

FDA *Consumer*

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Keeping an Eye on
Contact Lenses



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◀ **Inside Front Cover Photo:**

FDA Consumer

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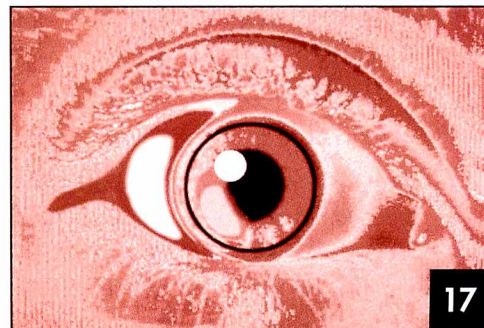
One of the hottest weapons in the battle against sun-damaged skin, alpha hydroxy acids may cause as many problems as they're supposed to solve.

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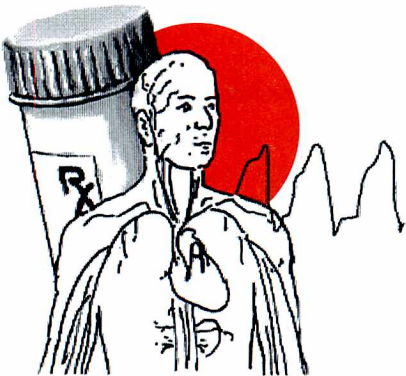
While the color and style may vary, all American-made and imported condoms must meet FDA requirements to ensure their safety and effectiveness. See page 22.



Medical Exams Advised For Some Diet Drug Users

The federal government is advising people who took the weight-loss drugs fenfluramine (Pondimin) and dexfenfluramine (Redux) to see their doctors and, in some cases, undergo a heart test, to determine whether they have developed heart or lung disease.

The recommendations, developed jointly by FDA, the national Centers for Disease Control and Prevention, and the National Institutes of Health and published in the Nov. 14 *Morbidity and Mortality Weekly Report*, followed the drugs' removal from the market in September. The drugs' manufacturer and marketer, Wyeth-Ayerst Laboratories and Interneuron Pharmaceuticals, withdrew the products at FDA's request after heart tests in five surveys indicated that about 30 percent of patients who took the drugs had heart valve abnormalities,



even though most had no symptoms.

The Department of Health and Human Services advises people who have ever taken one or both of these drugs to see

their doctors for a medical history and physical examination to check for a heart murmur, shortness of breath, or other signs of heart or lung disease. Patients who show such signs should undergo an echocardiogram, a test that uses sound waves to examine the inside of the heart.

Even if a patient has no symptoms of heart or lung disease, HHS advises an echocardiogram for all former fenfluramine and dexfenfluramine users before they undergo an invasive procedure for which the American Heart Association recommends antibiotic treatment for preventing bacterial endocarditis—a serious and potentially fatal infection of the heart's lining.

Red Meat Irradiation Approved

Red meat is the latest food product to get FDA's OK to undergo irradiation—a process in which food is subjected to radiation to make it safer to eat.

The radiation, from radioactive or machine sources, will help control disease-causing bacteria, such as *Escherichia coli* O157:H7 and *Salmonella*, in fresh or frozen beef, lamb and pork. The process does not make food radioactive or noticeably change taste, texture or appearance.

After reviewing a substantial number of studies that looked at the chemical, nutritional, toxic, and bacterial effects of irradiation on various meat products, the agency concluded that irradiation is safe in reducing disease-causing microbes in or on meat and that it does not compromise meat's nutritional value.

FDA has already approved irradiation for these products: poultry to control



pathogens; pork to control the trichina parasite; fruits, vegetables and grains to control insects; and spices, seasonings and dry enzymes to control microorganisms.

FDA considers irradiation a complement to, not a replacement for, proper food-handling practices by meat producers and processors and consumers.

Dangerous Bleeding Prompts Anti-Clotting Drug Warning

Following more than 30 reports of bleeding in the spinal column associated with an anti-clotting drug, FDA is warning doctors to carefully monitor patients using certain anticoagulants. The drugs are used in patients undergoing some types of surgery to prevent complications from blood clots in deep leg veins.

The adverse events involved patients treated with Lovenox (enoxaparin sodium) Injection. The agency said that similar reactions could be expected with other drugs of this type, known as low molecular weight heparins, as well as heparinoids. The other drugs are

Fragmin (dalteparin sodium injection), Normiflo (ardeparin sodium) Injection, and Orgaran (danaparoid sodium) Injection.

The problems with these drugs may occur when they are used at the same time as spinal or epidural anesthesia, or spinal puncture. The combinations may cause bleeding or hematomas (collection of blood) in the spinal column that could result in permanent paralysis if not treated immediately.

FDA has asked the manufacturers of these drugs to add a boxed warning to the labeling discussing the risks.

Health-care professionals should report adverse events to the drug manufacturer or to FDA's MedWatch program by calling 1-800-FDA-1088 or by faxing 1-800-FDA-0178.

Law to Reform Food, Medical Product Regulation

President Clinton signed a law last November designed to improve FDA's regulation of food, medical products, and cosmetics. The FDA Modernization Act, the first major food and medical products reform legislation in 35 years, builds on previous agency reforms that

have achieved record low approval times for drugs and medical devices.

Key provisions of the law include:

- Reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA) for five more years. This law has cut the average drug review time in half, while maintaining consumer protection, by using fees from manufacturers to speed up drug reviews.
- Initiatives to streamline biological product regulation and increase patient access to experimental drugs and medical devices.
- Procedures to streamline the filing and approval of new therapies for serious or life-threatening conditions.
- Expanded distribution, by manufacturers, of reliable information about unapproved, or "off-label," uses of drugs and medical devices, provided that manufacturers commit to conducting research and filing supplemental applications for approval of these uses.
- Expansion of a program that allows low-risk medical devices to be reviewed initially for safety and effectiveness by FDA-accredited outside experts.
- Procedures that allow FDA to authorize health and nutrient content claims that link a health benefit to a particular food component.
- Regulation of over-the-counter products under one national system. The law prohibits states from imposing different or additional requirements than those mandated by FDA.

Proposed Guidance Covers Pharmacy Benefits Managers

Concern over improper health practices such as substituting one therapy over another for financial gain has

prompted FDA to propose a guidance covering the practices of some pharmacy benefits management companies (PBMs).

Managed-care health insurance programs hire PBMs to determine what medicines the plan will pay for. The proposal, published in the Jan. 5 *Federal Register*, applies to PBMs owned or influenced by manufacturers or distributors of medical products.

While PBMs can be useful tools for managing health-care costs, the agency says, practices such as "switching" medications based on financial incentives could have serious health implications for patients.

The deadline for comments on this proposal is April 6. Submit written comments to: Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Drive, Room 1-23, Rockville, MD 20857.

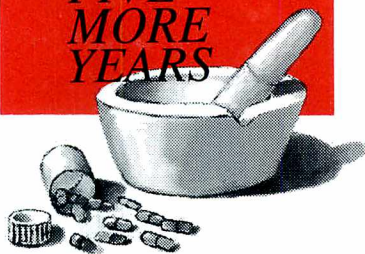
Warnings Added on Posicor

In response to more than 20 reports of drug-associated adverse reactions, FDA and the manufacturer of the hypertension and chronic angina drug Posicor (mibefradil) are warning doctors to take new precautions when prescribing this drug.

The warnings added to Posicor's labeling include advice to doctors not to prescribe the drug to patients at high risk of developing dangerously low heart rates. This includes those whose heart rates are already relatively low and those taking another drug that slows heart rate.

In addition, doctors are warned

PDUFA
FIVE
MORE
YEARS



against giving the drug to patients who are also taking some statin drugs to reduce cholesterol. Doctors should not prescribe Posicor to patients on lovastatin or simvastatin because of the increased risk of muscle injury that can cause potentially life-threatening kidney and heart damage. Also, pending further information, doctors are strongly discouraged from prescribing Posicor to those on atorvastatin or cerivastatin. Fluvastatin and pravastatin, however, are metabolized differently from the other statins and, therefore, combining these drugs with Posicor is not expected to increase the risk of muscle injury.

The labeling also warns against the simultaneous use of Posicor, any statin drug, and either of the immunosuppressants tacrolimus or cyclosporine.

Health-care providers should report any adverse events to the manufacturer, Roche Laboratories, at 1-800-526-6367, or to FDA at 1-800-332-1088, by fax at 1-800-332-0178, or by mailing in a MedWatch form available on the agency's Website at <http://www.fda.gov/medwatch/report/hcp.htm>.

Laser Pointers Pose Risk For Children

Following two reports of eye injuries from children's misuse of hand-held laser pointers, FDA warned parents and school officials about the risk.

Laser pointers are generally safe when used as intended by teachers and lecturers to highlight areas on a chart or

screen. However, price reductions have led to wider marketing, and FDA is concerned about promotion and use of the products as children's toys.

Light energy from a laser pointer aimed into the eye can be more damaging than staring directly into the sun. Federal law requires a warning on the product label about this potential hazard from lasers. Momentary exposure, as from an inadvertent sweep of the light across a person's eyes, causes only temporary flash blindness. But even this can be dangerous to someone who is driving or performing some other activity for which vision is critical.

FDA Research Uncovers Clues on Serious Diseases

FDA scientists recently published the results of two studies that may change the way some life-threatening illnesses are treated.

In one study, researchers from FDA's Center for Biologics Evaluation and Research and the University of Sydney have discovered a key mechanism by which proteins called chemokines direct the traffic of immune cells in response to attacks on the body from disease or infections. Published in the Dec. 1, 1997, issue of the *Journal of Experimental Medicine*, this discovery may have potential implications for the treatment of AIDS, cancer, heart disease, and other serious medical conditions.

Researchers with the same center, in collaboration with scientists at the National Institutes of Health, also have detected factors that may make certain strains of HIV-1 more likely than others to be transmitted through sexual contact. These findings, published in the December 1997 issue of *Nature Medicine*, may further the development of HIV vaccines and treatment.

Stamp Marks Early Public Health Law

This new stamp showing a late 19th century medicine label marks the passage of the Pure Food and Drugs Act of 1906, which prohibited the sale of adulterated or misbranded food and drugs. The stamp, issued in February, is included in a 15-stamp sheet celebrating the first decade of the 20th century. The U.S. Postal Service will be issuing other stamps commemorating the 20th century over the next several years.





End-of-Year Approvals

A device alternative to hysterectomy for excessive menstrual bleeding, as well as medical products to treat osteoporosis, diabetic ulcers, kidney transplant rejection, and a cancer of the immune system were some of the products FDA approved as 1997 came to a close.

- **Evista** (raloxifene), one of a new class of drugs called selective estrogen receptor modulators (SERMs), can help prevent bone thinning from osteoporosis primarily in postmenopausal women. Clinical data on Evista indicate that it acts like estrogen, though to a lesser degree, in increasing bone density and lowering blood lipids, and it did not adversely affect breast and uterine tissue. Unlike estrogen, however, it does not increase "good cholesterol" levels.

The most serious side effect associated with Evista is increased risk of blood clots. Women with a history of blood clots in their veins should not use the drug. Also, women who are pregnant or may become pregnant should not use the drug because of its potential danger to fetuses.

Manufacturer: Eli Lilly and Co., of Indianapolis.

- **Fortovase** (saquinavir) is a new formulation of a protease inhibitor for treatment of HIV infection. Fortovase comes in a soft gelatin capsule and delivers more drug through the body than its predecessor, Invirase.

In a clinical study, twice as many patients who took Fortovase had undetectable virus levels in the blood at 16 weeks of treatment compared with those who took Invirase.

Fortovase was the first HIV drug approved after an FDA advisory committee recommended a more stringent reporting system for clinical study results.

Manufacturer: Hoffmann-La Roche Inc. of Nutley, N.J.

- **Meridia** (sibutramine) is an appetite suppressant to be used along with a reduced-calorie diet to help manage obesity, a chronic disease that contributes to 300,000 deaths annually in this country.

The drug works by inhibiting the reuptake of the neurotransmitters norepinephrine and serotonin. During clinical trials, there were no reports of pulmonary hypertension, a rare but serious side effect of the anti-obesity drugs fenfluramine and dexfenfluramine, which were taken off the market in September 1997. Also, echocardiograms showed no more valve disease in pa-

tients on Meridia than those on placebo.

Manufacturer: Knoll Pharmaceutical Co., of Mount Olive, N.J.

- **Neumega** (interleukin eleven) reduces the need for frequent platelet transfusions following high-dose chemotherapy. Platelet transfusions, while very safe, carry small risks of infectious disease transmission and bacterial contamination.

Neumega is injected daily under the skin when chemotherapy ends. In clinical studies, 28 percent of patients treated with Neumega avoided platelet transfusions, compared with 3 percent in the untreated group. Possible side effects include fluid retention, which can be a serious problem for some patients, and abnormal heart rhythms, which in studies returned to normal when the treatment ended.

Neumega is not effective for patients undergoing bone marrow transplants.

Manufacturer: Genetics Institute Inc., of Cambridge, Mass.

- **Propecia** is the first hair loss treatment in pill form. It is marketed for men only because, in women, it causes birth defects and has not otherwise been shown to be safe and effective.

The drug's active ingredient, finasteride, was first approved in a larger dose as a treatment for prostate enlargement.

Manufacturer: Merck and Co., of West Point, Pa.

- **Regranex Gel** (becaplermin) is the first biotechnology product for treating and healing deep diabetic foot and leg ulcers. These ulcers, which about 15 percent of the country's 16 million diabetics develop, increase the risk of infection and amputation.

The gel is used topically, along with standard ulcer management measures.

Manufacturer: Ortho-McNeil Pharmaceutical, of Raritan, N.J.

- **Rituxan** (rituximab) is the first biotechnology product to treat patients who have a cancer of the immune system called low-grade B-cell non-Hodgkin's lymphoma and who have not responded to chemotherapy or other standard treatments. FDA reviewed the license application in five months and approved the product in nine.

By targeting and destroying specific white blood cells involved in the disease, Rituxan shrinks tumors with less severe side effects than most cancer treatments.

Manufacturer: IDEX Pharmaceuticals Corp., of San Diego, and Genentech Inc., of San Francisco.

- **ThermaChoice** is a uterine balloon catheter heat system alternative to hysterectomy or surgical destruction of the uterine lining when excessive, non-cancerous menstrual bleeding can't be controlled by drugs. The outpatient procedure is usually done without general anesthesia and takes about a half hour. Studies showed it safely controlled bleeding for at least one year in more than 80 percent of participants.

As the balloon heat treatment also destroys the lining, it is not for use in women who still plan to have children. Pregnancy is possible after treatment if some lining cells survive. However, scientists believe such pregnancies would carry considerable risk to the mother and fetus, so treated women must use effective

contraception or undergo sterilization.

Manufacturer: Gynecare-Ethicon Inc., of Menlo Park, Calif.

- **Tobi** (tobramycin for inhalation) is the first inhaled antibiotic for people with cystic fibrosis, an inherited condition that can lead to diminished lung function and chronic lung infections. Tobi suppresses *Pseudomonas aeruginosa* bacteria, a potentially dangerous microorganism that affects the lungs or respiratory system of most people with cystic fibrosis.

A reformulation of the injectable form of tobramycin, which FDA approved in 1975, Tobi helped improve lung function and reduce bacteria in sputum in clinical trials. Side effects included voice alteration and ringing in the ears.

Manufacturer: PathoGenesis Corp., of Seattle.

- **Toronto SPV Valve** is a new type of heart valve for adults with defective natural or prosthetic aortic valves. The tissue valve, taken from a pig, is supported by the patient's aorta, unlike previous tissue valves, which require metal or plastic supports called stents. With increased space from elimination of the stent, doctors can implant larger valves for improved blood flow.

In a study of about 600 patients ages 33 to 93 in the United States, Canada, and the United Kingdom, the new valve was safe and provided good blood flow.

Manufacturer: St. Jude Medical Inc., of Minneapolis.

- **Transderm Scop** (scopolamine patch) is a small, tan-colored patch that is placed behind the ear before surgery to prevent the nausea and vomiting related

to some pain relievers and anesthesia.

Each patch should be used only once and for no longer than three days. It should not be used by children.

Manufacturer: Novartis Consumer Health, of Summit, N.J.

- **Zenapax** (daclizumab) is the first monoclonal antibody to help prevent acute kidney transplant rejection. Used with a standard course of immunosuppressive therapy, it helps prevent kidney rejection with minimal additional side effects.

FDA reviewed and approved the license application for this biologic in six months.

Manufacturer: Roche Laboratories Inc., of Nutley, N.J.

Free Info on Food Safety

To order single copies of the new FDA backgrounders—HACCP: A State-of-the-Art Approach to Food Safety (BG 97-11) and FDA Food Code (BG 97-12)—write to FDA, HFI-40, Rockville, MD 20857, or fax your order to 301-443-9057. Include the publication numbers.

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

Time To Spring Into Action Against *Seasonal Allergies*

by Rebecca D. Williams

By the time her daughter, Brooke, was 18 months old, Nancy Sander of Fairfax, Va., had discovered the child was allergic to much of the environment around her. Her eyes watered and her nose ran constantly. Worse yet, her allergy symptoms triggered frightening asthma attacks.

Now a 19-year-old college student, Brooke has her dorm room decked out with an air cleaner, dust mite-proof casings on the pillows and mattresses, a stash of prescription eye drops, nose sprays, and antihistamines, and a sympathetic roommate who does the vacuuming (which kicks up the dust that triggers her allergies).

"I realize she's not your typical college student," says Sander, "but she knows her quality of life is better if she does these things. Rather than hide indoors all spring, she increases her medication as needed. She washes her hair every day to keep the allergens out of it, takes her medication before she has symptoms, and she gets out there and enjoys life."

About 26 million Americans endure chronic seasonal allergies, while the number of people with milder symptoms may be as high as 40 million, according to the National Center for Health Statistics. One study puts the annual costs of "hay fever," as it's commonly called, at \$2.4 million for medications and another \$1.1 billion in doctors' bills.

For most people, allergies to plants that bloom in the spring and fall are merely annoying. For those with asthma or severe allergic reactions, however, these allergies may be life-threatening.

"It's better to get good treatment than to let it go," says William Storms, M.D., an allergist and professor of medicine at the University of Colorado Health Sciences Center in Denver. "We have learned a few things about this disease. First, it does affect a patient's quality of life—productivity, educational performance. Second, it may lead to secondary diseases such as otitis media [ear infections], sinus infections, and asthma."

