

FDA CONSUMER

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

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Cosmetic Safety:
More Complex Than At First Blush



SODA POP

MOTOR OIL

10W-40

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What Happens if the Packaging Gets into the Food? 8
Does the plastic wrap get into the cheese it covers? Does the microwave carton get zapped into the popcorn? FDA has some answers to a number of food packaging questions while it continues to research others.

Aligning Eyes: Straightening Out Strabismus 12
Diagnostic tests, corrective eye glasses, surgery, and a new therapy derived from the toxin that causes botulism are helping people with a number of different types of eye misalignments, collectively known as strabismus.

Cosmetic Safety More Complex Than at First Blush 18
Though serious injury from cosmetics is rare, care needs to be taken so that eye infections, skin rashes, and other ugly problems don't become byproducts of the quest for beauty.

Caring for Cats and Dogs 24
More than half of all American homes have house pets, most of them cats and dogs. Owners serve their furry friends well by taking an active part in preventing pets' health problems and properly treating those that do occur.

When Smell and Taste Go Awry 29
The closely connected senses of smell and taste can become confused or decreased. When the problem is related to drug treatment, stopping the drug can be a cure. If it stems from other causes, such as illness or chemical exposure, other therapies may sometimes give relief.

On the Teen Scene: Using Over-the-Counter Medications Wisely 34
Medicines you can buy without a prescription need to be taken with the same care as those a doctor prescribes. And teenagers looking for help for chickenpox or flu need to be especially aware of the ingredients in the products they buy.

Updates	2	Investigators' Reports	40
Vitamin of the Month	38	Summaries of Court Actions	45
Notebook	39		

Inside Front Cover Photo: Does soda pop from a recycled plastic bottle that held motor oil in its first life pose a health problem? These and other food packaging safety issues are discussed in an article beginning on page 8.



U.S. Marshals Seize Generic Drugs

On behalf of FDA, U.S. marshals in four states last September seized certain generic prescription drugs made by Pharmaceutical Basics, Inc. (PBI), of Denver after PBI failed to recall 26 of its products. The agency requested the recalls because of uncertainties about data submitted before the drugs were approved and has notified the firm it will withdraw the approvals.

False statements, discrepancies, and omissions in records and information submitted to support applications for marketing approval raised doubts about whether PBI's products conferred the same therapeutic effects as other generic and brand-name versions of the drugs. PBI previously recalled its carbamazepine products because of similar concerns. (See "Epilepsy Drug Recalled" in the Updates section of the June 1991 *FDA Consumer*.)

FDA is unaware of any reports of problems from use of the drugs, which were sold under PBI's name and the names of numerous private and "store brand" labels. Since all the involved drugs are made by other firms, no shortages are expected. Consumers who have questions should talk to their physicians or pharmacists.

The products FDA asked PBI to recall are:

- acetohepamide—250-milligram (mg) and 500-mg tablets
- baclofen—10-mg and 20-mg tablets
- benzotropine mesylate—0.5-mg, 1-mg, and 2-mg tablets
- chlorthalidone with amitriptyline hydrochloride—5-mg/12.5 mg and 10-mg/25-mg tablets
- chlorpropamide—100-mg and 250-mg tablets
- clorazepate dipotassium—3.75-mg, 7.5-mg, and 15-mg capsules
- desipramine hydrochloride—25-mg, 50-mg, 75-mg, and 100-mg tablets
- dipyrindamole—25-mg, 50-mg, and 75-mg tablets
- flurazepam hydrochloride—15-mg and 30-mg capsules
- hydrocodone bitartrate with acetaminophen—5-mg/500-mg tablets
- hydroxyzine hydrochloride—10-mg, 25-mg, and 50-mg tablets
- lorazepam—1-mg and 2-mg tablets
- megestrol acetate—20-mg and 40-mg tablets
- methyclothiazide—5-mg tablets
- metoclopramide hydrochloride—10-mg tablets
- minoxidil—2.5-mg tablets

- oxybutynin chloride—5-mg tablets
- prazepam—5-mg and 10-mg capsules
- reserpine with hydroflumethiazide—0.125-mg/50-mg tablets
- sulfamethoxazole with trimethoprim—400-mg/80-mg and 800-mg/160-mg tablets
- temazepam—15-mg and 30-mg capsules
- timolol maleate—5-mg, 10-mg, and 20-mg tablets
- tolazamide—100-mg, 250-mg, and 500-mg tablets
- trazodone hydrochloride—50-mg and 100-mg tablets
- trimipramine maleate—25-mg, 50-mg, and 100-mg capsules
- warfarin sodium—2-mg, 2.5-mg, and 5-mg tablets

Two Agencies Look at Lead in Wine

A program to reduce consumers' exposure to lead from table wines was announced in September by FDA and the Bureau of Alcohol, Tobacco and Firearms. This



is part of the U.S. government's overall efforts to reduce exposure to lead in the environment.

The agencies said their long-term plans include eliminating the use of lead foil capsules to cover the outside rim and cork of some wine bottles and setting a tolerance for lead residues in table wines produced in the future.

The announcement followed a review at ATF's request by FDA scientists of the potential risks of lead in table wine.

FDA intends to propose soon a regulation banning the future use of lead foil capsules. ATF test data show that

the capsules can increase lead levels in wine by leaving lead salt deposits on a bottle's rim. These deposits dissolve when the wine is poured into a glass or container.

Wine consumers can reduce their lead exposure from foil-wrapped wines by removing the foil and cork and wiping the rim and exposed cork with a wet cloth or with a cloth moistened with vinegar or lemon juice before drinking the wine.

"Pregnant and lactating women have long been advised to avoid alcoholic beverages, including wine," said FDA Commissioner David A. Kessler, M.D. "The recent findings provide another good reason to do this because even low levels of lead may pose a hazard to the fetus or nursing infant."

Health and Human Services Assistant Secretary for Health James O. Mason, M.D., added, "Most physicians advise expectant mothers to avoid alcohol because of other potential hazards to the developing fetus. The government requires such a warning on alcoholic beverages. But it is important that pregnant women also be aware that continued exposure to even low levels of lead can cause impairment of the unborn child's brain function and performance and adversely affect the child's learning capability—throughout its life."

FDA has informed ATF that foreign and domestic table wines sold in the United States that contain lead levels above 300 parts per billion (ppb) could be harmful to consumers. FDA intends to propose a rule to establish a limit on lead in table wine. ATF has the authority to detain and seek recall of these products.

ATF issued a public report of test results on July 31. Its data showed that only 3 to 4 percent of table wines tested contained more than 300 ppb of lead.

Although ATF also analyzed a smaller number of other alcoholic beverages, FDA said that the data do not indicate that other classes of alcoholic beverages—including beer, sparkling or dessert wines, or spirits—warrant immediate concern.

(See also "Getting the Lead Out . . . of Just About Everything," in the July-August 1991 *FDA Consumer*.)

Collagen Corp. Corrects Labels After Seizure

U.S. marshals in California seized \$5 million worth of injectable collagen on Aug. 17 because the labels failed

to include a warning about certain diseases, as FDA requires. Three days later, Collagen Corp. of Palo Alto agreed to correct its labels.

The FDA-requested seizure took two collagen products off the market: Zyderm and Zyplast, intended for injection into or under the skin to correct facial defects such as scars, pockmarks and wrinkles.

The labeling on the products did not include a change the agency had approved last February that provided a warning to physicians and consumers about a possible association between injectable collagen and connective tissue diseases, including, for example, juvenile rheumatoid arthritis, rheumatoid arthritis, and scleroderma. The approved language says that injectable collagen may not be an appropriate treatment for patients with these and other connective tissue diseases. Such patients could have an increased chance of severe allergic reaction to collagen, or collagen could be less effective for them.

The company, however, omitted the phrase "systemic connective tissue diseases such as juvenile rheumatoid arthritis," implying that the only diseases of concern were rheumatoid arthritis and scleroderma.

"The omission could mislead physicians about the safety of the product in certain patients," said FDA Commissioner David A. Kessler, M.D. "We will continue to act against instances of clearly violative behavior and make sure that consumers as well as health professionals are not misled."

Collagen Corp. is seeking an agreement with FDA on how to properly relabel the seized goods so they will comply with the law.

Drug VNRs Need Review

Pharmaceutical companies that use video "news releases" to discuss their drug products must begin submitting those videos to FDA for review, according to a letter to pharmaceutical companies issued by the agency last July.

The videos, which are aired on network and cable television, often appear to be genuine television news reports or documentaries, and FDA is concerned that consumers who see them may believe they are watching an unbiased, independent news report.

In its letter, FDA reminded companies that video news releases (often abbreviated VNRs) fall into the

category of promotional material and are therefore subject to FDA review. The Food, Drug, and Cosmetic Act gives FDA the authority to review advertising and promotional materials that discuss or promote drug products.

FDA also wants to see any other material that accompanies the video, such as scripts, press releases, and package inserts.

Signed by Carl C. Peck, M.D., director of FDA's Center for Drug Evaluation and Research in Rockville, the letter also says that FDA's lack of a response to a video submission does not mean that the agency approves of the material.

More information concerning FDA's policy on video news releases or other public relations material can be obtained from the Division of Drug Marketing, Advertising and Communications, HFD-240, 5600 Fishers Lane, Rockville, Md. 20857; telephone (301) 227-6824.

CDC Alerts Doctors to Cholera

The national Centers for Disease Control recently alerted U.S. doctors about preventing, diagnosing and treating cholera, a potentially fatal intestinal disease spreading in epidemic proportions through South and Central America.

In the Aug. 16 issue of *Morbidity and Mortality Weekly Report*, which is distributed to physicians and public health officials across the country, CDC said it does not expect a major outbreak of cholera in the United States, but it warned physicians to be aware of the symptoms and treatment of the disease.

CDC also issued a "Cholera Preparedness Plan," outlining steps for proper surveillance, treatment, laboratory diagnosis, investigation of outbreaks, and public education about cholera.

As of Aug. 21, there were 283,731 cases of cholera and 3,059 deaths reported to the Pan American Health Organization since the epidemic began in January. Most cases have been in Peru, Ecuador and Colombia, and the few U.S. cases have been linked to travelers to South America.

Cholera is rarely fatal when treated properly. Anyone with severe, watery diarrhea should seek medical attention immediately.

The bacterium that causes cholera is spread through

contaminated water and food, but it can be eliminated with common sanitation methods such as chlorine disinfection and proper cooking.

FDA continues to test certain imported foods for cholera bacteria. Last July, FDA found a strain of cholera similar to the one causing disease in South America in two samples of seafood from Mobile Bay, Ala. Also, CDC found cholera in an oyster sample from the bay.

All three samples were taken from areas closed to harvesting, and there have been no reported cases of cholera resulting from Mobile Bay seafood.

Just how this strain of cholera got into the Gulf of Mexico remains a mystery, according to Joseph Madden, director of FDA's Office of Microbiology, and the public health risks are still unknown.

As of late September, FDA had found four Mobile Bay oyster specimens that had tested positive for the disease-causing strain of cholera bacteria. The Alabama Department of Conservation and Natural Resources closed the bay to harvesting until further notice.



Baldness Remedy Approved for Women

Rogaine, a topical form of the drug minoxidil, approved in 1988 for hereditary pattern baldness in men, was also approved for treating this condition in women on Aug. 13, 1991.

The condition known as androgenetic alopecia generally appears as a bald spot at the top of the head in men, but in women it usually causes hair loss or thinning over the entire head.

Rogaine is in pregnancy category C, which means that adequate and well-controlled studies have not been conducted either in pregnant women treated with Rogaine or with oral minoxidil. Also, the excretion of the drug in breast milk in a woman treated for high blood pressure with oral minoxidil has been reported. Therefore, Rogaine should not be used by pregnant or nursing women.

(See also "Hair Apparent? For Some, a New Solution to Baldness" in the December 1988-January 1989 *FDA Consumer*.)

More OTC Help for Itching

FDA has approved over-the-counter marketing of 1 percent topical hydrocortisone for itching due to eczema, insect bites, poison ivy, oak and sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, and psoriasis, and for external genital and anal itching.

The label warns to stop use of the product and consult a physician if the condition worsens or if symptoms persist more than seven days or clear up and recur within a few days.

Topical hydrocortisone has been available over the counter in strengths up to one-half percent in the United States since 1980, but the 1 percent formulation was available by prescription only until FDA approved the switch to OTC status on Aug. 30, 1991.

Strengths up to 1 percent have been available over the counter for several years in some European countries, including Great Britain, Denmark and Sweden.

(For more on prescription to OTC switches, see "Rx to OTC: The Switch Is On" in the March 1991 *FDA Consumer*.)

Heart Drug Study Halted

An investigational study of moricizine, a drug that suppresses heart rhythm disturbances, was halted by the National Heart, Lung, and Blood Institute (NHLBI) because of excessive patient deaths. The multi-center, international study, known as the Cardiac Arrhythmia Suppression Trial (CAST II), was designed to determine whether moricizine (Ethmozine) could improve long-term survival of patients with mild heart rhythm disturbances following a heart attack.

The drug, which is marketed by Du Pont Merck Pharmaceutical Co., is approved by FDA for use by patients with severe, life-threatening arrhythmias, and is currently being taken by between 5,000 and 10,000 arrhythmia patients. These patients should continue taking the drug, and if they have questions they should check with their physicians.

The NHLBI study, which began in 1987, originally involved two drugs in addition to moricizine: encainide and flecainide. Patients received gradually increasing doses of one of the drugs until their arrhythmias were effectively suppressed, at which point they were placed in the main study of long-term therapy (with half the patients receiving the drug and half receiving a placebo).

In April 1989, use of encainide and flecainide was halted because there were more deaths in patients taking these drugs than in those taking the placebo (see the Updates section of the July 1989 *FDA Consumer*). But the study continued with moricizine; at that point only four patients on moricizine had died, compared with 11 receiving the placebo.

By the end of last July, however, data from the moricizine study, which involved 1,346 patients, showed that 97 in the moricizine group had died, compared with 74 in the placebo group. NHLBI notified the clinical scientists to have the patients stop taking moricizine. The institute also notified FDA, the manufacturer, and regulatory agencies in Canada and Sweden involved in the study. In addition, Du Pont Pharmaceuticals sent a letter to more than 100,000 physicians informing them of the preliminary CAST II results.

Agency Implements Safe Medical Devices Act

New device legislation, the Safe Medical Devices Act of 1990, signed into law on Nov. 28, 1990, is being implemented by FDA.

Congress amended the Food, Drug, and Cosmetic Act to provide greater assurance of the safety and effectiveness of the 1,800 types of medical devices that FDA regulates. The new legislation gives FDA additional power to obtain earlier knowledge of serious device problems, remove defective products from the market more quickly, and track devices from the manufacturer to the consumer.

The new law has codified the process that permits devices substantially equivalent to devices on the market before the 1976 Medical Device Amendments to be marketed without going through a full approval process. In the past, the agency has asked manufacturers for additional data and now has explicit authority to require manufacturers to submit clinical data to establish that a device is as safe and effective as the device to which it is being compared.

FDA can implement several of the requirements immediately, while others may take months or several years as regulations are being developed. For example, FDA now requires manufacturers of products that do not undergo the full-scale approval process to include in their pre-market submission a summary of safety and effectiveness information associated with their devices or a statement agreeing to make the information available to the public upon request.

The Safe Medical Devices Act expands medical device reporting, already required of manufacturers, to hospitals, nursing homes, and outpatient treatment and diagnostic facilities to include reporting deaths and life-threatening illnesses and injuries attributed to devices.

Under the new law, manufacturers of certain permanent life-sustaining or life-supporting devices will be required to adopt an effective system of tracking those devices. They would have to maintain records to speed patient notification when problems arise. FDA believes this will provide a link between manufacturers, health professionals, and patients.

New law provisions currently in effect emphasize stronger enforcement authority and allow FDA to order a recall to remove defective products from the market, apply civil penalties for violations of the act, and temporarily suspend pre-market approval of products that are found to be hazardous to health.

The law allows FDA to use special controls such as guidelines, standards, and post-market surveillance studies to ensure the safety and effectiveness of devices that need additional controls in order to be safely marketed. Before a device is mass produced, FDA may require manufacturers to conduct design validation activities to ensure that the device will operate as intended.

In addition, Congress added a humanitarian provision to allow devices to treat or diagnose conditions of diseases affecting fewer than 4,000 people to be approved

with less effectiveness data than is otherwise required.

FDA is informing the public, manufacturers, and health-care facilities of the new requirements through *Federal Register* notices, seminars, conferences, and publications.

New Version of Simplese

A new version of Simplese, a fat substitute approved by FDA last year for use as a thickener or texturizer in frozen desserts only, will soon be used for all food categories, including cheese spreads, mayonnaise, and baked goods, the manufacturer announced.

