing to FDA, HFE-88, Rockville, MD 20857.

## Leukemia Drug Approved For Prostate Cancer

A drug already approved by FDA for leukemia has been given another approval: initial chemotherapy for pain related to prostate cancer that has progressed despite standard hormone treatment.

Studies showed that Novantrone



(mitoxantrone), in combination with steroids, can reduce the intense pain that occurs as cancer cells multiply and spread to the bone. The drug combination also was shown to stabilize or reduce reliance on analgesic pain relievers.

FDA's Nov. 13 approval of Novantrone's new use came less than six months after the manufacturer applied for the new use. The application was one of the first following FDA's announcement of a new plan to speed cancer drug approvals.

Prostate cancer is the second leading cause of cancer deaths in the United States. Of the 310,000 new cases that were expected to be diagnosed last year, more than 40,000 of them will likely become resistant to hormone therapy.

In clinical trials, the Novantrone-steroids combination significantly reduced pain in 38 percent of patients, compared with 21 percent of those treated with steroids alone. Patients responding to Novantrone had an average eight months of pain relief, compared with two months for those given steroids alone. However, survival rates for both groups were the same.

Immunex Corp., Seattle, markets Novantrone.

(For more on prostate cancer, see "Prostate Cancer: New Tests Create Treatment Dilemmas" in the December 1994 *FDA Consumer*.)

### **Toll-Free Number Gives Cosmetics, Colors Information**

A toll-free automated FDA information line is in place with taped messages about dozens of topics concerning cosmetics and color additives.

The line gives information on cosmetics- and colors-related recalls and other current public health issues. It also provides general information on such topics as cosmetic labeling and ingredients, hair dyes, aromatherapy, and sun care, and tells how to report adverse reactions. For additional information, callers can request that related documents be faxed or mailed to them.

The telephone number is (1-800) 270-8869. Callers must use a touch-tone telephone to access the information line, which can be reached 24 hours a day.

### **Ivermectin Approved For Two Parasitic Diseases**

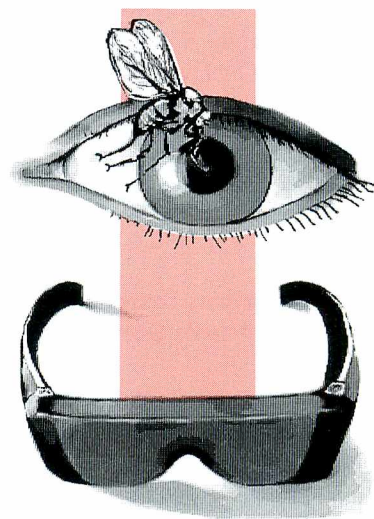
The antiparasitic animal drug ivermectin was approved by FDA to treat two human parasitic diseases, strongyloidiasis and onchocerciasis.

Strongyloidiasis is common in many tropical countries and is occasionally acquired in some areas of the United States. Infection is usually confined to the small intestine. It can persist for many years, causing abdominal pain, diarrhea, and elevated levels of white blood cells. In people with weakened immune systems, the infection can spread through the body and be fatal.

Onchocerciasis, commonly known as river blindness, is most often found in Africa and South and Central America. The parasite is transmitted by the bite of a black fly, which deposits immature forms of the parasite under the skin. There, the worms mature and the adult females produce more larvae. The immature worms migrate under the skin,

causing intense itching. They can also migrate to the eyes, causing inflammation and blindness.

Ivermectin is better tolerated than other drugs approved to treat these conditions, and it is more effective than the previously approved treatment for onchocerciasis. In clinical studies, a single



dose of ivermectin cured between 64 and 100 percent of patients with strongyloidiasis who had normal immune systems. In studies of onchocerciasis, a single dose of the drug reduced the number of larvae under the skin an average of 83 percent at three days and 99.5 percent at three months. Adverse reactions to the drug differ depending on which disease is being treated but can include skin rashes, itching, dizziness, diarrhea, and nausea.



Merck & Co. Inc., of West Point, Pa., sells ivermectin in the United States under the trade name Stromectol. (Elsewhere it is marketed as Mectizan.) Before its approval on Nov. 25, 1996, ivermectin had been available here for limited human use as an investigational drug.

Ivermectin has been used worldwide since 1987 to treat river blindness. More than 5.2 million people have received the drug through the World Health Organization's Onchocerciasis Control Program and Merck's Mectizan Donation Program.

(See also "Treating Tropical Diseases" in the January-February 1997 *FDA Consumer*.)

### First Prescription Drug For Severe Mouth Sores

The first prescription treatment for painful, severe canker sores in the mouth in people with normal immunity has been approved by FDA. The medical name for these sores is aphthous ulcers.

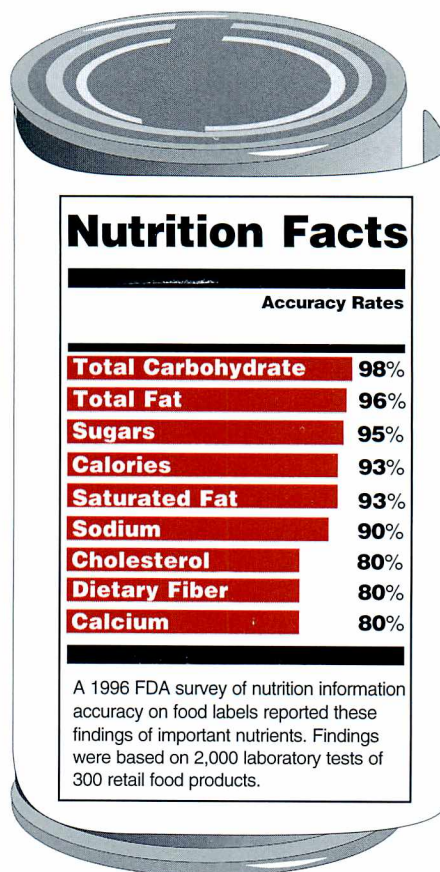
The agency approved the drug, Aphthasol (amlexanox oral paste, 5 percent), Dec. 17. In clinical studies, Aphthasol reduced ulcer healing time by a day to a day and a half, compared with a placebo or no treatment. Pain was relieved as the ulcers healed. Some participants reported stinging or burning where the medicine was applied, and, less frequently, nausea and diarrhea.

While people with AIDS acquire especially virulent aphthous ulcers, the new drug's safety and effectiveness in individuals with weakened immunity has not been assessed at this time.

Users should apply Aphthasol paste directly to their ulcers four times a day, following oral hygiene after meals and before bedtime. If the ulcers have not healed in 10 days, patients should visit their dentists or health-care providers.

Aphthasol is manufactured by Block Drug Co. Inc., Jersey City, N.J.

### Accuracy of Information On Nutrition Labels



### FDA Offers Quick Info On Blood Product Recalls

Health providers and consumers can get immediate information about blood product and plasma recalls from two new FDA communication systems.

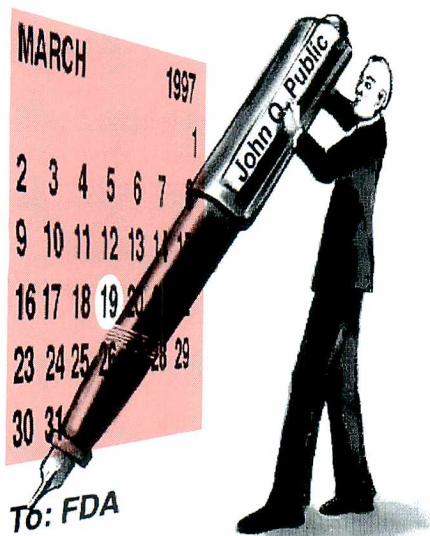
The agency's Center for Biologics Evaluation and Research has established a 24-hour toll-free number—(1-888) CBER-BPI—and an automated electronic mailing list. Both provide current information on recalls and market withdrawals of therapeutic products derived from blood, such as immune globulins and clotting factors to treat hemophilia. In a recall, a product is taken off the market because it violates a federal law. In a market withdrawal, a product is removed from the market by the manufacturer for some other reason.

These new systems augment CBER's existing methods of notification, which include the FAX Information System (1-888-CBER-FAX), a consumer information line (1-800-835-4709), and a link from FDA's home page on the World Wide Web (<http://www.fda.gov/>).

### Public Can Comment On Device Proposal

The public has until March 19 to comment on an FDA proposal to make it easier for desperately ill patients to be treated as soon as possible with promising but unapproved medical devices undergoing research. Current rules allow use on a crisis basis only.





Written comments on the proposal, published in the Dec. 19, 1996, *Federal Register*, may be sent to the FDA Dockets Management Branch, HFA-305, 12420 Parklawn Drive, Room 1-23, Rockville, MD 20857. The *Federal Register* document is available at some libraries and on FDA's World Wide Web site at <http://www.fda.gov/cdrh/fr1219af.html>.

Under the proposal, experimental devices could be granted "treatment use" status, meaning they could be used to treat or diagnose only patients whose illness poses a significant threat of death within months or premature death if the course of disease is not altered quickly. The proposal would ensure that data gathered from the treatment could be used to evaluate product safety and effectiveness. It also would ensure integrity of the clinical studies and prevent commercialization of the device during this phase.

Normally, a sponsor must obtain an Investigational Device Exemption, or IDE, from FDA to use an experimental device on human patients. Only patients enrolled in the studies can be treated with the device. Then, in the marketing application, the sponsor uses the study data to show product safety and effectiveness.

Under FDA's proposal, patients would not have to be enrolled in a study. But a sponsor desiring "treatment use" for an experimental device would have to submit a Treatment Use IDE application to FDA, showing that:

- The device is intended to treat or diagnose a serious or immediately life-threatening disease or condition.
- No comparable or satisfactory alternative device or other therapy is commercially available.
- The device is under investigation in an approved IDE or that such studies have been completed.
- The manufacturer is pursuing marketing approval.

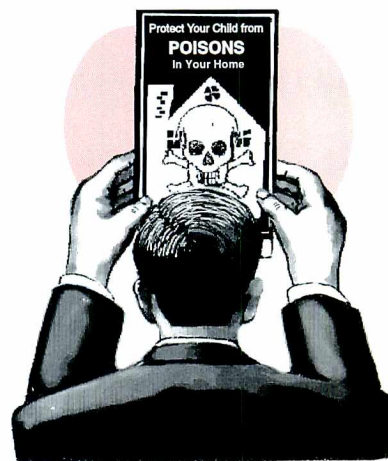
FDA would have 30 days to consider the application, the same as for standard IDE applications.

### Brochures Available

Safe weight loss and poison prevention are the subjects of two brochures for people with low reading skills, now available from FDA. Their titles and publication numbers are:

- Losing Weight Safely (FDA) 96-1247
- Protect Your Child from Poisons in Your Home (FDA) 96-1262

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



### Correction

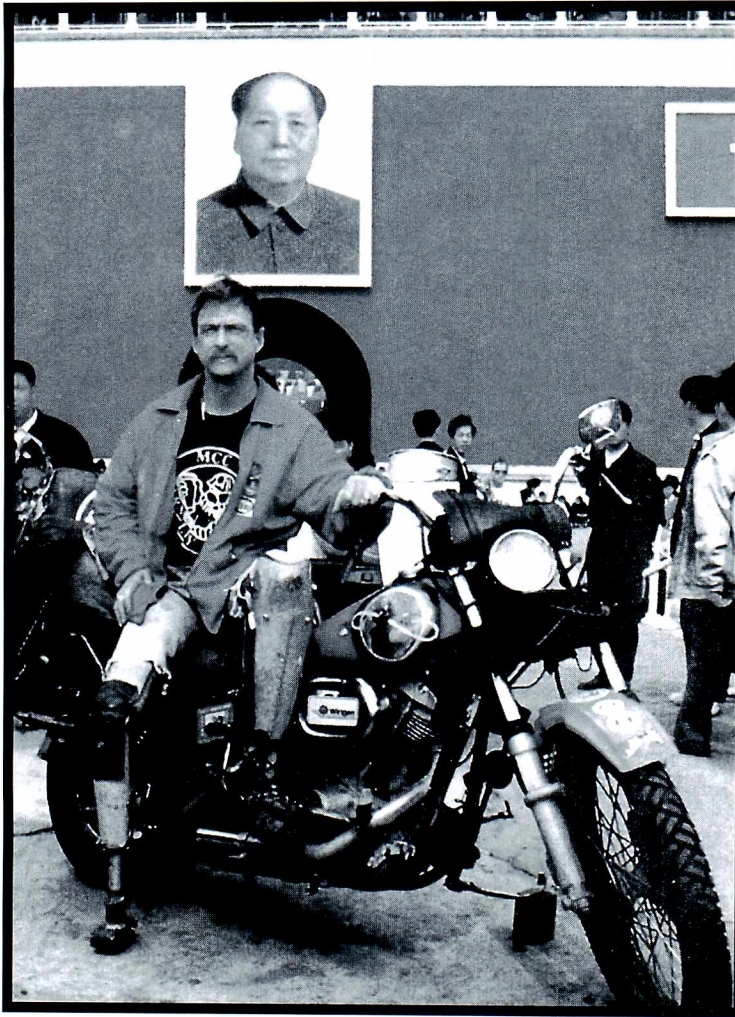
"Three Free Reprints" in the December 1996 *FDA Consumer Updates* section listed an *FDA Consumer* reprint that is not available at this time. The reprint "Adults Need Tetanus Shots, Too" was a limited printing only. The article originally published in the July-August 1996 *FDA Consumer*.

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



# Big Steps Forward For AMPUTEES

by Robert A. Hamilton



*Double amputee David Barr poses on his Harley in Tiananmen Square, Beijing, during one of many stops on an around-the-world motorcycle trip. His adventurous spirit—and two good prostheses—helped make the trip possible.*

David S. Barr of Bodfish, Calif., took an 80,000-mile motorcycle trip that spanned North and South America, Europe, Asia, and Africa.

"Only 70 people have ever done anything like it before," Barr said. "There've been more people in outer space than have made this trip."

What makes it more extraordinary is that Barr, 41, is a double amputee. Fighting in Angola in 1981, he lost one leg above the knee and the other below the knee. But that hasn't kept him from

riding a two-wheel 1972 Harley Davidson and writing a book about his around-the-world motorcycle trip.

And that is not all. Barr is one of only a handful of double-amputee parachutists who jump with special prosthetics. And he walks 3 or 4 miles a day and mows his own grass.

Advances in prosthetics, and the example set by amputees such as Barr, have shown more and more people that an amputation does not always mean confinement to a wheelchair. At private companies and key centers such as Northwestern University in Chicago and the University of Utah at Salt Lake City, research that sounds like something out of "The Six Million Dollar Man" could give amputees even more control over artificial limbs.

Physical therapist Marie A. Schroeder, who is chief of the Food and Drug Administration's restorative devices branch, explains that FDA regulates prostheses, but manufacturers do not have to undergo a full review for each new device. Instead, they must register the products and keep a record of any complaints.

"But if there's a significant change in the technology, we could get involved," Schroeder said.

For instance, she said, her branch has seen some interest in implantable electrodes for stimulating muscles in spinal cord injury cases. Such devices would require review by FDA.

Some innovators are also exploring ways to use computers to design and manufacture custom prostheses, to attach muscles directly to a prosthesis, to develop powered fingers with micro-electronics, and even to use brain waves to power prostheses.

For thousands of years, inventors have



tried to replicate what nature cannot replace. Prostheses have been used since at least 300 B.C., when crude devices consisting of metal plates hammered over a wooden core, were attached to an amputated limb.

Advances in the science of prosthetics burgeon during and immediately after wars, when large numbers of people need to be fitted with artificial limbs. The technology of modern prosthetics has changed little since shortly after World War II.

"There's a real need for revolution in design," said Giovanni M. Ortega, research and development project manager at Sabolich Prosthetics & Research in Oklahoma City, Okla., a division of NovaCare. "The systems that we have, have been around for a long time, and at best there have been only improvements. As far along as we've come, we're still far behind many other industries in terms of implementing new technologies."

Estimates of the amputee population in the United States vary widely, from fewer than 400,000 to more than 1 million. About 9 out of 10 amputations involve the leg, from the foot to above the knee.

Three-quarters of all amputations are the result of disease, often cancer or peripheral vascular disease. The latter is a narrowing of the arteries in the extremities that is often associated with diabetes. Most other amputations are the result of workplace or automobile accidents. And a small fraction, perhaps 3 percent, are due to birth defects that constrict bone growth.