Spring is traditionally the main season when allergies blossom because of new growth on trees and weeds. But fall, with a whole different set of blooming plants as well as leaf mold, is a close second. In addition, people who are allergic to pollens are also often sensitive to dust mites

(microscopic insects that feed on human skin cells), animal dander (tiny skin flakes shed by animals), and molds, which lurk indoors in any season.

The Food and Drug Administration regulates medications and biological products that offer allergy relief. Combined with a number of strategies to minimize a person's contact with allergens, these can make life bearable for even the worst allergy sufferer.

What Is an Allergy?

An allergy is the body's hypersensitivity to substances in the environment. Allergic reac-

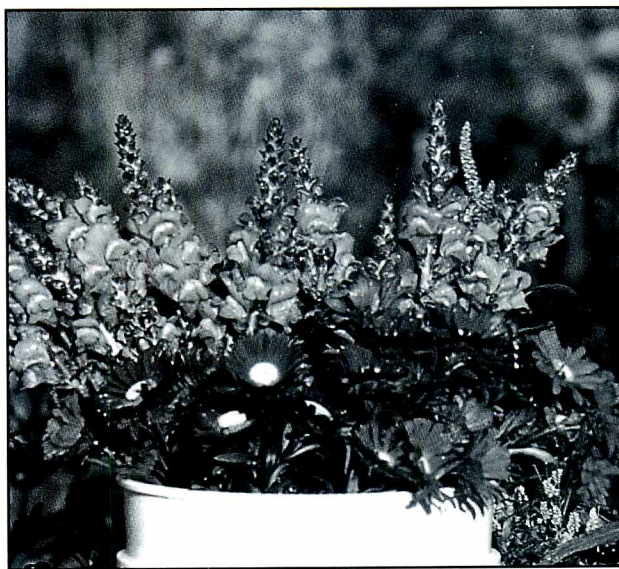


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Dangerous Side Effects

Two prescription antihistamines, first touted for their effectiveness without causing drowsiness, are now known to have dangerous side effects. Seldane (terfenadine), and Hismanal (astemizole) have been shown to react with a number of other medications to cause life-threatening cardiac arrhythmias.

Seldane's manufacturer, Hoechst Marion Roussel, Kansas City, Mo., withdrew the medication along with Seldane-D (terfenadine, pseudoephedrine) from the market voluntarily last winter.

Patients taking antibiotics, antifungal medications, and some medications to treat HIV infection should talk to their doctors about the risks of taking any products containing terfenadine or Hismanal (astemizole).

tions range from mild itching, sneezing or eczema (inflamed, itchy skin), to severe hives, hay fever, wheezing, and shortness of breath. An extreme allergic reaction can result in anaphylactic shock, a life-threatening situation in which a person's airway swells shut and blood pressure drops.

Scientists believe allergies originated millions of years ago as a way for the human body to rid itself of parasites and invading worms. The body fights these and other invaders by producing an antibody called immunoglobulin E (IgE for short) in the intestines and lungs. Without modern parasites to fight, IgE reacts to other foreign substances in the body. IgE triggers immune cells to release a number of chemicals, one of which is histamine. Histamine produces hives, watery eyes, sneezing, and itching. The more a person is exposed to allergens, the more the body produces IgE; hence, allergies often get worse with age.

The Nose Knows

The most common symptom of seasonal allergies is allergic rhinitis, otherwise known as hay fever. Symptoms of



Are spring blossoms or fall flowers the source of your seasonal allergy? Because there are so many plants in bloom each season, allergy tests, like the one the nurse (below) is administering, may be the only way to know your sneezing source.

Image provided by © 1994 PhotoDisc, Inc.

PNH ©Gerald Davis, 1983



allergic rhinitis closely mimic those of the common cold.

But there are differences. A cold runs its course in 7 to 10 days. Allergic rhinitis can drag on for weeks or months. Despite its nickname, "hay fever" does not cause fever. With a cold, nasal discharge may be thick and yellow. In allergies, it is generally thin and clear. An allergy is often accompanied by eye, skin or mouth itchiness and can often be traced to a specific trigger.

The first step in handling chronic allergies is a visit to an allergist. The doc-

tor will begin by taking a detailed medical history. From that, he or she can establish a list of suspected allergens. To confirm the diagnosis or figure out puzzling allergy symptoms, the doctor may order an allergy skin test.

With this test the practitioner makes a series of punctures, each containing a small amount of one suspect allergen in solution, in a grid pattern across the surface of the patient's back. If the patient is allergic to any of the allergens, a raised red spot like a hive, called a "wheal and flare," will appear after

Keep It Clean



Image provided by © 1994 PhotoDisc, Inc.

You can reduce your allergic misery if you take steps to keep the culprits out of your house.

For seasonal allergies caused by plants and trees, keep windows shut and the air conditioner on. Purchase an air filter to clean out pollens, molds and dust. Use a dehumidifier in damp areas like the basement. Install wood, tile or vinyl floors rather than carpet because they can be mopped regularly. If you do have carpets, have someone else do the vacuuming or buy a machine designed to reduce dust emissions.

Minimize clutter, book collections, and bric-a-brac, which collect dust and pollens. Keep pets outside or bathe them regularly if they're indoors, and don't let them sleep in your bed. Wash your hair

every day to rinse off dust and pollen, and if you've been in the yard, leave shoes at the door and wash your clothes in hot water as soon as possible.

Since many hay fever sufferers are also allergic to dust mites, "The most cost-effective thing is to buy a mattress cover," advises Berrilyn Ferguson, M.D. Mattress and pillow covers can provide a barrier between you and the dust mites in your bed, where they live and breed. In addition, treat carpets with an anti-allergen spray that kills dust mites.

You won't be able to eliminate every allergen from your home, but with these steps you can make it a comfortable place even during the peak of allergy season. ■

about 20 minutes, at that site.

Depending on the patient's history, a person may be tested for as few as six allergens or as many as 80. Beware of physicians who suggest testing for 200 to 300 allergens, says Berrilyn Ferguson, M.D., an associate professor and otolaryngologist (ear, nose and throat doctor) at the University of Pittsburgh School of Medicine. At that quantity, the skin may react to everything and the test will be useless.

A more sensitive test—the intrader-

mal test—works by injecting a drop of extract into the skin. "The intradermal test is advisable if the puncture test is negative, to avoid a serious overdose reaction," says Paul Turkeltaub, M.D., director of the division of allergenic products and parasitology in FDA's Center for Biologics Evaluation and Research.

Treating the Symptoms

Once the causes and severity of the patient's allergies are determined, the doctor can prescribe a treatment plan.

The first, most obvious, step is to avoid the allergen. (See accompanying article, "Keep It Clean.")

The next step in treating allergies is medication. Antihistamines, which interfere with the effect of histamine, are often prescribed. A major side effect of antihistamines is drowsiness, and some types produce more than others. The term "nonsedating" antihistamine is widely used to describe some prescription drugs, but it is not 100 percent accurate and is not a term used by FDA.

"It's really a matter of degrees," says Peter Honig, M.D., a medical officer in FDA's division of pulmonary drug products in the Center for Drug Evaluation and Research. "All the antihistamines produce drowsiness in patients, but some do more so than others." Benadryl (diphenhydramine hydrochloride), for example, is a common brand name oral antihistamine available without a prescription. It is well known to cause

drowsiness in about half of people who take it. For those people, it's best taken at night. Two prescription antihistamines that have less sedation are Allegra (fexofenadine) and Claritin (loratidine).

Among nose sprays, there is Astelin (azelastine hydrochloride), an antihistamine. Other nasal sprays contain steroids to combat congestion. These include Beconase and Vancenase (both contain beclomethasone dipropionate), Flonase (fluticasone propionate), Nasalide (flunisolide), and Nasacort (triamcinolone acetate). The drawback to these medications is that they may take a week or so to be maximally effective and can sting and even damage the nasal septum (the soft bony division in the middle of the nose) if the spray is directed at it. Tell your doctor if you have any bloody discharge while using these sprays.

Less stinging but still helpful is the nasal spray Nasalcrom (cromolyn sodium). This nasal spray helps turn off the allergic process in the nose before it starts. It must be taken more often than a nasal steroid. Doctors often recommend this for children because it is extremely safe and it is available without a prescription.

Don't be tempted to treat an allergy with an over-the-counter decongestant nasal spray for more than three days. After a few days of use you may get a "rebound" effect, and your nose may be-

Over-the-Counter and Through the Pharmacy

Hay fever strikes some 10 to 30 percent of Americans, and more than half of them turn to over-the-counter medications instead of a doctor's prescription to control their symptoms. Pharmacy aisles are crowded with dozens of individual allergy drugs featuring various combinations of the half dozen active ingredients approved by FDA for allergy relief. Given the variety, consumers may find themselves posing some common questions:

Q. *My hay fever strikes every spring and fall. I sneeze, my eyes water, and my throat itches. How do I choose the best medicine for me?*

A. For typical hay fever symptoms, three over-the-counter options can help: oral antihistamines, decongestants (both oral and nasal sprays), and a nasal spray containing cromolyn sodium.

Brands such as PediaCare, Comtrex, Robitussin, and Benadryl, as well as generic store brands, contain antihistamines, either chlorpheniramine or diphenhydramine. These drugs are effective for runny noses, sneezing, and itching, but can make you drowsy.

"If the OTC antihistamines are effective in relieving symptoms but are too sedating, a newer less sedating antihistamine can be obtained by prescription," says Linda Hu, M.D., a medical reviewer in FDA's division of OTC drugs. Antihistamines work on a runny nose, but not as well on a stuffy one, so many brands combine an antihistamine with a decongestant (for ex-

ample, pseudoephedrine). Decongestants can also be found in fast-acting nasal sprays, but these may have a rebound effect and after about three days they'll make your nose even more congested. They are better used for a short-lived cold than an ongoing allergy. One nasal spray that doesn't cause a rebound effect is Nasal crom (cromolyn sodium). This drug is helpful to prevent your symptoms if started a few days before the allergy season begins and taken continuously. It causes few side effects and will not make you drowsy.

Remember that it's the active ingredient that is important, and many products contain more than one. Read the labels to make sure you're not combining drugs with the same ingredients. Look at the ingredients in the drug product and choose the type of ingredient that will best treat the symptoms you have.

Q. *My job requires a lot of driving. Is it safe to take an antihistamine in the morning before I go to work?*

A. Probably not. Antihistamines may affect your ability to drive or use machinery even if you don't feel sleepy.

"Drowsiness is the most common side effect of antihistamines and may be a problem for users who need to remain alert," says Hu. "Also, alcohol should be avoided because it may increase the drowsiness caused by antihistamines. If you need to be alert, some prescription antihistamines are less sedating."

Q. *I have emphysema and high blood pressure. Can I take an over-the-counter allergy medicine?*

A. Antihistamines should not be used by anyone with breathing problems such as emphysema or bronchitis, anyone with glaucoma, by those taking sedatives or tranquilizers, or anyone with difficulty in urination unless directed by their doctors. These drugs dry up secretions and may cause urinary retention and drowsiness, according to Hu.

Antihistamines may also cause dryness of the mouth and eyes and blurred vision.

Decongestants, which are in many OTC allergy medicines, can raise blood pressure. Ask your doctor what, if anything, you can take. Decongestants should not be used by people with heart disease, thyroid disease, or diabetes unless a doctor says it's OK. If you're taking a drug containing an MAO inhibitor (sometimes used to treat depression), never use a decongestant.

Q. *I've tried every medicine on the shelves, and I'm still miserable each spring. What else can I do?*

A. See your doctor. There may be prescription drugs that are more helpful to you, you may need allergy testing or shots, or your symptoms may be caused by something else entirely. ■

—R.D.W.

come even more congested than before. These drugs are more useful for short-term use to relieve nasal congestion associated with a cold.

Allergy Shots

What should you do if you've tried every drug in the pharmacy and still sneeze from January to December? Allergy shots, also known as immunotherapy, can offer long-lasting relief for many people.

Getting allergy shots is a long process. Over the span of three to five years, the allergy patient receives a small injection of the offending allergens usually twice a week at first, then less often with larger doses as time goes by. These small doses desensitize the body's immune system to each allergen. After at least six months to a year, the sneezing, itching and hives may begin to subside. After about five years, it's possible for

many to stop the shots completely.

"I am more productive, less irritable, and less fatigued since taking allergy shots," says Knoxville, Tenn., resident Beth Crawford, who is allergic to every tree, grass and pollen outdoors, plus dust mites, mold and animal dander indoors. Her allergies occur year-round and have plagued her since childhood.

"Now I have more confidence. I don't have to worry about whether I'm going

to have a sneezing attack in public," she says. A clinical social worker, Crawford's job requires occasional public speaking; in addition, she sings in her church's choir. "Now I can sing or give a speech without worrying. I know this sounds silly, but I can get ready in the morning much more quickly because I don't have to spend 30 minutes sneezing. And my husband says we have a substantial savings in Kleenex!"

About a third of patients who get allergy shots are cured after treatment, another third have a partial relapse, and the rest will relapse completely. Those not cured may be helped by resuming the shots.

Another approach to allergy shots is called "rush immunotherapy." Patients spend several days receiving repeated shots to desensitize them against allergens. They then go on the maintenance schedule earlier. Studies have suggested rush immunotherapy can be at least somewhat effective under certain circumstances, but more study is needed to show widespread safety and effectiveness. Currently, no allergen extracts are approved by FDA for this approach.

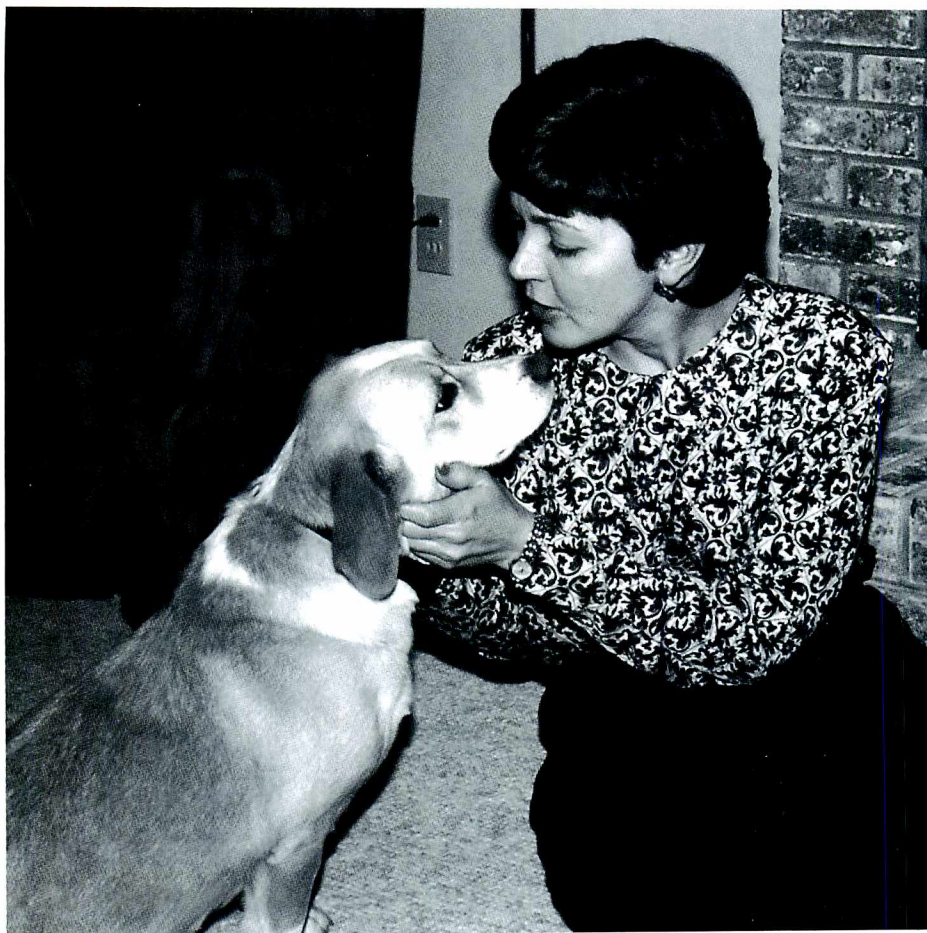
In the Nose, Not the Head

Allergies can certainly be life-threatening, but for most people they are merely annoying. For many, occasional sneezing, itching and watery eyes is no big deal. Others grow accustomed to the inconvenience and accept it as part of spring or fall, even if their symptoms are more severe.

"It's a quality of life issue," says Ferguson. "It's interesting how impaired people with allergies are. Some are just a little bit, but others have serious effects. I think if you are a productive person, you would want to treat your allergies and be as productive as possible."

"I didn't seek treatment earlier because my allergies had just become a way of life," remembers Crawford. "You just get used to it—I had severe allergies and I didn't even know it. Now I realize how much treatment has improved my quality of life. I should have done it years earlier—it was definitely worth it." ■

Rebecca D. Williams is a writer in Oak Ridge, Tenn.



Beth Crawford plays with her dog Annie, something she was unable to enjoy before starting shots for her allergies to animal danders and plant pollens.

Extracts for Allergy Serum

FDA has been working to standardize the biological extracts used to test and treat patients with allergies.

"Extracts prepared from natural sources such as pollens, animals and foods that trigger allergic reactions will vary in potency if they are not standardized," says Paul Turkeltaub, M.D., director of FDA's division of allergenic products and parasitology in the Center for Biologics Evaluation and Research. "Without standardization, each extract is an unknown. One batch could be stronger than the next. It makes it more difficult to treat patients and it also raises safety concerns."

Manufacturers are working to standardize extracts so they are consistent in potency from lot to lot. Currently, FDA has approved standardized allergy ex-

tracts for short ragweed, bee and other stinging insect venoms, dust mites, and cats.

Moreover, FDA is requiring that eight grass and pollen extracts be standardized. "The availability of the grass and pollen extracts will enhance their safe and effective use in diagnosis and treatment of grass allergies," says Turkeltaub. Nonstandardized extracts of cockroach (an important cause of inner-city asthma), giant ragweed, mold, peanuts, dog dander, and feathers are proposed for future standardization.