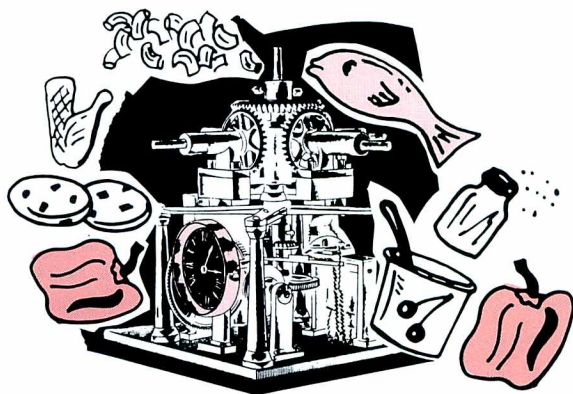
The new, non-frozen version of Simplese, manufactured by NutraSweet Company, a subsidiary of Monsanto Company, is made from a whey protein concentrate that can withstand the higher temperatures needed for baking. Whey protein concentrate is an ingredient on FDA's "generally recognized as safe" (GRAS) list. (Safety assessments of components on the GRAS list are based either on specific studies or on experiments based on history of uses.)

FDA has informed the manufacturer that it has no objection to the marketing of the whey ingredient as a fat substitute as long as it complies with FDA's regulation for whey protein concentrate and the source of the protein is identified on the label of the product in which it is used.

The original Simplese formula approved last year is made from egg whites and milk protein, and the company will continue to use the original formula for frozen desserts such as low-fat ice cream substitutes. However, that version of Simplese cannot be used in cooking because baking or frying cause it to lose its creaminess.

Both the original and this year's versions of Simplese are made by blending and heating in a process called microparticulation. In this process, the protein is shaped into microscopic round particles that roll easily over one another, creating the feel of a creamy liquid with the texture of fat. (See "Fat Substitutes—A Taste of the Future?" in *FDA Consumer*, December 1990.)

The NutraSweet Company also markets aspartame, a sugar substitute widely used in low-calorie beverages and other products. NutraSweet's original Simplese was the first fat substitute to be approved by FDA. Since then, a number of others have come on the market.



Food Info at Your Fingertips

A new computer service offering round-the-clock food safety information is now available free through FDA's Center for Food Safety and Applied Nutrition.

The service, called "FDA PRIME CONNECTION," offers technical information on retail food, milk, seafood, and other food safety topics. Users can connect to the service using a modem, then search the references electronically and download the information to their own computers.

The system includes technical text references, the interstate certified shellfish shippers' list, the fish list, the interstate milk shippers' list, and the 40-chapter food-borne pathogenic micro book.

The service is geared for local and state food regulatory officials, but it is also available to the food industry and general public. Inspection officials can use the program to get information on FDA's new model retail food codes, and they can incorporate that information into the FDA Integrated Electronic Inspection System during inspections.

The service operates 24 hours a day, seven days a week. It is compatible with most computers and is available free through a local or toll-free call.

To request an application or get more information, contact FDA PRIME CONNECTION, HFF-342, 200 C St., S.W., Washington, D.C. 20204-0001, or phone (202) 485-0140.

Information on Proper Medicine Use

Proper use of prescription medicine requires more than the doctor writing, pharmacist filling, and the pa-

tient taking the prescription. Safe and effective use of medicines also requires an exchange of information between health-care professionals and patients, according to the National Council on Patient Information and Education (NCPIE).

To spread that message, NCPIE has produced posters, brochures, and camera-ready artwork. Some of the titles available include:

- Medicines, What Every WOMAN Should Know
- Alcohol and Medicines: Ask Before You Mix
- Medicine: Before You Take It, Talk About It
- A Parent's Guide for Medicine Use by Children
- Break the Rx Silence Barrier: Talk About Prescriptions

For an order form listing all titles and price information, write to:

NCPIE
666 11th St., N.W.
Suite 810
Washington, D.C. 20001
or call:
(202) 347-6711

Tampering Protection Tips

Tips on how consumers can protect themselves from over-the-counter drug tampering are offered in a new brochure jointly produced by FDA and the Nonprescription Drug Manufacturers Association.

The brochure, *Buying Medicine? Stop, Look, Look Again*, also explains what consumers should do if they suspect tampering.

For free copies, write to FDA, HFI-40, 5600 Fishers Lane, Rockville, Md. 20857, or the Nonprescription Drug Manufacturers Association, Office of Public Affairs, 1150 Connecticut Ave., N.W., Washington, D.C. 20036. The association's phone number is (202) 429-9260.

(Also see "Look Twice: How to Protect Yourself Against Drug Tampering" in the October 1991 *FDA Consumer*.)

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



What Happens if the Packaging Gets into the Food?

by Judith Foulke

We've come a long way since making popcorn meant shaking a pan of oil and kernels over high heat on the stove. Now, in less time than it takes to get through a commercial on Monday night football, we can pop a package in the microwave and get popcorn ready to serve in its own container. Our breakfast muffin heats up the same way, and sometimes we even get eggs on the side.

Heating and eating popcorn or breakfast in the same wrappers that come from the grocery is a great convenience, and in this era of two-career families, convenience foods are in great demand. But is some of the wrap getting cooked into our food?

And what about packaged food—like bread and cheese—that's not heated? The wrap is pressed directly against the food, often for a long time. Sometimes, especially with cheese, we can faintly taste or smell the plastic wrap on the end pieces. Does that mean that we're eating more than cheese?

Food packaging is big business. A consultant for the Institute of Packaging Professionals says that 55 percent of all packaging made in the United States is for food. And the market is growing, especially for microwavable packaging. For popcorn alone, about 1.4 billion bags were sold in 1989, and FDA projects sales to nearly double to 2.6 billion bags by 1994.

Manufacturers are vigilant about the materials that go into their food packages. It's not good business if their packaging material makes someone sick—and they know that the Food and Drug Administration is watching, too.

FDA monitors packaging that comes in contact with food, whether it is used for transport from the food processor to the grocery, or from the grocery to the home—or while it is being stored in the pantry or cooked in the microwave.

Scientists are investigating whether components of microwave packaging, such as those in this popcorn container, migrate into food at a level that poses a health hazard.

Manufacturers are required by law to obtain approval from FDA for all the materials used in food packages before they can be marketed. Components that have been shown to cause cancer in humans or animals cannot be used.

After evaluating the migration and safety data, FDA writes a regulation for each new component, specifying its conditions for use in food packaging and approving it as an "indirect" food additive. Packaging components that already are on FDA's "generally recognized as safe" (GRAS) list for use in food or in food packages do not need a separate regulation.

The GRAS list was established with the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act. The only other components of packaging that do not require a regulation are those that have a "prior sanction"—that is, those that were determined safe for use before 1958.

Bread Bags

Sometimes people use food packages for purposes other than FDA-regulated uses. For example, an article in the June 1991 *American Journal of Public Health* on research by the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School reports that some people are turning bread bags inside out and reusing them to store food or pack lunches. Because the lead-containing ink used on the outside of some bread bags touches the food, the food can become contaminated with the lead. (Right side out, the lead-based ink printing on the bread wrapper does not come in contact with the bread.) Based on the study's findings, the scientists said that a weak acid, such as vinegar, in contact with the label printing could, estimating conservatively, extract about 5 percent of the lead from the ink in as little as 10 minutes.

Most likely, no one would store vinegar in a plastic bag. But, for perspective, the authors of the study observed that a 100-square-centimeter surface (about the surface area of a peeled orange, which is slightly less acidic than vinegar), in con-

tact with the label printing, could leach about 100 micrograms of lead within 10 minutes. When eaten by an adult on a daily basis, 100 micrograms of lead converts to approximately 4 micrograms of lead per deciliter of blood.

FDA scientists have found that for adults, toxicity is associated with blood lead levels as low as 30 micrograms per deciliter. In fetuses, infants and children, toxic effects can be observed at blood lead levels of 10 micrograms per deciliter. Because of the toxic effect on the fetus, this level is also of concern for pregnant women. Researchers project that the average American routinely carries about 5 to 6 micrograms of lead per deciliter in the blood. (For more about lead, see "Getting the Lead Out . . . of Just About Everything," in the July-August 1991 *FDA Consumer*.)

The authors of this report conclude that using inverted bread wrappers to store or transport food probably does not pose an immediate threat to health, but nevertheless strongly recommend against such use. Also, the risk of lead contamination is not the only problem with inverted bread wrappers. For example, who else handled the bag before it was turned inside out? There may have been dirty hands, insects, or microbial contaminants from other sources, none of which should be in contact with food.

Plastics

Now, about that end piece of cheese that tasted a bit like the plastic it was wrapped in. The FDA regulation that deals with indirect additives says that if a regulated food-packaging material were found in an appropriate test to impart an odor or taste to a specific food product, the food is adulterated and therefore subject to regulatory action. Sometimes when cheese is not refrigerated for a short while (such as during the trip home from the grocery), the end pieces taste a little like plastic, even though it is safe to eat. Off-odor and taste is a problem for food processors and they try not to let off-taste happen. It doesn't help sales if the package is safe but the cheese on the ends tastes a little like the package.

Flavor trading also works in reverse. For example, that plastic jug you use to mix your orange juice in the morning still smells like juice even after you've scrubbed it with soap and hot water. That problem is known in the industry as "flavor scalping." Plastic containers sometimes absorb flavors from citrus and other foods, lessening the flavor in the juice. The industry is trying to correct this. The containers are safe, but sometimes they dilute the taste of your good orange juice.

Migration of package components is rarely a problem with containers that hold dry food, such as cereal. But when a food is wet—and especially if it contains alcohol, acid or fat—chemicals from the packaging material could migrate into the food. FDA evaluates such uses and ensures that the materials are safe for the intended use before authorizing that use by regulation. (See accompanying article.)

Microwavable Packages

Regulations approving the safety of packaging materials heated with food were written before the advent of microwavable packaging. These regulations did not anticipate the development of microwave packaging components, called heat susceptors, that act like a frying pan when you crisp a waffle, brown the bottom of a pizza, and pop popcorn, for instance.

Heat susceptor layers in a microwave package reach temperatures of 400 to 500 degrees Fahrenheit, a much higher temperature than was envisioned when the regulations were written. Heat susceptor packages are multilayered, with food contacting the hot layer, usually a polyethylene terephthalate (PET) film with a thin coating of aluminum on the back. The heat susceptor layer is bound to the outer paper or paperboard by an adhesive. Popcorn bags have an additional grease-resistant paper layer between the heat susceptor and the food.

FDA's laboratory studies have shown that at high temperatures, components of the PET film migrate at levels far in excess of those that the agency anticipated when it initially regulated the PET film as an indirect additive. In addition, FDA studies show that at these high temperatures, the PET food-contact layer cracks, facilitating the migration of the adhesive components of the package, as well as their degraded products, directly into food. (Adhesives were originally approved for use in packaging where a functional barrier would be between it



Many processed foods are packaged using recyclable materials. In this sampling of products, the Wheaties and Cheerios boxes are made of recycled paperboard, the Hidden Valley dressing bottle is made from 20 percent recycled glass, and the Pepsi aluminum cans are 100 percent recyclable. The Jif peanut butter jar is made with PET plastic, which is recyclable.

(Photo courtesy of The Grocery Manufacturers of America, Inc.)

and the food, resulting in minimal migration.)

A third concern is that the high temperatures achieved by heat susceptors may cause the paper parts of the package to burn or char and partially decompose. These breakdown products could migrate into the food.

The aluminum component of the heat susceptor film is on the GRAS list, and FDA does not consider it a food additive problem. But because of the migration problem of the other components at high temperatures, FDA has requested additional data from manufacturers in order to reevaluate the regulations to ensure the safety of the packaging components. In September 1989, FDA published in the *Federal Register* an advance notice of proposed rule-making, asking manufacturers for additional safety data.

In response to this notice, the bulk of new data was submitted by the Susceptor Microwave Packaging Committee, composed of 33 member companies of the Society of Plastics Industries and the National Food Processors Association. Fifteen companies submitted a total of 42 heat susceptor packages to the committee for study.

Based on the data submitted by industry and on FDA's own data, several hundred components could migrate out of heat susceptor packages at extremely low levels at temperatures ranging from 400 to 500 degrees Fahrenheit.

One migrant chemical that has warranted special concern is benzene, which is known to cause cancer in humans. A 1988 FDA study of 11 heat susceptor packages purchased from supermarkets showed that there were detectable low levels of benzene in eight of them.

Industry data confirmed the presence of benzene in four of the committee's 42 samples. The packaging industry reports that these four package constructions have either been withdrawn from commercial use or have been reformulated.

At this stage of FDA's study, it's not clear whether the use of heat susceptor packaging represents a health hazard. Edward Machuga, Ph.D., in FDA's division of food and color additives, says that the agency is not aware of any hazard that would result from the use of heat susceptor packaging during the limited time needed by FDA to complete its review of this type of packaging.

FDA is completing its evaluation of heat susceptor packaging based on the data now in its files. This means evaluating not only the data submitted in response to the advance notice but also the data submitted years ago in petitions that led to the current regulation of these components at lower temperatures.

"If no high temperature migration data are available for a particular component," says Dr. Machuga, "we will calculate a worst-case estimate of dietary exposure based on the use level in the

Recycled Plastics

There is a growing industry, government and consumer interest in recycling materials in the United States, including the recycling of plastics (polymers) for use in food-contact situations. FDA supports these recycling goals and is also aware of its responsibility to ensure the safety of materials that may come in contact with food.

One of the problems with recycled materials in food packaging, say FDA scientists, is that a plastic bottle may have been used (in its first life) to hold, for instance, motor oil. If that bottle were recycled, contaminants from the motor oil could remain. FDA has appointed a task force to develop a set of principles for recycled plastic food-contact materials. The group's recommendations are expected before the end of this year.

Recycled glass and cans pose no problems, says Robert Testin, Ph.D., associate professor in Clemson University's Packaging Science Department. In order to melt them for recycling, temperatures must be very high—so high that most contaminants are removed.

But paper and plastics are recycled at much lower temperatures, and contaminants could remain. Some recycled products could be made of newspaper. Newspaper may contain dioxins and furans, a complex mixture of related compounds that are formed in trace amounts when chlorine or chlorine derivatives are used as the primary bleaching agents in making white paper products. The most toxic dioxin is 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), which has been shown to cause cancer in laboratory test animals.

The paper industry is participating in a voluntary program to reduce TCDD levels in all food-contact paper products to 2 parts per trillion (ppt) or less. Industry representatives have informed FDA that 82 percent of food-contact bleached paper products met the 2 ppt or less TCDD standard as of Dec. 31, 1990, and that all of these products are expected to meet this standard by the end of 1992. In milk cartons, the TCDD level is even lower—it averages 0.4 ppt. (See "Deciding About Dioxins" in the February 1990 issue of *FDA Consumer*.)

At present, the only uses for recycled plastic materials in food packaging reviewed by FDA are in egg (in the shell) cartons, berry baskets, harvesting crates, and soda bottles. Richard White, consumer safety officer in FDA's food and color additives division, explains that egg cartons made with polystyrene and berry baskets and harvesting crates made with polyethylene terephthalate (PET) are washed, ground and remolded to be recycled safely for the same uses.

The only FDA-reviewed procedure for recycling plastic soda bottles made with PET involves a regeneration process that breaks the plastic into its monomers (small molecules that are basic repeating links), which are then reprocessed into PET again. Other approaches to recycling plastic bottles are currently being evaluated by FDA.

Industry has technology to separate out components during recycling from packages that contain more than one material, such as both plastic and paper. It is also investigating the possibility of using recycled plastic as a buried layer in multilayered packages so that the recycled layer will not be in direct contact with food.

FDA realizes that recycling packaging for food contact use is a complex issue, and problems posed by recycled materials are currently under review. ■

—J.F.

package. We will then determine if existing toxicological studies support this worst-case estimate of dietary exposure. If they do not, then additional data will need to be submitted in the form of a food additive petition. The manufacturer might be required to perform additional

toxicological feeding studies or to carry out studies that would provide an assessment of dietary exposure under actual use conditions." (For more on microwave packaging, see "Keeping Up with the Microwave Revolution" in the March 1990 *FDA Consumer*.)

"Sous Vide"

Dry boil-in-bag foods, such as rice in plastic mesh-like packages, have been around for about 30 years, and FDA scientists have determined that the components of those packages are safe at boiling-water temperatures. But a fairly recent innovation, vacuum-packed refrigerated foods known by the French words "sous vide," a very different process, also gets dropped into boiling water in home preparation.

Processors of "sous vide" foods seal raw ingredients, often entire recipes, in plastic pouches, then vacuum out the air. They then minimally cook the pouch under precise conditions and immediately refrigerate it. Some processors replace some of the air with nitrogen or carbon dioxide. Processing food in this manner eliminates the need for the extreme cold of freezing and the intense heat of canning, thus better preserving taste.