### Preventing Amputation

Because so many amputations result from disease, considerable attention has been paid to prevention. For example, the American Diabetes Association recommends people stop smoking, which can speed the progress of peripheral vascular disease. Patients with diabetes should monitor their blood glucose levels carefully, eat a healthy, balanced diet, see their doctors regularly, control their weight, and check their feet each

day for small cuts or blisters.

Electric blankets and heating pads carry warning labels that say people with diabetes should not use them without talking to their doctors first. This is because people with diabetes may lose sensation in their limbs. Patients can be seriously burned by an electric blanket or heating pad because they cannot feel how hot it really is.

Patients are also advised to develop an exercise plan after consulting with their doctors. Regular exercise maintains strength, flexibility, and blood flow to damaged areas and can help control pain. However, it's important not to stress the legs, feet or joints. Some good exercises are bicycling or easy rowing on a rowing machine. Swimming and aqua aerobics are also good choices.

"We know of many things that can help people avoid amputation, but unfortunately, it's no fun to do daily foot care or wear only proper fitting, well-designed shoes," said Jennifer Mayfield, M.D., chairwoman of the association's Foot Care Council. "Everybody keeps waiting for a magic bullet, and that would be nice, but it's not coming anytime soon."

Richard J. Gusberg, M.D., chief of vascular surgery at Yale University, said one of the first signs of peripheral occlusive disease is claudication, an aching, tired feeling in the leg muscles when they are exercised.

"The vast majority of people with claudication remain stable, or nearly stable, for an indefinite period of time," Gusberg said. In most cases the progress of the disease can be slowed if people control the risk factors, which includes reducing blood pressure, controlling their diabetes through diet or insulin, and reducing cholesterol levels. Regular exercise has also proven effective because it can strengthen circulation, he said.

The drug Trental (pentoxifylline) is approved by FDA for people with peripheral artery disease. Its use can decrease the thickness and stickiness of blood, and can reduce the deformities of red blood cells, so the blood can get through the narrowed arteries, but it is not effective in all patients, Gusberg said. The use of other drugs in treating occlusive disease has largely been abandoned, he said.

*(Continued on page 9)*



*A foot-and-ankle prosthesis.*

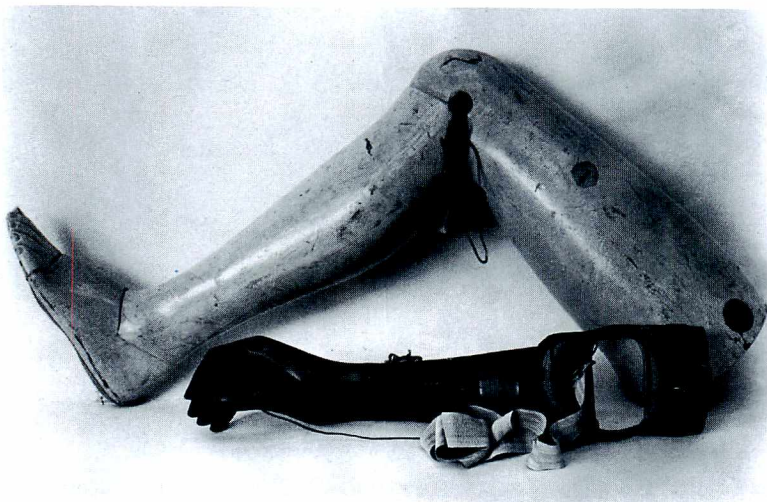
*(Photo courtesy of Endolite North America Ltd.)*



**F**or centuries, wood and leather were the only materials for prostheses, but today's physical therapist has a much wider range available.



NCP 1633



WWI 941

*Advances in prosthetics typically have occurred during and immediately after wars. Top left, a Civil War veteran holds onto straps that apparently help secure a leg prosthesis, presumably made of wood. Left are typical prostheses used by World War I amputees. Above, a World War II veteran adjusts his artificial limb.*

*(Photos courtesy of the National Museum of Health and Medicine, Armed Forces Institute of Pathology)*



(Continued from page 7)

If the disease progresses, the patient might develop gangrene, or ulcers in the leg, as blood flow is reduced.

"When people get to that stage, most of them need to be evaluated for a bypass operation," Gusberg said. Replacing the arteries in the lower leg is effective for five years or more in 70 to 80 percent of cases.

### Sensory Loss

Another danger with diabetes is a deadening of the nerves in the extremities. John F. Glass, a biologist with FDA's pacing and neurological devices branch, said there are now a variety of devices that measure sensory loss in the affected limbs. In a patient with diabetes, loss of sensation because of nerve damage signals a need for diligence. Even minor injuries, undetected because the feeling is gone and thus left untreated, can become infected easily and lead to gangrene.

"If you're aware of sensory loss, you want to keep a close watch on it," Glass said. "There's a range of measurement devices, from those that detect general loss of sensation, to those that assess the specific degree of sensory loss, or that can quantify sensitivity to pressure or temperature."

Many of the devices are easy-to-use mechanical implements with no significant health risk to patients. One of the simplest is a hand-held device that looks like an old typewriter eraser with thin wires attached to it. The wires are placed on the toes or fingertips to see if there is tactile sensitivity.

Such simple devices are typically not reviewed by FDA before they are made available to the public. They are intended for use by the patient for monitoring only, not self-diagnosis.

"Loss of sensation in an extremity could indicate a lot of other conditions or disorders, so we would encourage the patient to see a physician immediately for a complete physical examination," Glass said.

### Unavoidable Limb Loss

Precautions such as Glass advocates can often delay the progression of the disease. Sometimes, though, the loss of a limb is unavoidable. In those cases,



*Dudley Childress, of Northwestern University Medical School, developed the theory behind this partial hand prosthesis that features electric-powered fingers. Three motors inside the device combine to provide a force of about 5.4 kilograms (12 pounds) for grasping. The human hand provides a force of 11 kg (25 pounds). (Photo courtesy of Northwestern University/Movco Media Productions)*

physical therapy starts a day or two after surgery. Since more than 9 out of 10 amputations involve one or both legs, physical therapy usually involves the use of parallel bars, and later a walker or crutches. Part of the training involves how to fall and get up safely.

There are other adjustments as well. Barr said the loss of both legs, and covering the stumps with plastic, means his body has become much less effective at cooling itself, so he has to be on the lookout for hyperthermia. And he learned other tricks to cope, as well.

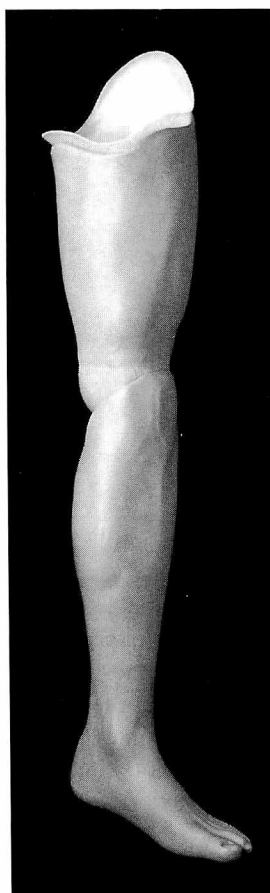
"I'm constantly on the move, never standing still, always readjusting my balance even when I'm staying in one place, because I don't want one particular area on the stump to get sore," Barr said.

Until recently, patients were not fitted with an artificial limb for four to eight weeks after surgery, but new techniques allow the use of a protective foam over a sterile bandage, and the prosthesis can be fit as soon as the day following surgery.

### New Prosthetic Materials

For centuries, wood and leather were the only materials for prostheses, but today's physical therapist has a much wider range available, including advanced plastics and carbon fiber, which are much stronger and lighter and more durable.

"The industry is really moving to-



*Cosmeses, such as this above-the-knee one, fit over prostheses to give the appearance of a normal limb. (This photo and photo on page 11 courtesy of Endolite North America Ltd.)*

wards composite materials, because they're lighter in weight, easier to work with, and more durable," said Douglas McCormack, vice president of the Amputee Coalition of America.

Silicone-based compounds used to make prosthetic arms, for instance, give





*Anthony Volpentest, who was born without hands and feet, set a new world record for the 100-meter race in the 1996 Atlanta Paralympic Games. His time of 11.36 seconds was 1.5 seconds behind the world record set by able-bodied Donovan Bailey in the 1996 Olympic Games.*

*(Photo by Stephen Schulte, courtesy of Orthotics and Prosthetics National Office)*

the appearance of real skin, unlike the rigid plastic or metal limbs of years ago, and they are more comfortable for the person wearing them. Women can get prosthetic feet with life-like toes for when they wear sandals; men can get legs with the appearance of hair.

But even materials that work out in one application might not work in another.

"We tested a silicone foot at one point. On a machine it was subjected to 300 pounds of stress for a million cycles, and it didn't have any problems. But an amputee broke it within a few minutes. It really surprised us. Torque and other stresses can fatigue the material quickly," said Sabolich's Ortega. "You'd be amazed at the toll that a

human body puts on even the strongest material."

New computer programs better determine where and what the forces are. But it's not just a question of choosing a material that will withstand those forces.

"With some of the new materials being developed, we could make a foot to take any of the pressures that the human body will give it," Ortega said. "The problem is it might not have any springiness. You give up flexibility for strength. You have to balance all the considerations in a prosthetic."

Prostheses are typically sold as components, so that someone who has an above-the-knee amputation would be able to choose leg, knee and foot units, often from different manufacturers, de-

pending on their individual needs.

Most of the units are adjustable. Shock absorbers in knees, for instance, can be made more flexible as a person gains controls over the artificial leg. Ankles can be adjusted to the weight and activity level of the patient.

Arm amputees today can choose between prostheses that are powered by a harness and cable attached to the residual limb, or externally powered devices. Powered arms can be controlled by switches mounted inside or outside the socket, that the patient can activate by flexing certain muscle groups.

### **Energy Requirements**

Some prosthetics research is aimed at providing active devices, which do part of the work of the amputated limb, as opposed to passive devices that are controlled by the residual limb. An amputee with prostheses expends two to three times more energy than a nondisabled person to perform even the simplest activities, such as walking across a room or climbing stairs.

"A semi-active system, in which the limb itself performs part of the function, could reduce that energy requirement significantly," said Sabolich's Ortega. "And there would also be a psychological benefit, because the prosthesis would no longer be just a dead limb, but something that is helping."

Ortega said one area Sabolich is researching would provide sensory feedback from the prosthesis to the remaining limb. For instance, in an artificial leg, pressure sensors in the foot would send a mild electrical signal to the thigh muscles when there is pressure on the back, front or sides of the foot.

That kind of feedback would be simi-





*British amputees Ashan McDonald, 9 (left), and Richard Bradbury, 8, pose for a publicity shot.*

lar to what they would get with the pressure of the ground against a natural foot, which would make their adjustment to the prostheses go more quickly, Ortega said.

Ortega said prosthetic designs are limited only by how large a power pack the amputee can carry.

"The crucial issue when it comes to trying to introduce any new prosthesis is the energy requirements," said Ortega. "Our muscles are so efficient, in terms of the power that they produce versus the fuel that they use, that we have a difficult time matching it."

Scientists are also working to build a better socket—the part of the prosthesis that attaches to the residual limb.

Dudley S. Childress, Ph.D., of Northwestern University's Rehabilitation Engineering Program, is working on applying the industrial practice known as rapid prototyping to socket production.

Sockets are now produced largely by hand. A cast is made of the residual limb, and plaster is poured into the cast to make a positive mold. The mold is then used to create a plastic or laminated polyester socket that fits over the residual limb.

Childress employs a computer-aided design program to measure the residual limb and design a socket. Then, using a modified "plastic deposition technology" called squirt shaping, a computer

lays down small amounts of polypropylene to produce the desired shape, to very tight tolerances. In industry, the technology is used to quickly produce prototypes of everything from car parts to military weapons, to test them before starting mass production.

"Essentially, every socket is a prototype, and there are potentially some significant advantages to applying these techniques to prosthesis manufacture," Childress said. "We can make a socket in about 50 minutes, which isn't bad, but as people continue to work with the technology, it may be possible to get that down even faster."

The process would also allow manufacturers to make sockets out of different types of material than have been used in the past, or alter the thickness or characteristics of the material very quickly.

Another innovation being explored at Northwestern is powered prosthetic fingers. That might be difficult if you were going to match real fingers, he acknowledged, but most of the time that's unnecessary. Picking up a spoon and holding a book don't require much power, just control. Small motor technology and power storage capability have both improved vastly in recent years.

"If you want to do something like squeeze orange juice, you need force," Childress said. "But even for people without a prosthesis, that's tiresome, so

we have all kinds of devices to do those jobs for us. So the intent of the powered fingers would be to provide prehensile [wrap-around] force."

Childress said his laboratory is also looking at devices that would improve the "feel" of prostheses over current devices. It would be comparable, he said, to the way power steering reduces the muscle power needed to steer a car, but you can still "feel" the road through the wheel.

Cables in artificial fingers and hands would connect to the muscles of the forearm, either through holes in the muscle that are surgically lined with skin, or tendons could be taken outside the residual limb and covered with skin. Either option would give the muscle the sense of how hard it is working and how fast it is moving.

### **Mundane, but Important, Needs**

Joan E. Edelstein, Ph.D., director of Columbia University's physical therapy program, stresses the need for prosthetics research to focus not just on high-technology improvements, but to the more mundane but critical things such as fit, to make them as comfortable as possible, particularly among the elderly, whose needs may not be fully considered.

"Most patients are older people who have lost a limb because of diabetes, and the assumption is that they're going to be relatively undemanding of their prosthesis," Edelstein said.

Better prostheses for the elderly might prevent skin breakdown and infections, yet hardly any research dollars are being spent in that area, she said, explaining that, "It's not as glamorous as developing better prostheses for sport, or for children, and they are very difficult problems to overcome."

Research often proceeds along several courses at once, she noted, and you can never know which might yield the next major breakthrough. ■

*Robert A. Hamilton is a writer in Franklin, Conn.*





*Mike Rodden*



# Fighting PHOBIAS

## The Things That Go Bump In The Mind

by Lynne L. Hall

From 50 yards away, you see the animal approaching. Silently it watches you as it slinks ever so much closer with each padded step. Stay calm, you tell yourself. There's nothing to fear.

But suddenly, panic seizes you in a death grip, squeezing the breath out of you and turning your knees to Jell-O. Your heart starts slam-dancing inside your chest, your mouth turns to cotton, and your palms are so sweaty you'd swear they'd sprung a leak. You'd escape this terrifying confrontation, if only you could make your legs work!

Just what is this wild and dangerous animal making you hyperventilate and turning your legs to rubber? A man-eating tiger, hungry for a meal? A lioness bent on protecting her cubs? Guess again. That's Tabby, your neighbor's ordinary house cat, sauntering your way. Ridiculous, right? How can anyone experience so much fear at the sight of such an innocuous animal? If you're one of the thousands who suffer from galeophobia—the fear of cats—or any one of hundreds of other phobias, sheer panic at the appearance of everyday objects, situations or feelings is a regular occurrence.

### Irrational Fears

A phobia is an intense, unrealistic fear of an object, an event, or a feeling. An estimated 18 percent of the U.S. adult population suffers from some kind of phobia, and a person can develop a phobia of anything—elevators, clocks, mushrooms, closed spaces, open spaces. Exposure to these trigger the rapid breathing, pounding heartbeat, and sweaty palms of panic.

There are three defined types of phobias:

- specific or simple phobias—fear of an object or situation, such as spiders, heights or flying
- social phobias—fear of embarrassment or humiliation in social settings
- agoraphobia—fear of being away from a safe place.

No one knows for sure how phobias develop. Often, there is no explanation for the fear. In many cases, though, a person can readily identify an event or trauma—such as being chased by a dog—that triggered the phobia. What puzzles experts is why some people who experience such an event develop a phobia and others do not. Many psychologists believe the cause lies in a combination of genetic predisposition mixed with environmental and social causes.

Phobic disorders are classified as part of the group of anxiety disorders, which includes panic disorder, post-traumatic stress disorder, and obsessive-compulsive disorder. Several drugs regulated by the Food and Drug Administration are now being used to treat phobias and other anxiety disorders.