No allergy extracts are approved for sensitivity to foods, latex, or chemicals such as hair sprays, perfumes or cigarette smoke. ■

—R.D.W.

New Success Against Stroke

**Prevention, Improved Therapies Help Fight
This Devastating Condition**

by John Henkel



Stroke ranks as the third leading killer in the United States, behind heart disease and cancer.

Rusty Van Sickle considers herself one of the lucky ones.

A victim of two massive strokes in 1993, one of which left her in a three-week coma, the Florida resident has, in her words, “come back.” She’s at the point where, with some accommodations, she can hold down a job in her field of social work.

“I can drive now,” says Van Sickle, 43. “I cook and do home chores. I do many of the things I used to do.” But, she adds, hinting at the long road she’s had to recovery, “I’ve had to relearn all of them.”

She has lingering effects such as a lack of visual sharpness and skewed spatial judgment. Paralysis on the left side of her body and damage to her brain’s balance center keep her confined to a wheelchair most of the time.

But she keeps a positive outlook and admits that her stroke was “not really that bad when you compare it with what others have been through.”

Stroke ranks as the third leading killer in the United States, behind heart disease and cancer. More than a half million Americans have a stroke each year, according to the National Institute of Neurological Disorders and Stroke (NINDS). Following a 25-year decline, stroke deaths are now on an upswing. Figures from the American Heart Association show that 158,061 Americans died of

Rusty Van Sickle, 43, suffered two massive strokes five years ago. Although she still has paralysis on her left side and balance and vision problems, she’s relearned enough skills to handle some cooking and other housekeeping tasks.

stroke in 1995, the latest year for which statistics are available—a 10 percent jump over the 143,769 deaths in 1992.

Some professionals have explanations. “The increase in stroke deaths is linked to the aging of the population and may also be the result of a decrease in the detection and treatment of high blood pressure,” says Russell Luepker, M.D., director of epidemiology at the University of Minnesota. He adds that high blood pressure is one of the primary risk factors for stroke, and that about one-third of the Americans who have it are unaware.

Stroke also is the most common cause of adult disability. “Millions of people are challenged by the devastating aftermath of stroke,” says Jan Breslow, M.D., president of the American Heart Association, adding that up to one-third of stroke survivors need help caring for themselves, 20 percent need help walking, and 70 percent are not able to perform the same job tasks they did before the stroke.

Amid these grim statistics, however, hope is emerging that the devastating effects of stroke can be lessened, possibly reversed, in many cases. Activase (alteplase), a genetically engineered version of the body’s own tissue plasminogen activator (t-PA) that can dissolve clots, was approved by the Food and Drug Administration in 1996 for treating the most common type of stroke. It had been approved earlier for treating heart attacks. In clinical trials, Activase boosted recovery odds significantly in selected stroke patients treated within the first three hours of the onset of symptoms.

FDA also has approved the anticoagulant drug Coumadin (warfarin) for treating patients at high risk of having a stroke, such as those with a heart valve

Heed Stroke’s Warning Signs

From the onset of stroke symptoms, time is precious. Getting emergency help within three hours can mean the difference between severe brain damage and full or partial recovery.

If you have *any* of the following warning signs, call, or have someone call, 911 immediately:

- sudden weakness or numbness in the face, arm or leg
- sudden dimness or loss of vision, particularly in one eye
- sudden difficulty speaking or understanding speech
- sudden severe headache with no known cause
- unexplained dizziness, unsteadiness, or sudden falls, especially in conjunction with the other warning signs.

Occasionally, strokes cause double vision, drowsiness, nausea, or vomiting. Also, because warning signs sometimes may last only a few minutes and disappear, it may be tempting to ignore them. But these “mini-strokes,” or transient ischemic attacks (TIAs), could be your body’s warning of a future full-blown stroke. So even if the symptoms go away quickly, seek medical help right away. ■

—J.H.

High blood pressure is one of the primary risk factors for stroke.

defect or who have suffered a heart attack. Doctors also prescribe low-dose aspirin to their patients who have had previous heart attacks or strokes because studies have shown that aspirin can prevent repeat heart attacks and strokes in these patients. Aspirin is an “antiplatelet” that can prevent the “clumping” of blood platelets that creates clots and triggers heart attacks and strokes. Last November, FDA approved another antiplatelet drug for treating stroke, Plavix (clopidogrel), and for several years, doctors have prescribed the drug Ticlid (ticlopidine hydrochloride), also approved as an antiplatelet.

Several drug treatments, including one designed to stop the rapid death of brain cells following a stroke, are in clinical trials now. Also under study is a spring-like device used to prop open blood vessels after blockages are removed, a therapy that may reduce the chance of stroke.

Medical professionals emphasize that there are at least five risk factors (see box on page 15) that, when treated, can decrease the possibility of stroke. Knowing stroke’s warning signs (see box on page 13) and seeking emergency help immediately if they appear can reduce the risk of death or disability significantly.

What Is a Stroke?

Sometimes called a “brain attack,” a stroke occurs when blood circulation to the brain fails. This cuts off oxygen and can kill brain cells, affecting neurological functions such as speech, vision, coordination, and thought.

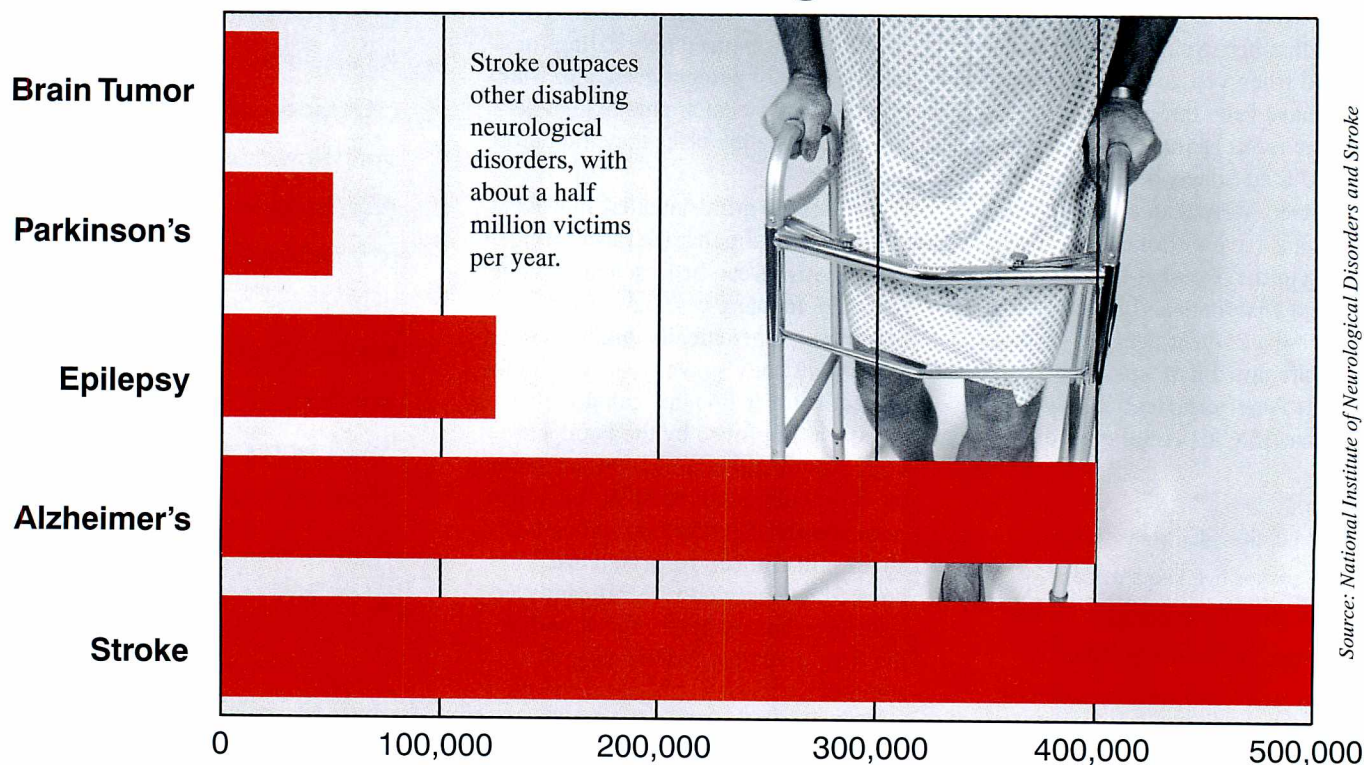
Strokes fall into two broad categories: those caused by blood-flow blockage and those caused by bleeding. An *ischemic stroke*, which occurs when a blood vessel in the brain or neck is blocked, is the most common stroke, responsible for about 80 percent of cases. Such blockages may form within a blood vessel of

the brain or neck (thrombosis), may migrate to the brain or neck as a clot from another part of the body (embolism), or may result from severe narrowing of an artery in or leading to the brain (stenosis).

Less common is *hemorrhagic stroke*, in which a blood vessel bursts, causing bleeding into the brain or in the spaces surrounding the brain.

Stroke is an equal threat to men and women. It occurs in all age groups and races, though African Americans suffer more severe strokes and have a death rate nearly double that of whites. Scientists have identified a “stroke belt” in the Southeastern states, especially in the coastal plain areas of the Carolinas and Georgia. A study in the May 1997 issue of the journal *Stroke* showed that stroke deaths in this Southern region are more than double those of the nation overall in ages 35 to 54. For ages 55 to 74, deaths in the belt are 1.7 times greater. Why? “It could be a wide range of

New Cases of Neurological Conditions



Control Stroke Risk Factors

The National Institute of Neurological Disorders and Stroke has identified five *treatable* risk factors associated with stroke. Agency officials emphasize that having a risk factor doesn't mean you'll have a stroke. And not having a risk factor doesn't mean you'll avoid a stroke.

But your likelihood of having a stroke grows as the number and severity of risk factors increase. Risk factors that can be controlled by medical treatment include:

- **High blood pressure.** This is by far the most important risk factor. Have your blood pressure checked by a qualified professional, and if it is high, seek medical attention to bring it into the normal range. Some over-the-counter (OTC) drugs may cause high blood pressure. For example, phenylpropanolamine (PPA), a widely used ingredient in OTC cough, cold, and weight-loss drugs, is under review because of concerns that the compound, especially in doses beyond those recommended, may elevate blood pressure and increase the risk of stroke. The Nonprescription Drug Manufacturers Association, at FDA's request, is sponsoring a study of PPA in OTC drugs and its possible relationship to an increased risk of stroke.

- **Cigarette smoking.** Studies have linked smoking to the buildup of fatty substances in the carotid artery, the main

neck artery supplying blood to the brain. Blockage of this artery is the main cause of strokes in Americans. Nicotine in cigarettes can raise blood pressure, and smoke can make blood thicker and more likely to clot.

- **Heart disease.** Disorders such as coronary artery disease, valve defects, irregular heartbeat, and enlargement of one of the heart's chambers can create clots that may break loose and cause a stroke. Regular physicals will pinpoint treatable problems.

- **History of stroke.** If you experience a "mini-stroke," or transient ischemic attack (TIA), with symptoms that quickly subside, seek emergency help. If you have had a stroke, consult with your doctor about what you can do to avoid a second stroke.

- **Diabetes.** This causes destructive changes in blood vessels throughout the body, including the brain. If blood glucose levels are high at the time of a stroke, brain damage is usually more severe than when glucose is well controlled. Treating diabetes can delay complications that increase stroke risk. (See "Diabetes Demands a Triad of Treatments" in the May-June 1997 *FDA Consumer*.) ■

—J.H.

things," says George Howard, professor of epidemiology at Bowman Gray School of Medicine in Winston-Salem, N.C., and lead author of the *Stroke* study. He says possible factors include the region's lifestyle choices such as smoking more or eating more fat and salt.

Though most strokes occur in adults over 40, children also have strokes, though these are typically caused by underlying conditions such as congenital heart disease or sickle cell anemia.

Sometimes young adults between 20 and 40 fall victim. Bill McGarry was a 22-year-old engineer in 1977 when a stroke plunged him into a three-month coma on advanced life-support machines. More than 20 years later, he still

has paralysis, blindness, and nagging problems such as greatly reduced mathematical and analytical abilities. Speech therapy allowed him to regain control of his vocal cords. In 1989, he received a master of education degree from the University of New Orleans and began working as a career counselor in 1990. He now lives independently in his own home in Austin, Texas.

The key to this kind of recovery, he says, is to stay focused on getting better and to not lose faith when rehabilitation reaches a plateau. Support from family and friends also is crucial. "Improvement is almost glacial at times," he says. "But it adds up ... a step here and a second there and eventually you can walk across the room or down to the corner."

For More Information

These organizations have information on stroke prevention, treatment and rehabilitation.

American Heart Association
7272 Greenville Ave.
Dallas, TX 75231
1-800-242-8721
<http://www.americanheart.org/>

Agency for Health Care Policy and Research
P.O. Box 8547
Silver Spring, MD 20907
1-800-358-9295
<http://www.ahrp.gov/>

National Institute of Neurological Disorders and Stroke
Office of Science and Health Reports
P.O. Box 5801
Bethesda, MD 20824
1-800-352-9424
<http://www.ninds.nih.gov/>

National Rehabilitation Information Center
8455 Colesville Road, Suite 935
Silver Spring, MD 20910-3319
1-800-346-2742
<http://www.caiss.net/naric/>

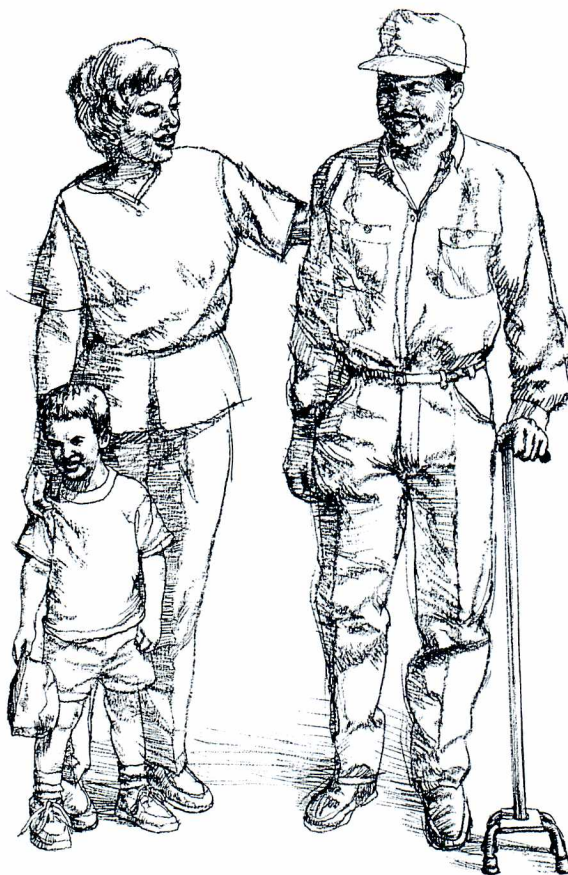
National Stroke Association
96 Inverness Drive, E., Suite One
Englewood, CO 80112-5112
1-800-787-6537
<http://www.stroke.org/>

In addition, these Websites have information on how to start or join a stroke support group in your area:

Stroke Support and Information
<http://members.aol.com/scmmlm/main.htm>

Stroke Connection Support Group
http://www.amhrt.org/Heart_and_Stroke_A_Z_Guide/strokecl.html

***Aspirin* can prevent the "clumping" of blood platelets that creates clots and triggers strokes.**



Turning the Tide

While strokes like McGarry's continue to cause devastating effects, new treatments now offer the potential for reversing or lessening stroke effects. The conclusion of a December 1996 symposium sponsored by NINDS that brought together experts from medical centers nationwide was that stroke is always a medical emergency. To survive or recover from it requires immediate care and effective responses from everyone in the "chain of care": medical technicians, emergency departments, and doctors. Public education also is crucial so stroke victims and those around them will recognize stroke symptoms and seek help quickly.

Before 1995, the medical community viewed stroke mainly as an "unfortunate medical problem requiring only supportive care and monitoring," writes Paul E. Pepe, M.D., of Pittsburgh's Allegheny General Hospital, in an overview of the NINDS symposium. Unless a patient had passed out or was having trouble breathing, the case often was not handled urgently.

Now the stroke-care landscape is changing—albeit slowly—as more emergency rooms adopt policies of treating appropriate stroke patients with the

bioengineered clot-dissolving drug Activase. In a dramatic five-year clinical trial sponsored by the National Institutes of Health and concluded in 1995, 624 patients received either intravenous Activase or a placebo within three hours of stroke symptoms' onset. The result was that 11 percent more of the Activase-treated patients had few or no signs of disability compared to the placebo group.

"One of the keys to the success of [the NIH study] was treating stroke as the true emergency that it is," says Thomas Brott, M.D., clinical investigator at the University of Cincinnati Medical Center, one of the study sites. "The concept that stroke is every bit as serious as heart attack is one that physicians must recognize in order for this new treatment to have widespread benefit."

Activase is indicated only for treating ischemic strokes. So before the drug is used, medical professionals must rule out hemorrhagic stroke by various tests, including a computerized axial tomography (CT) scan, which can indicate hemorrhages through sectional views of the brain.

Despite Activase's promise, it has been slow to catch on as a stroke treat-

ment. In a November 1997 American Heart Association conference, researchers presented findings estimating that of 200,000 stroke patients who might have benefited from the drug, only 6,000 received it. Though some of these patients reached the emergency room too late to get the drug, others were not treated because emergency personnel were not trained or prepared to administer it, the researchers say.

Another drug, Coumadin (warfarin), can cut in half the 80,000 strokes that occur each year due to the rapid and erratic heartbeat condition called atrial fibrillation. But it too is underused, according to a study by the Agency for Health Care Policy and Research (AHCPR). Atrial fibrillation makes people more prone to form blood clots in the heart that can lodge in the brain and cause strokes. Though Coumadin can thin blood and keep clots from forming, only a quarter of atrial fibrillation patients undergo the therapy. AHCPR researchers say 50 to 75 percent of all atrial fibrillation patients over 60 should receive this blood-thinning therapy.