The "sous vide" method of packaging can be used for most foods, including pasta, vegetables, fish, chicken, and beef. These types of food fit right into today's often hectic lifestyle, but they must be handled with care, say FDA food scientists. The danger here is not from packaging components migrating into the food—the packages are made with plastic materials that can safely be heated at boiling temperatures. The possible harm could come from the food itself spoiling because harmful bacteria that are present in most foods may not be destroyed in "sous vide" processing, and could grow in unrefrigerated conditions.

FDA recommends that "sous vide" foods be used by the expiration date printed on the package, be refrigerated constantly, and be heated according to the time and temperature of package directions. (For more on "sous vide" foods, see "The Big Chill" in the September 1989 *FDA Consumer*.)

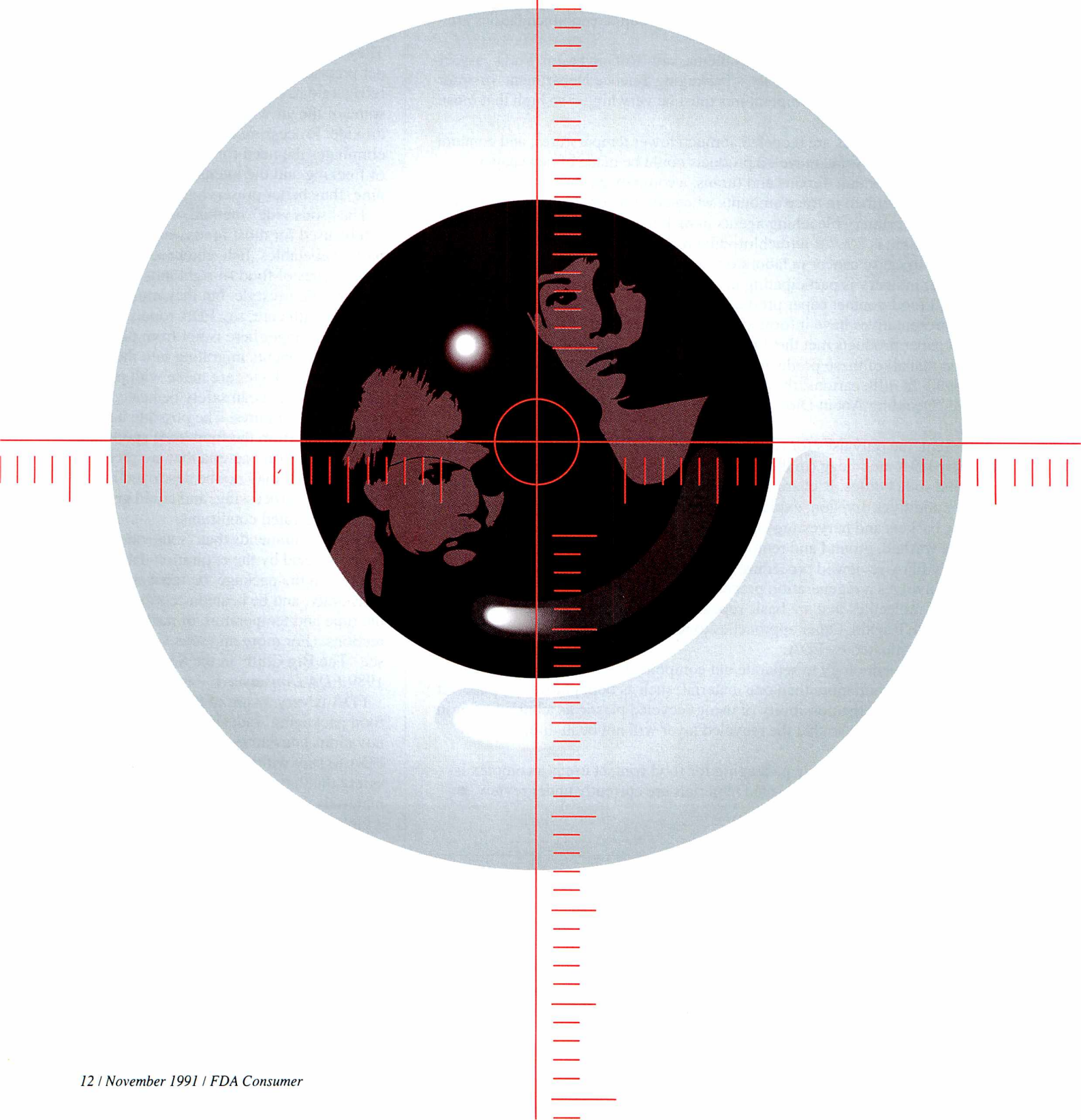
FDA is very aware of the benefits of food packaging. Industry researches innovations constantly and works with FDA to stay within the parameters of safety that have been set for packaging materials that contact food. If FDA finds a violation, it contacts the manufacturer, and corrective action is taken. Any imminent danger to health is acted upon immediately with recall or regulatory action. ■

Judith Foulke is a staff writer for FDA Consumer.

Aligning Eyes

Straightening Out Strabismus

by Dixie Farley



“**W**hy do you have that patch on? Did your eye fall out?” Kindergartner Kimberly May answered the jeer with a shrug. In 1974, it was Kim’s first day of school in Gaithersburg, Md., and she and the boy harassing her were waiting with other children for the building to open. Standing nearby, Kim’s 7-year-old brother Erik replied with gusto: “You dumb thing. She’s got amblyopia, and she needs the eye patch so she can see better. So there.”

Although Erik couldn’t explain how Kim’s amblyopia (decreased vision) resulted from strabismus (eye misalignment), he defended his sister with the few terms and facts he’d overheard at home. And although Kim couldn’t find comfort in knowing that many other youngsters wear eye patches for amblyopia, she took heart from her brother’s support.

Strabismus affects approximately 4 percent of U.S. children under age 6. Amblyopia occurs in about 2 percent of the general population.

Anne May, a registered nurse, discussed her daughter’s condition with the teacher, emphasizing that strabismus would not hamper Kim’s ability to do class work. With agreement from Kim and her teacher, May also spoke to the class.

“I told them one eye sometimes is weak but can often be strengthened by patching,” May says. “We took the patch off to show them her eye was OK under there. After that, there were only one or two remarks, from students absent that day.”

In Kim, strabismus occurred as crossed eyes. In others, it may manifest as eyes that turn out, up or down. Its name can be traced to the Greek word *strabismos*, to look obliquely or with unstraight eyes; some use the terms “squint” and “lazy eye.” Strabismus can

disable sight in one eye, yet leave the other with 20/20 vision. Strabismus can be acquired from diverse causes at any age. There are more than a dozen variations. (See accompanying article.)

Sight: A Team Effort

Healthy eyes move together to send similar images along the optic nerve to the brain for fusion into a single 3-dimensional picture at the brain-vision junction, or visual cortex. Toward this end, six muscles (see illustration) attached to the outside of each eye contract and relax to move the eyes in perfect synchronization, permitting fusion, or binocular vision, across a large area of the visual field.

Strabismic eyes, on the other hand, do not move in unison. A muscle may pull too weakly or too strongly against its opposing muscle, creating an imbalance that causes one eye to drift from parallel alignment with its mate; more than one pair of muscles may be imbalanced.

Since each eye fixates on an object at a different point in space, the images received by the brain are dissimilar. The brain is unable to fuse the dissimilar images, resulting in double vision, which can be very disturbing. To avoid this disturbance, the brain may suppress vision in the deviating eye, allowing clear sight to develop solely in the straight eye. Decreased vision in the suppressed eye is called amblyopia. Prolonged amblyopia causes a loss in 3-dimensional viewing and depth perception.

The “squint” or turn usually is constant but may be intermittent and may occur in only one eye or alternate between the two eyes. Vision in people with alternating strabismus generally remains good in each eye individually.

While strabismus clearly stems from muscle imbalance, the causes of such imbalance are many and are not all completely understood.

“There’s a strong genetic influence, but there are also many anatomic and neuromuscular reasons,” says John F. O’Neill, M.D., an ophthalmologist (a physician who specializes in eye disease) and director of the Pediatric Ophthalmology and Strabismus Service at Georgetown University’s Center for Sight in Washington, D.C. “One group of children may have eyes that turn, usually inward, from the day they are born. Another group may have perfectly healthy and straight eyes their first few years of life. However, as these children mature and start focusing more carefully on objects, the effort to see clearly causes their eyes to cross. Another group of children with neurologic conditions, such as cerebral palsy, not only may have poor movement of their arms and legs, but the eye muscle system is affected as well.”

Strabismus can be associated with many other conditions that cause poor vision in one or both eyes—for example, cataract, Down syndrome, thyroid disease, eye tumor, damage to the fetal central nervous system from toxoplasmosis (a parasitic infection that can pass from the mother during pregnancy), damage to a nerve supplying the eye muscle (perhaps from birth trauma), or eye disuse due to a high refractive error (such as extreme farsightedness) or different refractive errors in each eye (such as nearsightedness in one eye and farsightedness in the other).

Is It Strabismus?

Maybe not. Some children have facial features that make the eyes look crossed when they aren’t, and some normal newborns have a temporary outward drift.

Eye alignment is not fully mature at birth. A true developmental eye drift typically shows up from birth to 3 or 4 months of age, when normal eyes are straightening, but may occur through childhood or later. Misalignment that

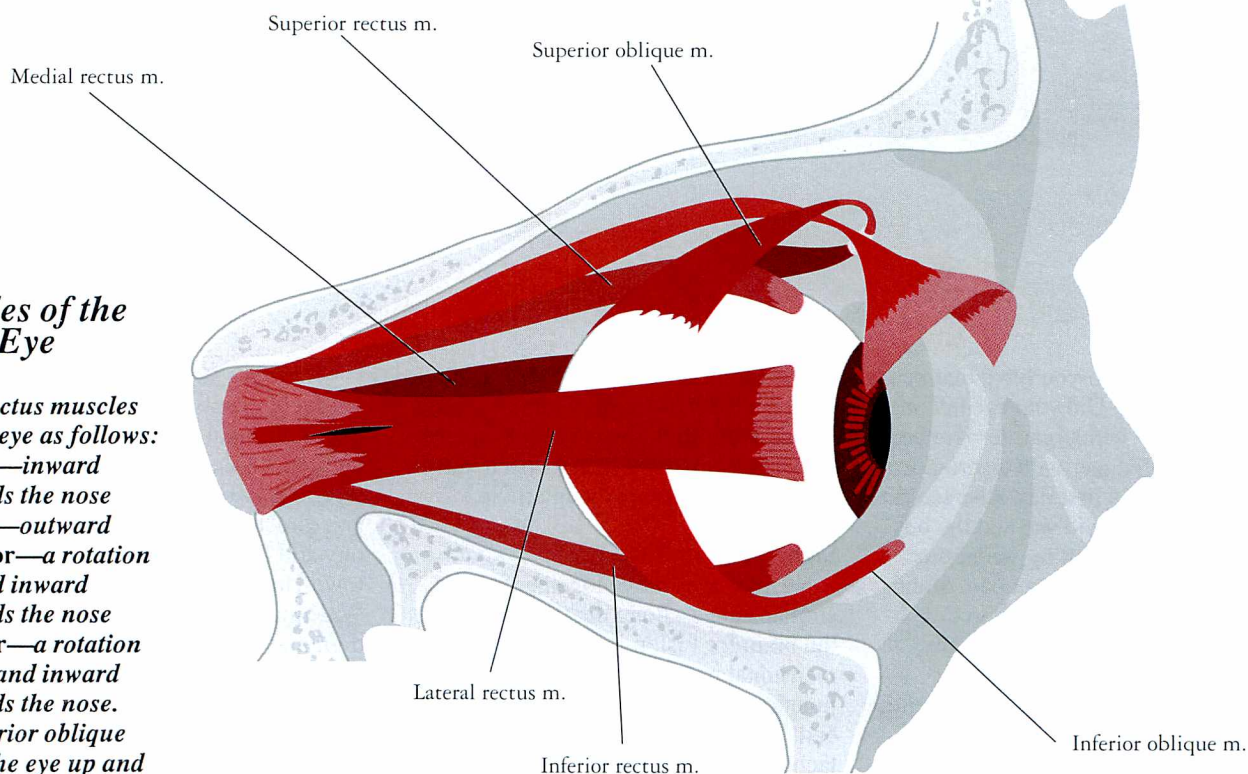
Muscles of the Right Eye

The rectus muscles turn the eye as follows:

- medial—inward towards the nose
- lateral—outward
- superior—a rotation up and inward towards the nose
- inferior—a rotation down and inward towards the nose.

The inferior oblique rotates the eye up and outward, and the superior oblique rotates the eye down and outwards.

(Source: Gray's Anatomy)



persists to age 5 or 6 months or occurs later should be assessed by an eye specialist. Early diagnosis is vital to detect and treat underlying causes and prevent severe vision disability.

"The first thing we do in examining children is to assess their vision, to determine the degree of visual attentiveness in each eye separately," O'Neill says. "We observe the child's ability to fixate on an object, and then we test how well each eye alone, and both eyes together, can follow that object in different directions and at different distances."

Many techniques are used to check the alignment and movement of the eyes to test for strabismus.

A quick screening method is the Hirschberg corneal reflex test, says Walter Sloane, M.D., an ophthalmologist with FDA's Center for Devices and Radiological Health, which regulates medi-

cal devices, including those used to test and treat the eye. The examiner directs an examining light onto the child's cornea (the transparent covering that admits light through the pupil) as the child looks at the light. In normal eyes, the light reflection appears in the center of both pupils. An eye that reflects light from a different place may be strabismic and should be further examined, Sloane says.

Another corneal reflex test is the Krimsky method. It compares the location of the reflected examining light in each pupil; again, light reflections that are dissimilar indicate strabismus. Prisms placed over one or both eyes align the reflections to estimate the amount of the turn.

The alternate cover test quickly spots misalignment. "The examiner rapidly covers and uncovers each eye, shifting back and forth from one eye to the other

like a windshield wiper," Sloane says. "If the child has any deviation, the eye will immediately move as the cover is shifted to the uncovered eye."

The cover-uncover test differentiates serious types of strabismus called tropias from latent drifts called phorias, which seldom require treatment.

"The brain immediately overcomes a phoria drift," Sloane says. "So when the drift is a phoria, we see movement immediately after the eye is uncovered as it responds to control by the brain."

"But when the eye with a tropia is covered, it becomes unhooked, so to speak, from the brain's control so that it drifts—in any direction—and remains turned in that position when uncovered until we cover its fellow eye, which has been staring at the object. When the fellow eye is covered, the turned eye is reconnected to the brain. The turned eye then moves to

Types of Misalignment

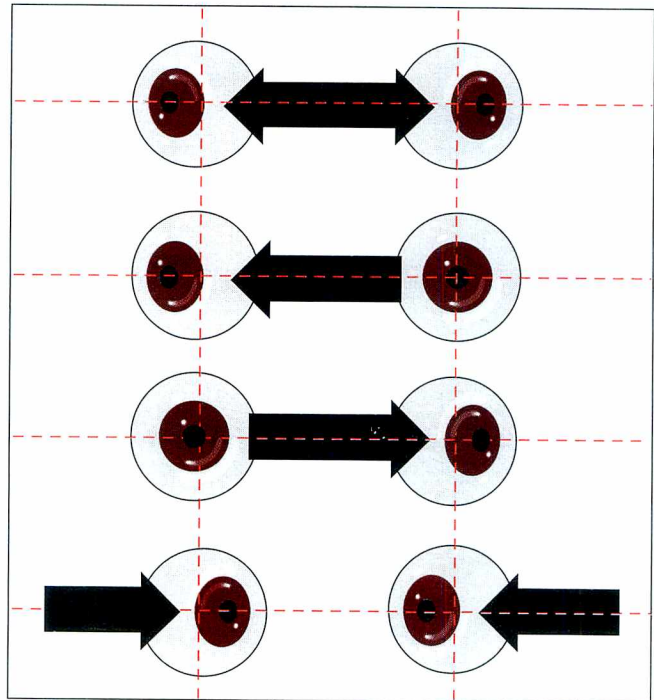
In most strabismus patients, the eye muscles are not paralyzed. Misalignments with paralysis arise from disturbances in the nerves serving the affected muscles. Here are summaries of the main strabismus variations:

Nonparalytic Types

- **Pseudostrabismus.** This is not true strabismus. Rather, aligned eyes appear crossed due to a wide, flat nasal bridge and prominent skin folds at the inner eyelids, which hide the eyes as they turn aside. The appearance resolves as the child matures. Lack of improvement warrants reevaluation in case true strabismus has developed.
- **Phorias.** Drift may be in any direction, but muscle imbalance is so minor the brain can fuse the images. Treatment is seldom necessary.
- **Infantile Esotropia.** Between birth and 3 to 4 months, the infant's eyes begin to cross, often intermittently at first but becoming constant by 6 months. The brain may alternate use of the eyes and see well with each, perhaps using the right eye to view objects at the left and vice versa. When one eye is habitually used, the other tends to develop decreased vision, or amblyopia.
- **Accommodative Esotropia.** When the eyes fixate on an object, they see a blurred image, usually at near viewing because most of these children are farsighted, sometimes severely. For slight blurring, the brain can sharpen the image, an effort called accommodation, which can cause the eyes to cross. This can occur between 6 months and 7 years but is most common around age 2 1/2. The drift may become more pronounced with increased effort to focus. Amblyopia can develop. Untreated constant drift can alter the eye muscles, complicating therapy.
- **Infantile Exotropia.** This markedly outward drift occurs in children under age 1 but is rare. Generally intermittent for a short time, the condition usually progresses to become constant in alternating eyes.
- **Intermittent Exotropia.** One eye drifts out on occasion, as during fatigue or illness. The patient may shut an eye in bright light, probably to avoid double vision, and at first may keep the eyes straight. Most often, the condition begins between 6 months and 6 years, mainly at distance with little or no drift in near viewing. It may progress from intermittent, to frequent, to constant at distance, to constant at near. Mild cases may be monitored without therapy.
- **Sensory Exotropia.** Serious vision loss in an eye, usually after age 5, can cause this constant outward drift. Binocular vision rarely improves.