### Dogs, Snakes, Dentists . . .

A person can develop a specific phobia of anything, but in most cases the phobia is shared by many and has a name. Animal phobias—cynophobia (dogs), equinophobia (horses), and zoophobia (all animals)—are common. So are arachnophobia (spiders) and ophidiophobia (snakes). And, of course, there's the fear of flying (pterygophobia), heights (acrophobia), and confined spaces (claustrophobia).

"One of the most common phobias is the fear of dentists [odontiatophobia]," says Sheryl Jackson, Ph.D., a clinical psychologist and associate professor at

the University of Alabama at Birmingham. "People who suffer with this phobia will literally let their teeth rot out because they are afraid to go to a dentist."

Jackson says that most specific phobias do not cause a serious disruption in a person's life, and, consequently, sufferers do not seek professional help. Instead, they find ways to avoid whatever it is that triggers their panic, or they simply endure the distress felt when they encounter it. Some may also consult their physicians, requesting medication to help them through a situation, such as an unavoidable plane trip for someone who is phobic about flying.

Drugs prescribed for these short-term situations include benzodiazepine anti-anxiety agents. These medications include two approved for treating anxiety disorders: Xanax (alprazolam) and Valium (diazepam). Beta blockers such as Inderal (propranolol) and Tenormin (atenolol), approved for controlling high blood pressure and some heart problems, have been acknowledged, partly on the basis of controlled trials, to be helpful in certain situations in which anxiety interferes with performance, such as public speaking.

Some phobias cause significant problems that require long-term professional help. "People usually seek treatment when their phobia interferes in their lives—the person who turns down promotions because he knows public speaking will be required, someone who must travel frequently but who is afraid of flying, or a woman who wants to have children but who has a fear of pain or blood. These are the people who seek long-term treatment," says Jackson.

While anti-anxiety medication sometimes may be used initially, systematic



desensitization may also be an effective initial approach. Jackson explains that this nondrug treatment works on the theory that the more a person is exposed to the object of his phobia, the less fear that object generates.

First, the patient and therapist establish a hierarchy of feared situations, from the least to the most feared. For someone who fears elevators, for example, stepping onto the elevator causes a certain level of anxiety; going up one flight causes another level of anxiety. With each additional flight the anxiety increases until it becomes intolerable.

Therapy begins with the patient and therapist practicing the least fearful event, riding out the anxiety until the physiological symptoms subside. This step is repeated until the anxiety level is acceptable. Then the person progresses to the next step in the hierarchy. Each successive step is repeated until the physical reactions and anxious mood decrease to the point where the person can step onto an elevator and ride to the top floor without panicking.

### **Everyone's Looking at Me!**

Social phobia is a complex disorder, characterized by the fear of being criticized or humiliated in social situations. There are two types of social phobias:

circumscribed, which relates to a specific situation such as "stage fright," and generalized social phobia, which involves fear of a variety of social situations.

People suffering from social phobia fear the scrutiny of others. They tend to be highly sensitive to criticism, and often interpret the actions of others in social gatherings as an attempt to humiliate them. They are afraid to enter into conversations for fear of saying something foolish, and may agonize for hours or days later over things they did say.

"I always believed that everybody else knew the secret to enjoying themselves in social situations, that I was the only one who was so afraid," says Lorraine from Birmingham, Ala., who asked that her last name not be used. "For a long time, I avoided as many situations as possible, even talking on the telephone. After a while, the loneliness and boredom would overwhelm me, and I would try again. I wanted to have fun, but I never really enjoyed myself because of the anxiety I felt. I always believed that others were looking at me and judging me."

Many people with social phobia are so sensitive to the scrutiny of others that they avoid eating or drinking in public, using public restrooms, or signing a check in the presence of another. Social

phobia may often be associated with depression or alcohol abuse.

Neurotransmitter-receptor abnormalities in the brain are suspected to play a part in the development of social phobias. Neurotransmitters are substances such as norepinephrine, dopamine and serotonin that are released in the brain. The substance then either excites or inhibits a target cell. Disorders in the physiology of these neurotransmitters are thought to be the cause of a variety of psychiatric illnesses.

Negative social experiences, such as being rejected by peers or suffering some type of embarrassment in public, and poor social skills also seem to be factors, and social phobia may be related to low self-esteem, lack of assertiveness, and feelings of inferiority.

Treatment can include cognitive-behavior therapy and medications, though no drug is approved specifically for social phobia. In addition to the anti-anxiety drugs and beta-blockers, medications may include the monoamine oxidase (MAO) inhibitor antidepressants Nardil (phenelzine) and Parnate (tranylcypromine), and serotonin specific reuptake inhibitors (SSRIs) such as Prozac (fluoxetine), Paxil (paroxetine), Zoloft (sertraline), and Luvox (fluvoxamine). Of the latter four drugs, Prozac, Zoloft and Paxil are approved for depression; Prozac, Paxil, Luvox, and Zoloft are approved for obsessive-compulsive disorder; and Paxil is approved for panic disorder.

Chris Sletten, Ph.D., a clinical psychologist and behavioral medicine specialist at the Mayo Clinic, says the use of SSRIs with behavior therapy is becoming more popular in the treatment of social phobia. Because there are fewer side effects associated with these drugs and a very low addiction potential, practitioners are more comfortable prescribing them. Plus, the antidepressant action of these drugs is helpful in treating patients who suffer from depression in addition to social phobia, he says.

"My therapist prescribed Prozac, and it has been an absolute godsend for me," Lorraine says. "After only a couple of months taking it, those voices in my head, the ones that always assured me that everyone was judging me—and finding me lacking—just seemed to shut

## **Getting Help**

For more information on these disorders and their treatment call:

American Psychological Association  
750 First St., N.E.  
Washington, DC 20002  
Telephone: (202) 336-5500  
World Wide Web: <http://www.apa.org/>

American Psychiatric Association  
1400 K St., N.W.  
Washington, DC 20005  
Telephone: (202) 682-6000  
World Wide Web: <http://www.psych.org/>

Freedom From Fear, Inc.  
308 Seaview Ave.  
Staten Island, NY 10305  
Telephone: (718) 351-1717

National Mental Health Association  
1021 Prince St.  
Alexandria, VA 22314-2971  
Telephone: (1-800) 969-6642  
World Wide Web: <http://www.nmha.org/>

Phobics Anonymous  
P.O. Box 1180  
Palm Springs, CA 92263  
Telephone: (619) 322-2673

National Alliance for the Mentally Ill  
200 Glebe Road  
Suite 1015  
Arlington, VA 22203-3754  
Telephone: (1-800) 950-6264

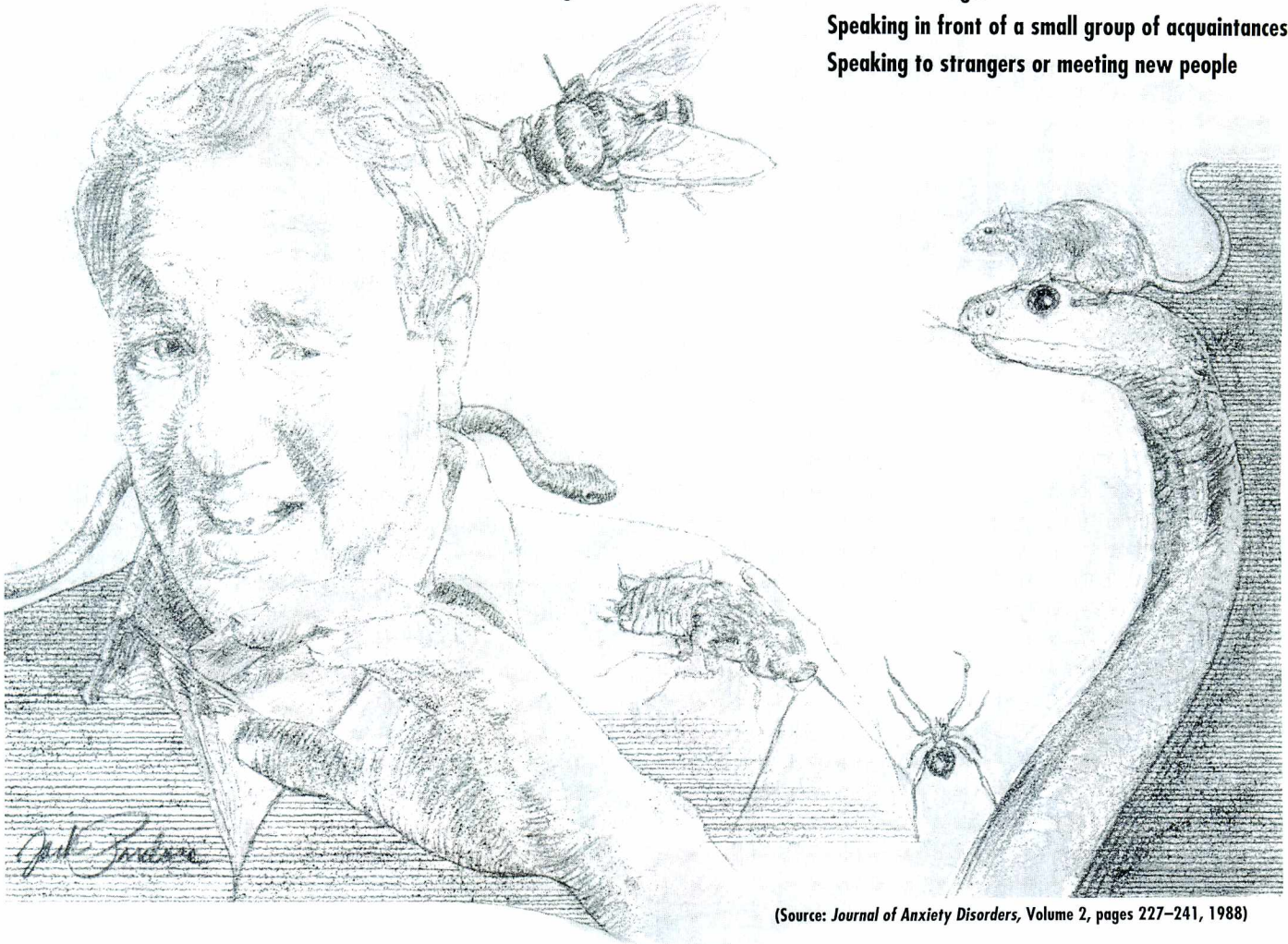
Anxiety Disorders Association of America  
6000 Executive Boulevard  
Suite 513  
Rockville, MD 20852  
Telephone: (301) 231-9350



# Ten Most Common Phobias

Spiders, bugs, mice, snakes  
Heights  
Being on public transportation  
Being in water

Being in a crowd  
Being in a closed place  
Storms  
Tunnels or bridges  
Speaking in front of a small group of acquaintances  
Speaking to strangers or meeting new people



(Source: *Journal of Anxiety Disorders*, Volume 2, pages 227–241, 1988)

up. I didn't feel high or drugged in any way. I felt like I always thought a "normal" person would feel. It's not a complete cure, of course. I still feel anxiety in social situations. But I don't avoid them as much. In fact, I actually pick up the phone now and ask friends to dinner, and I can relax enough to have fun. It's a whole new life for me."

## The Wide Open Spaces

Agoraphobia comes from Greek, meaning literally "fear of the marketplace," but it usually is defined as a fear of open spaces. Sletten says it stems more from the fear of being someplace where you will not be able to escape. It is closely identified with panic disorder, and in many cases, agoraphobia is directly related to the fear of experiencing a panic attack in public.

A person with panic disorder suffers

sudden bouts of panic for no apparent reason. These attacks can occur anywhere at any time. One minute everything is fine, the next the person is engulfed by a feeling of terror. The heart races, breathing comes in gasps, and the entire body trembles. The attack may last only minutes, but its memory is etched indelibly in the brain, and the anticipation of another causes almost as much terror as the attack itself.

People who suffer agoraphobia avoid places and situations where they feel escape would be difficult in case an attack occurs. This could be anywhere—the grocery store, a shopping mall, the office. As the fear of an attack increases, the agoraphobic's world narrows to only a few places where he or she feels safe. In the most severe cases, this is limited to the home.

Agoraphobia is the most disabling of

all the phobias, and treatment is difficult because there are so many associated fears—the fear of crowds, of elevators, of traffic. As with social phobias, treatment involves behavioral therapy combined with anti-anxiety or antidepressant medications, or both. Paxil has received FDA approval for use in treating panic disorders with or without agoraphobia, and at press time, Zoloft was being considered for this additional use.

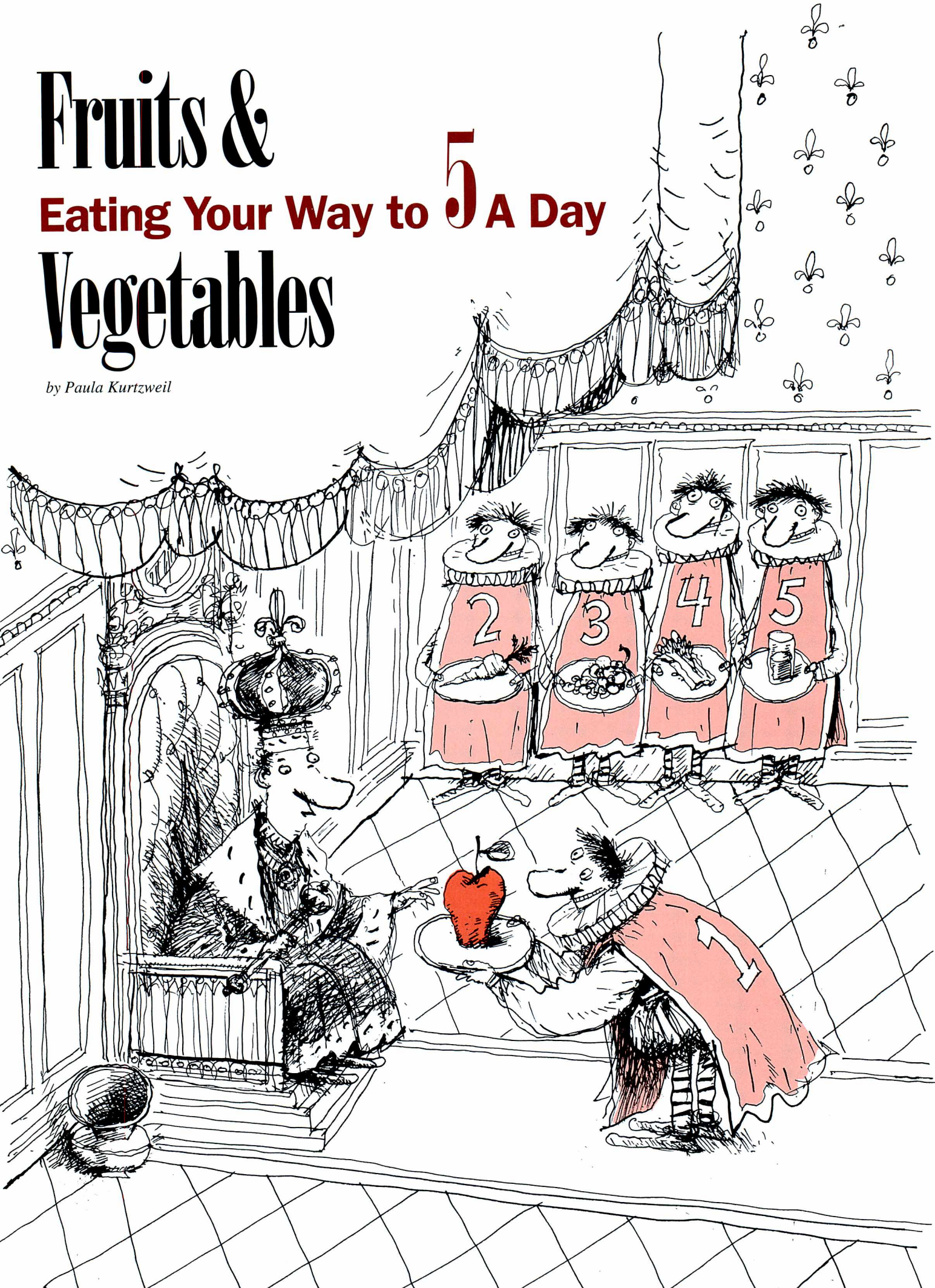
"The most important thing for people with phobias to remember," says Sletten, "is that phobic disorders do respond well to treatment. It's not something they have to continue to suffer with." ■

*Lynne L. Hall is a writer in Birmingham, Ala.*



# Fruits & Eating Your Way to 5 A Day Vegetables

by Paula Kurtzweil





Are you taking the 5 A Day challenge? You may be if you find yourself:

- snacking on raw vegetables instead of potato chips
- adding fruit to your cereal at breakfast
- using the salad bar when you go out for lunch or to the grocery store
- loading up on juice instead of a usual coffee, tea or soda.