AHCPR also has reported on carotid endarterectomy, a surgical procedure that removes fatty plaque from the arteries that carry blood from the heart to the brain. Because carotid artery blockage is a major cause of stroke, the surgery can be beneficial and cost-effective for patients with stroke-related symptoms and a high-degree of blockage. But AHCPR stresses that surgery benefits diminish when applied to patients without symptoms but with known blockages. Identifying blockages in asymptomatic patients can involve expensive and invasive diagnostic methods such as angiography, which carries its own risk of stroke and other complications. For that reason, AHCPR does not advocate large-scale screening of asymptomatic people.

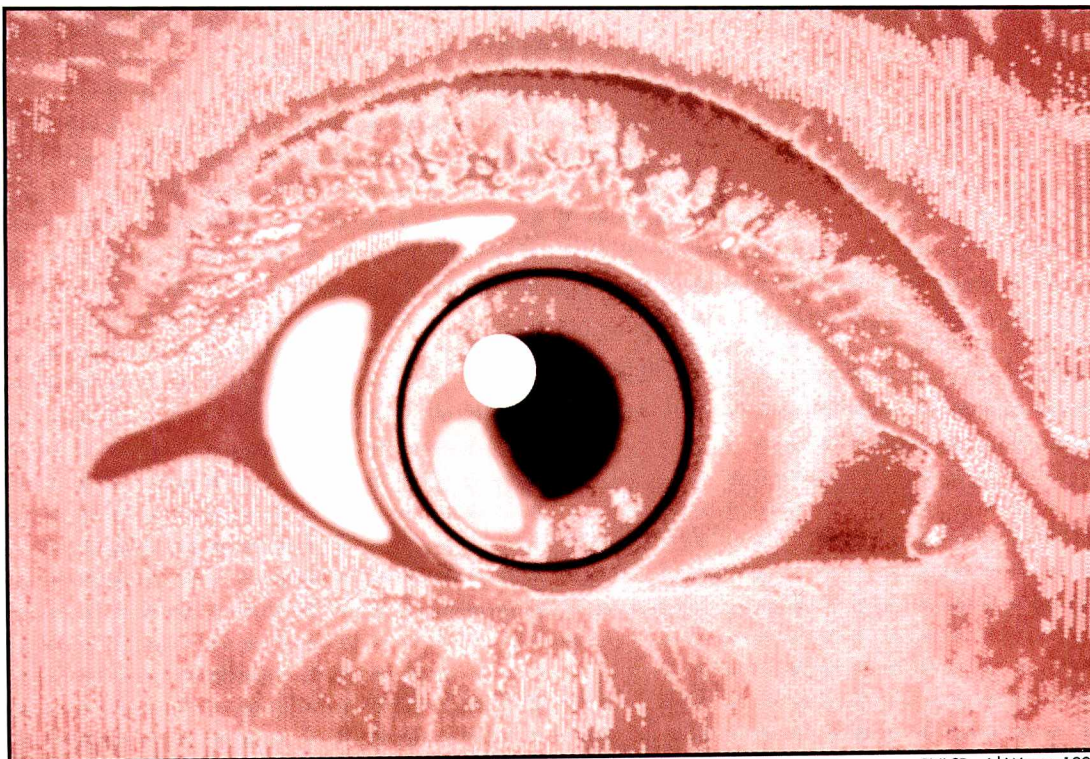
Though stroke occurrence overall is on a slight upswing, there's reason to be hopeful. Medical professionals say it is unlikely that stroke will ever be eliminated completely. But medical weapons such as Activase and Coumadin hold promise to at least help curb the disorder's destructive path. ■

John Henkel is a staff writer for FDA Consumer.

Keeping An Eye On *Contact Lenses*

Safety, Options Shape Contact Lens Decisions

by Dixie Farley



PNI ©David Wager, 1994

IMAGINE WEARING YOUR CONTACT LENSES for a few hours and then, after you pop them out, still seeing clearly the rest of the day. For certain individuals with nearsightedness, that image can be reality, thanks to a new lens the Food and Drug Administration recently cleared for marketing.

The OK rigid gas-permeable contact lens, made by ConTEX, Sherman Oaks, Calif., is the first lens designed to correct nearsightedness by temporarily reshaping the transparent tissue known as the cornea that covers the iris and pupil. It is just one of many choices for the 28 million Americans who wear contact lenses.

These medical devices, sold under more than 350 brand names, offer numerous options, including rigid-lens handling ease, soft-

At a Glance

Ophthalmologists (M.D. or D.O.) are eye surgeons who study and treat eye diseases and can also perform the duties of optometrists.

Optometrists (O.D.) examine eyes, diagnose and treat vision problems, and prescribe eyeglasses and contact lenses. In most states, they also can prescribe medicine.

Opticians grind and dispense eyeglasses and in some states dispense contact lenses. ■

While the ability to hold water increases oxygen permeability of soft lenses, it increases their fragility as well.

Buyer Beware

Sorting help from hype in any media—the World Wide Web, television, or print—can pose a problem. So remember: *If a claim sounds too good to be true, it probably is.*

Here are some recent examples of potential problems:

- **Special effects contacts** promoted on the Web with names like “Vampire” and “Reptilian” may sound fun to try, but they could be risky, says FDA’s James Saviola, O.D. “We currently have no information that shows pigments in these lenses are safe in the eye.” While FDA hasn’t been strict about similar lenses used on a very limited basis by entertainers, Internet advertising takes them beyond isolated theatrical usage.
 - **Buying mail-order contacts with no prescription** calls for caution, says Saviola. “If your current lens has a 14-millimeter (mm) diameter and 8.7 base curve, and the mail-order company switches to another brand lens with a 14.0-mm diameter and 8.8 curve, it seems like it’s about the same size and shape and should fit well. Maybe it will. But the new brand is a different material. It may leave your eyes uncomfortable.”
 - **A misleading print ad** for Acuvue contacts was corrected last year after an FDA warning. The ad showed a man and woman half indoors and half outdoors on a sunny beach—no protective eyewear. “Open your eyes to the UV around you,” it stated. “And you’ll be glad Acuvue contact lenses are introducing UV protection.”
- Writing to Vistakon Inc., of Johnson & Johnson Vision Products Inc., FDA warned: “The combination of this picture and the accompanying language implies that wearing the Acuvue UV-absorbing lens outside offers as much protection as one would naturally have indoors.” Warnings in tiny print that the lenses were not substitutes for UV-absorbing eyewear did not “counteract the overall message” that the lenses provided full UV protection, the agency wrote. The company also corrected a similar TV ad.
- **Misleading pricing** a few years earlier prompted consumer lawsuits against Bausch & Lomb for selling the same lens under three different names, at three different prices.
 - **Charges of false claims** were settled by the Federal Trade Commission last November against J. Mason Hurt, O.D., of Bartlett, Tenn. Hurt had touted his Precise Corneal Molding orthokeratology treatment as a permanent cure for defective vision. A consent agreement prohibits Hurt from making further false claims and requires reliable scientific evidence for future claims. ■

—D.F.

lens comfort, bifocal vision, a rainbow of colors, no-fuss disposables, and even protective help against ultraviolet radiation.

Shaping Up

The idea behind the OK lens is not new. Since the early 1960s, some optometrists have used conventional daily-wear rigid lenses to reshape corneas. This procedure is called orthokeratology, or Ortho-K. FDA considers such treatment of an individual patient to be the practice of medicine and therefore not subject to regulation. Selling contacts not cleared for Ortho-K to practitioners for this use is illegal marketing, however, so the agency is helping manufacturers obtain clearances specifically for Ortho-K. (See the accompanying article, “Buyer Beware.”)

Studies before FDA began regulating contact lenses, in 1976, show that Ortho-K appears to be safe, says James Saviola, O.D., chief of the vitreoretinal and extraocular devices branch at FDA’s Center for Devices and Radiological Health. “The lower your amount of nearsightedness, the greater your probability of success with Ortho-K,” he says.

Ortho-K reshaping involves the use of a series of lenses that apply pressure to the sides of the cornea. Once the desired result is achieved, use of daily-wear maintenance lenses is crucial to retain the reshaping. If you wear the maintenance lenses faithfully, Saviola says, “you may only need to wear the lenses for a portion of the day and then see pretty clearly without them the rest of the day.”

However, Ortho-K does not work for everyone. Some people do not experience any significant reduction in nearsightedness. “An individual’s response is difficult to predict,” Saviola says. “It may take weeks or months to have an effect.”

Safety Concerns

The most serious safety concern with any contact lens is related to overnight use. Extended-wear (overnight) contact lenses—rigid or soft—increase the risk of corneal ulcers, infection-caused eruptions on the cornea that can lead to blindness. Symptoms include vision changes, eye redness, eye discomfort or pain, and excessive tearing.

Saviola says the risk of corneal ulcers
(Continued on page 20)

Proper Care Gives Safer Wear

- Follow, and save, the directions that come with your lenses. If you didn't get a patient information booklet about your lenses, request it from your eye-care practitioner.
- Use only the types of lens-care enzyme cleaners and saline solutions your practitioner okays.
- Be exact in following the directions that come with each lens-care product. If you have questions, ask your practitioner or pharmacist.
- Wash and rinse your hands before handling lenses. Fragrance-free soap is best.
- Clean, rinse and disinfect reusable lenses each time they're removed, even if this is several times a day.
- Clean, rinse and disinfect again if storage lasts longer than allowed by your disinfecting solution.
- Clean, rinse and air-dry the lens case each time you remove the lenses. Then put in fresh solution. Replace the case every six months.
- Get your practitioner's okay before taking medicines or using topical eye products, even those you buy without a prescription.
- Remove your lenses and call your practitioner right away if you have vision changes, redness of the eye, eye discomfort or pain, or excessive tearing.
- Visit your practitioner every six months (more often if needed) to catch possible problems early.

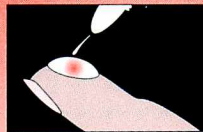
Caring for Contact Lenses

Clean



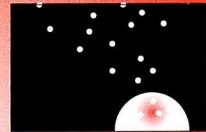
Remove surface dirt

Rinse



Rinse dirt away

Enzyme



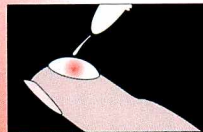
Remove deep deposits

Disinfect/Store



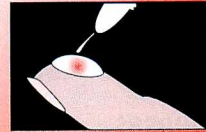
Eliminate bacteria

Rinse



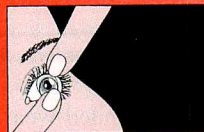
Rinse dirt away

Wet



Prepare lens surface

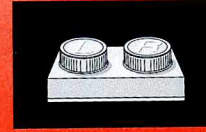
Insert



Lubricate/Rewet



Clean Lens Case



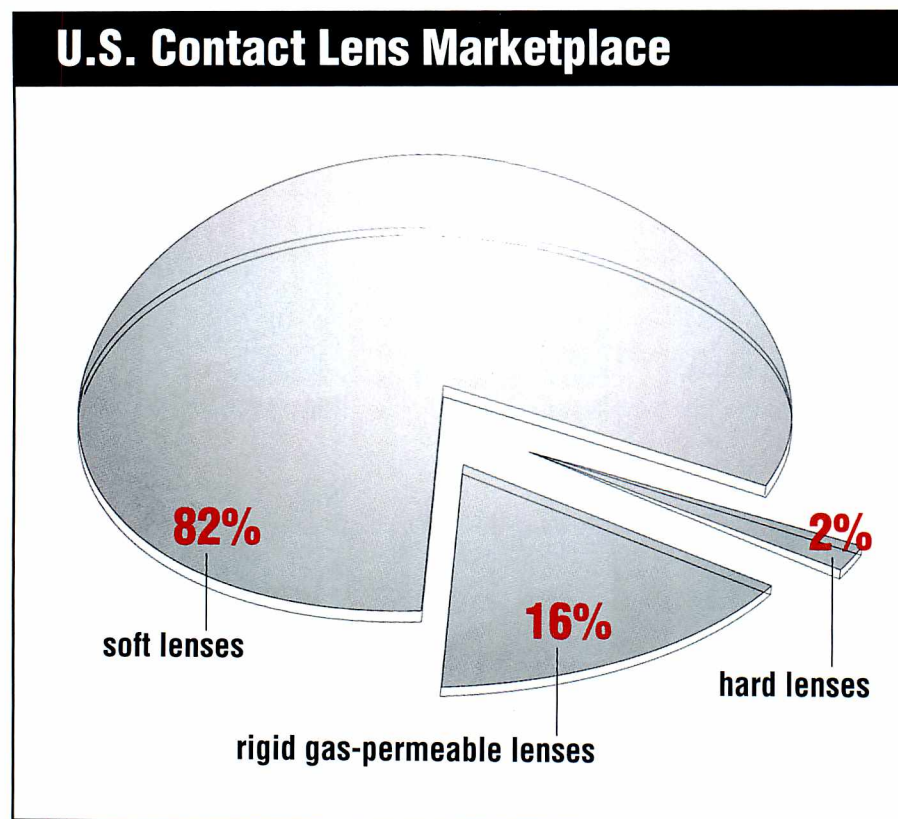
Watch Out:

- Never use saliva to wet your lenses.
- Never use tap water, distilled water, or saline solution made at home with salt tablets for any part of your lens care. Use *only* commercial sterile saline solution.
- Never mix different brands of cleaner or solution.
- Never change your lens-care regimen or products without your practitioner's okay.

- Never let cosmetic lotions, creams or sprays touch your lenses.
- Never wear lenses when swimming or in a hot tub.
- Never wear daily-wear lenses during sleep, not even a nap.
- Never wear your lenses longer than prescribed by your eye-care practitioner. ■

—D.F.

The use of homemade saline from salt tablets is one of the biggest contributors to infection in **contact lens** wearers.



(Source: Contact Lens Council, Landover, Md.)

(Continued from page 18)

for people who keep extended-wear lenses in overnight is 10 to 15 times greater than for those who use daily-wear lenses only while awake.

When the eyes are open, he explains, tears carry adequate oxygen to the cornea to keep it healthy. But during sleep, the eye produces fewer tears, causing the cornea to swell. Under the binding down of a rigid contact lens during sleep, the flow of tears and oxygen to the cornea is further reduced. This lack of oxygen leaves the eye vulnerable to infection.

Extended-wear rigid lenses also can cause unexpected, sometimes undesirable, reshaping of the cornea.

FDA's concerns about the use of extended-wear lenses include use of the lenses by some practitioners for Ortho-K.

Soft extended-wear lenses also bind down on the closed eye, but they are porous and allow some tears through during sleep. Because they have so little form, their binding has little effect on the shape of the eye.

FDA has approved extended-wear lenses for use up to seven days before removal for cleaning. Still, there are risks with use of extended-wear lenses, "even if it's just one night," Saviola says. Daily-wear lenses are removed daily for cleaning and are a safer choice, provided they aren't worn during sleep.

Another sight-threatening concern is the infection *Acanthamoeba* keratitis, caused by improper lens care. This difficult-to-treat parasitic infection's symptoms are similar to those of corneal ulcers.

The use of homemade saline from salt tablets is one of the biggest contributors to *Acanthamoeba* keratitis in contact lens wearers. "FDA no longer condones the use of salt tablets, and neither should a concerned pharmacist," writes Janet Engle, Pharm.D., in the 1996 *Handbook of Nonprescription Drugs*. Engle is associate dean for academic affairs and clinical associate professor of pharmacy practice at the University of Illinois in Chicago.

Microorganisms may also be present in distilled water, so always use commercial sterile saline solutions to dissolve enzyme tablets. Heat disinfection is the only method effective against *Acanthamoeba*, and it also kills organisms in and on the lens case. (See "Proper Care Gives Safer Wear.")

The Options

Soft lenses are much more comfortable than rigid lenses, thanks to their ability to conform to the eye and absorb and hold water. You can get used to soft lenses within days, compared with several weeks for rigid. An added benefit is that soft lenses aren't as likely as rigid lenses to pop out or capture foreign material like dust underneath. Extra-thin soft lenses are available for very sensitive people.

While the ability to hold water increases oxygen permeability of soft lenses, it increases their fragility as well.

Rigid lenses generally give clearer vision. They can be marked to show which lens is for which eye. They don't rip or tear, so they're easy to handle.

Also, rigid lenses don't absorb chemicals, unlike soft lenses, which Saviola says are like sponges. "They'll suck up any residues on your hands—soap, lotion, whatever."

Both soft and rigid lenses offer bifocal correction. In some models, each lens corrects for near and distance vision. In others, one lens is for near vision, and the other is for distance. Middle-aged people who have good distance vision but need help for reading can get a monovision reading lens for one eye.

Soft lenses additionally come as disposable products (defined by FDA as used once and discarded) or as planned-replacement lenses.

With planned-replacement lenses, the practitioner works out a replacement schedule tailored to each patient's needs, says Byron Tart, director of promotion and advertising policy at FDA's devices center. "For patients who produce a higher level of protein in their eyes or don't take as good care of their lenses, it might be healthier to replace the lenses

Extended-wear lenses increase the risk of corneal ulcers.

more frequently," he says.

Some practitioners prescribe disposables as planned-replacement lenses, which are removed, disinfected and reused before being discarded. Saviola cautions that lenses labeled "disposable" don't come with instructions for cleaning and disinfecting, while those labeled specifically for planned replacement do. Whatever lenses your practitioner prescribes, be sure to ask for written instructions and follow them carefully.

Very few people wear hard lenses (see chart on page 20), but they are available for people who have adapted to them and want them. Hard lenses are not the same as rigid gas-permeable lenses, since they do not allow oxygen transmission through the lens.

Contacts Not for Everyone

People with inadequate tearing (dry eye syndrome) usually can't tolerate contacts, says Donna Lochner, chief of the intraocular and corneal implants branch of FDA's devices center. In addition, Lochner says, "Severe nearsightedness often can't be corrected effectively with contact lenses."

Saviola notes that certain working conditions, such as exposure to chemical fumes, may be undesirable for contact-lens wearers. Contacts may be ruled out by allergy to lens-care products or by corneal problems, such as a history of viral infection of the cornea. "Extra caution," he says, "should be exercised with diabetics, because they're susceptible to infection and have trouble healing."

Cosmetic use of contacts is limited in children. Adolescence is the youngest age as a rule to consider contact lenses, says Saviola, but some practitioners do fit 9- to 11-year-olds. "You may prescribe for a younger child who has the motor skills and responsibility to handle contact lenses."

For some people who haven't been able to wear contacts and want to, implantable lenses may be an option in the future.