Paralytic Types

- **Third-Nerve Palsy.** The eye drifts out and down, the eyelid droops, and the patient can't turn the afflicted eye. The condition tends to be congenital (inherited or due to trauma in the womb or during birth). Cases acquired after birth may be from head injury, brain tumor, inflammation, infection, or, in adults, diabetes mellitus.
- **Fourth-Nerve Palsy.** The patient characteristically tilts the head to avoid double vision and compensate for an up or down drift. Descending stairs may be difficult because the



Types of eye misalignments are (from top to bottom): exotropia with both eyes turning out, exotropia with right eye turning out, exotropia with left eye turning out, and esotropia with both eyes turning in.

eye is weak in looking down, especially when turning towards the nose. The palsy may be congenital or result from head trauma.

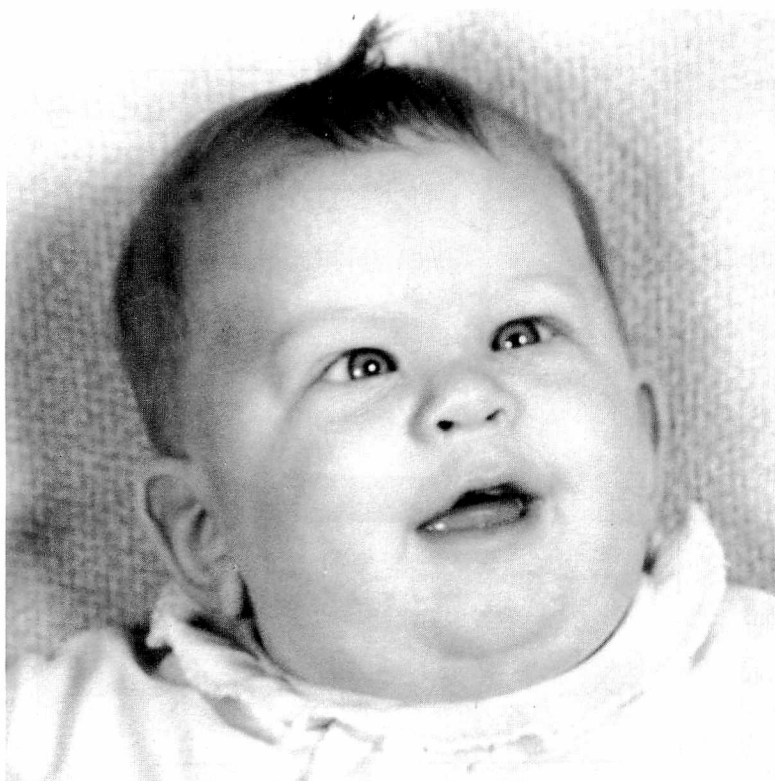
- **Sixth-Nerve Palsy.** Markedly cross-eyed with limited ability to turn the afflicted eye (or eyes) out, the patient may turn the head toward the paralyzed muscle to see better, which helps preserve binocular vision. Rarely congenital, sixth-nerve palsy mainly results from head trauma but may also be due to meningitis or brain tumor. In children, the palsy may occur up to three weeks after illness such as a bad cold.

Syndromes

These forms are believed to stem from structural defects in the eye muscles or associated nerves or in other nearby tissue. Some examples are:

- **Double-Elevator Palsy.** The eye drifts down and can't raise the gaze.
- **Duane's Syndrome.** The affected eye retracts somewhat into the socket when turning towards the nose, causing a squint.
- **Brown's Syndrome.** The eye has limited upward movement when turning in.
- **Mobius Syndrome.** The eyes cross, and the patient can't turn the eyes out. There may be bodily defects elsewhere, such as partial tongue paralysis and clubfoot. ■

—D.F.



When Kimberly May was 5 months old, her right eye clearly crossed, as shown by the top photo taken in November 1969. A year later (bottom photo), after surgery and eye-patching, both eyes look straight ahead.

fixate on the object, as if to say, 'Oops, I was facing the wrong direction.' ”

One new method, a “preferential looking technique,” uses Teller acuity cards. These devices are similar to educational flash cards, but instead of letters or numbers they have black and white stripes ranging in patterns from very broad to very narrow, simulating large to small pictures or letters.

“Vision is gauged,” O’Neill says, “by how attentively a child, even a baby, looks at each pattern.”

The use of drops to dilate the eyes allows inspection of the back of the eye to detect eye disease that may be contributing to the drift.

Depending on the findings, other tests may be required.

Best Chance to See

Prompt attention to correcting eye misalignment will provide the most satisfactory outcome of treatment. Indeed, if some cases of strabismus are left untreated until age 6, permanent visual impairment can result.

Treatment has three primary goals, O’Neill says: foremost, to obtain the best possible vision in each eye; second, to gain the best possible alignment of each eye alone and as a pair; and, finally, to provide the best opportunity for binocular vision. Corrective eyeglasses, patching, or both are the mainstay therapies, with about 30 percent of patients needing surgery, he says.

Corrective eyeglasses can help children as young as 6 months of age. They’re most effective when there is significant farsightedness and the eyes turn in, and they’re the only therapy needed in about a third of these patients whose eyes turn in. Prisms incorporated in eyeglasses may relieve double vision in some older patients.

To force use of a “lazy” eye while preserving vision in the preferred eye, patching is very effective.

“If a child doesn’t develop vision equally in each eye early in life,” O’Neill says, “it may never develop fully. For a 4-month-old child, patching might be used only an hour or two a day. A child that age probably takes 2 or 3 naps a day, so I’d patch for only one of those waking periods. But you have to be cautious. When you patch an eye at this early stage of development, you inactivate it.

If you cover it for too long a period at this time, the child can lose sight in that eye, and the loss could be irreversible.”

In 1969, when Kim May was first patched at age 6 months, doctors didn’t have as much information about early development of vision.

“We were told to patch her straight eye 24 hours a day for an entire week, removing the patch only for changing it and for bathing,” her mother says. “And then we were to patch the other eye. But at the end of that week, when I took the patch off and started covering her crossed eye, the straight one was basically blind. She couldn’t see her baby bottle. I had to put it into her hand. Her brain had totally switched over to the crossed eye.”

Sight did return to Kim’s temporarily vision-disabled left eye. She had surgery on it in September 1970 and on the right eye in 1975 and 1980 to realign the imbalanced muscles. With corrective eyeglasses, Kim today at age 22 has 20/30 vision in her left eye and 20/25 in her previously crossed right eye.

Surgery Can Help

Some 60,000 to 80,000 operations are performed each year to correct strabismus. When the eyes turn out, up or down, correction usually requires surgery. Sometimes a second operation is required. With current knowledge and techniques, it’s uncommon for a patient (about 1 in 20) to need a third operation, O’Neill says. The need for further corrective surgery, he says, depends on the stability of the muscle system and the degree of muscle response (over- or under-response) to the surgical adjustment.

Complications related to strabismus surgery are infrequent. Besides general risks such as bleeding and infection that accompany any surgery, complications may include postoperative double vision, and—rarely—excessive tissue reaction with scarring.

By weakening or strengthening an eye muscle (or muscles), strabismus surgery alters the muscular pull on the afflicted eye in order to align its movements with the other eye. The ophthalmologist can weaken or strengthen a muscle function by repositioning the muscle on the outside of the eye (never cutting into the eyeball) and also can strengthen a muscle by cutting out (resecting) a small piece

of its tendon. Techniques with adjustable sutures allow additional muscle repositioning within the first day following surgery.

When the patient is a child, general anesthesia is always used. Some adults may have local anesthesia.

After surgery, bandages frequently are unnecessary and there is just redness in the eye. The parents are given an antibiotic ointment to put in the child’s eyes, and the doctor generally will see the patient again in two or three days.

New Treatments

Following a number of years of investigations, FDA, in December 1989, licensed a therapy for strabismus patients age 12 and older: Oculinum, an injectable form of sterile, purified *Botulinum* toxin, type A. Before FDA granted approval, the agency’s Center for Biologics Evaluation and Research reviewed safety and effectiveness data on Oculinum.

Wiley Chambers, M.D., an ophthalmologist with FDA’s Center for Drug Evaluation and Research who contributed to this review, points out, “Oculinum can be used effectively to treat certain adults with strabismus, but its effect in children hasn’t been adequately evaluated.

“We limited it to patients over age 12,” he says, “because children under that age have a chance of developing amblyopia, and more information is needed to reliably assure muscle balance and prevent the risk of amblyopia. When amblyopia isn’t a consideration, a lot of people think it’s worth trying, to avoid an operation.”

Unfortunately, effectiveness is unlikely in opposing-muscle weakness, severe misalignment, and certain other circumstances.

The toxin derives from *Clostridium botulinum* bacteria and is very potent. If accidentally eaten in contaminated foods, it can cause botulism poisoning that may result in paralysis, even death. In the treatment of strabismus, however, it is used in extremely dilute concentrations, and there have been no reports of botulism poisoning from Oculinum use in patients with strabismus or blepharospasm, an eye spasm disorder the product also is licensed to treat. In some 8,340 injections, nine accidental punctures and 16

instances of excess bleeding occurred. None resulted in vision loss. The most common side effects are eyelid droop and eye irritation.

Oculinum is injected into an eye-turning muscle, outside the eye, through an electromyographic needle that guides placement by recording the muscle’s electrical activity. Anesthetic eye drops generally are used before the injection.

The toxin “turns off” the muscle by paralyzing it. Scientists theorize the paralysis affects muscle pairs by causing the injected muscle to lengthen, thus prompting the opposing muscle to shorten.

About half of patients require repeated treatments. In a recent study of 677 patients, 55 percent showed improvement six months later. Correction may be permanent, provided the injected muscle is paralyzed well enough and long enough and the opposing muscle is intact.

Another new therapy may benefit patients who acquire crossed eyes after age 6 months. It involves the use of eyeglasses overlaid with thin plastic prisms.

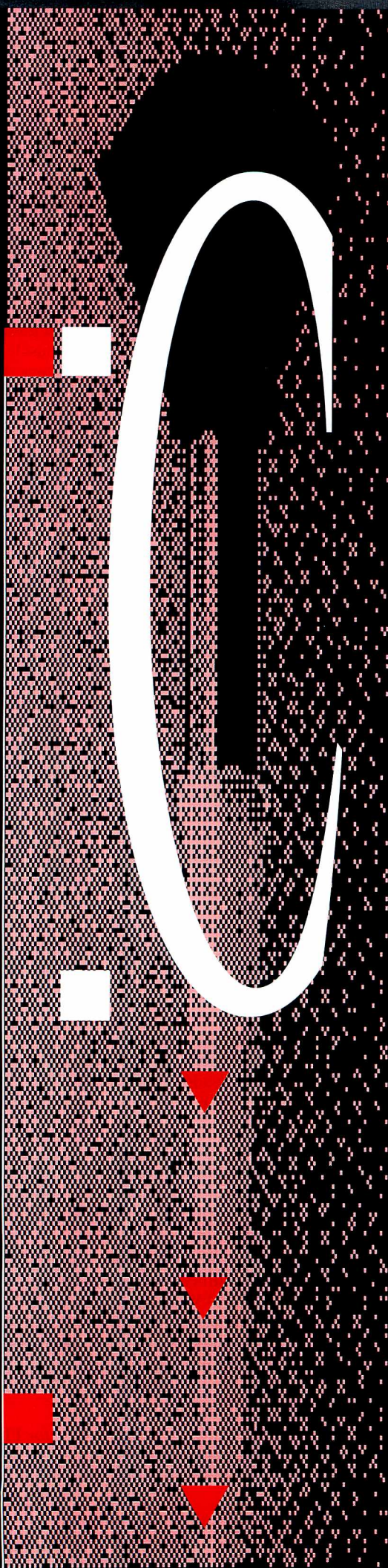
In September 1990, the University of Iowa Hospitals and Clinics in Iowa City announced the results of a six-year study led by William Scott, M.D., in which 14 medical centers tested the efficacy of treatment with prism eyeglasses before surgery in patients who had no previous eye surgery.

“By knowing the exact prism power that corrects the misalignment,” Scott says, “we can more accurately determine the surgical adjustment needed on the eye muscles, thus reducing the possible need for additional surgery.” The eyes of about 83 percent of patients who used the special eyeglasses were straightened by the surgery, compared with 72 percent of patients without them.

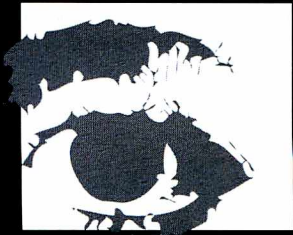
Appropriate management offers strabismus patients the best possible circumstances for improvement.

“The key most often is early detection and treatment,” says Georgetown’s O’Neill. “Without proper care, strabismus in an infant or in a child early in life will generally get worse, not better. Children do not outgrow strabismus when the eyes truly are ‘crossed’.” ■

Dixie Farley is a staff writer for FDA Consumer.



COSMETIC
SAFETY
M O R E
COMPLEX
THAN AT
F I R S T
B L U S H



by Dori Stehlin

The European cosmetic known as ceruse was used faithfully—and fatally, because it was mainly white lead—by wealthy women from the second century until well into the 19th century to make their faces look fashionably pale.

Nothing on the market today approaches ceruse's deadliness. But many consumers wonder about the eye makeup, lipsticks, foundations, and nail products that are on the shelves. Are there any risks in using these cosmetics? Are long lashes, even skin tone, and brightly colored nails worth any risk at all?

Serious injury from makeup is a "pretty rare event," says John E. Bailey, Ph.D., director of FDA's division of colors and cosmetics. "We don't see it happen that often."

Even one of the most serious problems, eye infections from a scratch on the eyeball with a contaminated mascara wand, has become rare. January 1989 was the last time an infection of this type was reported to FDA.

In 1990, FDA headquarters received approximately 100 reports of adverse reactions to cosmetics. Less than 25 were about makeup and, of those, most were either allergic reactions or skin irritation. (The other complaints were about hair products, soaps, fragrances, and lotions.)

Although industry probably received about 50 reports for every one made to FDA, says Bailey, the problems reported to the companies are along the same lines—allergies and skin irritation.

The agency can't do much about isolated allergic reactions or irritation problems. It's up to the individual to avoid the product that caused the reaction and any other products that contain the offending ingredient. (See "Contact Dermatitis: Solutions to Rash Mysteries" in the May 1990 *FDA Consumer*.)

But that doesn't mean reporting the problem isn't important.

"We look for clusters," says Bailey. "If we see we're getting a number of complaints for the same product, then that is cause for concern."

Unlike reports of allergic or irritation reactions, even one report of an acute injury, usually caused by a contaminated product, results in quick action by the agency. "We'll inspect the establishment, talk to the consumer, talk to the doctor, collect samples, and analyze them to determine the extent of contamination," says Bailey.

Moldy Oldies

Contaminated makeup is the result of either inadequate preservatives or product misuse. But contamination doesn't necessarily translate into serious injury for the user.

"Cosmetics are not expected to be totally free of microorganisms when first used or to remain free during consumer use," according to a 1989 FDA report on contamination of makeup counter samples in department stores. The report was based on a survey which found that over 5 percent of samples collected were seriously contaminated with such things as molds, other fungi, and pathogenic organisms.

Every time you open a bottle of foundation or case



of eye shadow, microorganisms in the air have an opportunity to rush in. But adequately preserved products can kill off enough of the little bugs to keep the product safe.