The challenge, offered by the National Cancer Institute—a branch of the National Institutes of Health—is to eat at least five servings of fruits and vegetables a day, and these are some ways consumers are rising to the occasion.

They're taking advantage of the healthful benefits of fruits and vegetables. Studies by the U.S. Department of Health and Human Services, U.S. Department of Agriculture, and the National Academy of Sciences suggest that the nutritional goodness of fruits and vegetables, with a diet that is low in fat, saturated fat and cholesterol and that contains plenty of whole-grain breads and cereals, may decrease the risk of heart disease and cancer.

Fruits' and vegetables' potential to help improve the health of Americans led NCI to begin a multi-year public education campaign in 1992. Its goal is to increase consumers' awareness of the importance of fruits and vegetables and to give consumers ideas on how they can increase their intake. With its partner, the Produce for Better Health (PBH) Foundation—a nonprofit consumer education foundation funded by the produce industry—NCI has taken the "5 A Day for Better Health" message to grocery stores, classrooms, television, work sites, churches, and elsewhere.

Food labeling of fresh, frozen and canned fruits and vegetables may carry the message, too. And if you need more specific nutrition information about a particular item, you can find it in the labeling of most products, as well. The Food and Drug Administration regulates this information, which corresponds to NCI's Five A Day guidance and the government's Dietary Guidelines for Americans.

### Emphasis on More

A 1991 NCI and PBH survey, which

has the best available, most up-to-date information on consumers' consumption of fruits and vegetables, found that the average American consumer eats only about three servings of fruits and vegetables a day. Forty-two percent eat less than two servings a day. Compare those figures with the five to nine servings a day recommended by the Dietary Guidelines for Americans and you can see that many of us have a way to go.

A major reason to eat more fruits and vegetables is their nutritiousness. Unless baked in a pie or dripping in butter, most are low in fat and calories—except avocados, coconut and olives, all of which contain fat naturally. Many are excellent sources of the important vitamins A and C and provide ample fiber.

In addition, many fruits and vegetables, particularly dried beans and peas, are significant sources of folate, a B vitamin that can help reduce the risk of certain serious and common birth defects. (See "How Folate Can Help Prevent Birth Defects" in the September 1996 *FDA Consumer*.)

Produce has other positive qualities. Many items, such as raisins, grapes, cherry tomatoes, and bananas, can be eaten on the spot, with minimal preparation. (Fresh produce in which the peel will be eaten should be rinsed with water beforehand to remove any surface dirt and bacteria.) NCI campaign literature refers to fruits and vegetables as the "original fast food."

"They're easy to pick up and eat," said

Daria Chapelsky, state coordinator for NCI's 5 A Day Program. "Just as easy as picking up fast food."

And, unlike other types of foods (such as those high in fat that many of us eat too much of), plain fruits and vegetables are items we don't need to restrict. Genda Potter, a registered dietitian for cardiac patients at Memorial Medical Center in Springfield, Ill., said that factor was a major reason she began a regular 5 A Day class for outpatients.

"I wanted to emphasize something positive," she said. "People often look on dietitians as people 'out-to-ruin-my-enjoyment-of-food.' But fruits and vegetables are foods they can add to their diet rather than something they're going to be told to take away."

### No Excuses

Still, for any number of reasons, consumers often find it difficult to eat more fruits and vegetables. They may avoid them because they believe they are too expensive or take too long to prepare. These and other perceived problems became evident to NCI in 1991, when it asked members of small group studies to come up with reasons people may not want to or might be unable to eat at least five servings of fruits and vegetables a day.

Their responses led NCI to develop ideas to help consumers overcome reported difficulties in meeting the 5 A Day goal. Some of those ideas follow, along with other information from nutri-

## What's a Serving Size?

Here's what the National Cancer Institute recommends as a serving of fruit and vegetables:

1 medium fruit or 1/2 cup of small or cut-up fruit

3/4 cup (180 milliliters) of 100 percent juice

1/4 cup dried fruit

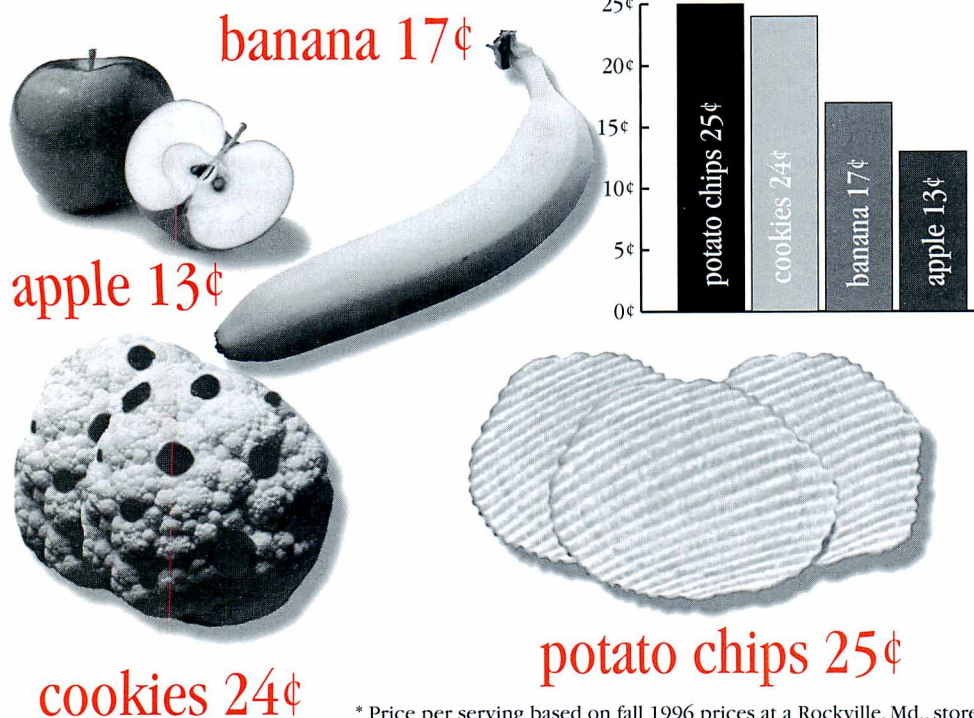
1/2 cup raw non-leafy or cooked vegetables

1 cup raw leafy vegetables (such as lettuce)

1/2 cup cooked beans or peas (such as lentils, pinto beans, and kidney beans)



# Price of Snacks Compared\*



\* Price per serving based on fall 1996 prices at a Rockville, Md., store.

tionists and food safety experts to help consumers overcome any reluctance they may have to eating fruits and vegetables.

## ***Perceived Problem: Fruits and vegetables cost too much.***

### ***Possible Solutions:***

It may help to realize, according to dietitians, that fruits and vegetables are actually good buys, if you consider that they are nutrient-dense, containing many of the vitamins and minerals we need more of—for example, vitamins A and C. But the foods we often buy in place of them—cookies and chips, for example—usually offer more of the nutrients—fat and sodium, for example—that most of us should eat less of. And the cookies and chips aren't cheap. For example, based on prices at a Rockville, Md., grocery store, a serving of potato chips costs about 25 cents and a serving of packaged chocolate chip cookies about 24 cents. A banana, on the other hand, sold for 17 cents, and the price of an apple ran as low as 13 cents.

"Compared to packaged foods, fruits and vegetables are not expensive," says Diane Quagliani, a registered dietitian

and spokeswoman for the American Dietetic Association.

And there are ways to reduce the costs of fruits and vegetables even further:

- Buy fresh fruits and vegetables in season. Not only will they be cheaper but they also will be at their flavor and nutritional peaks, Quagliani says.
- Clip coupons for money off on your favorite canned and frozen fruits and vegetables and juices.
- Watch local grocery advertisements for reduced prices on your favorite fruits and vegetables.
- If you're not partial to a particular brand, compare prices of different brands of canned and frozen fruits and vegetables and juices and buy the cheapest.

## ***Perceived Problem: Fruits and vegetables take too long to prepare.***

### ***Possible Solutions:***

- Take advantage of grocery store salad bars, which offer ready-to-eat raw vegetables and fruits and prepared salads made with fruits and vegetables.
- Shop for precut and cleaned fruits and vegetables. Many grocery stores now carry packaged precut fruits, such as

melons and pineapple; cleaned and cut-up salad greens and stir-fry vegetables; and cleaned, peeled baby carrots.

- Keep on hand canned and frozen fruit, canned and bottled juices, and dried fruits. Just open and use.
- Stock up on frozen vegetables for easy cooking in the microwave oven.
- Prepare fruits and vegetables ahead of time; for example, wash and, if feasible, cut up fresh produce and store it in the refrigerator for handy, immediate use.

## ***Perceived Problem: Fresh fruits and vegetables spoil too quickly.***

### ***Possible Solutions:***

- If you shop once a week or less often, buy both fresh and processed—that is, canned or frozen—fruits and vegetables, and juices. Use the fresh first; save the processed items for use later.
- Buy both ripe and not-so-ripe fresh fruits and vegetables—for example, yellow and green bananas—so that the not-so-ripe items will last a few days longer and be ready for eating after you've finished the ripe ones.
- Keep fruits and vegetables where you can see them often—on the top shelf of the refrigerator, or, for fruits that don't need refrigeration (such as bananas and apples), on the table or counter or another easy-to-spot-place. The more often you see the fruits and vegetables, the more likely you may be to eat them.

## ***Perceived Problem: Fruits and vegetables contain harmful pesticides.***

### ***Possible Solutions:***

It is a fact that pesticides are used in the production of most fruits and vegetables sold in this country. They help protect crops from insects, diseases, weeds, and mold, thus helping to in-

(Continued on page 21)

## **Clip or Copy**

The following two pages are provided as an easy-to-use handout with important information on food safety. It is specially designed for posting (in the kitchen, for example) or for making additional copies. Permission to reprint is not required. ►



# Safe Handling Of Fruits & Vegetables

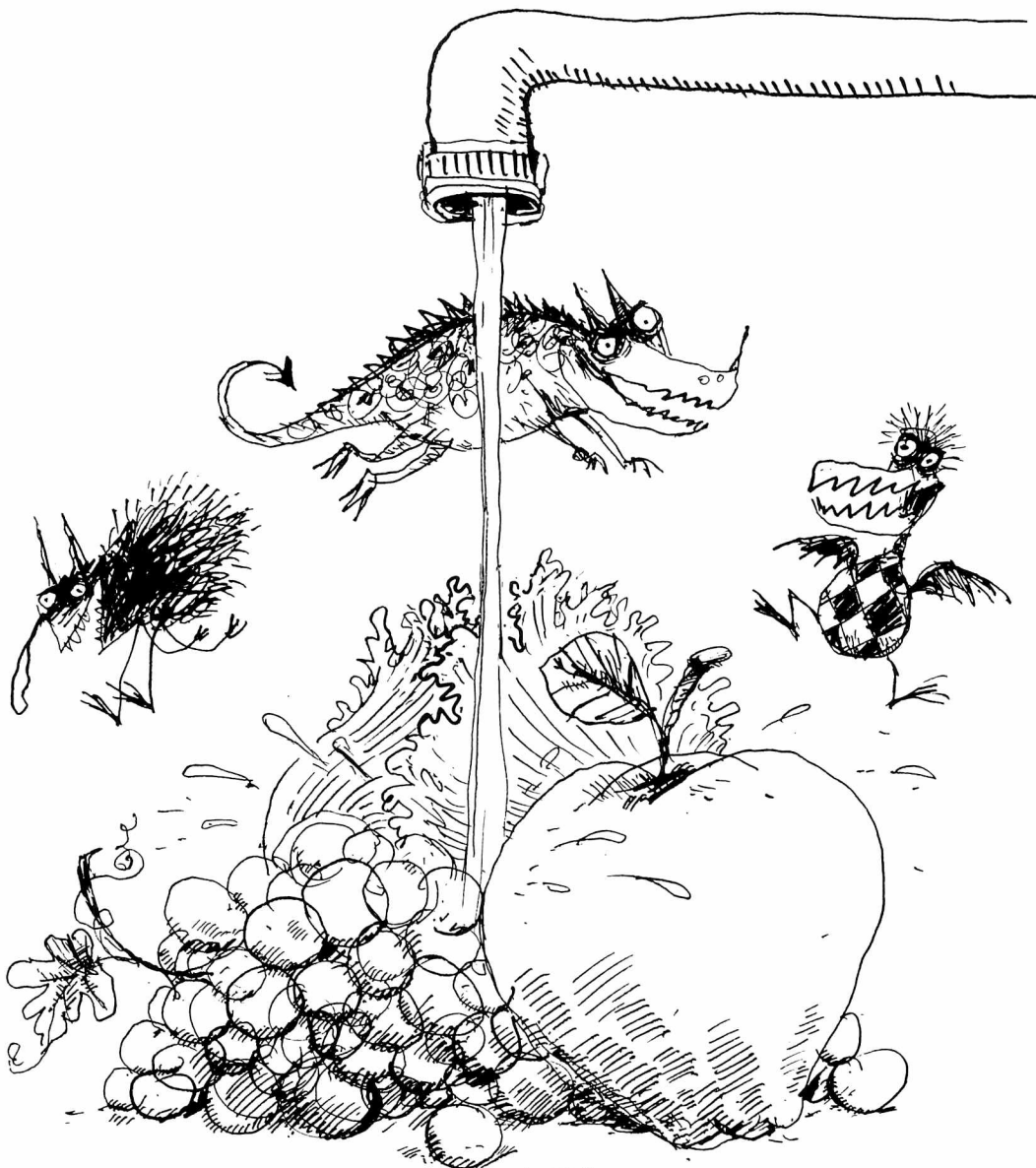
***E. coli* in fresh apple cider.**

***Salmonella* in melons.**

***Shigella* in tossed salad.**

These aren't dishes you'd want to order from a menu. They're descriptions of several causes of food-borne illness reported in recent years. The bacteria *Escherichia coli* O157:H7, *Salmonella* and *Shigella* in these fruits and vegetables were the culprits.

Although not commonly associated with food poisoning, fruits and vegetables can harbor disease-causing bacteria.





Their growth environment, such as soil, is a rich source of microbes. Poor agricultural practices—such as irrigation with unsanitary water—also may introduce bacteria. Poor storage and transportation practices can result in contamination, too, as can poor food handling by grocers, restaurants and consumers in the home.

FDA regulates certain production practices aimed at reducing bacterial contamination. For example, FDA

bars the use of animal fertilizers and allows only potable water for irrigation. These regulations apply to foreign producers that sell fruit and vegetables in this country and to domestic producers that market their products across state lines.

Industry practices, such as rinsing fresh fruits and vegetables with chlorinated water and transporting them in refrigerated cars, help reduce the

risk further. Restaurants and grocers also have certain standards to follow, based on their local food safety laws. These laws are often based on FDA's model food code for food establishments.

But, just as with other foods, safe handling of fruits and vegetables doesn't end there. Consumers have a responsibility, too. Below are some pointers to keep in mind when handling fruits and vegetables, and other foods, as well.



## TIPS For Safe Handling Of Fruits & Vegetables

- **Wash hands** with warm water and soap for at least 20 seconds before and after handling food, especially fresh whole fruits and vegetables and raw meat, poultry and fish.
- **Rinse raw produce in warm water.** Don't use soap or other detergents. If necessary—and appropriate—use a small scrub brush to remove surface dirt.
- **Use plastic,** rather than wooden, cutting boards. Bacteria can hide in the grooves of wooden ones.
- **Wash cutting boards** with a solution of 1 teaspoon (5 milliliters) of chlorine bleach in 1 quart (about 1 liter) of hot water. Always wash boards after cutting raw meat, poultry or seafood and before cutting another food to prevent cross-contamination.
- **Store cut, peeled and broken-apart fruits and vegetables** (such as melon balls) at or below 41 degrees Fahrenheit (5 degrees Celsius)—that is, in the refrigerator.
- **Stick with pasteurized juices and cider.** If you do buy unpasteurized cider, boil it for 5 minutes before drinking. This will kill bacteria.
- **When buying from a salad bar,** avoid fruits and vegetables that look brownish, slimy or dried out. These are signs that the product has been held at an improper temperature. ■



(Continued from page 18)

crease crop yield. "They allow for production of a plentiful and affordable food supply," said John Jones, Ph.D., pesticides and chemical contaminants strategic manager in FDA's Center for Food Safety and Applied Nutrition.