Doctors are studying ring segments, "shaped like parentheses," Lochner says, which are implanted in the cornea. "They flatten out the cornea, changing the shape to give the correct optical

Eyeing Your Prescription

The Federal Trade Commission is reconsidering whether to require that practitioners release contact lens prescriptions to patients, as is required for eyeglasses.

According to the American Optometric Association, state laws mandate this release in Alabama, Arizona, Colorado, Delaware, Florida, Georgia, Indiana, Iowa, Louisiana, Maine, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, South Dakota, Texas, Vermont, Virginia, Washington state, and Wyoming. Some practitioners in the other states may release prescriptions upon request. ■

power." Lenses that are implanted inside the eye are also being studied to correct refractive error, she says.

Correcting vision is not the only use for contact lenses.

Some soft contacts are used as bandage lenses after photorefractive keratectomy laser surgery for nearsightedness. The surgery removes the outer cell layer of the cornea, creating a large abrasion on the eye. "It's excruciatingly painful," Saviola says, "if you don't have a protective covering on the cornea after the anesthetic wears off."

Collagen eye shields are used as bandage lenses to relieve pain from other abrasions or sores on the cornea. They dissolve in a couple of days.

Comparison Shopping

Companies that sell contact lenses compete stiffly for business, offering discounts and premiums such as a second set free.

But a discount for the lenses might not save you money if the price doesn't include other needed products and services, such as a thorough eye examination, lens-care kit, and follow-up visits to make sure you're adapting. A moderate cost for a package that has everything you need may be the best deal.

Before you make an appointment, ask the practitioner these questions:

- Will you give me my prescription?

(You may want the prescription if you decide to go to another practitioner or order lenses from an alternate source.)

- What tests are included in the eye examination?
- What do you charge for the examination, lenses, evaluation, fitting, lens-care kit, follow-up visits, and service agreements?
- What is your refund policy if I can't adapt to contact lenses?
- How many types and brands of contact lenses do you sell?
- How much do you charge for replacement lenses?

Asking questions about any new prescription treatment is always a good idea. Like medicines, contact lenses provide benefits and pose risks. But even with the increased risk of corneal ulcers posed by extended-wear lenses, Saviola says this risk alone isn't enough to say the devices aren't safe and effective if properly used.

"If people are informed," he says, "then they're making a judgment based on available information. That's the thing we always struggle with, conveying enough information to people and having the practitioner convey enough information, so that the consumer can make an informed choice." ■

Dixie Farley, who was on the staff of FDA Consumer for more than 13 years, retired from federal service in January.

Condoms

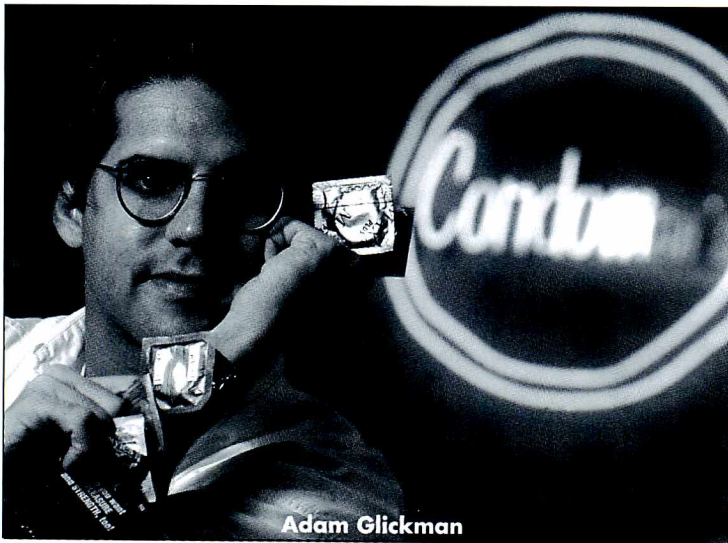
by Tamar Nordenberg

Barriers To Bad News

What

do condoms have in common with toothpaste and toilet paper?

Not enough, according to Adam Glickman, owner of the Condomania stores in New York and Los Angeles. Glickman, who has sold condoms by the millions to individuals and organizations such as the



Peace Corps and Planned Parenthood, says condoms should be viewed as ordinary, like toothpaste and toilet paper. "People have gotten past asking, 'Isn't brushing my teeth every morning a hassle?' Given the world we live in, wearing condoms is something you just have to do, like brushing your teeth. The stakes are too high."

Luis Lopez knows first-hand what's at stake. About 10 years ago, Lopez, now 31 and a health

educator with the People With AIDS Coalition of New York, became infected with the HIV virus, which causes AIDS, during a casual sexual encounter.

"I thought people with AIDS had purple spots or looked really skinny," Lopez says. "I thought by being discriminating about who I slept with, I could keep myself safe. We know now that makes no sense."

We know now that abstaining from sex is the only foolproof protection from the sexual passage of HIV and other sexually transmitted diseases (STDs). We know, too, that for those who choose to have sex with someone who has *any chance* of being infected, using a latex condom during every sexual encounter can significantly reduce the risk of HIV and other sexually transmitted diseases, while protecting against pregnancy.

In the United States, someone is infected with HIV every 13 minutes.



Luis Lopez was infected with HIV 10 years ago.

For those who can't or won't use latex condoms, the Food and Drug Administration has cleared two alternative barrier methods of birth control, a male condom made of polyurethane and a condom that is worn by the woman. Both help protect against pregnancy and may provide some level of protection from STDs.

Life-Saving Barrier

A male condom, sometimes called a "rubber" or "prophylactic," is a sheath that fits snugly over a man's erect penis, with a closed end to catch the sperm and stop them from entering the woman's vagina. No prescription is needed to buy a condom.

Data show that if a condom is used correctly with every act of sexual intercourse for one year, about three out of every 100 women are expected to get pregnant.

Besides sperm, latex condoms act as a barrier to a wide variety of viruses, bacteria, and other infectious particles. By preventing contact with many sores and minimizing the exchange of infectious fluids, condoms can help prevent the transmission of sexually transmitted diseases, including HIV, gonorrhea, chlamydia, syphilis, herpes infection, and genital ulcers.



Condoms are sold in many varieties (above) to meet different personal preferences. But all condom-like products—even those labeled “novelty”—must meet FDA's requirements for effectiveness.

Handle with Care

To get the maximum protection against pregnancy and sexually transmitted diseases, remember the following things when using condoms:

- Store condoms in a cool, dry place out of direct sunlight. Don't make the common mistake of storing them in a glove compartment, wallet or purse.
- Don't use a condom if the package is damaged or the rubber material is sticky, brittle, discolored, or otherwise deteriorated. Don't use a condom after the expiration date or more than five years after the manufacturing date.
- *Never reuse a condom.* Use a new condom with each sexual act that involves contact with the penis.
- Handle a condom carefully to avoid damaging it with fingernails, teeth, or other sharp objects.
- Put on the condom after the penis is erect and before intimate contact. Place the condom on the head of the penis and unroll it all the way to the base. Leave an empty space at the end of the condom to collect semen. Remove any air remaining in the tip by gently pressing the air out toward the base of the penis.
- Ensure adequate lubrication during intercourse. When needed with latex condoms, use only water-based lubricants such as K-Y jelly or glycerin. Don't use oil-based lubricants such as baby oil, petroleum jelly, massage oil, body lotion, or cooking oil because they can weaken the latex. Oil-based lubricants may be used with polyurethane, however, without damaging the material.
- After ejaculation, hold onto the rim of the condom and carefully withdraw the penis while it is still erect. ■

—T.N.

Millions of Americans are infected with these diseases each year, and hundreds of thousands of them become seriously ill or die as a result. According to the Centers for Disease Control and Prevention, in the United States, someone is infected with HIV every 13 minutes. CDC estimates that 65 percent of these AIDS cases can be attributed to sexual contact.

The best protection from such diseases is to not have sex or to have a mutually monogamous relationship with someone who is known to be uninfected. However, for those who are sexually active, studies have shown that proper and consistent use of latex condoms is the best defense.

A 1994 European study published in the *New England Journal of Medicine* looked at HIV transmission rates of heterosexual couples with one HIV-infected partner. The study compared the transmission rates for couples who used condoms consistently to those who didn't. Of the 123 couples who consistently used condoms, none of the HIV-free partners became infected during the study, whereas 12 of the 122 partners who didn't consistently use condoms became infected.

"The scientific evidence is compelling," says Herbert Peterson, M.D., chief of CDC's women's health and fertility branch. "We're not guessing about this."

The spermicide nonoxynol-9, used in some condoms, has been shown to be effective as a contraceptive, and may reduce the risk of transmitting certain STDs. But the spermicide has not been proven to prevent sexual transmission of HIV.

Similarly, lambskin (or natural membrane) condoms, while effective for contraception, should not be used for disease protection because the naturally occurring pores in lambskin are large enough to allow some viruses to pass through.

Hole Check

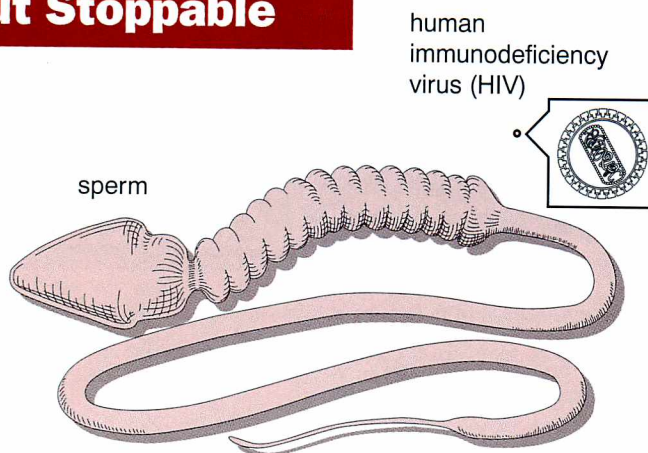
Since 1976, FDA has regulated condoms to ensure their safety and effectiveness. Currently, manufacturers of American-made and imported condoms electronically test each condom for holes and other defects. Also, before distributing the condoms to retailers, manufacturers perform additional testing on random condoms from each batch, usually involving a "water leak" test to find holes and an "air burst" test to check condom strength.

FDA oversees the testing procedures by periodically inspecting the manufacturing facilities, and the agency tests some condoms in its own laboratories to confirm their quality.

Condoms are sold in various colors, shapes or packaging to suit different

Small but Stoppable

Even though sperm are enormous compared to HIV, both are much too small to see. But even HIV, which is among the tiniest of STD organisms, cannot pass through a latex condom.



For the Female

The pouch-shaped Reality female condom enables women to protect *themselves* against pregnancy and AIDS and other sexually transmitted diseases.

The female condom is made from polyurethane and, like the male condom, is a nonprescription barrier method of birth control. The device has a closed end that is inserted deep inside the vagina to catch the sperm and an open end that remains outside the body. A female condom should not be used with a male condom because the devices will not stay in place.

Over the course of a year, between 5 percent and 21 percent of women who use the female condom are expected to

get pregnant, depending on whether the condom is used correctly with every act of vaginal intercourse. The female condom also provides some level of protection against STDs.

As with other condoms, follow label directions carefully to ensure that the material is not deteriorated or torn. ■

—T.N.



personal preferences. But, whether they glow in the dark or taste like strawberries, products that sufficiently resemble a condom must comply with FDA's requirements, even if they are labeled as "novelties." The only condom-like products that need not comply are those that can't be used like condoms. For example, some novelty products have the closed end removed or are sealed so they can't be unrolled.

Correct and Consistent

Although condoms are generally expected to break less than 2 percent of the time—with more than half of the breakages occurring before ejaculation—real-life pregnancy rates over a year of condom use may be as high as 15 percent.

Inconsistent or incorrect use of condoms explains the discrepancy, according to Lillian Yin, director of the division in FDA that regulates condoms and other reproductive devices. One national survey of heterosexual adults with multiple sex partners found that only 17 percent used a condom every time they had sex.

"People say they use condoms," Yin says, "but do they use them each and every time and use them correctly? That's another ballgame. We hear it all the time—'We tried to use it, but'"

But what? Partner trust was the most-cited reason for not wearing condoms in

a recent study sponsored by the National Institutes of Health. But be careful, CDC cautions, because even a trustworthy partner could unknowingly have a sexually transmitted disease.

Many participants in the NIH study said they didn't always wear a condom because sex feels better without them. Lopez responds, "If you don't use them, you run the risk of something that feels much worse."

Sometimes a couple can't use a latex

condom because one partner is allergic to latex. For these people, FDA has approved condoms made from polyurethane.

If a man objects to wearing a condom for some other reason, Planned Parenthood suggests possible replies. For example, to the partner who says, "I guess you don't really love me," the organization suggests responding, "I do, but I'm not risking my future to prove it." If the man still chooses not to wear a condom, the Reality female condom cleared by FDA in 1993 offers an alternative. (See "For the Female.")

Using condoms consistently is a start, but using them correctly is another key to protecting oneself. User error, not poor condom quality, leads to most breakages. But a few simple rules can minimize breaks and leaks. (See "Handle with Care.")

Even when used correctly, condoms aren't perfect, CDC acknowledges, comparing them to other important safety-enhancing behaviors like wearing seatbelts and bicycle helmets. Imperfect as they are, condoms can significantly reduce the rates of unintended pregnancies and sexually transmitted diseases.

"Correct and consistent condom use," says CDC's Peterson, "could break the back of the AIDS epidemic." ■

Tamar Nordenberg is a staff writer for FDA Consumer.

More Safer Sex Information

CDC National AIDS Hotline
1-800-342-AIDS
(1-800-342-2437)
<http://www.cdcnac.org/>

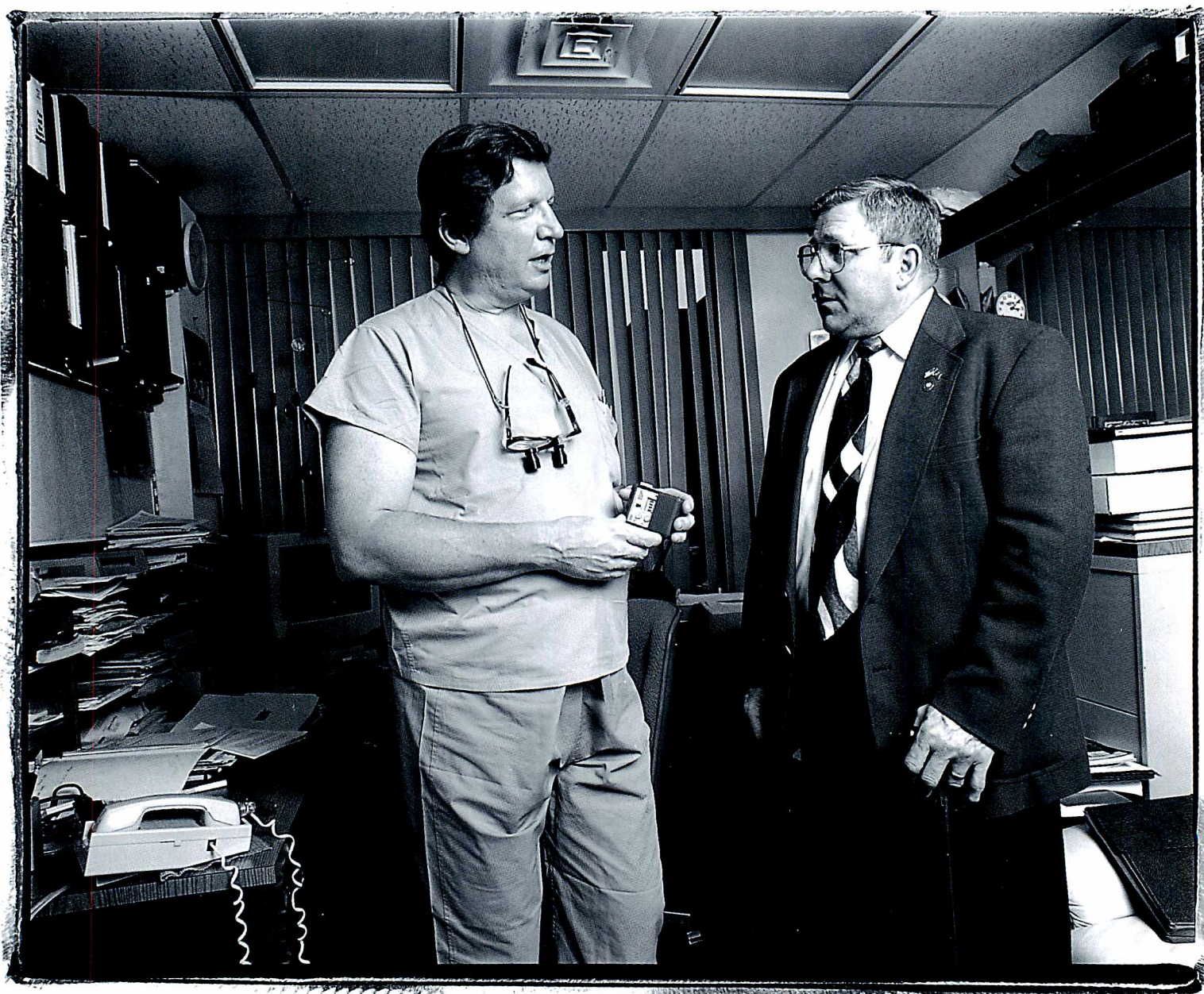
CDC National STDs Hotline
1-800-227-8922

Planned Parenthood Federation
of America
1-800-230-7526
<http://www.ppfa.org/ppfa/>

What To Do When Your

BACK **Is In** **PAIN**

by Carol Lewis



While logic would point to injuries from sports or traumatic accidents as the cause of the pain, sometimes the simplest of movements will have painful results.

During his 27 years as a hospital corpsman, Richard Mettetal lifted injured people and remained suspended by harness from helicopters for long periods. For the 54-year-old Thurmont, Md., resident, the legacy of those years of public service is chronic back pain that has plagued him since 1984.

"It's been so long now, I can't remember when I didn't feel the pain," Mettetal says. "And I'm so angry that I can't do all that I want because of it."

Work-related back pain is among the most common occupational disorders in the United States, according to the National Institute for Occupational Safety and Health in Cincinnati, Ohio. Delay in return to work remains an expensive component in the overall cost of back pain for workers' compensation claims, as well, the institute notes. And back pain is responsible for more loss of work time and increased medical expenses related to treatment than any other ailment, says Robert Shields,

M.D., an osteopathic physician practicing general medicine in Plano, Texas.