Occasionally, however, a product will be seriously contaminated. According to FDA data, most cases of contamination are due to manufacturers using poorly designed, ineffective preservative systems and not testing the stability of the preservatives during the product's customary shelf life and under normal use conditions.

Driving and Making Up Don't Mix

Consumers must take an active role in keeping product contamination and potential infection to a minimum once they take a product home, says Gerald McEwen, Ph.D., vice president for science for one of the cosmetic industry's trade associations, The Cosmetic, Toiletry and Fragrance Association (CTFA).

"You need [to follow] good personal hygiene—clean hands, clean face," he says. "And common sense."

One of the riskiest things a woman can do is put on mascara while she's driving, says McEwen. "You hit a bump and you scratch your eyeball," he explains. "Once you've scratched your eyeball, you have all kinds of possibilities of contamination. We're not talking about disease germs here. We're talking about normal bacteria that are all over the air. Those get into that kind of a cut, and without proper medical attention you can go blind."

Testing the Testers

There's something else that is definitely taboo when using makeup—sharing.

"Never share, not even with your best friend," says Irene Malbin, CTFA's vice president of public relations. Sharing cosmetics means sharing germs, and the risk, though small, isn't worth it, says Malbin.

Shared-use cosmetics—the testers commonly found at department store cosmetic counters—are even more likely to become contaminated than the same products in an individual's home, according to the 1989 FDA report.

FDA followed its 1989 report on makeup testers with a survey of corresponding unopened retail packages. The survey found only negligible contamination, and the agency concluded that the preservatives couldn't handle the challenge of constant use.

"At home, the preservatives have time—usually a whole day—to kill the bacteria that is inevitably introduced after each use," says Bailey. "But in a store, there may be only minutes between each use. The preservatives can't handle it."

If you really want to test a cosmetic before you buy, "you should insist—must insist—on a new, unused applicator," says CTFA's Malbin. She says that some companies use cotton swabs for that purpose.

Allergic Reactions

Do the preservatives themselves pose any safety risk?

According to a study of cosmetic reactions conducted by the North American Contact Dermatitis Group, preservatives are the second most common cause of allergic and irritant reactions to cosmetics. Fragrances are number one. Although the study is more than 10 years old, the results can still be considered valid today, says Harold R. Minus, M.D., an associate professor of

The Meaning of Makeup

Draize test: an animal test used to determine the effects of different substances on the eye

fragrance: any natural or synthetic substance or substances used solely to impart an odor to a cosmetic product

* **fragrance-free:** products so labeled may still contain small amounts of fragrances to mask the fatty odor of soap or other unpleasant odors

* **hypoallergenic:** cosmetics that are less likely to cause allergic reactions.

in vitro: From the Latin meaning "in glass," *in vitro* tests do not involve the use of living vertebrate animals

lanolin: a natural extract of sheep wool used as a moisturizer, which is a common cause of allergic reactions, but is rarely used in pure form

* **natural:** ingredients extracted directly from plants or animal products as opposed to being produced synthetically

* **non-comedogenic:** products so labeled do not contain common pore-clogging ingredients that could lead to acne

parabens (methyl-, propyl-, and butyl-): the most widely used preservatives in the United States, commonly used in shampoos, foundations, facial masks, hair-grooming aids, nail creams, and permanent wave products

propylene glycol: the most common moisture-carrying vehicle in cosmetics other than water.

(* There are no official, government definitions for these terms.) ■

—D.S.

A woman tries out eye shadow in a store by using disposable applicators and single-use samples, which are rapidly replacing the shared-use testers that could harbor germs.



dermatology at Howard University Hospital. (For more information on this study, see "Cosmetic Allergies" in the November 1986 *FDA Consumer*.)

People who have had allergic reactions to cosmetics may try hypoallergenic or allergy-tested products. These are, however, only a partial solution for some and no solution at all for others.

"Hypoallergenic can mean almost anything to anybody," says Bailey.

"Hypo" means "less than," and hypoallergenic means only that the manufacturer feels that the product is less likely than others to cause an allergic reaction. Although some manufacturers do clinical testing, others may simply omit perfumes or other common problem-causing ingredients. But there are no regulatory standards on what constitutes hypoallergenic.

Likewise, label claims that a product is "dermatologist-tested," "sensitivity tested," "allergy tested," or "nonirritating" carry no guarantee that it won't cause reactions.

"FDA tried to publish regulations [in 1975] defining hypoallergenic to mean a lower potential for causing an allergic reaction," says Bailey. "In addition, we were going to require that companies submit information to FDA establishing that in fact their products were hypoallergenic." However, two cosmetic manufacturers, Almay and Clinique, challenged the proposed regulations in court, claiming that consumers already understood that hypoallergenic products were no panacea against allergic reactions. In July 1975, the U.S. District Court for the

District of Columbia upheld FDA's regulations, but the two companies appealed. On Dec. 21, 1977, the U.S. Court of Appeals for the District of Columbia reversed the district court's ruling.

What's "Natural"?

Like hypoallergenic, "natural" can mean anything to anybody.

"There are no standards for what natural means," says Bailey. "They could wave a tube [of plant extract] over the bottle and declare it natural. Who's to say what they're actually using?"

Revlon, Inc., uses natural plant extracts in its New Age Naturals cosmetics line, says Dan Moriarity, Revlon's director of public relations. "But the base formulas are the same as our conventional products," he says. In addition, because these products contain fragrances, they don't fit Revlon's definition of hypoallergenic, he explains.

Anyone who has ever had poison ivy knows that "natural" and "hypoallergenic" are not necessarily interchangeable terms. For example, some manufacturers of cosmetics marketed as natural products use naturally occurring vitamins E and C as preservatives. But, according to Alexander Fischer, M.D., author of *Contact Dermatitis*, "Topical vitamin E is a potent sensitizer which can produce both delayed allergic contact dermatitis and immediate allergic hives."

In addition, natural doesn't mean pure or clean or perfect either. According to the cosmetic trade journal *Drug and Cosmetic Industry*, "all plants [including those

used in cosmetics] can be heavily contaminated with bacteria, and pesticides and chemical fertilizers are widely used to improve crop yields."

Safety Testing

Whether driven by altruism, liability, or the bottom line, most companies see the need for safety testing. But safety testing can rarely be mentioned without bringing up the controversy surrounding the use of animals for those tests.

Many companies have begun to label their products with statements indicating that no animals have been used in testing.

"As far as we know," says Neil Wilcox, D.V.M., director of FDA's Office of Animal Care and Use, "what these companies do is use, for the most part, old reliable ingredients that have been proven safe [based on past animal data and a history of safe use] and then test the final product on people."

"There's kind of a fine point here," says CTFA's McEwen. "These companies that say they don't test on animals are skirting the issue. Practically every ingredient that's used in cosmetics was at some point tested on animals. Prob-

ably a statement like 'no *new* animal testing' would be more accurate."

But what if a company wants to use a new ingredient?

Unlike drugs, FDA does not require pre-market approval for cosmetics. However, if a safety problem with a cosmetic product arises after it's been marketed, FDA can take legal action to obtain the manufacturer's safety data on the product. Because there is not yet enough information on alternatives to animal testing to validate their use in ensuring human safety, FDA, at this point, would only accept animal safety data.

The most widely used, and possibly most controversial, animal test, the Draize Eye Irritancy Test, involves putting drops of the substance in question into the eye of an albino rabbit. Investigators then note if any redness, swelling, cloudiness of the iris, or corneal opacity occurs. In addition, the ability of the eye to repair any damage is noted.

"Draize may be impossible to replace with a single alternative test," says Sidney Green, Ph.D., a toxicologist with FDA's Center for Food Safety and Applied Nutrition.

Beauty on the Safe Side

Besides never putting on makeup while driving, consumers should follow other precautions to protect themselves and the quality of their cosmetics:

- Keep makeup containers tightly closed except when in use.
- Keep makeup out of sunlight; light can degrade preservatives.
- Don't use eye cosmetics if you have an eye infection, such as conjunctivitis, and throw away all products you were using when you first discovered the infection.
- Never add any liquid to bring the product back to its original consistency. Adding water or, even worse, saliva could introduce bacteria that could easily grow out of control. "If it has lost its original texture and consistency," says McEwen, "the preservatives have probably broken down."
- Never share.
- Throw makeup away if the color changes or an odor develops. Preservatives can degrade over time and may no longer be able to fight bacteria.

"We don't have a hard and fast rule on [when to throw cosmetics out]," says McEwen. McEwen says makeup can be kept indefinitely as long as it looks and smells all right and the consistency doesn't change. "It would be difficult to have any kind of bacterial growth and not have it be noticeable," he explains.

However, Janice Teal, a microbiologist who heads the product and package safety division of Avon Products, Inc., disagrees. "Even after the preservatives have stopped working, you may not be able to see or smell anything different," she says.

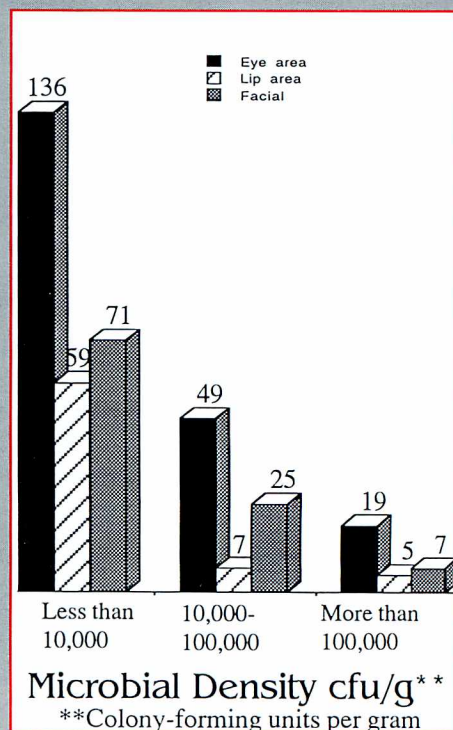
She agrees with McEwen that there is no absolute date for discarding various products, but says Avon recommends that consumers throw mascara away after three months. They can keep other makeup products a few months longer.

"Mascara is our biggest concern because of the wand," she says. "Normally, the eye is a good barrier to bacteria, but one slip and that wand can scratch the cornea and introduce all kinds of bacteria." ■

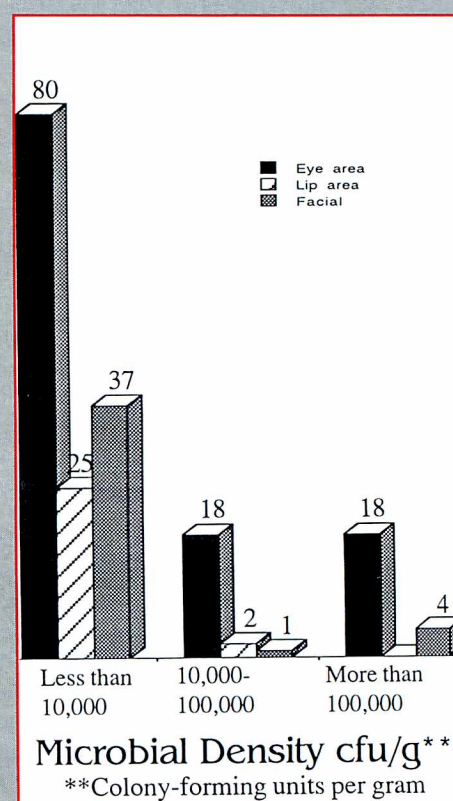
—D.S.

Results of FDA's Counter Sample Survey

Counter Samples Contaminated with Bacteria*



Counter Samples Contaminated with Yeast or Mold*



*FDA investigators collected 3,000 samples from cosmetic testers displayed in over 150 retail outlets.

Taking
extra care
when
putting on
eye
makeup
will help
avoid
injuries.



Regulating Cosmetics

The U.S. Food, Drug, and Cosmetic Act defines cosmetics as “articles other than soap which are applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.”

FDA has classified cosmetics into 13 categories:

- skin care (creams, lotions, powders, and sprays)
- fragrances
- eye makeup
- manicure products
- makeup other than eye (e.g., lipstick, foundation and blush)
- hair coloring preparations
- shampoos, permanent waves, and other hair products
- deodorants
- shaving products
- baby products (e.g., shampoos, lotions and powders)
- bath oils and bubble baths
- mouthwashes
- sunscreens

It is against the law to distribute cosmetics that contain poisonous or harmful substances that might injure users under normal conditions. Manufacturing or holding cosmetics under insanitary conditions, using non-permitted colors, or including any filthy, putrid or decomposed substance is also illegal.

Except for color additives and a few prohibited ingredients, a cosmetic manufacturer may use any ingredient or raw material and market the final product without government approval. The prohibited ingredients are:

- biothionol
- hexachlorophene
- mercury compounds (except as preservatives in eye cosmetics)
- vinyl chloride and zirconium salts in aerosol products
- halogenated salicylanilides
- chloroform
- methylene chloride

Manufacturers must test color additives for safety and gain FDA approval for their intended use.

Cosmetic firms may voluntarily register their manufacturing plants with FDA, file cosmetic formulas, and report adverse reactions.

Cosmetic labels must list ingredients in descending order of predominance. Trade secrets (as defined by FDA) and the ingredients of flavors and fragrances do not have to be specifically listed. ■

—D.S.

Reports

Consumers and their dermatologists should report cosmetic adverse reactions to:

Food and Drug Administration
Center for Food Safety and Applied
Nutrition
Division of Colors and Cosmetics
200 C St., S.W.
Washington, D.C. 20204

He explains that because the Draize test measures three different areas of the eye, replacing Draize will probably take a combination of alternative tests, “but we’ve not seen that combination yet.”

Wilcox explains that for FDA to approve other methods, those methods will have to produce test results that can be reproduced in other labs. In addition, databases will have to correlate historical animal test results with newer lab results.

“Database development and cooperation [between industry and FDA] is pivotal to the validation process,” says Wilcox.

The cosmetics industry has taken one step towards database development—the Cosmetic Ingredient Review. The basic purpose of the review is to gather information from the scientific literature and from company files on the safety of cosmetic ingredients and make that information publicly available.

FDA’s division of toxicological review and evaluation is currently evaluating two alternatives for the Draize eye test. One is Eytex, manufactured by Ropak Corp., Irvine, Calif., a chemical assay that produces opacity similar to that of an animal cornea upon exposure to irritants. The other is vertebrate cell cultures from humans and mice.

But until alternatives have been scientifically verified, the option for animal testing must be available for new ingredients and new products, says Wilcox. “No one wants to think of animals being used for anything other than kindness and human companionship,” he says. “But it’s important that we continue to recognize the risk to human health if unreliable tests are used.” ■

Dori Stehlin is a staff writer for FDA Consumer.

Caring for Cats and Dogs

by Rebecca D. Williams

At the ripe old age of 18, Camron, a long-haired Siamese and Himalayan cat, is no stranger to the vet's office. At the first sign of trouble, his owner, Sally Klein of Corvallis, Ore., takes him for a checkup. She even bought an insurance plan that gives Camron free office visits.

"I take real good care of him. He has better health insurance than I do," Klein says with a laugh.

More than half of all households in the United States have some kind of pet, and the number is rising, according to a survey by the Pet Food Institute. By far the most popular pets are dogs and cats. The number of dogs owned by Americans increased 13 percent between 1982 and 1990, while the number of cats owned rose 44 percent.

As pet ownership has increased over the years, so have advances in nutritional and medical care for pets. In the 1860s, the first commercially prepared dog food, a biscuit, was sold in England. In the 1930s and 1940s, canned pet food was introduced in the United States.

Consider the advanced techniques some veterinarians offer today: contact lenses for the nearsighted, hip replacements for dogs with bone deformities, animal blood banks for pets in surgery or accidents, and ultrasound machines to diagnose heart ailments, to name a few.

These procedures are advanced, however, and often only available in veterinary schools. Most pets will never get contacts or an ultrasound test. But their chances for good health have improved with the availability of vaccinations, vet-

erinary drugs, nutritionally balanced food, and an increasing number of pet owners who are willing to pay for it all.

"Veterinary care for pets has continued to progress as we've had more leisure time and income," says Sandra Woods, D.V.M., with FDA's Center for Veterinary Medicine. "For pets, the quality of medical care has improved with the lifestyle of the owners."

Many aspects of health care for pets are regulated by the federal government. The U.S. Department of Agriculture supervises vaccines, the Food and Drug Administration regulates veterinary drugs that treat diseases, and the Environmental Protection Agency regulates chemicals to kill ticks and fleas. USDA, FDA, and the Federal Trade Commission regulate pet food labeling and advertising claims.

By following sound veterinary advice, pet owners may extend and improve their dogs' and cats' lives for years, according to Woods.

"It's important for pet owners to establish a regular veterinary care program, pick out a vet they like, and schedule the pet for regular exams," she says.