"They are not contaminants. They are substances applied intentionally for a specific purpose and therefore are subject to very rigorous regulatory control," he said. "A new pesticide law enacted in 1996 puts even tighter controls on the use of pesticides."

Several federal agencies share responsibility for pesticide oversight. The Environmental Protection Agency registers pesticides for food use and sets tolerance levels—the upper permitted limit for pesticide residues in individual foods. FDA enforces these limits for all foods except meat and poultry, which fall under USDA's jurisdiction.

FDA collects and analyzes almost 10,000 samples of fruits and vegetables yearly for pesticide residues. Since 1987, when the agency began reporting

the results of its monitoring program annually, more than 99 percent of domestic fruit and vegetable samples and more than 95 percent of imported samples have been found free of illegal pesticide residues or had low-level residues that fell within established tolerances. Violations mainly occurred because low-level pesticide residues not approved for a particular product were identified in that food. However, most of the pesticides causing these violations were approved for use on many other foods, Jones said.

"Most violations are not due to the presence of banned pesticides, such as DDT, chlordane and heptachlor, or to very high levels of residues," he said. "Most are due to very low-level residues on the wrong commodity."

So, FDA's position is that the U.S. fruit and vegetable supply does not contain excessive pesticide residues and that the benefits of eating fresh produce far exceeds any risk from residues, Jones said.

However, if you're still concerned, here are some steps you can take to reduce your risk further:

- Wash fruits and vegetables with water and scrub with a dish brush when appropriate: for example, before eating apples, cucumbers, potatoes, or other produce in which the outer skin or peeling is consumed.
- Throw away the outer leaves of leafy vegetables, such as lettuce and cabbage.
- Peel and cook when appropriate, although some nutrients and fiber may be lost when produce is peeled.

### What to Eat

For the most part, any fruit or vegetable will do in helping consumers reach their 5 A Day goal. But certain types of fruits and vegetables should be selected regularly because of their nutritional value. These include those that are good sources of vitamins A and C and fiber.

Variety also is important because fruits and vegetables provide other nutrients, such as folate, potassium, calcium, and iron. Varying choices increases the likelihood of getting all the nutritional

## What About Waxes?

A thin wax-like coating is often applied to some fruits and vegetables after harvesting. This is mainly to keep the produce fresh longer by sealing in moisture.

"Contrary to belief, it is not applied just to make fruits and vegetables look pretty," a United Fresh Fruit and Vegetable Association brochure says.

Some fruits and vegetables typically—but not always—coated with wax are apples, melons, grapefruit, peaches, oranges, rutabagas, cucumbers, squash, and tomatoes, according to the association.

FDA regulates these waxes, or coatings, as food additives approved or "generally recognized as safe" for human consumption. However, some consumers have concerns about their use. Vegetarians and others who avoid animal products may worry that fruits and vegetables contain animal-based waxes, such as oleic acid. Some people fear that

the wax traps pesticides, making the fruit or vegetable unsafe to eat—even though FDA's pesticide monitoring program indicates that pesticide residues on fruits and vegetables are consistently within acceptable safe limits.

If consumers want to avoid waxed fruits and vegetables, FDA regulations that took effect in 1994 may help them identify the appropriate products for them. These regulations require produce packers or grocers to provide point-of-sale information about the presence of waxes on fresh fruits and vegetables. This information can appear on labels of individual products, packing cartons (if they are used at the point of sale), or on counter cards or signs. The information will say that the product is:

- Coated with food-grade animal-based wax to maintain freshness, or
- Coated with food-grade vegetable-, petroleum-, beeswax-, and/or shellac-based wax or resin to maintain fresh-

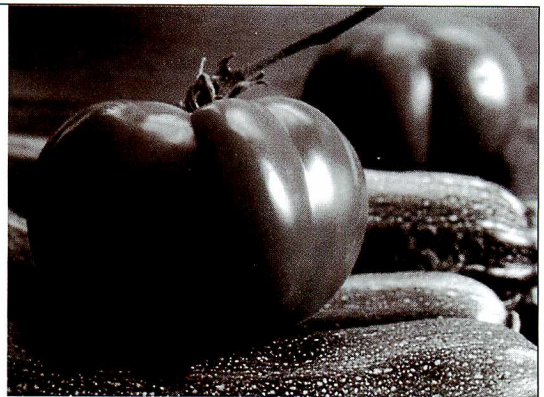


Image provided by © 1994 PhotoDisc, Inc.

ness. If only one of these types of waxes is applied, the label can simply identify the type, such as "vegetable-based."

FDA also will allow the statement "No wax or resin coating" on fresh fruits and vegetables that do not contain wax.

Besides reading labeling information, consumers can reduce their concerns about waxes by rinsing fruits and vegetables with warm water and, when appropriate, scrubbing with a brush. This will eliminate much of the wax. ■

—P.K.



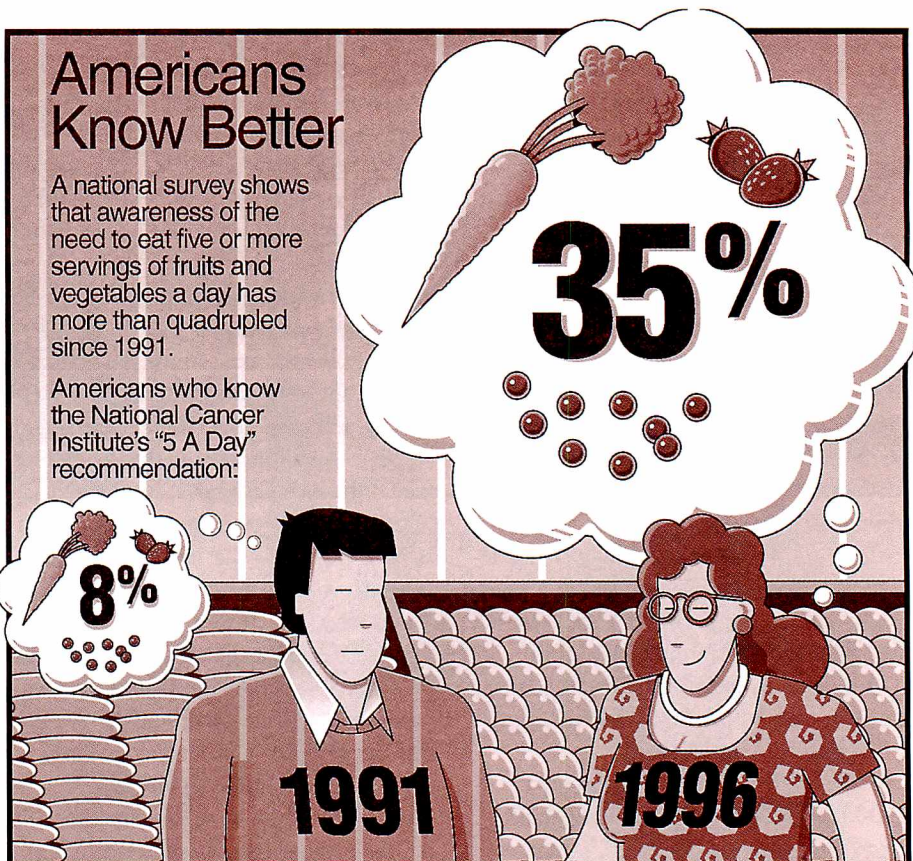
advantages of fruits and vegetables.

Also, nutrition experts advise against replacing all fruits and vegetables in the diet with dietary supplements because supplements often do not contain all the known—and perhaps unknown—nutritional benefits of fruits and vegetables.

Preparation presents another nutritional concern. Since a reduced-fat, reduced-saturated-fat intake is important to a healthful diet, it's important not to overindulge in fruits and vegetables prepared with high-fat ingredients. Some dishes to look out for include fried vegetables, such as french fries; cooked vegetables in cheese or cream sauces or with added bacon or butter; fruit pies or fruit served with whipped cream; and dips for raw vegetables. Some of these high-fat foods now have reduced-fat versions, such as low-fat dips and whipped toppings.

#### A Label with a Lot

You can determine the nutritional value of fruits and vegetables by looking at the Nutrition Facts panel on the side or back of labels of frozen and



Source: National Cancer Institute

A National Cancer Institute Graphic

## More Information

### 5-A-Day Program

National Cancer Institute

EPN 232

6130 Executive Blvd., MSC 7330

Bethesda, MD 20892-7330

Telephone: (1-800) 4-CANCER

World Wide Web: [http://](http://www.dcpnci.nih.gov/5aday/)

[www.dcpnci.nih.gov/5aday/](http://www.dcpnci.nih.gov/5aday/)

### Produce for Better Health Foundation

1500 Casho Mill Road

Newark, DE 19174-6035

Telephone: (302) 738-7100

### FDA

Office of Consumer Affairs (HFE-88)

Rockville, MD 20857

Telephone: (1-800) 532-4440

(10 a.m. to 4 p.m. Eastern time, Monday through Friday)

Also check with:

- grocery stores
- state health departments. Ask for the 5 A Day coordinator.

canned items. Nutrition information also is available for many fresh items, under FDA's voluntary point-of-purchase nutrition information program for raw foods. This information may appear on the labels of packaged fresh fruits and vegetables or on posters or brochures at or near the point of purchase.

The nutrition information lists the kinds and amounts of important nutrients in a serving of the fruit or vegetable and gives the Percent Daily Value, which shows how much those amounts contribute to the daily diet.

Some information is required: for example, the amount of fat, fiber, vitamins A and C, and iron and calcium, even if there is none. Some labels will carry additional information, such as the amount of folic acid and iron, depending on the types of label claims made.

You can quickly find fruits and vegetables that provide the nutrients you're looking for—for example, vitamin A or C or both—by looking for short descriptive terms on the front, side or back of the food label. For example, an orange juice label may say "provides 100 percent of the Daily Value for vitamin C." A pack-

age of frozen broccoli may state "good source of fiber." These claims refer to the contents of one serving of the item.

Less frequently, you may see longer claims describing the relationship between the labeled food or one or more nutrients in the food to a certain disease or medical condition. Only claims approved by FDA can be used in food labeling. Three approved health claims pertain to fruits and vegetables. These claims can describe how:

- fruits and vegetables may help lower the risk of some cancers
- fruits, vegetables and grain products that contain fiber, particularly soluble fiber, may help reduce the risk of coronary heart disease
- fiber-containing grain products, fruits and vegetables may help reduce the risk of some cancers.

In addition, in spring 1996, FDA approved a claim stating that a diet with adequate folic acid may reduce the risk of certain birth defects. This claim might appear, for example, on labels of dried beans, brussels sprouts, asparagus, tomato juice, and orange juice—foods that are excellent or good sources of folate.



# A High Five

In selecting your daily intake of fruits and vegetables, the National Cancer Institute recommends choosing:

- At least one serving of a vitamin A-rich fruit or vegetable a day.
- At least one serving of a vitamin C-rich fruit or vegetable a day.
- At least one serving of a high-fiber fruit or vegetable a day.
- Several servings of cruciferous vegetables a week. Studies suggest that these vegetables may offer additional protection against certain cancers, although further research is needed.

## High in Vitamin A\*

apricots  
cantaloupe  
carrots  
kale, collards  
leaf lettuce  
mango  
mustard greens  
pumpkin  
romaine lettuce  
spinach  
sweet potato  
winter squash  
(acorn, hubbard)

## High in Vitamin C\*

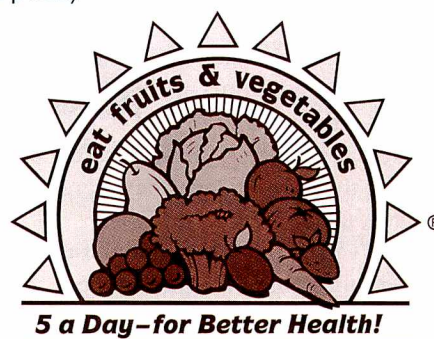
apricots  
broccoli  
brussels sprouts  
cabbage  
cantaloupe  
cauliflower  
chili peppers  
collards  
grapefruit  
honeydew melon  
kiwi fruit  
mango  
mustard greens  
orange  
orange juice  
pineapple  
plum  
potato with skin  
spinach  
strawberries  
bell peppers  
tangerine  
tomatoes  
watermelon

## High in Fiber or Good Source of Fiber\*

apple  
banana  
blackberries  
blueberries  
brussels sprouts  
carrots  
cherries  
cooked beans and peas  
(kidney, navy, lima,  
and pinto beans, lentils,  
black-eyed peas)  
dates  
figs  
grapefruit  
kiwi fruit  
orange  
pear  
prunes  
raspberries  
spinach  
strawberries  
sweet potato

## Cruciferous Vegetables

bok choy  
broccoli  
brussels sprouts  
cabbage  
cauliflower



\*Based on FDA's food labeling regulations

(Source: National Cancer Institute)

## A Campaign Continues

Are consumers paying attention to all this information?

In a way, yes, according to a 1996 NCI/PBH survey. That survey found that the percentage of consumers who were aware of the need to eat at least five servings of fruits and vegetables a day rose from 8 percent in 1991 to 35 percent in September 1996.

But whether the information has

helped increase Americans' consumption of fruits and vegetables remains to be seen. Late last year, NCI planned to analyze national food consumption data—the most recent of which was collected in 1994—to determine whether fruit and vegetable intake had increased since the 1991 survey. According to Gloria Stables, a registered dietitian and NCI's 5 A Day Program director, NCI plans to release the results this year.

Meanwhile, NCI, the produce industry, state health departments, and other groups will continue the 5 A Day campaign through at least the year 2000. Said Stables, "This is the largest national public-private nutrition education program ever launched." ■

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



## Barring People From The Drug Industry

by Tamar Nordenberg

*This is one in a series of articles on FDA activities and concerns.*

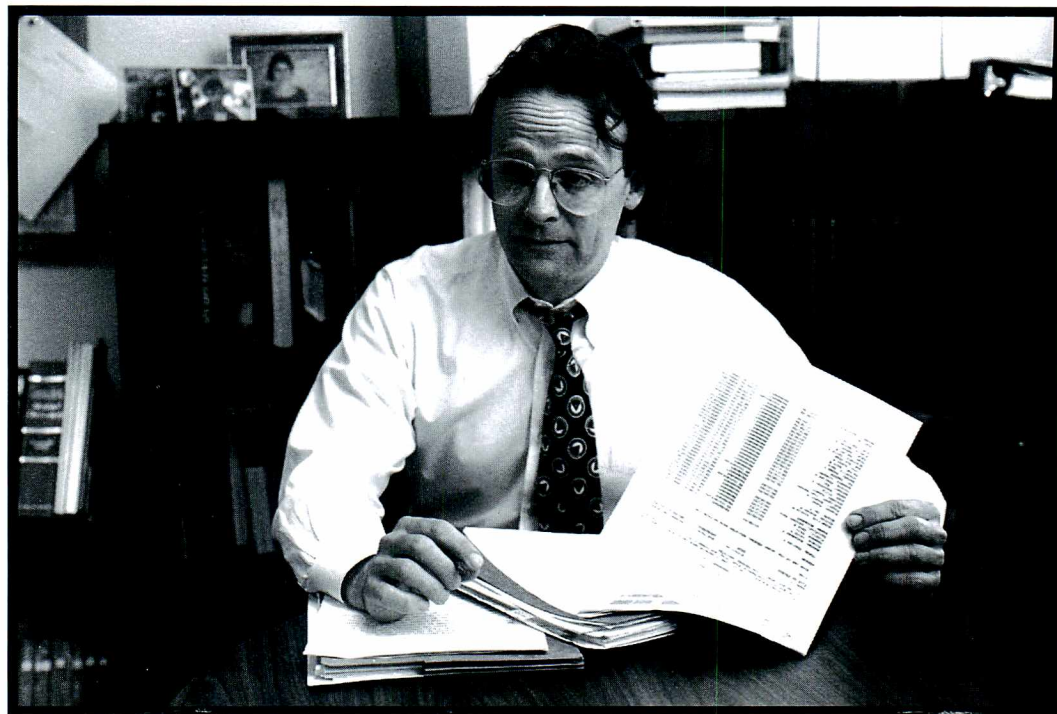
*"Some may object that the bill is unduly harsh, but let us not forget, this bill is only aimed at those who have engaged in criminal misconduct, those who put corporate profits ahead of public safety."*

*—Generic drug company representative Kip Schwartz, testifying before Congress about debarment.*

For putting unlawful profit ahead of consumer safety, 38 drug industry employees are facing a lifetime bar on practicing their livelihood. They were convicted, under the Federal Food, Drug, and Cosmetic Act, of felonies that included submitting false data to the Food and Drug Administration, lying to FDA investigators, paying or accepting bribes, and selling prescription drug samples. As a result, the 38 were "debarred" by FDA from working for a drug company.