"This is one of the most common problems I see in my medical practice," he says. "Low back pain strikes 8 out of 10 adults at some point in their lives."

Understanding Back Pain

Back pain comes in two forms, acute and chronic, and is most often felt in the lower back. Acute pain comes on suddenly and intensely, usually from doing something you shouldn't be doing or from doing it in the wrong way. The pain usually lasts a short while. Chronic pain is recurring; any little movement can set it in motion and, for whatever reason, it lingers on and on for what can seem like an eternity.

Although back pain is usually preventable, experts claim that 4 out of 5 Americans will experience it at some time in their lives, given that the lower back supports most of the body's weight. The stability of the lower back depends on the integrity of the vertebral bodies and the intervertebral disks.

To understand the many ways you can do injury to your back, consider that each of us has between 24 and 25 bones in and around our backs, including the neck and chest areas, which are held together by ligaments and muscles. Throw in some major nerves, a few disks (which act as shock absorbers), and joints that guide the direction of movement of the spine, and stack them all up, explains Shields. "Expect to twist and

bend them in a multitude of directions, and try to imagine what might go wrong."

Shields says you can sprain the ligaments, strain the muscles, rupture the disks, and irritate the joints. While logic would point to injuries from sports or traumatic accidents as the cause of the pain, sometimes the simplest of movements will have painful results. In addition, arthritis, congenital disorders, poor posture, obesity, and psychological problems due to stress can be the source of back pain. Complicating the issue further is the fact that back pain can also directly result from internal problems such as kidney stones, kidney infections, blood clots, or bone loss.

Even with modern technology, however, the exact reason or cause of back pain can be found in very few people, according to the *Clinical Practice Guideline for Understanding Acute Low Back Problems*, published in 1994 by the Department of Health and Human Services' Agency for Health Care Policy and Research. X-ray examinations explain only a small proportion of the non-specific complaints doctors receive.

Pain Management Options

Mettetal's troubles began 14 years ago when he nearly collapsed from excruciating pain searing down his leg. His initial diagnosis was a ruptured disk. Since then, even with four major surgeries to repair the problems, his pain has only worsened. Out of desperation, he has

Richard Mettetal (right) discusses pain treatment with his doctor, Richard B. North, M.D., associate professor of neurosurgery at Johns Hopkins University in Baltimore, Md. North is holding a pain relief device similar to the one he implanted in Mettetal in 1990.

Although back pain is usually preventable, experts claim that 4 out of 5 Americans will experience it at some time in their lives.

tried medications, physical therapies, and pain clinics—all in an attempt to restore some semblance of a functional life.

The *Journal of the American Medical Association* concluded in a 1996 surgical back pain study that more than \$50 billion is spent on the diagnosis and treatment of back pain in the United States. Since the causes are so varied, what works for one person might fail with another.

For most people, drugs work well to control pain and discomfort. But any medication can have side effects. Back pain experts say that over-the-counter, nonsteroidal anti-inflammatory drugs (NSAIDs)—including acetaminophen (Tylenol), naproxen (Aleve), and ibuprofen (Nuprin, Motrin IB and Advil)—can be of value in reducing the pain. More severe pain may require prescription medications such as oxycodone-release (Oxycontin), acetaminophen with codeine (Tylenol with Codeine), and meperidine (Demerol).

Peter Rheinstein, M.D., director of the medicine staff in FDA's Office of Health Affairs, says the many effective NSAIDs available on the market today means there is less need for narcotics. However, he cautions that all NSAIDs cause gastrointestinal bleeding, and advises that patients suffering from other medical conditions need to consult with their doctors about other treatment options for managing their back pain.

"If you have an ulcer, for example, or are taking a blood thinner," Rheinstein says, "you are at an increased risk for gastrointestinal bleeding and should have your doctor prescribe medication that won't aggravate the ulcer or cause any kind of drug interaction."

Exercise and Physical Therapy

Bed rest was once thought to be an effective treatment for back pain, but recently its therapeutic benefit has been questioned. In a

study published in the 1996 issue of *Spine*, Finnish researchers experimented to find out whether exercises to mobilize the back worked better than bed rest. Subjects in the mobility test, who were encouraged to continue normal activities and have no daytime rest, appeared to have better back flexibility by the seventh day than their immobile counterparts, who remained in bed for the duration of the experiment.

"Most people think that a week of bed rest will take away the pain," says David Lehrman, M.D., chief of orthopedic surgery at St. Francis Hospital and founder of the Lehrman Back Center in Miami. "But that's not so. For every week of bed rest, it takes two weeks to rehabilitate."

Vert Mooney, M.D., professor of orthopedic surgery at the University of California, San Diego School of Medicine, says that bed rest for low back pain should be limited to one day and exercise should begin immediately. He explains that exercises which increase flexibility and tone and strengthen muscles can get back pain sufferers up and around by hydrating disks that become painful from loss of fluid. "Exercise can actually pump fluid back into the disk," Mooney says, "and it is important to keep the patient moving so that the disk remains fully hydrated."

However, FDA's Rheinstein says, "For some people, bed rest is just the most comfortable position for the first couple of days."

Spinal manipulation, or osteopathic manipulative therapy and chiropractic, are therapies commonly practiced for correcting abnormalities that are thought to eventually cause disease and inhibit recovery. Shields uses this type of manual manipulation technique on the majority of his patients. Occasionally, however, the spasm is too great or the muscles are too traumatized—for example, following an automobile accident or a fall—and the pain or swelling must be "calmed down" using a muscle relaxer for a day or two before manipulation.

Surgical Procedures

Doctors recommend back surgery much less often now than in the past, and only for certain conditions that do not improve after other treatments have been tried. FDA has approved or cleared medical devices such as the Intervertebral Body Fusion device, Anterior Spinal Implant, and Posterior Spinal Implant to treat degenerative disk disease and stabilize and fuse the spine.

Implantable spinal cord stimulation devices are another aid in the management of chronic pain of the trunk and limbs. These devices electrically stimulate the spinal cord by discharging a one-time or continuous stream of electrical pulses. The implanted portion of the device consists of a pulse generator (which contains an internal power source similar to that used in a cardiac pacemaker) and lead extensions that are connected to electrodes placed in the spinal canal. The nonimplanted components of the system include the programming device and screening pulse generator, which are controlled by the physician or patient.

Acupuncture

Acupuncture is a centuries-old Chinese healing technique that employs needles placed at specified points on the body. FDA classified acupuncture needles in 1996 as medical devices for "general use" by trained professionals.

The needles are required to have proper labeling, and good manufacturing practices must be followed. Manufacturers must include on the label the statement "for single use only" and provide information about device material steril-

Back to Exercise

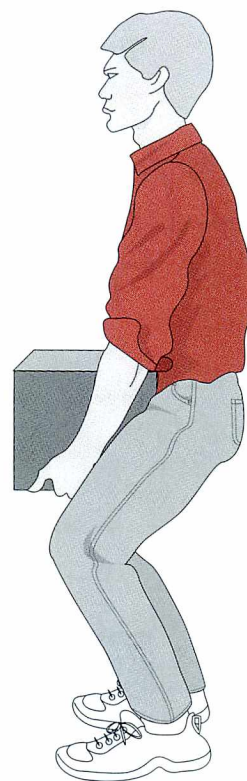
Trying to move an immovable object is the number one cause of back problems in the United States. It encourages you to push, pull, twist, bend, lift, and strain the wrong way. Even an unexpected awkward turn can be the onset of low back pain, and people who are in poor physical condition or perform work that requires long periods of sitting or standing are at greater risk for back problems. These people also recover more slowly. And the more time you spend in front of the TV or computer, the more you must do to prevent back pain, say experts. Emotional stress or long periods of inactivity may make back symptoms seem worse, but good posture and body mechanics will ultimately re-

duce the stress on your back.

To reduce the incidence of self-inflicted back problems:

- **Be careful.** Learn to lift and lean properly. Avoid positions that cause sudden, quick or jerky movements.
- **Exercise.** Strengthening the muscles of the back and abdomen helps to minimize the frequency, and possibly the severity, of future incidents.
- **Lose weight.** If you are more than 10 percent over your ideal body weight, you can reduce further incidents by losing weight through dietary restriction of calories and aerobic exercise, as prescribed by your personal physician. ■

—C.L.



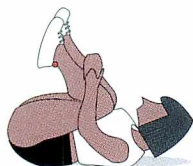
ity and compatibility with the body. The needles must also bear a prescription label restricting use to qualified practitioners as determined by individual states.

Harold Pellerite, assistant to the director of compliance in FDA's Center for Devices and Radiological Health says, "I think today's society is more receptive to alternative medicine. This just points to the need for our agency to be able to have some degree of control over what the American public is exposed to."

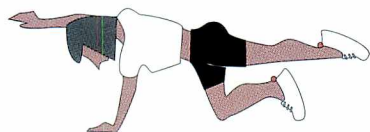
Complicating the evaluation of effectiveness of treatment is the fact that most back problems clear spontaneously. How can you tell if the problem was relieved by a particular treatment or if it would have gone away in the same period without treatment? "You really can't," says Shields.

Out of all these options, only two things have given Mettetal any measure of relief—the Spinal Cord Stimulation System and acupuncture. But, as Shields points out, "One of the most important things to keep in mind is that pain is caused by a variety of underlying problems, and it is naive to think that one modality will help improve all back pain." ■

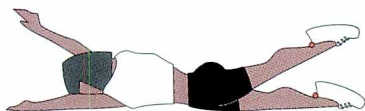
Carol Lewis is a writer in FDA's Office of Consumer Affairs.



A. Lie flat on your back. Hug your knees to your chest and at the same time, bring your chin to your chest. Repeat twice, holding for 15 seconds each.



B. Begin on your hands and knees. Simultaneously raise and straighten your right arm and left leg until they are parallel to the ground. Hold for 2 seconds and come back slowly to a starting position. Repeat with left arm and right leg, alternating 10 times.



C. Lie facedown, arms extended overhead, palms on floor. Simultaneously raise your right arm and left leg as high as comfortably possible. Hold for 10 seconds and slowly return to start. Repeat with left arm and right leg, alternating 10 times. Gradually build up to 20 times.



D. Lie facedown, arms at your side and place heels under couch. Slowly raise chest off the floor as high as you comfortably can. Hold for 2 seconds and return to start. Gradually increase to 20 times.

Strong lower-back muscles and abdominals work together in maintaining a pain-free and healthy back. These exercises will help strengthen the muscles of the lower back, but it is important that you begin your exercises slowly and increase levels gradually. Always begin any exercise program with stretching. Talk to your doctor before attempting any exercises, especially if you are already experiencing back pain. (Source: National Capital YMCA of Washington, D.C.)

Smooth Sailing or Rough Seas?

Alpha Hydroxy Acids


For Skin Care

by Paula Kurtzweil



Though popular, products with alpha hydroxy acids carry some risks, including increased sun sensitivity. FDA advises AHA users to regularly use sunscreen products with an SPF (Sun Protection Factor) of at least 15.

PHOTOGRAPHS BY NORMAN WATKINS



AHAs attract customers with their supposed ability to reduce wrinkles, spots, and other signs of aging, sun-damaged skin.

Baby boomers and others who once sought the sun's rays with little thought of skin damage are now paying the price—billions of dollars annually for cosmetics containing alpha hydroxy acids (AHAs).

Derived from fruit and milk sugars and served up in creams and lotions, AHAs attract customers with their supposed ability to reduce wrinkles, spots, and other signs of aging, sun-damaged skin. Some scientific evidence suggests they may work.

But are these products safe? Since 1989, the Food and Drug Administration has received more than 100 reports of adverse reactions in people using AHA products. Their complaints included severe redness, swelling (especially in the area of the eyes), burning, blistering, bleeding, rash, itching, and skin discoloration.

FDA believes reactions from AHAs are probably even more widespread. Past experience suggests that for every adverse reaction report the agency receives, the manufacturer receives 50 to 100. "This would translate into approximately 10,000 adverse reactions being received for AHA-containing products," says John Bailey, Ph.D., acting director of FDA's Office of Cosmetics and Colors.

Also, their relative newness (they've been widely available only since about 1992) means that their long-term effects are unknown. An industry-sponsored study found that people who use AHA products have greater sensitivity to sun, raising the specter of greater risk of photoaging and skin cancer.

"There are many unanswered questions in front of us," Bailey says.

"AHAs are unlike anything else ever introduced onto the cosmetic market on such a wide scale. They are not your traditional cosmetics."

In spring 1997, the National Toxicology Program of the National Institute of Environmental Science accepted FDA's proposal to study AHA safety. While FDA awaits the results, expected by the year 2000, the agency is cautioning consumers to take extra care with AHA products: for example, avoiding the sun when possible, otherwise using adequate sun protection, and reporting adverse reactions immediately to doctors or FDA directly.

"These are very, very popular products," Bailey says. "Very little about the process restricts their sale. And it's a somewhat alarming idea to put acids on the skin. It raises obvious safety questions."

AHAs Are Everywhere

AHA cosmetics are believed to have derived from the "chemical peels" that dermatologists and plastic surgeons have used for years. The peels, typically trichloroacetic acid, phenol, resorcinol, and salicylic acid, help remove undesirable signs of skin aging, such as discoloration, roughness and wrinkling. The chemicals cause the skin to lose its outer layer, or peel off, revealing a fresher-looking layer of skin. Known as chemical exfoliation, the procedure is done in doctors' offices so that doctors can control the process and prevent deep skin burns from the highly acidic solutions.

Cosmetic manufacturers began to market similar but milder versions of these chemical peels containing AHAs for salon and at-home use around 1989.

They quickly caught on, and by 1992, mass marketing had begun. Today, says Lisa Berger, a cosmetic sales manager for a Hecht Co. department store in Washington, D.C., "every [cosmetic company] has AHA products. There used to be only three product lines; now there are 20."

The AHAs used most often in cosmetics are glycolic acid and lactic acid, although there are others, and many are used in combination. Increasingly, says Zoe Draelos, M.D., a dermatologist in High Point, N.C., manufacturers are using poly-AHAs, which have larger molecules, and BHAs, such as salicylic acid, an ingredient in aspirin. According to Draelos, who consults for several large U.S. cosmetic companies, these products may produce less skin irritation.

Typically, AHA products sold to consumers have an AHA concentration of 10 percent or less. The concentration of AHA products used by trained cosmetologists may run between 20 and 30 percent, while those used by doctors can range from 50 to 70 percent.

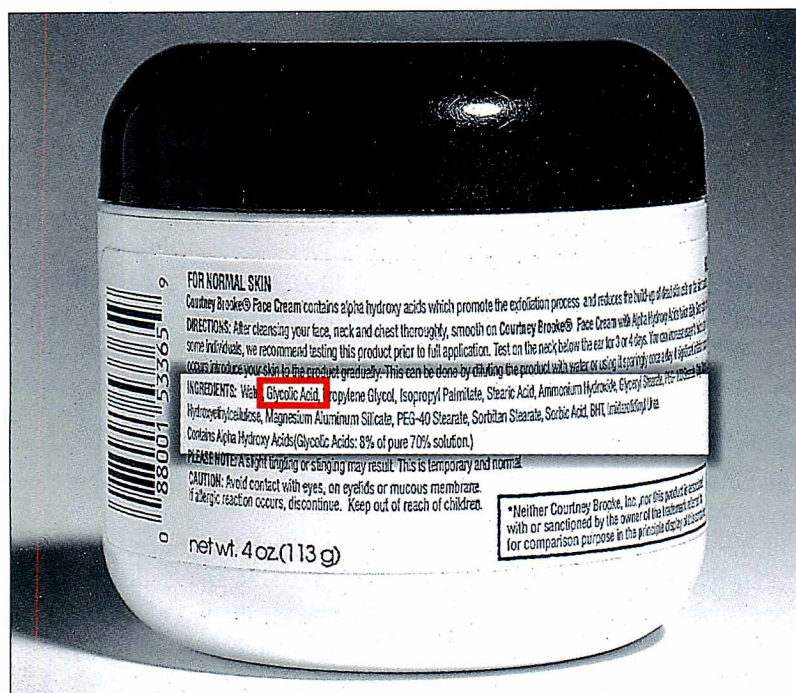
Though sold to consumers mainly in face and body creams and lotions, AHAs also can be found to a lesser degree in other cosmetics, such as shampoos and cuticle softeners. Available everywhere, from discount pharmacies to fine department stores, the products typically range in price from a few dollars to as much as \$60 a bottle.

Product Status

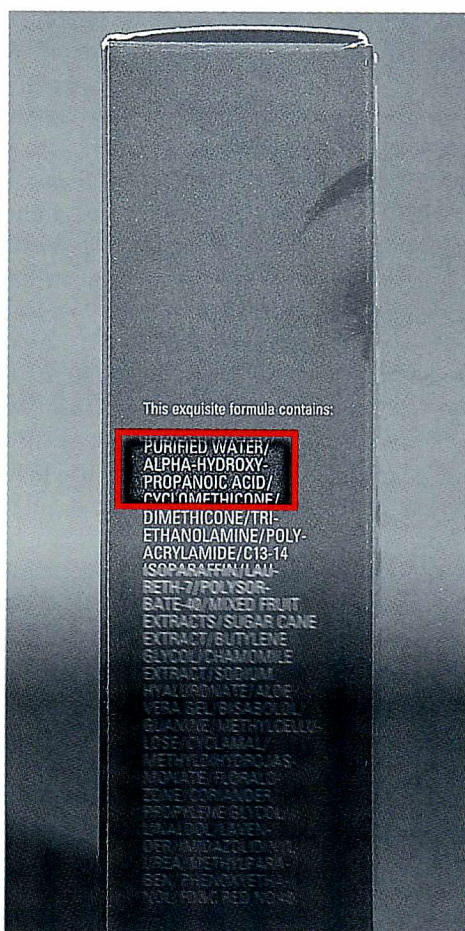
Some in the cosmetic industry have suggested that AHA products are more than simple cosmetics, coining the term *(Continued on page 33)*

“*A* **HAs are unlike anything else ever introduced onto the cosmetic market on such a wide scale. They are not your traditional cosmetics.”**

—John Bailey, Ph.D., acting director of FDA’s Office of Cosmetics and Colors



To learn whether a product contains alpha hydroxy acids, check the ingredient list.