"Owning a pet is a 10- to 15-year commitment," says Woods, "and unless you are willing to make this commitment both emotionally and financially, you shouldn't become a pet owner."

For those willing to make the commitment, there are a number of guidelines that can prolong a pet's life.

Puppy Love, Cuddly Kittens

So you've chosen the pick of the litter. Now what? Be prepared to rearrange your life somewhat for a young animal, and get into the habit of regular visits to

the veterinarian to detect diseases early.

First, a puppy or kitten needs a series of vaccinations. Many pet diseases are easier to prevent than cure; in fact, some that can easily be prevented, such as rabies and feline leukemia, cannot be cured at all (see accompanying article on vaccines).

A new pet is also likely to explore its environment, so both cats and dogs should wear some kind of identification tags. Even a house cat or puppy can slip through the door and get lost in the neighborhood.

Just as new parents child-proof their homes, it's a good idea for new pet owners to make their homes safe for curious





animals. According to the American Humane Association, common household substances such as cleaning fluid, bleach, gasoline, and detergents can poison an exploring pet.

Because dogs are guided by smell, they may be misled about what's good to eat. A puddle of antifreeze in the driveway, for example, smells and tastes sweet to a dog but is extremely toxic. Likewise, cats may be attracted to play with small or breakable objects that could get caught in their throats, such as needles, marbles, glass, or brittle plastic. Many plants, such as marigolds, poinsettias and amaryllis, are also poisonous to pets.

Veterinarians will also recommend that the average family pet be either neutered (castrated) or spayed (ovaries removed). This is best done when the pet is between 6 and 8 months old.

In most cases, removing a dog or cat's reproductive organs before it reaches maturity improves its personality, at least from a human's point of view. Males will be less likely to roam, fight or act aggressively to other animals. Male cats will be less likely to spray their scent glands to mark territory. And female pets won't go in heat (a period of ovulation and sexual excitement). Nor will they produce litters of unwanted puppies or kittens.

Puppies and kittens may be cute, but, according to the National Animal Control Association, about 10 million of them are destroyed in animal shelters each year in the United States because they have no homes.

To Purr-fect Health

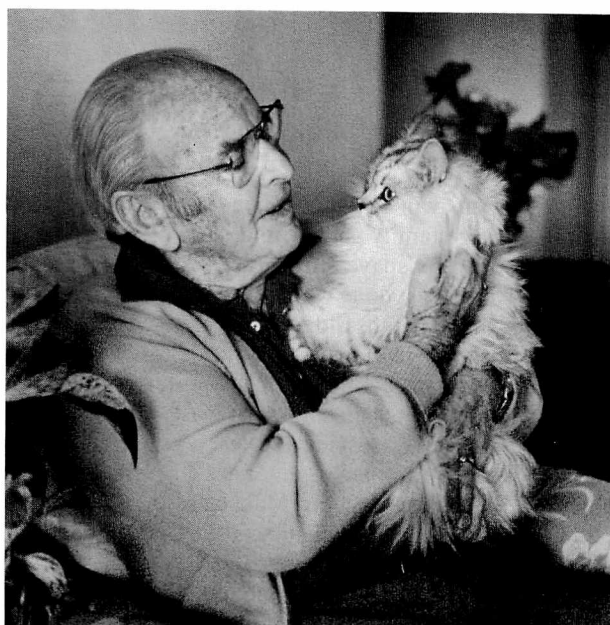
To keep your pet purring happily into middle age, veterinarians offer a number of preventive health measures for adult dogs and cats.

The first is good nutrition. Feeding a pet can seem like a guessing game at times. Dogs tend to wolf down their food in a few minutes, while cats often prefer to nibble all day long. Sometimes it's



A pet patient receives routine dental cleaning from Pam Schank, certified veterinary technician at Mesa Veterinary Hospital in Golden, Colo.

Vince Lotito of Arvada, Colo., gives Zeno, a purebred Persian cat, the kind of loving care necessary to keep pets healthy and happy. (Photos courtesy of the American Animal Hospital Association)



hard to tell if the pet's getting too much or not enough food. A veterinarian should be able to determine the amount and type of food that's best for your pet.

Most veterinarians advise against feeding pets food from the table. First, it encourages the pet to beg for scraps. Also, human food is often high in minerals that can crystallize in a pet's bladder and fat that can put on extra pounds.

"If you've got a family dog living predominantly off table scraps," Woods says, "he's not going to have the resistance to live as long as a dog who lives off scientifically tested food."

In addition to good nutrition, pets also need exercise to keep weight down and maintain muscle tone. Dogs need to be walked and played with every day. Cats, while they tend to play on their own with toys, often seek attention and contact with humans.

Dental care is also important for dogs and cats. If you can train your pet to let you clean its teeth, you may be able to prevent not only tooth loss, but also infection and even heart problems. Bad breath is not normal for dogs—it indicates a dental problem. Imagine your dentist's reaction if you didn't brush your teeth for years!

At least once a week if possible, remove soft tartar by going over the pet's teeth with a toothbrush, piece of cotton, or a damp cloth dipped in baking soda. When it's time for an annual checkup, schedule a professional tooth scaling to remove plaque and hard tartar.

When a puppy is between 2 and 8 months old, it should lose its milk teeth and get permanent teeth in their place. Examine the pet's mouth several times a month to make sure the teeth are falling out properly, and report any problems to your vet.

In addition to dental problems, dogs and cats can pick up a number of illnesses in a normal lifespan. Today, veterinarians can treat many of them. Here are some diseases to watch for:

- **Bloat** is when a dog's stomach twists and fills with gas. Seek veterinary care to treat the condition, which is fatal un-

Pets are better off with commercially prepared food, veterinarians say, even though they may beg for table scraps.

less the pressure is relieved.

- **Brucellosis** is a bacterial infection in dogs that can also be transmitted to humans from the sick pet. It causes similar symptoms in both: reproductive failures, enlarged lymph nodes, and fever. Antibiotics can treat the infection.

- **Hip dysplasia** is a genetic malformation of the hip joint seen particularly in large breeds of dogs. Surgery may ease the pain. Some dogs get better as they grow older, while others have no symptoms as puppies and get worse with age.

- **Ear mites** can infect and irritate a dog or cat's ears. A vet will prescribe topical insecticides to get rid of them.

- **Heartworms**, spaghetti-like worms that live in a dog's heart and major blood vessels, can cause congestive heart failure in dogs. They begin as larvae implanted through mosquito bites. Regular doses of certain anthelmintic drugs, which kill parasites, can prevent heart worms.

- **Heat stroke** occurs when a dog's body temperature is very high (105 to 110 degrees Fahrenheit, or 41 to 43 degrees Celsius). Potentially fatal, it is caused by inadequate ventilation, water or shade. The dog should be bathed in ice water immediately and taken to a veterinarian.

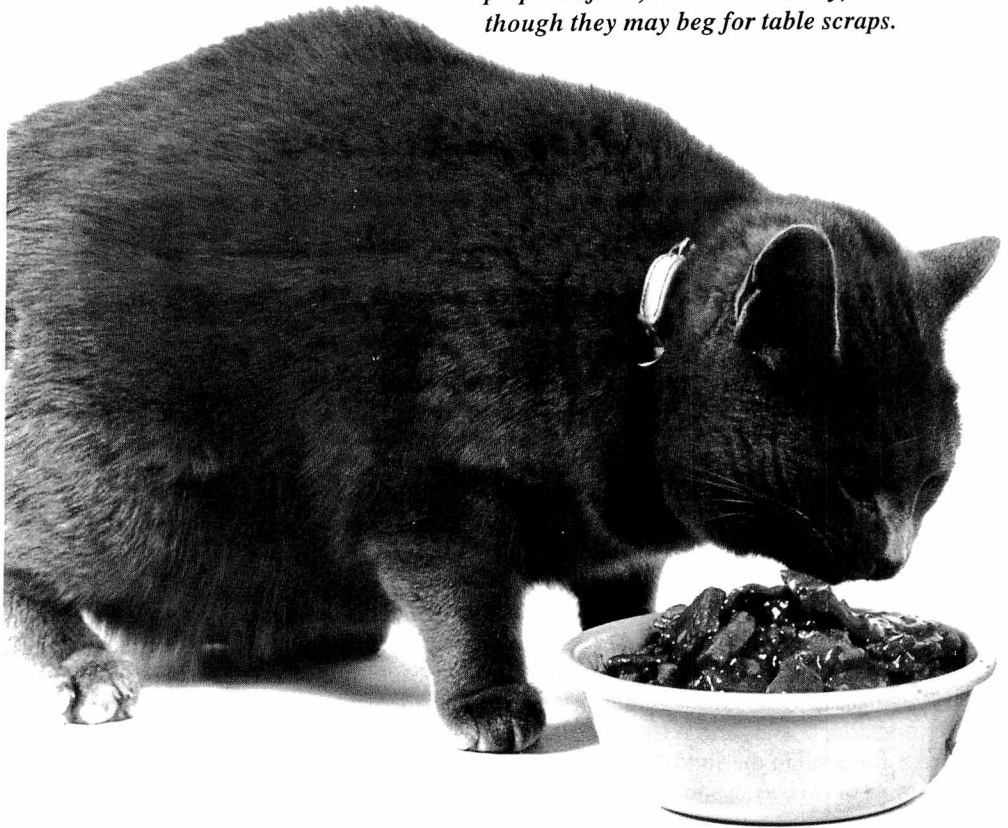
- An **impacted anal gland** is a painful condition in dogs. The glands on either side of the anus, thought to be used when a dog marks its territory, get clogged with the fluid they secrete. A veterinarian can squeeze out the liquid, or, in severe cases, remove the gland surgically.

- **Mange** is an infection that dogs get from mange mites. It causes skin lesions, open sores, and rashes. The treatment is usually an insecticidal ointment or dip.

- **Pano, or eosinophilic panosteitis**, is a painful condition of lameness in a puppy. A genetic condition, it's caused by changes in the long bones as the puppy grows up. Most dogs grow out of it by 2 years of age.

- **Pyoderma** is a skin infection in both dogs and cats that causes papules, erosions and ulcers. It can be treated with antibiotics.

- **Pyometritis** is a bacterial infection in



female dogs and cats that causes the uterus to fill with pus. A life-threatening condition, it is treated in most cases by removing the uterus. Some mild cases can be treated with prostaglandins.

- **Tapeworms** are long, flat worms that live inside a dog or cat's intestines. They can be treated with oral and injected anthelmintic medications.

- **Tick-borne diseases** such as Rocky Mountain Spotted Fever, tick paralysis, and Lyme disease cause a variety of symptoms and are occasionally fatal. The first treatment is to find and remove the tick. After that, antibiotics, intravenous fluids and steroids can treat the diseases.

- **Toxoplasmosis** is a parasitic infection in cats that can be transmitted to humans through feces, as when cleaning the litter box. If the parasite infects a pregnant woman during the first three months of pregnancy, it can cause miscarriage, premature birth, or blindness in the unborn child. Antibiotics can clear up the infection in the cat.

It's not always easy to tell when a pet is sick, since it can't complain. Animals do show symptoms, however. These are common ones to look out for:

- diarrhea for more than one day
- lack of appetite
- repeated vomiting, gagging, sneezing,

or coughing

- lack of grooming behavior
- watery eyes, dull coat, tired appearance.

Also, a change in routine could signal an illness, says Woods. A dog who usually chases 30 tossed balls in the back yard but now only retrieves three or four of them may be suffering from a thorn in the paw or bruised paws.

"If your cat usually climbs up and sleeps on the window sill, but no longer does this," Woods says, "perhaps there is something wrong with her leg."

She Ain't What She Used to Be

With a good diet and regular veterinary care, a family pet may live well into old age. According to Woods, small and medium dogs live 12 years or more, while giant breeds live about nine years. Cats are considered "geriatric" at 18 years old, but some live to be as old as 30.

Elderly pets are usually not as frisky as they used to be. A dog might have trouble retrieving sticks, and a cat might not be able to climb the stairs as easily as it once did.

Elderly pets also spend more time sleeping. Their body functions decline, and they become more susceptible to

Pet Immunizations

According to the American Animal Hospital Association, vaccinations can prevent the following diseases in cats and dogs:

For Dogs

- **Rabies**, a deadly disease for animals and humans, is caused by a virus that spreads through nerve fibers and the spinal cord, eventually attacking the brain. Rabid wild animals such as raccoons, squirrels or skunks can pass the disease to pets through bites. Vaccinations are available for dogs, cats, sheep, cattle, horses, and ferrets (see "Mad Dogs and Friendly Skunks: Controlling Rabies," in the June 1990 *FDA Consumer*).
- **Parvovirus**, a sometimes fatal viral infection, causes sudden loss of appetite, vomiting, and severe diarrhea.
- **Parainfluenza** is a respiratory infection that can be severe in older dogs and puppies. It is one of the causes of canine cough.
- **Coronavirus** is the second leading cause of viral diarrhea in dogs.
- **Infectious hepatitis** in dogs can cause severe liver damage and possibly death.
- **Canine distemper** is a highly contagious, often fatal infection that causes flu-like symptoms, including discharge from both the eyes and the nose, coughing, and even pneumonia.
- **Leptospirosis** is a bacterial infection in dogs that can cause permanent kidney damage or death.
- **Bordetella** is a respiratory infection that is often a factor in canine cough.
- **Lyme disease** is a potentially disabling disease for humans and animals. Spread by tick bites, if caught early it can be treated with antibiotics.

For Cats

- **Rabies**—see above.
- **Feline distemper, or panleukopenia**, is the most widespread disease of cats. It is almost always fatal in kittens, first causing severe diarrhea, vomiting, fever, and lethargy.
- **Rhinotracheitis** is an upper respiratory viral infection that causes fever, eye and nose discharge, coughing, and salivation. It is not usually fatal, but cats can be carriers of it for life.
- **Pneumonitis** infection is like a human cold, with symptoms such as coughing and sneezing. The disease can sometimes be passed to humans, causing pink eye.
- **Leukemia** in cats causes tumors, malignant changes in blood-forming cells, and appetite or weight loss. There is no cure, but it can be prevented by a vaccine. ■

—R.D.W.

disease. They may put on weight since they're not burning up as many calories as they used to. Extra pounds strain an animal's heart, lungs and muscles and lower its resistance to disease. A veterinarian can recommend special diets with high fiber, low fat, and fewer calories for aging pets.

Veterinarians say there are a number of steps that owners can take to make the older pet's life more comfortable.

Protect the older pet's bed from cold drafts. Keep the animal in a steady routine, serving meals at the same time and place. Avoid leaving the pet in a strange place like a kennel, unless it is accustomed to it.

Kidney dysfunction plagues as many as 80 percent of all older dogs. A veterinarian can prescribe a special diet that is low in protein and phosphorus to help the problem.

Hearing and sight may also deteriorate in the aging pet. A pet who doesn't respond to your verbal commands may be going deaf. That also means the pet won't be able to hear oncoming cars, so it's especially important to keep it off the street or driveway.

Most of all, an older pet may need more comforting and affection than before. Eighteen-year-old Camron, for instance, sleeps more and wants more attention in his old age, according to his owner, Klein. He no longer plays outside, but spends most of his days lounging in a sunny spot indoors.