Most worked for generic drug firms (firms that make drugs that are equivalent to the first, brand-name versions) in positions like "vice president for quality control" or "director for research and development."

The word "debar" means to shut out or exclude. FDA's authority to debar people from the drug industry comes from the Generic Drug Enforcement Act of 1992, often called the "debarment act" because it authorizes, and sometimes even requires, FDA to forbid people (or firms) convicted of certain crimes—basically, crimes related to FDA's regulation of drugs—from participating in the drug industry.



*David Read, chair of FDA's Debarment Task Force, with the list of people debarred from the drug industry.*

Other parts of this act give the agency additional authorities. (See accompanying article.)

When a person is debarred, FDA notifies the public by publishing a notice in the *Federal Register*. Also, FDA keeps an up-to-date debarment list. A copy of the list can be obtained by contacting FDA's Office of Enforcement (HFC-230), 12720 Twinbrook Parkway, Rockville, MD 20852; phone: (301) 827-0410; fax: (301) 827-0482; E-mail: [tchin@fdaem.ssw.dhhs.gov](mailto:tchin@fdaem.ssw.dhhs.gov).

Each time a company—any drug company, not just a generic drug maker—applies for approval of a drug, it must submit to FDA a signed statement that no debarred people worked on the application. If a drug firm employs a debarred person, even as a consultant or contractor, it can be fined up to \$1 million. The person illegally working in the industry can be fined up to \$250,000.

### Cleaning Up Generics

The law is broader than its title implies, affecting in large part brand-name as well as generic drug companies. It is called the "Generic Drug Enforcement Act" because Congress passed the public protection measure in response to the confidence-shaking discovery in 1989 of widespread corruption in the generic drug industry.

That year, FDA learned that some generic drug companies had committed illegal acts—things like falsifying data on drug formulations and illegally giving money to FDA chemists reviewing their drug applications—to gain preferential treatment.

"The data falsifications weren't just honest mistakes by generic companies," says David Read, chair of FDA's Debarment Task Force, which meets as necessary to make debarment policy decisions. "They were calculated attempts to



circumvent FDA's regulations. They constituted serious violations of the public trust."

To restore confidence in generic drugs, FDA fired agency employees who had taken bribes and reinspected drug manufacturing facilities. FDA also tightened its regulatory processes, for better verification of data used to support approval decisions.

### Protection, Not Punishment

Even with improved procedures, FDA lacks the resources to audit every piece of data in every drug application. "The drug approval process is based on a system of trust," Read says. "The agency receives hundreds of drug applications a year, each consisting of many volumes. When Congress created the new drug approval process, it was relying on drug companies and the agency to be fundamentally honest in their dealings with each other."

Debarment supplements FDA's existing compliance instruments—injunctions, seizures, recalls, civil penalties, and criminal sanctions. By rooting out dishonest people, the debarment act bolstered FDA's efforts to clean up the generic industry.

Under the law, a debarred person can't work for a drug firm "in any capacity." According to the U.S. Court of Appeals for the District of Columbia, even a job as a cook in a drug firm's cafeteria would be forbidden because of the opportunity for close contact between the debarred person and the drug firm's management. "All direct employment by a drug company, whether in the board room or the cafeteria or somewhere in between" is forbidden, the court said.

Besides direct employment, some jobs for a contractor that provides services to a drug firm are also off-limits.

"Debarment is a serious measure, but it's not intended as punishment," says Read. "It protects the public by ensuring that people with a history of dishonest conduct in the drug approval process will no longer be participants in that process."

Some debarees have claimed that the law is unconstitutional—that it is an *ex post facto* law—because it applies to crimes committed before the Generic Drug Enforcement Act was even passed in 1992. Because the law is a public protection measure and not punishment,

## Act's Other Authorities

Mandatory debarment isn't the only authority given to FDA by the Generic Drug Enforcement Act. Other authorities include:

**Civil Penalties:** Besides fines for violating a debarment, fines of up to \$1 million may also be imposed on a company for bribery, false statements, or other wrongful conduct involving a generic drug application.

**Permissive Debarment of Individuals:** FDA has the option to debar, for up to five years, individuals convicted of certain crimes, described in the act, that are related to the regulation of drugs but do not require mandatory debarment. In January 1997, FDA used this authority for the first time, debarring the head of a blood plasma facility convicted of falsifying blood records.

**Debarment of Firms:** Firms are also subject to mandatory or permissive debarment. They can be prohibited from submitting applications for generic drug approval (in this case, the law lives up to its name and only applies to generics) for certain crimes relating to the development or approval of generic drug ap-

plications. They can be debarred for up to 10 years, depending on the seriousness of the crime and other factors, and they can be debarred permanently if they are convicted a second time while debarred.

**Suspension of Distribution:** FDA can suspend marketing of some or all of a company's drug products if the company is under investigation for certain conduct that may influence the safety or effectiveness of a drug.

**Temporary Denial of Approval:** FDA can withhold approvals of generic drug applications if the firm is under active criminal investigation for dishonest conduct involving its drug applications (for example, bribery or material misrepresentations).

**Withdrawal of Approval:** For a generic drug that's already been approved, FDA may withdraw that approval if the company used bribery or fraud to get approval or if the company can't produce the drug properly. ■

—T.N.

courts have found that it is not illegal to debar people for conduct occurring before the law existed.

For the same reason, the act doesn't violate the constitution's double jeopardy clause because it doesn't *punish* someone twice for the same offense.

### Termination

Even the permanence of so-called "mandatory debarment" doesn't make debarment punishment. All debarments except one so far have been mandatory debarments, meaning that the types of convictions—federal felony convictions relating to the development, approval or regulation of a drug product—*compelled* FDA to exclude the people from the industry.

Unlike "permissive debarment," which

lasts up to five years, mandatory debarments of individuals are considered permanent. Although the mandatory debarments are imposed for a lifetime, the label of permanent may be misleading because the law provides a way for debarees to apply for "termination" of the debarment. They *may* be allowed to return to the drug industry if they substantially assist in the investigations or prosecutions of others in drug-related cases and submit persuasive evidence that they are rehabilitated and are no longer a threat to the drug approval process.

So far, no debarments have been terminated. But, Read says, "A small number of the people debarred so far may be eligible to have their debarments terminated." ■

*Tamar Nordenberg is a staff writer for FDA Consumer.*



# *Menopause* New Attitudes Towards

by Sheryl Weinstein

*I* imagine a cocktail party conversation in 1966 turning to menopause. It would have been as unlikely as a female high school student yearning to be a soccer star.

But times have changed. Just as participating in sports has now become significant to many young women, so has being open and even activist about menopause become equally important to their mothers.

The first women of the post-World War II generation known as baby boomers are now reaching the age of 50, one year away from the average age of menopause among U.S. women. By the end of this century, more women than ever before will be experiencing the sometimes uncomfortable symptoms that accompany the end of menstruation and natural childbearing capacity.

For many years, U.S. doc-





tors knew little about and paid little attention to menopause. "About 20 years ago, medical attitudes started changing," says Isaac Schiff, M.D., chief of obstetrics and gynecology, Massachusetts General Hospital. "We Ob-Gyns used to think that when women reached age 50, they weren't interested in sex anymore. But studies in retirement communities showed otherwise. We also began to see an increase in the female life expectancy. When a woman reaches age 50, she typically has another 30 years to live. As physicians, we became interested not only in the quantity of her life, but the quality of it."

The pace of medical inquiry has accelerated over the last five years, as the first of the baby boomers turned 45 and started experiencing menopausal symptoms. "It's not uncommon to hear it discussed at cocktail parties," says Schiff. "This is a radical turn-around from the way the mothers of these women treated it. Speak to a 50-year-old woman and she'll say, my mother never discussed it with me."

With such thinking, a new attitude toward treatment and research has emerged, says Schiff. Until recently, there were few studies on menopause. One of the largest and potentially most fruitful is the Women's Health Initiative, sponsored by the National Institutes of Health, which will study 164,500 women of various racial and ethnic backgrounds across the United States. The scientific investigation, which will not be completed until 2005, is expected to find out whether a low-fat diet, hormone replacement therapy, calcium, and vitamin D might prevent heart disease, breast and colorectal cancers, bone fractures, and memory loss.

### **Hormone Replacement Therapy**

As many as 15 to 25 percent of postmenopausal American women take hormone replacement therapy, according to an article in the January 1995 issue of the *Journal of Obstetrics and Gynecology* by Diane Wysowski, Ph.D., of the Food and Drug Administration, and colleagues. Women take estrogen to alleviate menopausal symptoms, especially hot flashes (sometimes called by doctors "hot flushes"), and also to protect bones.

Since the 1940s, FDA has approved many estrogen drugs to reduce menopausal symptoms. In the 1980s, FDA also began approving specific estrogen drugs to prevent osteoporosis (literally "porous bones," a condition in which bones break easily). The agency has approved four estrogen drugs—Premarin, Estraderm, Estrace, and Ogen—for long-term use to prevent osteoporosis. Other approved uses for estrogen drugs include the treatment of symptoms of vaginal atrophy, which may include itching, burning or dryness around the vagina, certain abnormal uterine bleeding conditions due to hormonal imbalance, and the comfort-promoting treatment of certain advanced cancers.

Many scientists believe that estrogen may fight heart disease by lowering harmful cholesterol (LDL), raising beneficial cholesterol (HDL), and strengthening the lining of the blood vessels, but this has not been clearly proven. Some research also suggests that estrogen may help prevent memory loss and Alzheimer's disease, but the scientific evidence remains speculative.

Nearly all the studies on heart disease and cognitive function have been retrospective or "look back" studies. The Women's Health Initiative Study will be prospective, that is, future-oriented, says Deborah Smith, M.D., a medical adviser in FDA's Office of Women's Health. Researchers will select a group of generally healthy women to treat and observe for a number of years to see if, and at what rate, they develop symptoms. Elements of the study will be scientifically controlled and data freshly recorded. Most important, treated and untreated women will be equally healthy at the start of the study. Retrospective studies depend on information sometimes clouded by time and memory loss, and women selected by their doctors for hormone replacement have usually been healthier than the women not so prescribed.

"The other important difference about the Women's Health Initiative is that it includes a clinical trial of estrogen," says Jacques Rossouw, the lead project officer for the study. "Participants will

have an equal chance of being on either estrogen or a placebo, and any differences in their health at the study's end can be ascribed to the estrogen."

### **Risks of Estrogen Therapy**

Estrogen is most commonly prescribed in pill form. It is also available in transdermal patches, which allow the drug to be slowly absorbed into the bloodstream, in vaginal creams, which treat localized discomforts.

Estrogen replacement therapy is not risk-free. "There's been much experimental evidence and patient experience showing estrogen given alone can lead to endometrial cancer," says FDA's Smith. For that reason, a woman who still has a uterus is usually prescribed progestin in addition to estrogen. This significantly reduces the risk of abnormal changes in the uterine lining.

**Women take estrogen to alleviate menopausal symptoms, especially hot flashes, and also to protect bones.**

Endometrial cancer is not the only risk from estrogen use. Gallbladder disease is another. Women who use estrogens after menopause are more likely to develop gallbladder disease needing surgery than women who don't use estrogens.

The drug's labeling also includes warning about abnormal blood clotting. Clots can cause a stroke, heart attack, or pulmonary embolus, any of which can be fatal.

Estrogen can produce uncomfortable side effects such as nausea and vomiting. It can enlarge breasts and make them tender. Women who use it can also retain excess fluid, which can aggravate conditions like asthma, epilepsy, migraines, and heart and kidney disease. A spotty darkening of the skin, particularly on the face, can occur.

For women who take progestin along with estrogen, menstrual-like bleeding and premenstrual symptoms often occur. Also under study is whether adding progestin counters the potential heart-



## How Hot Flashes Happen



Hot flashes, the most common sign of approaching menopause, occur as the brain's hypothalamus adjusts to decreased estrogen production by the ovaries. The hypothalamus—some functions of which are manipulated by estrogen—regulates body temperature. When it senses lower estrogen levels, the hypothalamus responds by rapidly changing body temperature.

protective effects of estrogen.

It is not known whether estrogen use increases the risk of breast cancer, or what effect adding progestin would have on this risk. In recent years, many studies on breast cancer and estrogen use have been conducted, with conflicting results, says Smith. Last year, following the publication in June 1995 of opposing views in two of the nation's most prestigious medical journals, the *New England Journal of Medicine* and the *Journal of the American Medical Association*, NIH scientists advised

the American College of Obstetricians and Gynecologists, the average age of menopause in the United States is around age 51. But some women go through natural menopause as early as age 35, while others don't experience it until their late 50s. Menopause occurs at any age with surgical removal of the ovaries.

During perimenopause, estrogen production is low and the ovaries stop producing eggs. As estrogen levels decline, certain signs may appear. The most common sign, the one that doctors sometimes call the "hallmark" of

women to consult their "medical caregiver for advice that is based on the individual's own personal health profile." Physicians urge women who receive estrogen therapy to have regular breast examinations by a health professional, perform monthly self-exams, and have yearly mammograms starting at age 50.

### Before Menopause

The medical term for the usually gradual period of change leading into natural menopause is "perimenopause." The two to three years following the last period are called the "climacteric." According to the American Col-

lege of Obstetricians and Gynecologists, the average age of menopause, is the hot flash. A hot flash is a sudden rush of heat to the neck, face, and possibly other parts of the body that may last from 30 seconds to five minutes. Some women go from feeling hot to feeling cold. The hot flash may begin with a sudden tingling in the fingers, toes, cheeks, or ears.

Some people used to think the hot flash didn't exist, that it was "all in a woman's head," says Smith.

Ironically, it *is* in a woman's head—but it has a very real physical cause. The hot flash is an alteration in thermal stability, which is maintained by the hypothalamus, a brain region located above the pituitary gland on the brain's floor. The hypothalamus operates the body's temperature regulation system. Estrogen levels manipulate some functions of the hypothalamus. During menopause, as the ovaries produce less estrogen, the hypothalamus senses and responds to the lower estrogen levels by rapidly changing body temperature. The result may be a hot flash.

Perspiration, sometimes extreme sweating, can accompany hot flashes. Many of them typically occur in the middle of the night, which causes some women to have trouble falling back to sleep. How many women are affected by hot flashes has not been clearly determined, and the reported numbers depend in part on whether healthy populations or women in medical settings are surveyed. Some scientists say as few as 30 percent of women are afflicted by them; others believe the figure is much higher.

According to Morris Notalovitz, M.D., Ph.D., and colleagues in the text *Menopause in Midlife Health*, 85 percent of perimenopausal women experience hot flashes. Fifty-four percent of the women experience them in their climacteric years; 25 percent of these women experience hot flashes up to 10 years after the climacteric. About 10 percent of the women who continue to have hot flashes still have them for 10 years after the climacteric, according to Notalovitz.

Obese women are less likely to have hot flashes because they have more estrogen, which is converted from adrenal hormones by stored fat. Many women cope with hot flashes by trying to relax until the discomfort passes and by low-



ering the room temperature, dressing in light layers of clothing, avoiding spicy food, and cutting back on caffeine and alcohol.

Vaginal dryness is another symptom of estrogen decrease and may lead to painful intercourse, vaginal infections, and urinary problems. Over-the-counter vaginal lubricants (Replens and others) may help. Prescription estrogen replacement creams are approved by FDA to relieve these symptoms.