Ingredient Terms

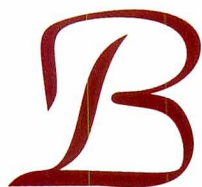
Here are some ingredient terms that indicate a cosmetic contains alpha or beta hydroxy acids.

Alpha hydroxy acids:

- glycolic acid
- lactic acid
- malic acid
- citric acid
- glycolic acid + ammonium glycolate
- alpha-hydroxyethanoic acid + ammonium alpha-hydroxyethanoate
- alpha-hydroxyoctanoic acid
- alpha-hydroxycaprylic acid
- alpha-hydroxypropionic acid
- hydroxycaprylic acid
- mixed fruit acid
- triple fruit acid
- tri-alpha hydroxy fruit acids
- sugar cane extract
- alpha hydroxy and botanical complex
- L-alpha hydroxy acid
- glycomer in crosslinked fatty acids alpha natrium

Beta hydroxy acid:

- salicylic acid



Buy AHA products with adequate label information: for example, a list of ingredients to see which AHA or other chemical acids are in the product.

(Continued from page 31)

“cosmeceutical” to describe them instead.

Under the 1938 Federal Food, Drug, and Cosmetic Act, cosmetics are defined as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance.” Drugs are defined as products intended for treating or preventing disease and affecting the structure or any function of the body. They are subject to premarket review and approval; cosmetics are not.

“The term ‘cosmeceutical’ is not recognized by law,” Bailey says. “These products, depending on their intended use, would be regulated either as cosmetics, drugs, or both as cosmetics and drugs.”

FDA has a particular concern about AHAs because, unlike traditional cosmetics, AHAs seem capable of penetrating the skin barrier. In reviewing the limited data on AHAs, FDA concluded in a 1996 report that certain formulations of AHA products can affect the skin in a manner similar to that of chemical peels—that is, increasing cell turnover rate and decreasing the thickness of the outer skin. The effect depends on the product’s pH level (a measure of its acidity), the AHA concentration, and the AHA vehicle cream, as well as how the product is used (for example, frequency of use and where on the skin it is applied).

Sun Sensitivity

An additional concern arose as FDA prepared its 1996 report on AHA safety: Some people who had reported adverse reactions cited increased sun sensitivity. In addition, one industry-sponsored study found that participants whose skin was exposed to 4 percent glycolic acid twice daily for 12 weeks developed minimal skin redness with 13 percent

less ultraviolet (UV) radiation exposure than normal. Three participants developed minimal redness with 50 percent less UV exposure than normal.

Another study that looked at the effects of glycolic acid on production of sunburn cells (markers for UV-induced skin damage) found that people who received the AHA product in the presence of UV radiation experienced twice the cell damage in areas where the AHA had been applied than those who were treated with the non-AHA product.

FDA’s concern is that people who are sensitive to sunlight may be particularly susceptible to UV rays, which can damage the skin and, over a long period, can cause skin cancer.

In 1997, the Cosmetic Ingredient Review Panel—the cosmetic industry’s self-regulatory body for reviewing and addressing safety of cosmetic ingredients—concluded that the AHA’s glycolic acid and lactic acid and their related chemical compounds are safe for use in products intended for consumer use when:

- the AHA concentration is 10 percent or less
- the final product has a pH of 3.5 or greater (lower numbers indicate greater acidity)
- the final product is formulated in such a way that it protects the skin from increased sun sensitivity or its package directions tell consumers to use sunscreen products.

For AHA products used by trained cosmetologists, the Cosmetic Ingredient Review Panel concluded that formulations of glycolic acid and lactic acid at concentrations of 30 percent or less and a pH of 3.0 or greater intended for only “brief” use at one time followed by thorough rinsing and daily use of sun protection are safe.

The panel’s conclusions actually serve as guidelines for cosmetic manufacturers, Bailey says. “This means that each manufacturer of an AHA product should

For More Information

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)

FDA’s Office of Cosmetics and Colors

Automated telephone information line:

1-800-270-8869

(Recorded messages available 24 hours a day.)

FDA’s World Wide Web site:

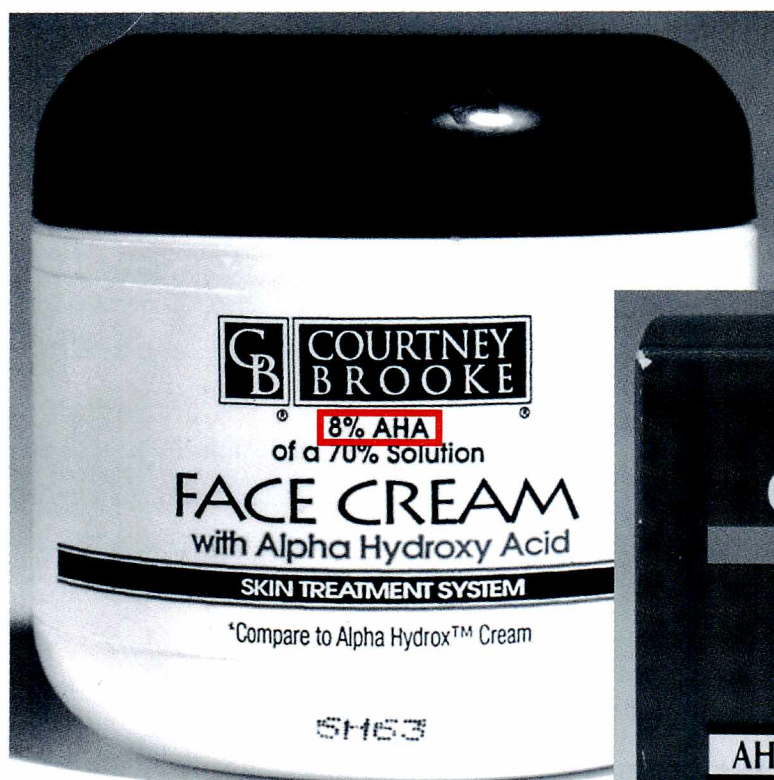
<http://vm.cfsan.fda.gov/~dms/cos-aha.html>

conduct appropriate testing on their products to measure whether or not the product increases the sensitivity of the user to UV radiation and, if so, should add sun protection to their product and warn consumers to take extra steps to protect themselves at all times.”

Meanwhile, FDA continues to study AHA safety. Later this year, scientists with the National Toxicology Program and FDA will use hairless mice to study the effect of AHAs on the risk of cancer associated with sunlight and UV radiation. The study will run for about three years.

Depending on the outcome of FDA’s

A HA cosmetics are believed to have derived from the “chemical peels” that dermatologists and plastic surgeons have used for years.



Though not required, some manufacturers list the concentration of alpha hydroxy acids on their products. According to the industry's Cosmetic Ingredient Review Panel, products with an AHA concentration of 10 percent or less are safe for consumers.

investigation, Bailey says, the agency may or may not take action against AHA products. “The absence of action by FDA to date doesn’t mean that there won’t be any in the future.”

Use with Care

Considering the questionable safety status, FDA and dermatologists advise consumers who use AHA products to follow these precautions:

- Always protect your skin before going out during the day. Use a sunscreen product with an SPF (Sun Protection Factor) of at least 15. Wear a hat with a brim of at least 4 inches (about 10 centimeters). Cover up with lightweight, loose-fitting, long-sleeved shirts and pants.
- Buy products with adequate label information: for example, a list of ingredients to see which AHA or other chemical

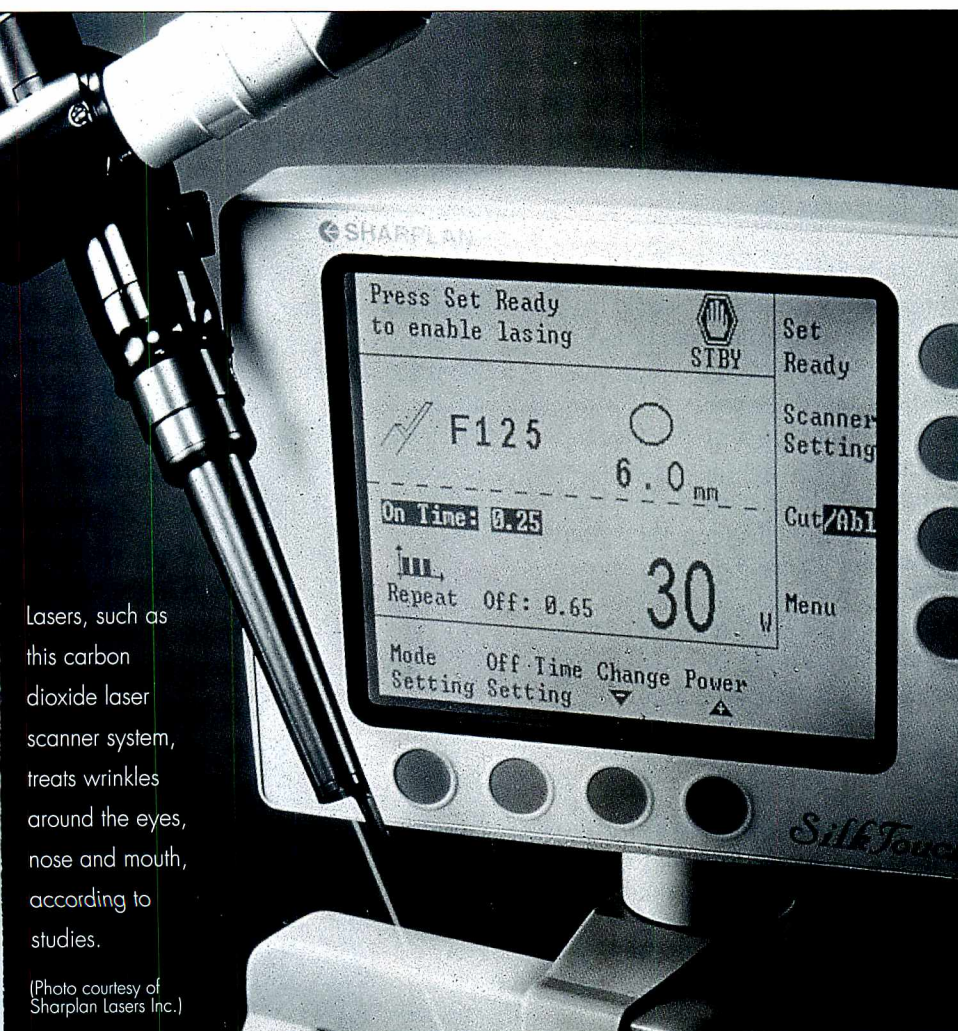
acids are in the product; the name and address of the manufacturer or distributor, which can serve as the contact if a problem or question arises; and a statement about the product’s AHA concentration and pH level. The first two pieces of information are mandatory; the third is optional. Consumers can call or write the manufacturer, however, to get information about a product’s AHA concentration and pH level.

Approved Treatments for Signs of Aging, Sun-Damaged Skin

These are the only products that have been studied for safety and effectiveness and approved by FDA for treating signs of sun-damaged or aging skin:

- **Renova (tretinoin emollient cream).** This vitamin A derivative, available by prescription only, is approved for reducing the appearance of fine wrinkles and mottled darkened spots and roughness of facial skin in people whose skin does not improve with regular skin care and use of sun protection. Renova does not eliminate wrinkles, repair sun-damaged skin, or restore skin to its healthier younger structure. Also, the safety of daily Renova use for longer than eight weeks has not been established, and it should not be used by women who are pregnant or trying to become pregnant. Renova has not been studied in people 50 and older or in people with moderately or darkly pigmented skin.
- **Carbon dioxide (CO₂) and Erbium:YAG (Er:YAG) lasers.** These medical devices are approved for treating wrinkles. The procedure requires removal of facial skin in a layer-by-layer manner. It is performed under anesthesia by a doctor in an outpatient surgical setting. ■

—P.K.



Lasers, such as this carbon dioxide laser scanner system, treats wrinkles around the eyes, nose and mouth, according to studies.

(Photo courtesy of Sharplan Lasers Inc.)

- Buy only products that comply with the Cosmetic Ingredient Review Panel's 1997 recommendations—that is, products with an AHA concentration of 10 percent or less and a pH of 3.5 or greater.
- Do a skin-sensitivity test on a patch of skin if you are a first-time user of any AHA product or are using a different brand or a product with a different concentration or pH than you are used to.
- Stop using the product immediately if you experience adverse reactions. Signs of adverse reactions include stinging, redness, itching, burning, pain, and bleeding or change in sun sensitivity. Even mild irritation is a sign that the product is causing damage, FDA's Bailey says, despite what the manufacturer may indicate on the product label. "Cosmetics shouldn't sting or cause irritation," he says.

If you have an adverse reaction, see a dermatologist. A dermatologist can tell you whether an adverse reaction is from the product or is an indication of an underlying disease, such as skin cancer. Dermatologists also can recommend appropriate skin-care products, and they will report your case, keeping your name confidential, to FDA's adverse reaction monitoring program.

You also can report your adverse reaction yourself to FDA. Reports can be made to local FDA offices, listed in the Blue Pages of the phone book or to FDA's Office of Consumer Affairs at 1-800-532-4440. Have the label and any other packaging information on hand. Be prepared to give the name of the product, the name and address of the manufacturer or distributor, and any identifiable product code numbers. Also be prepared to state where and when you bought the product, if you can remember, and whether you saw a doctor. "We'd like to know about it even if it's only a mild reaction," Bailey says.

Bailey adds that these precautions are important until AHAs' safety is better known. "We are told that AHAs are here to stay," he says. "But they are not reviewed for safety before they are put on the market. And we don't have enough information to say that they are safe." ■

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



The Notebook: a potpourri of items of interest gathered from FDA news releases, other news sources, and the Federal Register (designated FR, with date of publication). The Federal Register is available in many public libraries.

■ Labels on all **over-the-counter pain relievers** will be required to warn consumers about risks posed by the interaction of heavy alcohol consumption and the use these products, under an FDA rule proposed last November. The products include aspirin, other salicylates, acetaminophen, ibuprofen, ketoprofen, and naproxen sodium. (FR Nov. 14)

■ The benefits from **eating more fruits and vegetables** far outweigh any risks from exposure to pesticides, says a panel sponsored by Canada's National Cancer Institute. The panel said using pesticides actually reduces cancer risk by making more fruits and vegetables available at lower prices. (Cancer, December 1997)

■ A single-dose treatment for **pediatric ear infections** has received FDA approval. Rocephin (ceftriaxone sodium) is an injectable antibiotic for treating acute otitis media, cited as the most frequent reason for doctor visits by children under 6. The new product is expected to be especially beneficial for children who cannot take oral medications or who have trouble complying with a dosing schedule. Hoffmann-La Roche Inc., of Nutley, N.J., markets Rocephin.

■ Though some studies suggest that zinc lozenges can reduce the length of a cold, a new analysis of six previous studies says the **verdict is still out on zinc's benefits**. The analysis says some earlier

studies were flawed because it is difficult to produce a dummy tablet that has the same bitter taste as zinc lozenges. As a result, study participants who actually received a zinc tablet may have been tipped off by taste and were, therefore, unable to be objective about the severity of their cold symptoms. (Archives of Internal Medicine, Nov. 12)

■ The **risk of death from heart disease and stroke** may increase after eating a high-fat meal because of a significant rise in the body's production of a component called Factor VII, according to a Danish study. An increase in Factor VII can form vessel-blocking blood clots and cause heart attacks or strokes. The study showed that Factor VII levels decreased after a low-fat meal. (Arteriosclerosis, Thrombosis and Vascular Biology, December 1997)

■ Certain **food products marketed as "organically produced"** would have to conform to national standards under a U.S. Department of Agriculture proposal. Included is a program that would accredit inspectors to certify that farms and harvesting and handling operations comply with the standards. The deadline for comments on the proposal is March 16. Write to Eileen Stommes, Room 4007-So., AgStop 0275, P.O. Box 96456, Washington, DC 20090-6456; fax to 202-690-4632; or e-mail through the program's Website at <http://www.ams.usda.gov/nop/> (FR Dec. 16)

■ A **vaccine against anthrax bacteria**, a deadly biologic agent, will be given to U.S. military personnel beginning this summer. FDA approved the vaccine in 1970. It has traditionally been given to

veterinarians and others who work with livestock.

■ **Adverse reactions** to drugs or biologic agents affect up to 30 percent of hospitalized patients, according to a study at the University of South Alabama. Researchers also determined that as many as 29 percent of outpatients require hospitalization for adverse drug reactions. Study authors urge physicians to treat adverse reactions immediately and report them to MedWatch, FDA's surveillance system for adverse reactions, at 1-800-FDA-1088. (Journal of the American Medical Association, Dec. 10)

■ Federal research indicates that 80 percent of girls and 60 percent of boys **don't get enough calcium** in their teen years to form healthy bone density. The Department of Health and Human Services has launched an educational program to reverse this trend. "A Crash Course on Calcium" includes a video featuring Olympic gold medalists Amy Van Dyken and Kristi Yamaguchi, a teacher's guide, a poster, and a brochure. These materials are free to schools through the Website www.vpw.com or by calling 1-800-WHY-MILK.





Court Halts Company's Use Of Unapproved Product From Russia

by John Henkel

The provider of an experimental diabetes treatment was permanently barred by court order from dealing in a product containing human and rabbit cells imported from Russia.

Loran Medical Systems Inc. was effectively put out of business Oct. 16 when Judge Stephen Wilson, of the U.S. District Court for the Central District of California, imposed a permanent injunction on the Oxnard, Calif., company. Despite warnings from FDA, the company had failed to correct a two-year history of violations.

The injunction prohibits the company from importing from Russia an experimental cell product made up of rabbit and human fetal and organ cells and injecting it into human patients. Loran claimed that the product could stimulate diabetic patients' own production of insulin and allow them to reduce or eliminate their need for insulin injections.

FDA considered Loran's cell product to fit the legal definition of a new drug because it was used to treat human disease. The product also fit the legal definition of a biologic because it was "analogous to a toxin and antitoxin," according to FDA regulations, and intended to treat disease through a specific immune process. So, to use the product in patients, the company needed either an approved investigational new drug application or a biologic license.

FDA officials say the agency put Loran on notice several times for violating the law before taking legal action against the company. When Loran failed to respond adequately, FDA initiated proceedings that led to a temporary restraining order in June 1996, a preliminary injunction the following month,

and, most recently, the permanent injunction.