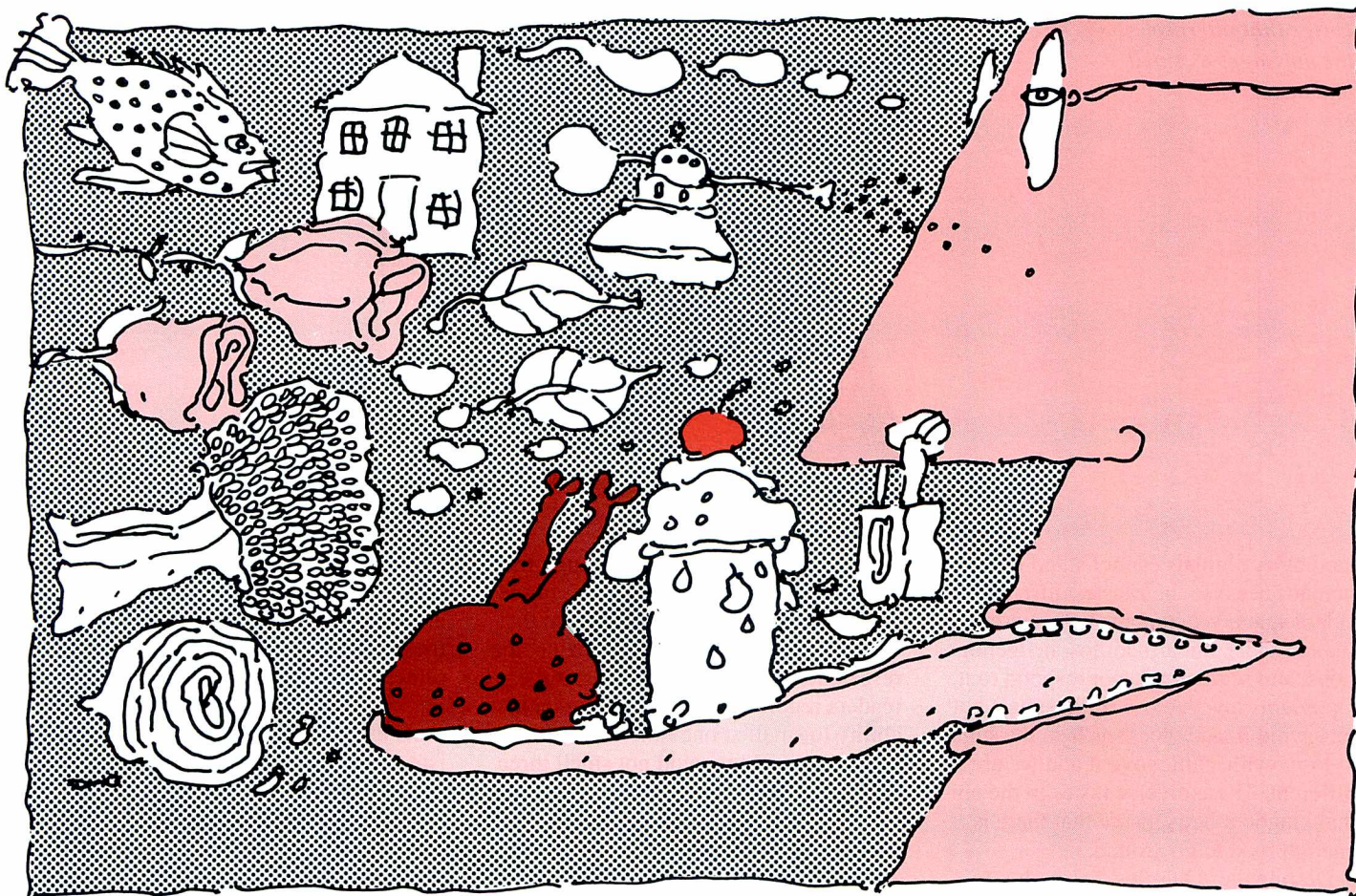
At night, Klein gives him a heating pad for extra warmth. And, on the advice of her veterinarian, she feeds Camron a high-fiber diet sprinkled with a laxative to ease his digestive troubles.

"He's losing his hearing and he's not as quick as he once was," says Klein. But, she adds, "He's still gorgeous." ■

Rebecca D. Williams is a staff writer for FDA Consumer. Judy Folkenberg also contributed to this story.

When Smell and Taste Go Awry

by Ricki Lewis, Ph.D.



Minutes after a sudden April shower, the rich, earthy scent of spring permeates the air. A whiff from a backyard grill evokes cherished images from childhood, and a crisp autumn day has its own aroma.

Imagine a spicy slice of pizza, or freshly brewed coffee, and your mouth waters in anticipation. But for 2 million people in the United States, the senses of smell and taste are dulled, distorted, or gone altogether. Many more of us get some idea of their plight when these senses are temporarily stifled by the sniffles.

Compared to the loss of hearing or

sight, being unable to taste or smell normally may seem more an oddity than an illness. But those with such ailments would probably disagree.

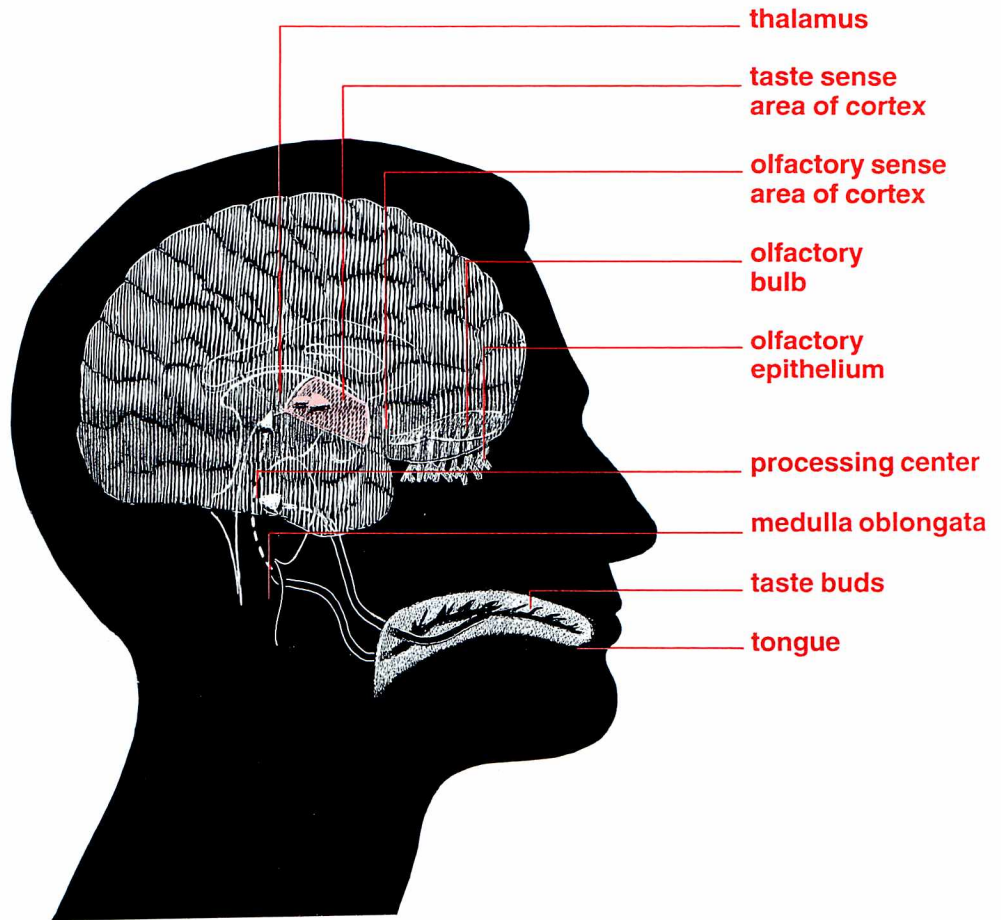
There are several reasons why knowledge about how the "chemical senses" of taste and smell work lags behind what we know about the other senses. One reason is that a problem with taste or smell often is not perceived as a serious medical condition.

"These disorders are not associated with significant morbidity and mortality, and affect fewer than 5 percent of the population, so it is not a major public health concern," says Lucinda Miller, Pharm.D., in the division of family medi-

cine at the Baylor College of Medicine in Houston. She adds that this attitude translates into skimpy research funding. In some situations, however, a poor or lacking sense of smell can be dangerous. Robert Henkin, M.D., Ph.D., of the Taste and Smell Clinic in Washington, D.C., recalls one patient who died in a house fire because he did not smell the smoke in time to escape.

Another hindrance to learning more about smell and taste is that the physical bases of these senses are difficult to study in a laboratory. Taste buds, for example, cannot easily be grown outside of the body, as can visual tissue such as rod and cone cells. And, more often than not,

The senses of smell and taste begin with detection by receptors in the tongue (taste buds) and receptors high in the nose (olfactory epithelium). Nerve impulses generated here travel through the medulla oblongata, processing center, and thalamus to the taste and smell areas of the brain's cortex that interpret the messages as smell and taste.



laboratory animals cannot stand in for humans because their tastes differ. Consider sugars. We humans love sucrose (table sugar), but armadillos, hedgehogs, lions, and sea gulls do not respond to it. Opossums love lactose (milk sugar) but rats avoid it, and chickens hate the sugar xylose, while cattle love it and we are indifferent. These diverse tastes in the animal kingdom help ensure that there is enough food to go around.

Despite these hurdles, research into smell and taste is starting to open up. An exciting recent discovery, by Linda Buck, Ph.D., and Richard Axel, Ph.D., of Columbia University in New York, was that hundreds of genes are responsible for the sense of smell. This explains the capacity of the human nose to detect thousands of distinct odors.

Many non-scientists have also helped explain our sense of smell. In September 1986, 1.5 million readers of *National Geographic* magazine scratched six scented patches in their issues, sniffed them, and sent the results identifying the aromas to biopsychologists Avery N. Gilbert, Ph.D., and Charles Wysocki, Ph.D., of the Monell Chemical Senses Center in Philadelphia. Although the in-

vestigators are still wading through the data, in preliminary results on a sample of 26,200 respondents published in the October 1987 issue of the magazine, the researchers said that two-thirds of the readers report temporarily losing their ability to smell at one time or another, and that 1 percent could not smell three or more of the sample scents.

Biology of the Senses

All senses work in basically the same way. Special nerve cells bearing sense receptors collect information from the environment. When these receptors are stimulated they send a message to the brain, where the cerebral cortex forms a perception, a person's particular view of the stimulus.

The ability to detect the strong scent of a fish market, the antiseptic odor of a hospital, the aroma of a ripe melon—and thousands of other smells—is possible thanks to a yellowish patch of tissue the size of a quarter high up in the nose. This fabric of sensation is actually a layer of 12 million specialized cells. The end of each cell sports 10 to 20 hairlike growths called cilia. Each cilium has a receptor that binds an odorant molecule—a bit of

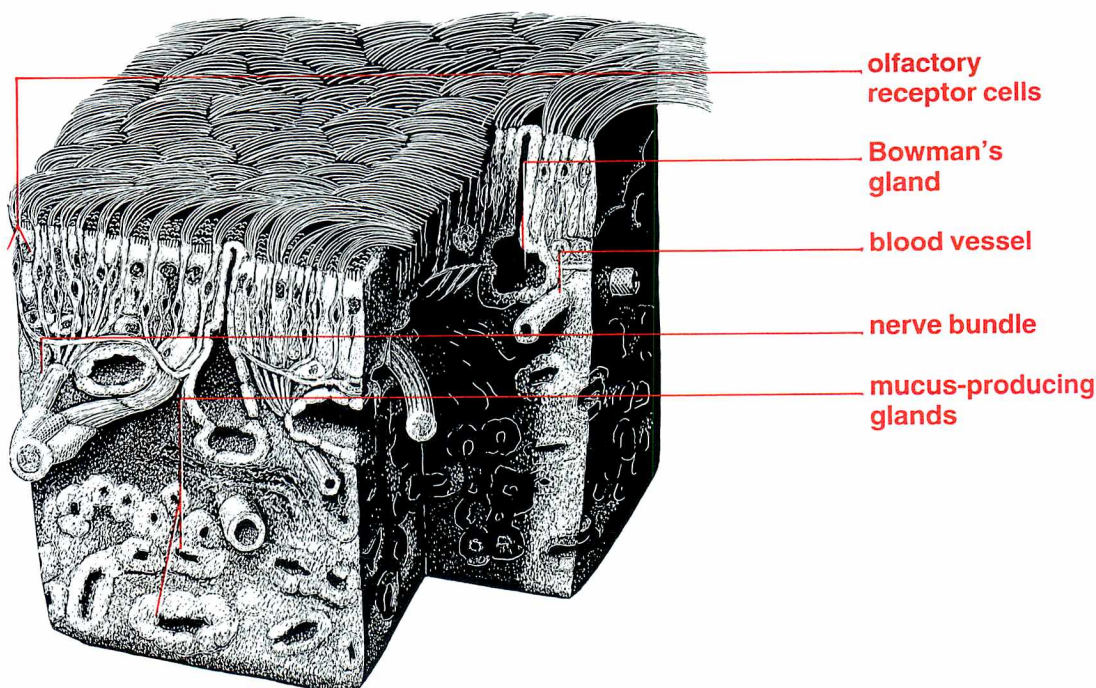
that fish or melon. The binding triggers a nerve impulse, and the message travels along the nerve cell, through a hole in the skull, to a part of the brain called the olfactory bulb. Although scientists do not know exactly how, the brain interprets the pattern receptors send it to register "hospital smell" or "cantaloupe."

The expert nose of the bloodhound is due to its 4 billion olfactory cells. Still, the human sense of smell is nothing to sneeze at—people can detect one molecule of green pepper smell in a gaseous sea of 3 trillion other molecules. Our 12 million smell cells and their many million more receptors allow us to discern some 10,000 scents. But, without air, there is nothing to smell, as astronauts can attest. In the vacuum of space, odorant molecules cannot reach their senses, and eating in space is a rather tasteless—and some would say joyless—experience.

Most of what we call taste is really smell. We usually realize this when a cold hits our nasal passages. Even though the taste buds aren't blocked, the smell cells are, and this dulls much of food's flavor.

"Smell and taste are two distinct

The sense of smell begins in a patch of tissue the size of a quarter, high in the nose, sketched here greatly magnified. In this tissue, the olfactory receptor cells are stimulated by odorant molecules dissolved in the mucus produced by surrounding glands, including the Bowman's gland. The receptor cells collect into bundles beneath the surface, forming the olfactory nerve, which leads to a region in the brain called the olfactory bulb.



neurophysiological systems. The sense of taste is only sweet, sour, salty, and bitter. Other components of flavor are mediated by the olfactory system," says Beverly Cowart, Ph.D., director of the taste and smell clinic at Jefferson University Hospital in Philadelphia. A third sensory system delivers information to the brain about a food's texture, temperature, and chemical irritancy.

Taste comes from 10,000 taste buds, which are clusters of cells resembling the sections of an orange. Taste buds are found on the tongue, cheeks, throat, and the roof of the mouth. Each taste bud houses 60 to 100 receptor cells. These cells bind food molecules dissolved in saliva, and alert the brain to interpret them. Cattle, with 25,000 taste buds, are the bloodhound equivalent in the taste department.

The body regenerates taste buds about every three days. Although the tongue is often depicted as having regions in which taste buds specialize in a particular sensation—the tip tastes sweetness, the front saltiness, the sides sour, and the back bitter—researchers find that taste buds with all specificities are scattered everywhere. In fact, a single taste bud

can have receptors for all four general types of tastes, says Henkin, who carried out much of the work describing the distribution of taste buds on the tongue.

Individual Differences

One person loves liver and onions; another gags at the thought. Of the 68 percent of women who can detect armpit odor (a chemical called androstenone), 72 percent report disliking it; of the 57 percent of men who can smell androstenone, only 50 percent dislike it. What accounts for these individual palates and noses? To some extent, what you taste or smell is in your genes. For example, the ability to smell a squashed skunk or freesia flowers is inherited.

Linda Bartoshuk, Ph.D., of the Yale University School of Medicine in New Haven, Conn., is fascinated by "why different people do not have the same experience when they eat." She and others have recently expanded upon a classical bit of genetic lore. It has been known for many years that 7 in 10 people inherit the ability to taste a bitter chemical called PTC (phenylthiocarbamide). PTC is a harmless chemical not found in food, but impregnated into paper strips for use

in laboratory teaching experiments. Bartoshuk finds that PTC "tasters" can detect many bitter substances that are tasteless to others.

"For example, tasters don't like the taste of saccharin, but non-tasters don't mind it. Potassium chloride [a salt substitute] tastes nasty to tasters, like salt to others. Table sugar, too, is sweeter if you are a PTC taster," she says. Bartoshuk also finds that the protein in milk tastes different to tasters and non-tasters, making cheese, for example, pleasantly tart to some, but bitter to others.

The ability to detect bitter tastes can show up very early in life, when smell and taste are particularly acute (see accompanying article). "We believe the possibility should be checked that some babies who fail to gain weight may be responsive to this bitter taste in milk," Bartoshuk adds.

Treating Disorders

Because there are several steps to smelling and tasting, there are plenty of ways for things to go awry. The direct connection between the outside environment and the brain makes the sense of smell very vulnerable to damage. Smell

A Lifetime of Smell and Taste

We can smell and taste from birth. Regina M. Sullivan, Ph.D., and co-workers at the University of California at Irvine Medical Center in Irvine recently studied day-old infants to determine their ability to connect an odor with a pleasant experience.

Half the group of 66 newborns received citrus odors and simultaneous stroking several times for a day. The other 33 babies experienced the odor alone, stroking alone, or stroking followed by the odor. The next day, all the infants were exposed to the odor five times, for 30-second periods. The only babies who turned toward the odor were those who received the odor during stroking, thereby associating the citrus smell with touch.

Taste buds are most numerous in children under 6, which may explain why youngsters are such picky eaters. Recognizing that children's heightened sense of taste might account for compliance problems in giving antibiotic medication, Michael E. Ruff, M.D., and co-workers in the departments of pediatrics and pharmacy at Tripler Army Medical Center in Honolulu asked 30 adults to rank the pleasantness of the taste of the active ingredients in the 14 most often prescribed pediatric antibiotic suspensions. If parents, with their diminished sense of taste compared to their offspring, find a particular antibiotic distasteful, then perhaps drug manufacturers can be alerted to those products that need work in the palatability department—a major task when a medicine must contain a naturally bad-tasting substance. In this taste test, cephalosporins tasted best, and penicillins the worst.