Other symptoms attributed to menopause include difficulty concentrating, depression, headache, memory loss, a feeling of insects crawling across the skin, and lower backaches, which may be related to osteoporosis.

Barbara Sherwin, Ph.D., at the University of Toronto, and colleagues have been researching an association between menopause and memory loss, even Alzheimer's disease, and whether estrogen can halt these problems. Sally Shumaker, Ph.D., of the Bowman-Gray School of Medicine, North Carolina, is leading a \$16 million study, the Women's Health Initiative Memory Study, to determine whether estrogen treatment affects a woman's risk of developing dementia after age 65. Wyeth-Ayerst Laboratories is funding the study.

Probably the disease with the strongest link to menopause is osteoporosis. Scientists believe women can help control bone loss with weight-bearing exercises, including walking, running or weightlifting. A low-fat diet, rich in calcium and vitamin D, is also believed to be important, as are cutting back on alcohol and stopping smoking. FDA has approved a nonhormonal drug to treat osteoporosis. (See "Boning Up on Osteoporosis" in the September 1996 *FDA Consumer*.)

Despite its sometimes annoying, peripheral problems, more than ever before menopause is now seen as a natural process, not a disease. "There's nothing embarrassing about it," says Schiff. "It's healthy. It's physiologic."

It is such new thinking that best explains why at cocktail parties and other places baby boomers congregate that menopause is a hot conversation topic. ■

*Sheryl Weinstein is a writer in Livingston, N.J.*

## More Resources

American College of Obstetricians and Gynecologists (ACOG)  
409 12th St., S.W.

Washington, DC 20024-2188

Telephone: (202) 484-3321

Send a self-addressed stamped envelope for three pamphlets about estrogen, osteoporosis and menopause.

North American Menopause Society (NAMS)

P.O. Box 94527

Cleveland, OH 44101

Telephone: (216) 844-8748

World Wide Web: <http://www.menopause.org/>

Answers written requests for information about menopause, and publishes a medical journal.

American Association of Retired Persons (AARP) Women's Initiative

601 East St., N.W.

Washington, DC 20049

Telephone: (1-800) 424-3410

Has a free fact sheet about hormone replacement therapy.

National Institute on Aging Information Center

P.O. Box 8057

Gaithersburg, MD 20898-8057

Telephone: (1-800) 222-2225

Has free information on menopause, exercise and nutrition.

Planned Parenthood Federation of America, Inc.

810 Seventh Ave.

New York, NY 10019

Has a booklet, "Menopause—Another Change in Life," available from the above address for \$3. It can also be downloaded free through the World Wide Web at <http://www.ppfa.org/ppfa/menopub.html>.

The Power Surge Reading Room

An on-line menopause discussion area with an electronic newsletter. It can be accessed in its entirety through America Online with the keyword "Women," followed by the "well-being" icon, and in part through the World Wide Web at <http://members.aol.com/dearest/news.htm>.

Women's Health Initiative

Federal Building, Room 6A09

7550 Wisconsin Ave.

Bethesda, MD 20892-9112

Telephone: (1-800) 54-WOMEN

Women interested in participating in the Women's Health Initiative can also find information at <http://www.nih.gov/od/odp/whi/> on the World Wide Web. ■





*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.*

■ **Some dairy products** that contain more than 1 percent fat, such as "2%" milk, may no longer use the term "lowfat" on the label, according to an FDA final rule. Instead, these products must be labeled "reduced fat." Products with 1 percent or less fat may continue to be labeled "lowfat." "Skim" will mean the same as "nonfat."

Effective January 1998, the rule holds dairy products to the same standards as low-fat claims for other foods, under the Nutrition Labeling and Education Act of 1990. (FR Nov. 20)



■ **Chlamydia**, a sexually transmitted disease, can spread as easily from women to men as from men to women, according to the National Institutes of Health. Over a four-year period, NIH researchers tested 494 couples involved in heterosexual partnerships. The study was the first to use both the traditional

cell culture test and the newer polymerase chain reaction (PCR) test for chlamydial genital infections.

Cell culture testing showed chlamydia in 8.5 percent of male participants and 12.9 percent of females. But PCR testing found the disease in 14.2 percent of males and 15.8 percent of females.

An estimated 50 million cases of chlamydia occur each year. The infections are associated with such diseases as pelvic inflammatory disease, which can lead to infertility and ectopic pregnancy. (*Journal of the American Medical Association*, Dec. 3)

■ **"Extralabel" uses** of certain approved animal and human drugs may be prescribed for animals, according to an FDA final rule. The rule is intended to give veterinarians greater flexibility in prescribing drugs.

There are restrictions, though. For example, an extralabel use may not be prescribed for food animals if this would result in residues that could be a public risk. Also prohibited from extralabel use are nine drugs, including clenbuterol, diethylstilbestrol (DES), and ipronidazole.

The rule went into effect Dec. 9. (FR Nov. 7)

■ **A food's fat content** listed on its label could be based on the reduced availability of fat to the body from a fat substitute in the food, according to an FDA proposed rule. The proposal stems from a petition filed by Nabisco Group. This proposal takes into account that some fat substitutes can limit the amount of fat and fatty acids the body absorbs from foods.

Written comments on the proposal must be submitted by April 21, 1997, to the FDA Dockets Management Branch, HFA-305, 12420 Parklawn Drive, Room

1-23, Rockville, MD 20857. (FR Dec. 20)

■ **Selenium supplements** may help protect against cancers of the lung, colon, rectum, and prostate, according to a University of Arizona study of 1,312 patients.

The study initially examined whether selenium could prevent two types of skin cancer, but found no reduction in incidence. However, midway through the study, researchers decided to evaluate selenium's value in preventing other types of cancers and in reducing cancer deaths.

When cancer cases were studied over an average 4.5 years in groups given either daily 200-microgram supplements of selenium or a placebo, the selenium group had 37 percent fewer cancers and a 50 percent reduction in cancer deaths. Selenium users had 63 percent fewer prostate cancers, 58 percent fewer colorectal cancers, and 46 percent fewer lung cancers. (*Journal of the American Medical Association*, Dec. 25)

■ **Recurring vaginal infections** may be helped by a daily diet of 5 ounces (141.75 grams) of yogurt containing the live bacteria *Lactobacillus acidophilus*, according to an Israeli study. Researchers gave 23 patients yogurt containing the live bacteria. Another 23 patients ate yogurt that had been pasteurized, which kills the bacteria. The group eating the live bacteria yogurt had significantly fewer cases of vaginal infections than the pasteurized group. For example, cases of bacterial vaginosis in the live cultures group dropped from 60 percent in the first month to 20 to 28 percent in the second month. (*Archives of Family Medicine*, Nov-Dec 1996)





# Message Sent Loud and Clear To Hearing Aid Marketer

by Tamar Norderberg

**T**he distributor of an under-\$30 hearing aid is paying \$515,000 to settle consumer fraud suits for falsely advertising its hearing aids and selling them without the required FDA approval. Under a 1996 court settlement, the distributor, Telebrands Corp. of Roanoke, Va., also was forced to recall the hearing aids, refund the purchase price to consumers, and stop selling or advertising the products without FDA clearance.

Seventeen states, supported by an affidavit from FDA, took Telebrands to court over the company's unproven marketing claims for its Whisper XL hearing aids. Newspaper ads and television commercials, some of them featuring entertainer Steve Allen, indicated the device was a bona fide hearing aid by telling consumers, "Take it to the movies, theater or lecture hall and you'll never miss a word" and saying, "Now you can enjoy the crisp clear sound of a TV or radio playing at low levels, without annoying everyone else in the room."

FDA started investigating Telebrands based on some 1994 advertisements in *Parade* magazine and various newspapers. The agency sent a warning letter to Telebrands in July 1994, stating that the Whisper XL was an adulterated product being illegally marketed without FDA clearance.

The agency classified the Whisper XL as a medical device because it fit the legal definition of a hearing aid: "a wearable sound-amplifying device that is intended to compensate for impaired hearing."

Telebrands protested FDA's classifica-



tion in several letters and a citizen petition it submitted to FDA in 1994. The company argued that the Whisper XL was not a hearing aid because it wasn't intended for people with hearing loss but rather for people with normal hearing to achieve "super hearing."

FDA responded by reiterating its position that the Whisper XL was a medical device—a hearing aid—that required FDA clearance for marketing. FDA said it based its decision in part on claims made in promotional labeling and advertising, including ads depicting older people using the product while doing normal daily activities, such as riding in a taxi, boarding an airplane, and watch-

ing television. This implied the product was intended to compensate for hearing impairment, the agency told the company, because people with normal hearing don't need sound amplification for these kinds of daily activities.

While never admitting the Whisper XL was a medical device, Telebrands offered to change its ads "to further expressly emphasize that the Whisper XL is intended to enhance normal hearing." The agency responded, in letters to Telebrands and in a September 1994 meeting with the company president and his attorney, that a market had already been established for the product and that relabeling the Whisper XL



would not overcome the impression that the product could compensate for hearing loss.

While FDA collected evidence to support an intended seizure of the hearing aids, a number of state attorneys general were looking at Telebrands' marketing practices. In September 1995, 17 states, led by the Minnesota Attorney General Hubert H. Humphrey III, sued the company for falsely advertising the Whisper XL and selling it without FDA clearance.

FDA decided to support the states' efforts rather than pursue seizure. "It was more efficient for FDA to support the individual actions brought by the states," says Eric Latish, chief of FDA's dental, ear, nose and throat, and ophthalmic devices branch.

FDA gave the states a sworn statement explaining its classification of the Whisper XL as an unapproved medical device, not just a sound amplification device for people with normal hearing. Such devices for people with normal hearing might not require FDA clearance.

"The agency wasn't making a judgment about whether the product did or didn't work," says Byron Tart, director of FDA's devices promotion and advertising policy staff. "Our issue was that the device was a hearing aid, and a

medical device without clearance to be marketed."

Minnesota and the 16 other states—Arizona, California, Connecticut, Florida, Illinois, Massachusetts, Missouri, Maryland, New Jersey, New Mexico, North Carolina, New York, Pennsylvania, Texas, Vermont, and Wisconsin—reached settlements with Telebrands on July 30, 1996. Telebrands, which had sold about \$12 million worth of the Whisper XL hearing aids, agreed to the terms without any admission of wrongdoing.

The Federal Trade Commission reached a separate agreement with Telebrands for violations of that agency's advertising and mail-order rules.

In a press release filed by Minnesota's Humphrey the day the settlement was reached, the attorney general called the Whisper XL a "cheap, poorly-performing device." Continuous use of the Whisper XL could cause hearing damage, the release said.

FDA never received any complaints of injuries from the product.

Telebrands apparently has stopped marketing the Whisper XL, according to FDA's Latish. Since the July settlement, agency officials have not seen any ads for the hearing aid and have not received any complaints.

Between August 1994 and August 1996, FDA sent warning letters to more than 10 other companies that made unsupported claims for their hearing aids. Some companies have already notified FDA that they will correct the violations by revising the claims or ceasing marketing of the products.

Do these kinds of false claims mean consumers should ignore all promotional claims they see and read about hearing aids? Not necessarily. One clue to look for is a product's price, says Minnesota Assistant Attorney General David Woodward. "People should be skeptical of claims like those made for the Whisper XL hearing device—that they'll hear a pin drop from 50 feet away or that they'll hear a deer coming before it hears them—especially for a [hearing aid] being sold for \$29."

Hearing aids typically cost between \$300 and \$3,000, according to the International Hearing Society. Says FDA's Tart: "Advertising is biased and intended to sell the product. Most consumers wouldn't know if a product had received clearance from FDA. But a hearing aid for \$29? That sounds too good to be true, and it was."

*Tamar Nordenberg is a staff writer for FDA Consumer.*

## Device Maker Sentenced For Violating Injunctions

When two injunctions didn't stop a Salt Lake City man from selling and promoting his unapproved medical devices, one of which he promoted as a cure for AIDS, the federal government went back to court.

As a result, in June 1996, Tim Themy-Kotronakis was convicted in the U.S. District Court for the District of Utah of criminal contempt for violating a 1989 and a 1994 injunction against his selling and promoting unapproved medical devices and a drug solution.

Judge J. Thomas Greene sentenced Themy-Kotronakis Oct. 25 to six months' probation and 50 hours of community service.

Themy-Kotronakis originally manufactured the Ster-O-Lizer, a device he said could sterilize surgical instruments. He began making this device in 1984. In 1993, he began a large-scale promotion of the AIDS Treating Machine. The only difference between the two devices is shape. The Ster-O-Lizer is completely rectangular, while the AIDS Treating Machine has a cylinder on top of a rectangular base.

The AIDS Treating Machine suppos-

edly turns salt water, or "Solution A," into a treatment to "de-activate" pathogens and viruses. According to the instructions, Solution A becomes a potent drug after exposure to the electric currents inside the cylinder. The drug can then be administered intravenously, intramuscularly, orally, rectally, or in any combination of these methods.

Themy-Kotronakis operated under several business names, most recently as Brinecell Inc. and T & T Medical Products.

After receiving complaints from health professionals about the "AIDS Treating Machine," James Moore, an in-



investigator with FDA's Salt Lake City resident post, inspected Brinecell in August 1993. During the inspection, Moore asked Themy-Kotronakis several times if he was manufacturing, marketing, promoting, or selling any medical devices. Each time, Themy-Kotronakis said no. He also denied operating under any other business name besides Brinecell. However, as the inspection continued, Moore noticed an envelope with the return address T & T Medical Products and the same street address as Brinecell. Also printed on the envelope was the statement "Ask about our AIDS Treating Machine." At that point, Themy-Kotronakis admitted he was promoting the machine for AIDS treatment. He added, however, that he was not going to sell any machines until he had FDA approval.

When Moore returned the next day to continue the inspection, Themy-Kotronakis would not allow him to enter the firm.

On Sept. 8, Moore, FDA investigator Frederic French, who was with the agency's Salt Lake City office at that time, and two U.S. marshals returned to Brinecell with an inspection warrant. This time, Themy-Kotronakis allowed them to enter.

During this inspection, Moore and French learned that Themy-Kotronakis had manufactured at least one AIDS Treating Machine and sent promotional letters all over the world. These measures indicated he intended to manufacture and sell the device and Solution A. Their inspection found that the device had not been evaluated for safety and effectiveness by FDA and that the device and Solution A were manufactured in complete absence of current good manufacturing practice requirements.

Themy-Kotronakis told the investigators he didn't realize he had to follow FDA laws and regulations. He said this even though the agency had cited him for violations seven times since September 1983, and seized his devices for violations in 1986 and 1987. Also, the

agency had enjoined him in 1989 based on these violations.

On March 21, 1994, at FDA's request, the Department of Justice filed in the U.S. District Court for the District of Utah a request to permanently enjoin Themy-Kotronakis from selling and promoting his AIDS Treating Machine, Solution A, and any other medical devices and drugs until he obtains FDA approval.

Themy-Kotronakis signed a consent decree of permanent injunction July 7, 1994. But within days he was violating the injunction by running help-wanted ads for a national sales manager to promote the Ster-O-Lizer, says Shelly Maifarh, a compliance officer with FDA's Denver district office. Although the July 7 decree specifically prohibited selling and promoting the AIDS Treating Machine, it applied also to all unapproved medical devices, including the Ster-O-Lizer, explains Maifarh. In addition, the 1989 injunction prohibiting Themy-Kotronakis from manufacturing and shipping unapproved devices was still in effect.

On Aug. 2, Themy-Kotronakis held a press conference at the Hilton Hotel



Conference Center in Salt Lake City to promote his AIDS Treating Machine and complain about the consent decree. During the next few months, he continued to promote both the AIDS Treating Machine and the Ster-O-Lizer in letters to individuals, firms and governments around the world. FDA investigators found these letters during an inspection Oct. 13 through 24.

Then, in May 1995, a Salt Lake City export broker told FDA that Themy-Kotronakis was trying to ship the Ster-O-Lizer to Spain. On June 2, U.S. marshals seized the device.

These violations prompted the Department of Justice, at FDA's request, to file a petition on June 12 with the U.S. District Court for the District of Utah requesting that Themy-Kotronakis be tried for criminal contempt of the two injunctions.

The court agreed, and a trial was held Jan. 29 and 30, 1996. On June 26, U.S. District Judge Greene found Themy-Kotronakis guilty of criminal contempt of both injunctions.