The case began in January 1995, when a routine inspection of Loran by FDA's Los Angeles district office turned up promotional material revealing that the company intended to treat diabetic patients with human and animal cell material from Russia. In April, FDA sent Loran a letter advising the company not to administer the cell product because it was an unapproved new drug and an unlicensed biologic. FDA also warned Loran that promotional materials for prospective patients contained false or misleading safety and effectiveness claims.

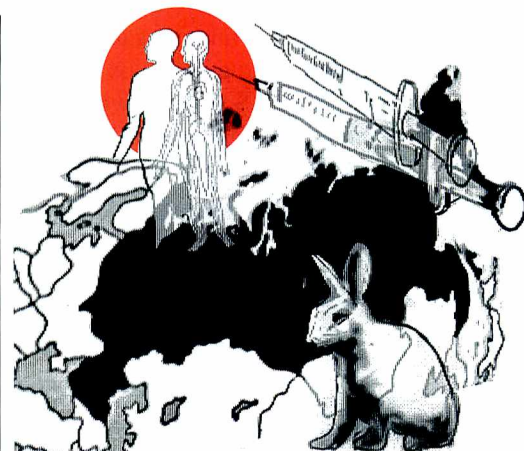
In a letter a month later, Loran replied that it didn't consider the cell product to be a biologic or a drug and felt it wasn't subject to FDA regulation.

An FDA inspection of Loran in November and December 1995 revealed numerous violations of clinical testing requirements, including promotion and sale of unapproved drugs, failure to follow import requirements, lack of adequate informed consent procedures, and failure to keep adequate records.

In a January 1996 letter, FDA again warned Loran citing the company's lack of conformance with procedures for conducting investigational studies because its product was an unapproved new drug and unlicensed biological product.

Again, Loran argued that its product was not a biological product or drug under existing statutes. In a March 1996 reply, FDA stated that it would proceed with enforcement action if the company didn't change its behavior.

In May 1996, an FDA investigator posing as a patient called a Loran representative, who told the investigator that Loran was planning to treat patients with



the imported cell product the following month. The representative gave the investigator other information, including the history of the procedure. The representative also said the procedure would cost \$20,000. Several days later, the investigator received promotional materials from Loran that claimed the procedure could effectively treat diabetes. At month's end, the company, still maintaining that it was breaking no laws, confirmed to FDA its plans to treat additional patients with the Russian product. This prompted the agency to seek the temporary restraining order, granted on June 20, 1996.

"We needed to put a quick stop to this scheduled treatment," says Mary Davis Lopez, compliance officer in FDA's Center for Biologics Evaluation and Research. She explains that FDA took immediate action because the agency, fearing possible patient exposure to communicable disease, saw the planned treatments as a potential health hazard. The later court actions put a permanent end to Loran's unapproved activity.

John Henkel is a staff writer for FDA Consumer.

Mail-Order Rx Drug Schemer Receives Prison Sentence

A federal judge in Texas sentenced a San Antonio man to two years and three months in prison for running a mail-order prescription drug operation that offered to supply U.S. citizens with more than 2,000 unapproved prescription drugs from Mexico. Older Americans in at least 20 states were the target for these discount priced drugs.

U.S. District Court Judge Donald Walter, sitting in the Southern District of Texas, sentenced Ronnie Serl Haas Oct. 7, 1997. Haas' June 12 conviction on six criminal counts included delivering misbranded drugs into interstate commerce and conspiring to defraud FDA.

Haas was director and general manager of North American Pharmaceutical Services (NAPS), an international mail-order prescription business based in San Antonio. Haas also managed and operated a counterpart to NAPS called Servicios Farmaceuticos de Norte America in Nuevo Laredo, Mexico, across the border from Laredo, Texas.

An investigation by FDA and the Texas State Board of Pharmacy found that NAPS placed advertisements for prescription drugs, such as Zantac (ranitidine), Premarin (conjugated estrogens), and Nolvadex (tamoxifen), in publications directed toward senior citizens. The ads invited customers to send their prescriptions to post office boxes in San Antonio and Laredo. Haas' Mexican affiliate then filled the prescriptions with unapproved generic versions of the drugs and shipped them into the United States.

The investigation began when Haas contacted U.S. Customs and FDA in September 1994. He wanted to know how, under FDA's personal importation policy, he could import prescription drugs approved in Mexico but unapproved in the United States into this

country. Haas, who is not a licensed pharmacist, told FDA he wanted to start a prescription mail-order business.

FDA advised Haas that his plans did not fit the personal importation policy, which allows individuals to bring into the country small quantities of drugs for personal use, as long as:

- the drugs do not pose unreasonable or significant safety risks
- their use will not be commercialized
- they are for a serious condition for which there is no satisfactory treatment available in the United States
- the quantities generally are for a treatment period of three months or less.

After meeting with Haas in September, Ray Strucker, a special agent with FDA's Office of Criminal Investigations in Austin, Texas, advised the Texas Pharmacy Board of Haas' intentions to start a prescription drug mail-order business.

On Oct. 6, Strucker, along with representatives of the pharmacy board, met again with Haas at his San Antonio facility. During that meeting, the representatives noted that NAPS was not li-

censed to practice pharmacy, and, as a result, its advertising of "Pharmacy Devices" and its practice of keeping prescriptions on file conflicted with state law. Strucker also reiterated FDA's personal importation guidelines.

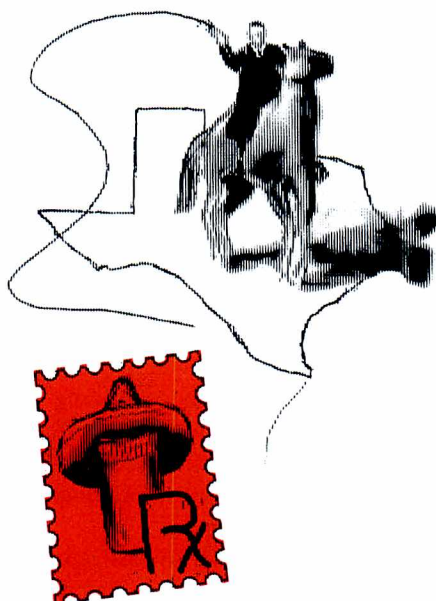
In January 1995, the Texas Pharmacy Board issued a warning letter to Haas, advising him to cease operations until he could comply with state requirements. A month later, Todd Cato, an import compliance officer with FDA's Dallas district office, informed Strucker that he had issued 61 detention notices during the previous 38 days for NAPS' packages containing unapproved drug products. U.S. Customs in Dallas had received the packages.

In February, the Texas Pharmacy Board placed an undercover order with NAPS, and OCI special agents recovered the package mailed in response. The package contained what FDA determined was a foreign version of the prescription drug Zantac. FDA ruled that the drug was illegal because its maker had never submitted a new drug application to FDA for approval. In addition, the directions, which were in Spanish, were inadequate.

FDA issued two warning letters to Haas in 1995, citing his operation as illegal and urging him to cease business immediately. Further investigation revealed that by November 1995, Haas had shut down the San Antonio facility, but he had begun to work out of his home. As a result, in February 1996, OCI special agents and the Texas Pharmacy Board executed a search warrant at Haas' residence and obtained records, invoices and packages of drugs as evidence.

After several opportunities to negotiate a plea, Haas decided to plead his case in front of a jury, which convicted him after a one-week trial. He began serving his prison term in November 1997.

—Herb Burkholz and Paula Kurtzweil



Selling Drug Samples Lands Doctor in Prison

A Kentucky doctor was fined \$40,000 and sentenced to 15 months in prison last November for Medicare fraud and selling drug samples that he had received free from drug companies. Upon his conviction, the state of Kentucky revoked his medical license.

Questions surrounding Kumaralingam Nagalingam's medical practice came to FDA's attention in January 1995, when a special agent with the U.S. Department of Labor told FDA of possible criminal violations reported by a former Nagalingam employee.

The next month, a special agent with FDA's Office of Criminal Investigations, J. MacKay Spears, and an agent with the U.S. Department of Health and Human Services interviewed four ex-employees of Nagalingam whose duties ranged from receptionist to nurse or nurse assistant.

In addition to describing Nagalingam's overbilling of Medicare by charging multiple times for a single medical test, the witnesses said Nagalingam sold sample drugs to his patients, usually for \$40 or more per supply of medication.

Drug companies give drug samples free to doctors to promote their products' use. The Prescription Drug Marketing Act, part of the Federal Food, Drug, and Cosmetic Act, prohibits the sale of drug samples, which are generally marked "Not for Resale" or "Physician sample—not to be sold."

Nagalingam instructed his employees to remove the drug samples from the original marked, sealed containers (called "punching" the drugs) and put them in standard pharmacy vials with his own office label.

Not only was Nagalingam financially profiting from the illegal sales, says OCI special agent Rodney Turner, but he was disturbing safeguards that help ensure the effectiveness of drugs. "Once you

take the drugs out of the packaging, the pedigree is lost," he says. "There's no way to know the expiration dates of these punched drugs or if they're even effective."

The government's investigation revealed that the doctor covered up his illegal drug sales by almost always taking cash payments and by not keeping standard, itemized records of the drugs sold and the amounts charged for them. Also, he instructed his office nurse to hide empty sample containers when drug company sales representatives made their calls and to keep the salespeople from seeing the doctor's unusually large stock of sample drugs.

During a search of Nagalingam's office in March 1995, OCI agents found a closet and kitchen-sized lab with shelves of sample drugs in their original packaging. Agents seized office records as evidence and spoke with employees, who said that sample sales made up more than 80 percent of the doctor's total pharmacy business. Based on employee accounts, FDA estimated that the doctor received \$20,000 to \$40,000 annually from these sales.

During the search, Nagalingam told an OCI agent that he was helping his patients, not hurting them, by beating regular pharmacy prices. "He said he was doing them a great favor," Turner says, "but these were elderly people in deep

poverty. If he really had their best interests at heart, he would have passed along the drug samples to his patients free like he was supposed to."

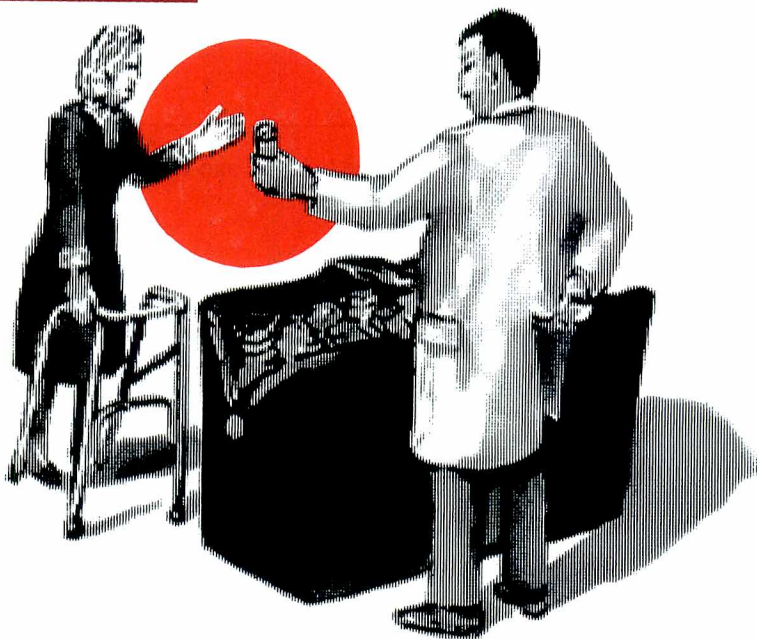
Initially, the doctor pleaded guilty to one of 14 counts charged of illegal sample drug sales and one of 10 counts charged of mail fraud related to his Medicare overcharges. But Nagalingam later withdrew his guilty plea in favor of a trial.

Based on further analysis of the evidence seized during the March search, Nagalingam's July 1997 trial in the U.S. District Court for the Eastern District of Kentucky involved 95 counts of sample sales and 27 counts of mail fraud. He was convicted on all these counts but found not guilty of an additional charge alleging that he counseled a witness to lie to a grand jury about the sample sales.

In fining Nagalingam and sentencing him to more than a year in prison, the judge said that the victims of the sample drug sales scheme were not the big drug companies, which the defense claimed could easily afford the loss, but the doctor's poor, elderly patients.

An investigation continues into Nagalingam's misdeeds, with the pursuit of a large civil penalty by the U.S. Attorney's Office and Department of Health and Human Services.

—Tamar Nordenberg



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: Lobster Tails, at Miami, Fla. (S.D. Fla.); Civil Action No. 94-1351.

CHARGED 6-30-94: While held for sale after shipment in interstate commerce at National Freezers, Inc., in Miami, Fla., the articles were adulterated in that they consisted in whole or in part of decomposed lobster—402(a)(3).

DISPOSITION: Pursuant to a consent decree of condemnation, the articles were reexported under bond. (F.D.C. No. 66960; S. No. 94-682-248; S.J. No. 1)

PRODUCT: Mushrooms, at Jacksonville, Fla. (M.D. Fla.); Civil Action No. 94-435-CIV-J-10.

CHARGED 5-3-94: While held for sale after shipment in interstate commerce at Grimes Distribution Services, in Jacksonville, Fla., the articles were adulterated in that they contained a poisonous or deleterious substance, lead, whereby they might have been rendered injurious to health—402(a)(1). The articles were also adulterated in that they had been shipped and held under insanitary conditions whereby they might have been rendered injurious to health—402(a)(4). The articles were misbranded in that the labeling was false and misleading because it represented and suggested that the articles were grown and packed in Taiwan when in fact they were not—403(a)(1).

DISPOSITION: The articles were destroyed. (F.D.C. No. 66948; S. No. 93-682-693; S.J. No. 2)

PRODUCT: Pollock Fillets, at Chicago, Ill. (E.D. Ill.); Civil Action No. 94C00922.

CHARGED 2-14-94: While held for sale after shipment in interstate commerce at Fulton Market Cold Storage Company, in Chicago, Ill., the articles were adulterated in that they consisted in whole or in part of decomposed seafood—402(a)(3).

DISPOSITION: The articles were destroyed. (F.D.C. No. 66928; S. No. 94-710-338; S.J. No. 3)

PRODUCT: Sauerkraut, at Bear Creek, Wis. (E.D. Wis.); Civil Action No. 94-C 0260.

CHARGED 3-8-94: While held for sale after shipment in interstate commerce at Flanagan Brothers, Inc., in Bear Creek, Wis., the article was misbranded in that its labeling was false and misleading because it represented and suggested that the article was fresh when, in fact, it was not fresh and contained chemical preservatives—403(a)(1). Also, the article was misbranded in that it was fabricated from two or more ingredients, and its label failed to bear the common or usual name of such ingredient—403(i)(2). **DISPOSITION:** The articles were reconditioned. (F.D.C. No. 66917; S. No. 93-718-826; S.J. No. 4)

Drugs/Human Use

PRODUCT: Dental Powder, at Simsbury, Conn. (D. Conn.); Civil Action No. 3:94CV287.

CHARGED 2-25-94: While held for sale after shipment in inter-

state commerce at Dental Clearing House, in Simsbury, Conn., there was an article of drug within the meaning of 201(g) which may not be introduced or delivered for the introduction into interstate commerce pursuant to 505(a), since it was a “new drug” within the meaning of 201(p) and no approval of an application filed pursuant to 505(b) was in effect for such drug.

DISPOSITION: The articles were destroyed. (F.D.C. No. 66796; S. No. 93-638-093; S.J. No. 5)

PRODUCT: Yeast-X Medicated Cream, at Lynchburg, Va. (W.D. Va.); Civil Action No. 97-0051-L.

CHARGED 7-10-97: While held for sale after shipment in interstate commerce at C.B. Fleet Company, in Lynchburg, Va., there was an article of drug which may not be introduced or delivered for the introduction into interstate commerce pursuant to 505(a), since it was a “new drug” within the meaning of 201(p) and no approval of application filed pursuant to 505(b) was in effect for such drug. The article of drug was misbranded in that its labeling was false or misleading because it suggested that the product was safe and effective in the treatment of vaginal yeast infections, but did not contain any ingredients which were generally recognized as a safe and effective treatment for such use—502(a). Also, the article was misbranded in that its labeling failed to bear adequate directions for use—502(f)(1).

DISPOSITION: The articles were destroyed. (F.D.C. No. 67195; S. No. 97-716-108; S.J. No. 6)

Drug/Veterinary

PRODUCT: Various articles of drug for veterinary use, at Syracuse, N.Y. (N.D. N.Y.); Civil Action No. 94-CV-197(FJS/MJGD).

CHARGED 2-15-94: While held for sale after shipment in interstate commerce at Nomera Resources Corporation, in Syracuse, N.Y., the articles were adulterated within the meaning of 501(a)(5), in that they were new animal drugs within the meaning of 201(w) which were unsafe within the meaning of 512(a)(1)(A) because no approvals of applications filed pursuant to 512 were in effect with respect to their intended uses. The articles were misbranded in that they were drugs fabricated from two or more ingredients and the label failed to bear the established name and quantity of each active ingredient—502(e)(1)(A)(ii). Also, the articles were misbranded in that the labeling failed to bear adequate directions for their intended use for the treatment of dermatitis—502(f)(1). The articles were further misbranded in that in that they were manufactured in an establishment not duly registered under 21 U.S.C. Section 510 and they were not included in a list required by 21 U.S.C. Section 510(j)—502(o).

DISPOSITION: The articles were destroyed. (F.D.C. No. 66903; S. No. 93-603-143; S.J. No. 7)

MISCELLANEOUS ACTIONS

ACTION: John Copanos v. Food and Drug Administration, at Washington, D.C. (D.D.C.); Civil Action No. 96-1128.

CHARGED 4-22-96: John Copanos (“Petitioner”) requested that the court review the Order of the Food and Drug Administration (“FDA”), which denied Petitioner’s request for a hearing, and FDA’s final Order issued, which permanently debarred Petitioner from providing services in any capacity to a person that has an approved or pending drug product application.

DISPOSITION: The Court of Appeals denied the review because Petitioner waived his retroactivity and constitution arguments by failing to raise them before FDA. The U.S. Supreme Court denied his petition for a writ of certiorari. (Misc. No. 1150; S.J. No. 8)

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