At press time, Themy-Kotronakis was appealing his conviction.

—Isadora Stehlin



## N.Y. Blood Center Agrees To Correct Deficiencies

After FDA found continuing breaches of blood safety laws and regulations at the New York Blood Center, the facility and three of its officers agreed in a consent decree with FDA and the Department of Justice to a series of measures designed to ensure the integrity of its operations and thereby the safety of the blood it provides.

The government filed the decree last Dec. 16 simultaneously with a civil complaint in the U.S. District Court for the Southern District of New York.

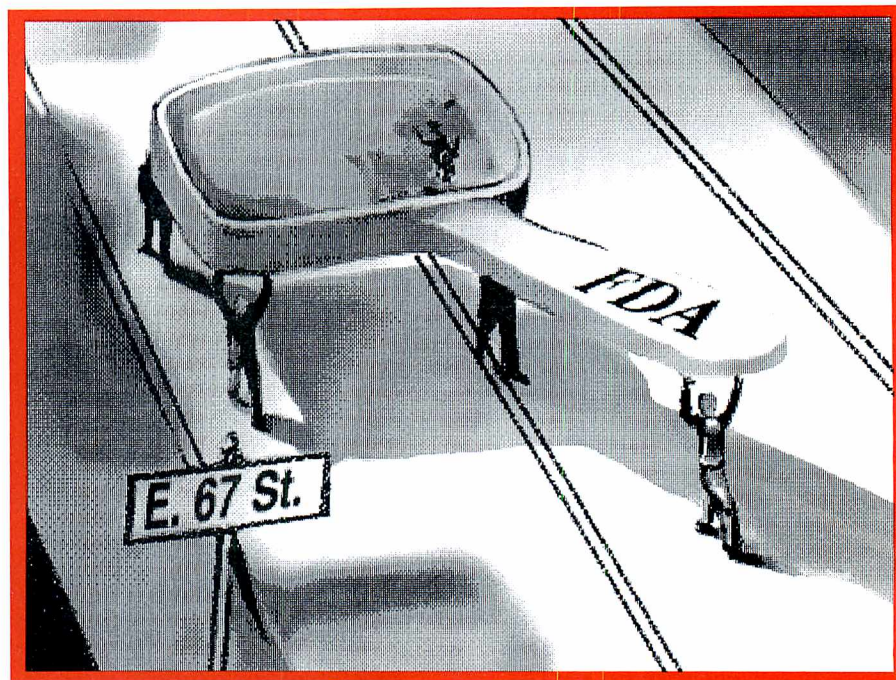
This consent decree is the latest in a series of actions by FDA to ensure the continued safety of the U.S. blood supply. FDA entered into similar agreements with Blood Systems Inc./United Blood Systems in 1996, and with the American Red Cross in 1993.

The New York Blood Center collects blood at both fixed and mobile donation sites in New York City and Melville, N.Y., and in New Jersey. It also performs blood donor testing for facilities in New Jersey, Pennsylvania and Tennessee and imports and exports blood products to and from Europe.

In late 1994, FDA investigators inspected the center's New York City facility on Amsterdam Avenue and found that the center was:

- engaging in allegedly improper testing practices
- not maintaining complete and adequate standard operating procedures
- not following the company's existing standard operating procedures
- not following the manufacturer's testing instructions
- keeping incomplete, inaccurate records
- not adequately training employees
- maintaining inadequate security controls of computerized operations to ensure data integrity.

These findings led FDA to issue the blood center a warning letter in March 1995. A month later, the director of FDA's New York district office met with



blood center senior officials, who then agreed to remedy deficiencies in their operations.

In late 1995, FDA investigators inspected the center's East 67th Street location, in New York City, examining a number of operations, including the center's interpretation of Western Blot testing. This test is done on blood from donors whose screening tests showed them to be reactive for infection with HIV, the AIDS virus. It helps distinguish true positive screening test results from false positive results.

Also that winter, FDA reinspected the Amsterdam Avenue location.

In those and follow-up inspections, FDA investigators found efforts for improving operations to be inadequate. The civil complaint followed.

Under the decree, approved by the court Dec. 17, 1996, the center agreed to:

- strengthen its quality assurance and quality control program
- assess its management controls and organizational structure to ensure they meet FDA rules
- improve its system for testing donated blood for infectious agents
- improve its management and supervision of technicians who perform the blood screening tests

- improve its formal training program for employees, including establishing ethics training
- improve its computer systems and record keeping
- improve its system for investigating suspected transfusion-linked infections and other problems
- improve its tracking and notification procedures concerning blood from donors who subsequently test positive for HIV
- improve its internal audit procedures
- put the improvements in place according to specific timetables.

FDA protects the U.S. blood supply with overlapping safeguards designed to prevent release of unsuitable products. Failure of an individual safeguard does not automatically translate into the release of unsafe products, but it may increase the potential risk.

For planned medical procedures, FDA generally advises patients that it is prudent to set aside their own blood, in advance, in case a blood transfusion is needed. The agency emphasizes that the risk of not having a medically necessary transfusion far outweighs the risk of receiving blood.

—Dixie Farley



# SUMMARIES OF COURT ACTIONS



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

## SEIZURE ACTIONS

### *Food/Contamination, Spoilage, Insanitary Handling*

PRODUCT: **Cocktail shrimp**, at Port Newark, N.J. (D. N.J.); Civil Action No. 91-3990.

CHARGED 9-13-91: While held for sale after shipment in interstate commerce at Port Newark Refrigerated Warehouse, in Port Newark, N.J., the articles were misbranded in that the package failed to bear a label containing an accurate statement of the net quantity of contents—403(e)(2).

DISPOSITION: A consent decree of condemnation ordered the articles destroyed. (F.D.C. No. 66254; S.J. No. 91-643-384; S.J. No. 1)

PRODUCT: **Infant formula**, at Orlando, Fla. (M.D. Fla.); Civil Action No. 96-182-CIV-ORL-19.

CHARGED 2-20-96: While held for sale after shipment in interstate commerce at 4C Transportation Warehouse, in Orlando, Fla., the articles were adulterated in that they were not processed in compliance with current good manufacturing practice requirements because the containers failed to bear lot codes—412(a)(3). The articles were misbranded in that the labels failed to bear a declaration of the nutrients in the order given and the unit specified and a statement of the number of fluid ounces supplying 100 kilocalories. The labels also failed to bear a statement of the amount of each nutrient supplied by 100 kilocalories and directions for use that contain the weight and volume of powdered formula to be reconstituted—403(j). DISPOSITION: A default decree of condemnation and destruction ordered the articles destroyed. (F.D.C. No. 67128; S. No. 96-712-384; S.J. No. 2)

PRODUCT: **Milk, evaporated**, at Angola, La. (M.D. La.); Civil Action No. 96-3331-B-2.

CHARGED 8-1-96: While held for sale at Louisiana State Penitentiary, in Angola, La., after shipment in interstate commerce, the articles were adulterated in that they were unfit for food because the cans of milk were heavily rusted and dented and were held under insanitary conditions whereby they might have become contaminated with filth—402(a)(3) and 402(a)(4).

DISPOSITION: The articles were destroyed. (F.D.C. No. 67145; S. No. 96-690-738; S.J. No. 3)

### *Drugs/Human Use*

PRODUCT: **Oxygen**, at Mesa and Phoenix, Ariz. (D. Ariz.); Civil Action No. Civ-90-0805 PHX PGR.

CHARGED 5-29-90: While held for sale after shipment in interstate commerce at Apollo Medical, Inc., in Mesa and Phoe-

nix, Ariz., the articles were adulterated in that the methods used in and the facilities and controls used for their manufacture, processing, packaging, and holding were not in conformity with current good manufacturing practice requirements—501(a)(2)(B).

DISPOSITION: A consent decree of condemnation was filed. Subsequently, the company declared bankruptcy and went out of business. The articles were seized and sold at auction. (F.D.C. No. 65858; S. No. 90-567-953; S.J. No. 4)

PRODUCT: **Oxygen**, at Pocatello, Idaho (D. Idaho); Civil Action No. CIV 94-0340-E-HLR.

CHARGED 8-3-94: While held for sale after shipment in interstate commerce at Maag Prescription & Medical Supply, Inc., in Pocatello, Idaho, the articles were adulterated in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding were not in conformity with current good manufacturing practice requirements—501(a)(2)(B).

DISPOSITION: The articles were reconditioned. (F.D.C. No. 66933; S. No. 94-628-683; S.J. No. 5)

### *Medical Devices*

PRODUCT: **In vitro diagnostic products**, at Loganville, Ga. (M.D. Ga.); Civil Action No. 3:95-CV-27-DF.

CHARGED 3-7-95: While held for sale after shipment in interstate commerce at Roach Laboratories, Inc., in Loganville, Ga., the articles were adulterated in that they were class III devices without an application for premarket approval—501(f)(1)(B). The articles were also adulterated in that the methods used in, and the facilities and controls used for, their manufacture, packing and storage were not in conformity with current good manufacturing practice requirements—501(h). DISPOSITION: The articles were donated to the Centers for Disease Control and Prevention. Subsequently, the firm ceased doing business, and the claimant filed a voluntary dismissal. (F.D.C. No. 66912; S. No. 93-654-171; S.J. No. 6)

## CRIMINAL ACTIONS

DEFENDANT: **New England Shrimp Company and G. Robert Randazzo**, at Ayer, Mass. (D. Mass.); Criminal No. 94-10039-RWZ.

CHARGED 10-28-94: *Count 1*: The defendants knowingly conspired to conceal that shrimp supplied by the New England Shrimp Company (NESC) contained tripolyphosphates (STPs), which were prohibited by contracts with several federal government agencies—18 U.S.C. section 1001. The defendants also knowingly conspired to make fraudulent claims for payment against several federal government agencies by submitting invoices where the shrimp failed to meet contract requirements—18 U.S.C. section 287. The defendants, with the intent to defraud, conspired to obstruct a federal auditor from performing quality assurance inspections of shrimp relat-



## SUMMARIES OF COURT ACTIONS (continued)

ing to contracts under which NESC received in excess of \$100,000 in a one-year period—18 U.S.C. section 1516.

*Counts 2 to 51:* The defendants knowingly made fraudulent claims for payment against the United States by submitting invoices for shrimp that did not meet the contract requirements—18 U.S.C. sections 287 and 2.

*Count 52:* The defendants, with the intent to defraud, conspired to introduce into interstate commerce shrimp adulterated with saccharin, an unsafe food additive—301(a) and 303(a)(2). The defendants, with the intent to defraud, also conspired to add saccharin to shrimp while the shrimp was held for sale after shipment in interstate commerce—301(k) and 303(a)(2).

*Counts 53 to 64:* The defendants, with the intent to defraud, knowingly introduced into interstate commerce adulterated shrimp—301(a) and 303(a)(2), 18 U.S.C. section 2.

*Count 65:* The defendants, with the intent to defraud, conspired to introduce into interstate commerce misbranded shrimp. The shrimp was misbranded in that its labeling failed to disclose that the shrimp had been colored with sodium hydroxide, and it failed to list the common or usual name for one of the ingredients from which the shrimp had been fabricated. The labeling also falsely represented that the shrimp was from the United States when, in fact, it was from China—301(a) and 303(a)(2). The defendants, with the intent to defraud, conspired to misbrand shrimp while it was held for sale after shipment in interstate commerce—301(k) and 303(a)(2). The defendants also conspired to falsely state that the shrimp was from the United States when, in fact, it was from China—18 U.S.C. section 1001.

*Counts 66 to 78:* The defendants, with the intent to defraud, introduced into interstate commerce shrimp that was misbranded in that its labeling failed to disclose that the shrimp was colored with sodium hydroxide. The labeling also failed to list the common or usual name for one of the ingredients from which the shrimp food was fabricated, namely sodium hydroxide, or designate such an ingredient as coloring. The shrimp was also misbranded in that its labeling falsely represented that it was from the United States when, in fact, it was from China—301(a) and 303(a)(2), 18 U.S.C. section 2.

*Count 79:* The defendants, with the intent to defraud, conspired to introduce into interstate commerce frozen raw breaded shrimp that was misbranded in that the shrimp represented a food for which a standard of identity was prescribed by regulation, but it did not conform to such standard of identity because it contained STPs, which were not permitted by the standard—301(a) and (k) and 303(a)(2), 18 U.S.C. section 371.

*Counts 80 to 97:* The defendants, with the intent to defraud, introduced into interstate commerce frozen raw breaded shrimp that was misbranded in that it was represented to be a food for which a standard of identity was prescribed by regulation, but did not conform to such standard because it contained STPs, which were not permitted by regulation—301(a) and 303(a)(2), 18 U.S.C. section 2.

*Counts 98 to 101:* Defendant Robert Randazzo willfully filed a Corporate Income Tax Return Form for NESC in which he overstated the cost of purchases made by the company when he knew that the amount filed was not the true cost of pur-

chases. Randazzo also overstated the amount paid to employees for work performed by including an amount he knew was not truly the salary of an employee—18 U.S.C. section 2, 26 U.S.C. section 7206(1).

**DISPOSITION:** The New England Shrimp Company was sentenced to pay a nominal fine after the court determined that it no longer had substantial assets. Defendant Robert Randazzo, who was found guilty on all counts, was sentenced to three years of imprisonment and two years of supervised release, and was ordered to pay a \$5,050 assessment. Randazzo appealed his conviction, but the Court of Appeals upheld the district court's ruling. (F.D.C. No. 66479; S.J. No. 7)

**DEFENDANT:** **Ortho Pharmaceutical Corp.**, at Raritan, N.J. (D. N.J.); Criminal No. 95-12 (WGB).

**CHARGED 1-11-95:** *Count 1:* The defendant knowingly conspired to impede a federal grand jury investigation—18 U.S.C. section 371.

*Count 2:* The defendant knowingly obstructed a federal grand jury investigation in that employees under the direction of high-ranking representatives shredded documents and other records responsive to the grand jury subpoena—18 U.S.C. sections 1503 and 2.

*Counts 3 to 10:* The defendant corruptly persuaded individuals to destroy documents and other objects for use in an official investigation conducted by federal agencies—18 U.S.C. sections 1512(b)(2)(B) and 2.

**DISPOSITION:** The defendant pleaded guilty to all counts and was ordered to pay a \$5 million fine and \$2.5 million in restitution. (F.D.C. No. 65986; S.J. No. 8)

## INJUNCTION ACTIONS

**DEFENDANT:** **Enzymatic Therapy, Inc., Terence Lemerond, and Bradley Lemerond**, at Green Bay, Wis. (E.D. Wis.); Civil Action No. 91-C-1174.

**CHARGED 11-5-91:** The defendants introduced into interstate commerce misbranded and unapproved new drugs—301(a) and 301(d). The articles were misbranded in that their labeling failed to bear adequate directions for their intended use—502(f)(1).

**DISPOSITION:** The articles were reconditioned. (Inj. No. 1232; S. No. 89-528-927; S.J. No. 9)

## MISCELLANEOUS ACTIONS

**ACTION:** **Barnes et al. v. Shalala**, at Verona, Wis. (W.D. Wis.); Civil Action No. 94C-0090C.

**CHARGED 2-3-94:** The plaintiffs alleged that the defendant violated the Federal Food, Drug, and Cosmetic Act, the National Environmental Policy Act, and the Administrative Procedure Act in approving the use of the synthetic bovine growth hormone (rBGH)—also referred to as bovine somatotropin (bST)—to increase milk production in cows.

**DISPOSITION:** The defendant filed a motion to dismiss, and several plaintiffs were dismissed for lack of standing. The case was resolved in the agency's favor on summary judgment. An appeal was not filed. (Misc. No. 1012; S.J. No. 10)



# Keep All Poison Away from Children

Our homes abound with poisonous substances: household cleaners, laundry detergent, bug killers, antifreeze and windshield wiper fluid, cosmetics, medicines, even dietary supplements, especially those with iron. To protect kids from these and other poisons:

- Lock poisonous substances in cabinets with childproof safety latches. These kinds of latches are available in hardware stores.
- Never leave a poisonous substance, even for one moment, in a place where children can reach it. Return poisonous substances to their safe place immediately after using.
- Buy products with child-resistant caps.

For more information, write to:  
Poison Prevention Week Council  
P.O. Box 1543  
Washington, DC 20013

National Poison Prevention Week  
March 16–22, 1997