Taste and smell hold up remarkably well with age, probably because the body frequently replaces receptor-bearing cells, even in the elderly. Monell researchers concluded from the National Geographic Smell Survey that "detection ability remains near youthful levels well into the seventh decade," but they found that ability to detect the intensity of odors and to describe odors wanes with time. These deficits may reflect changes in thought processing, such as taste and smell recognition, rather than in the sense organs, suggests Richard Mattes, Ph.D., of Monell.

One disturbing finding is that older people are less likely to find the smell of chemicals called mercaptans offensive than are younger people. Mercaptans are added to odorless natural gas to serve as a warning if gas is escaping from an oven, for example.

Disease and drugs can affect smell and taste and may also account for the lessened acuity of these senses in older people, according to James Weiffenbach, Ph.D., sensory psychologist at the National Institute of Dental Research in Bethesda. "Among the participants in the Baltimore Longitudinal Study of Aging of the National Institute of Aging, we found that whether you are healthy or not is a more powerful determinant of taste complaints than whether you are younger or older. So maybe older people report more taste complaints because they are more likely to have medical problems," he says.

Weiffenbach also mentions a telling "overlooked point": that of senior citizens living in retirement centers where the food really isn't as tasty as the home-cooked cuisine they may have been used to. "They know the food doesn't taste as good as it did 10 years ago, because it really doesn't," he says.

■

—R.L.

and taste disorders can be triggered by colds and flu, allergies, nasal polyps (swollen mucus membrane inside the nose), a head injury, chemical exposure, a nutritional or metabolic problem, or a drug or disease. In many cases, a cause cannot be identified.

Taste or smell, or both, can be absent, diminished, heightened, or distorted (see chart of terms). Interestingly, Richard Mattes, Ph.D., and co-workers at Monell find that while those with taste or smell loss eat to compensate and gain weight, those with distorted smell or taste find eating so disturbing that they lose weight.

It is difficult to imagine how greatly enjoyment of life can be affected by a loss in the senses of smell and taste. Judith Birnberg, of Long Island, N.Y., wrote about her plight in the March 21, 1988, "My Turn" column in *Newsweek* magazine. Birnberg spent a year sneezing inexplicably, and was suddenly left with the ability to sense only the texture and temperature of food. She was unable to smell or taste. For years, Birnberg lived on her memories of smelling piping hot coffee and peeled oranges. Her condition, attributed to "allergy and infection," mysteriously comes and goes. When taste and smell are intact, she rushes off to the nearest restaurant—but more often than not, her sensory acuity fades before the food arrives.

Birnberg had blood and urine tests galore, CAT scans, and biopsies, had her sinuses drained, and took zinc supplements. Nothing worked. Finally, she found relief with prednisone. This strong steroid drug reduces swelling of the mucous membranes in the nose, and may therefore improve the sense of smell, but its efficacy as a treatment for smell disorders has not been proven.

Feeling better, Birnberg went about smelling everything. "I inhaled all odors, good and bad, as if drunk," she wrote. Prednisone, though, suppresses the immune system, so she can only take it intermittently.

Distorted Sensation

A group of 12 travelers touring Peru and Bolivia prepared for a day of hiking in the Andes mountains. A day before, three of them had begun taking aceta-

Types of Smell and Taste Disorders

These are the terms that doctors are likely to use when discussing taste and smell disorders:

	Smell	Taste
loss of sensation	anosmia	ageusia
diminished sensation	hyposmia	hypogeusia
heightened sensation	hyperosmia	hypergeusia
distorted sensation	dysosmia	dysgeusia

zolamide (Diamox), a drug that prevents acute mountain sickness, which each had previously suffered. The headache, nausea, weakness, and shortness of breath of acute mountain sickness typically begins when one reaches 5,900 feet elevation, and can progress to severe respiratory problems by 9,000 feet. These hikers planned an expedition to 12,000 feet. All went well, but the night after the climb, the group went out for beer. To three of the people, the brew tasted unbearably bitter, and a drink of cola to wash away the taste was equally offensive. At fault: acetazolamide.

The taste distortion caused by this particular drug makes biochemical sense. The drug inhibits an enzyme that normally dismantles bitter-tasting carbonic acid before it has a chance to register on the taste buds.

"The drug stirs up anything with carbonation, enabling the person to taste the terribly bitter taste of carbonic acid," says Baylor College of Medicine's Miller. She has studied the drug's temporary effects on taste and believes the problem is more widespread than drug manufacturers realize. "People are scared, because it is a strange taste. Some people may not report it, and may not make the connection to the drug. They blame it on altitude sickness," she adds.

Acetazolamide isn't the only drug to

alter the chemical senses. "Drugs can alter taste and smell in many potential ways, affecting cell turnover, the neural conduction system, the status of receptors, and changes in nutritional status," says Monell's Mattes.

Drugs containing sulfur atoms are notorious for squelching taste. They include the anti-inflammatory drug penicillamine, the anti-hypertensive captopril (Capoten), and transdermal (patch) nitroglycerin to treat chest pain. The antibiotics tetracycline and metronidazole (Flagyl) cause a metallic taste.

Cancer chemotherapy and radiation treatment often alter taste and smell, but this is rarely reason to change therapy. "A taste and smell problem is probably not life-threatening, and treating something like cancer is the first priority," Mattes says.

Exposure to toxic chemicals can affect taste and smell, too. A 45-year-old woman from Altoona, Pa., suddenly found that once-pleasant smells had become offensive. Her doctor, Joseph Silverman, M.D., traced her problem to inhaling a paint stripper. Hydrocarbon solvents in the product—toluene, methanol, and methylene chloride—were the culprits responsible for her "cacosmia," the association of an odor of decay with normally inoffensive stimuli. She said she was helped by an antidepressant medication. However, since this type of drug is

not approved for treating such disorders, this was an experimental use of the drug.

Taste distortions can be very upsetting. "It's easier for people to understand losing a sense than to suddenly have everything twisted. Since smell mediates a lot of food's flavor, when you don't smell at all, food tastes bland. You can perk it up by adding salt, sugar, lemon juice or spices. But for dysosmics, food is actively unpleasant," says Cowart.

Sometimes a foul taste can persist with no food involved. This is a "taste phantom," a sensation that comes out of nowhere, says Bartoshuk. The condition is fairly common among women past menopause. At Yale, Bartoshuk helps pinpoint the source of phantom tastes. "Is it caused by a molecule in the mouth that shouldn't be there, or is brain stimulation abnormal? We can tell the difference by using anesthesia, which is a nerve inhibitor," she says.

If she anesthetizes the mouth and the bad taste goes away, then it's due to molecules there. If, following anesthesia, the patient gets worse, this points to the brain as the cause of the problem.

There are a number of special centers where people with absent or distorted senses of smell and taste can seek help. These include: Monell, facilities at Yale University, the State University of New York Health Science Center in Syracuse, the Hospital of the University of Pennsylvania in Philadelphia, Georgetown University in Washington, D.C., the University of Colorado in Denver, and the University of Connecticut Health Center at Farmington.

With researchers' increasing understanding of the complex interplays between the environment and our nervous systems that provide the nonessential but intensely enjoyable senses of smell and taste, it's likely that more and more sufferers of deficits in these systems will be identified and helped. Those of us with healthy senses can appreciate the complex neural connections that enable us to fully experience that April rain, July barbecue, and October's fragrant fallen leaves, and the myriad taste combinations that make dining so pleasurable. ■

Ricki Lewis, a writer in Scotia, N.Y., has a Ph.D. in genetics and is the author of a college biology text.



Using Over-the-Counter Medications Wisely

by Judith Levine Willis

This article is part of a series with important health information for teenagers.

Pharmacy shelves are filled with medicines you can buy without a prescription. But teens should be aware that just because a drug is available over the counter (often abbreviated OTC), that doesn't mean it's always free of side effects.

On the contrary, you need to take OTC drugs with much the same caution as drugs prescribed by your doctor. Special care is necessary if you use more than one of these products at the same time, or if you take an OTC product while also being treated with a prescription product. And there are some OTC drugs that shouldn't be taken by people with certain medical problems. If possible, you should ask your parent, pharmacist or physician for advice before taking any OTC product you haven't used before.

Besides getting expert advice, the most important thing you can do before buying an OTC drug is to read the label. The name of the product isn't always the same as the name of the drug it contains, and some products contain more than one ingredient. (See illustration.)

Aspirin and Other Fever Reducers

Reading the label becomes especially important for teens when it comes to products containing aspirin (acetylsalicylic acid) or their chemical cousins, other salicylates,

**ACTIVE INGREDIENTS: EACH 5 mL
(ONE TEASPOONFUL) CONTAINS:**

Guaifenesin, USP	100 mg
Dextromethorphan Hydrobromide, USP	10 mg
Phenylpropanolamine Hydrochloride, USP	12.5 mg

in a palatable aromatic syrup with alcohol 4.75%.

DIRECTIONS:

Adults and children 12 years of age and over: 2 teaspoonfuls every 4 hours not to exceed 12 teaspoonfuls in 24 hours, or as directed by a doctor.

Children 6 to under 12 years of age: 1 teaspoonful every 4 hours not to exceed 6 teaspoonfuls in 24 hours, or as directed by a doctor.

Children 2 to under 6 years of age: 1/2 teaspoonful every 4 hours not to exceed 3 teaspoonfuls in 24 hours, or as directed by a doctor.

Children under 2 years of age: consult a doctor.

It's very important to read the label of every OTC medicine. For example, the cough formula on the left and cold medicine on the right both contain phenylpropanolamine. A person taking both products at the same time might get too much of this ingredient, which is also in some OTC diet pills. The cold medicine also contains aspirin in the form of acetylsalicylic acid and should not be taken by children and teenagers with symptoms of flu or chickenpox because of the risk of Reye syndrome.

which are used to reduce fever or treat headaches and other pain. Teenagers (as well as children) should *not* take products containing aspirin or salicylates when they have chickenpox, flu, or symptoms that might be the flu (this includes most colds). Children and teenagers who take aspirin and other salicylates during these illnesses may develop a rare but life-threatening condition called Reye syndrome. (Symptoms usually occur near the end of the original illness and include severe tiredness, violent headache, disorientation, belligerence, and excessive vomiting.)

Acetaminophen (sold under brand names such as Datril and Tylenol) can also reduce fever and relieve pain and has not been associated with Reye syndrome. Remember, though, because fevers in most colds don't normally go above 100 degrees Fahrenheit and don't cause much discomfort, you usually don't have to take any drug for the fever. If you think you have a cold but your temperature is running higher, consult your doctor because you might have flu or a bacterial infection.

Sniffle and Cough Combinations

OTC drugs to relieve stuffy noses often contain more than one ingredient. Some of these products are marketed for allergy relief and others for colds. They usually contain both an antihistamine

and a nasal decongestant. The decongestant ingredient unstuffs nasal passages; antihistamines dry up a runny nose. But some of these products may also contain aspirin or acetaminophen, and some contain a decongestant alone. Some of these drugs are "extended-release" or "long-acting" preparations that continue to work for up to 12 hours. Others are immediate-release products and usually work for four to six hours. Again, it's important to read the label—and check with the pharmacist—to be sure you're getting the right product for your symptoms.

Most antihistamines can cause drowsiness, while many decongestants have the opposite effect. Still, it's hard to predict whether any one product will make you sleepy or keep you awake—or neither—because reactions to drugs can vary from one person to another. So it's best not to drive or operate machinery until you find out how the drug affects you. In addition, alcohol, sedatives and tranquilizers intensify the drowsiness effect of antihistamines, so it's best not to take them at the same time unless a doctor tells you to. Some brand names of products containing both antihistamines and decongestants are Allerest, Actifed and Dimetapp.

Brand names of products that contain only antihistamines include Dimetane, Chlor-Trimeton and Benadryl. (But you should be aware that closely related

products with similar names may have other ingredients. For example, Dimetane Decongestant contains an antihistamine and a decongestant, and Chlor-Trimeton Decongestant and Benadryl Plus contain both a decongestant and acetaminophen.)

If you decide you want to try to unstuff your nose without pills, there are other medications in the form of nasal drops and sprays sold OTC for this purpose. As with pills, some of these are long acting (up to 12 hours) and some are shorter acting. And, as with pills, most have some side effects. Many of the products contain a nasal decongestant such as oxymetazoline or phenylephrine. When used for more than three days or more often than directed by the label, these drops or sprays can sometimes cause a "rebound" effect, in which the nose gets more stuffy. Other nose drops and sprays are formulated with a saline (salt) solution and can be used for dry nose or to relieve clogged nasal passages.

As you can see, selecting a product to treat a stuffy nose can be tricky. So can choosing a product to treat a cough. In addition to one or more ingredients specifically for coughs, many cold or cough syrups contain the same ingredients that are in pills to treat allergies and colds. This means that if you're taking acetaminophen pills or cold pills, you'll want to read the label or consult the pharmacist to make sure that you're not getting a double dose of the ingredients by taking a cold or cough syrup.

There are several different types of ingredients to treat coughs, depending on the kind of cough you have. Some ingredients make it easier for you to bring up phlegm, while others suppress the cough. Before taking any kind of cough medicine, it's a good idea to first try drinking plenty of liquids and adding moisture to the air by using a vaporizer or boiling water. Sometimes just doing these things will reduce the cough enough that you won't have to take any medicine. If a cough lasts more than a few days, see your doctor.

Diet Pills

FDA recently banned 111 ingredients in OTC weight control products because they had not been proven effective. Among the substances were alcohol, ascorbic acid (vitamin C), caffeine, several forms of sugar, guar gum, phenacetin (a pain reliever), sodium, and yeast.

Two other ingredients in OTC diet

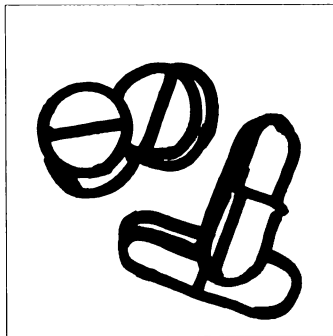
Products Containing Salicylates

The following products don't have aspirin in their brand names but they contain aspirin or other salicylates and shouldn't be taken by teens who have symptoms of flu or chickenpox unless told to do so by a doctor. (Ingestion of salicylates during these illnesses increases children's and teens' risk of Reye syndrome.)

- Alka-Seltzer Effervescent Antacid and Pain Reliever (also the extra-strength version)
- Alka-Seltzer Plus Night-Time Cold Medicine
- Anacin Maximum Strength Analgesic Coated Tablets
- Ascriptin A/D Caplets (also the regular and extra-strength versions)
- BC Powder
- BC Cold Powder Multi-Symptom Formula
- BC Cold Powder Non-Drowsy Formula
- Bayer Children's Cold Tablets
- Bufferin (all formulations)
- Excedrin Extra-Strength Analgesic Tablets and Caplets
- Pepto-Bismol
- Ursinus Inlay-Tabs
- Vanquish Analgesic Caplets

In addition, many products to treat arthritis contain aspirin.

(This list contains many common products, but isn't all-inclusive. So be sure to read the label before purchasing any OTC medication.) ■



products, benzocaine and phenylpropanolamine (PPA), are still being reviewed by FDA. PPA can increase blood pressure if taken at too high a dose. In fact, some experts think these products may cause problems for some people at the recommended doses.

Some cold and allergy medicines (both in pills and syrups) also contain PPA. Unless you read the ingredient labeling carefully when you're taking both cold and diet products, you may not realize that you're getting more PPA than is safe.

Most teens are better off avoiding OTC diet pills unless told to take them by a doctor. Researchers have found that getting more exercise is a better way to lose weight over the long run than using pills.

Stomach Help

When your stomach gets upset, it's understandable that you want the quickest relief possible. But unless the problem continues for several days or is severe, drugs are usually not necessary.

If you're constipated, drinking more

water, getting more exercise, and eating high-fiber foods, such as fruits and vegetables, will often solve the problem.

Though appropriate for some medical conditions, laxatives can be habit forming and can make constipation worse when overused. Not having a bowel movement every day does not necessarily mean that you're constipated—for some people it's normal.

If you have diarrhea, it's a good idea to rest, eat only small amounts of food at a time, and drink plenty of fluids to prevent dehydration. OTC products marketed to stop diarrhea may contain loperamide (Imodium A-D), or attapulgite (Diasorb, Kaopectate and others), or bismuth subsalicylate (Pepto-Bismol and others). Bismuth subsalicylate is presently being reviewed by FDA, as part of an ongoing evaluation of OTC drugs, to determine its effectiveness against diarrhea. Teens should avoid products with bismuth subsalicylate if they have flu or chickenpox symptoms because of the risk of Reye syndrome mentioned earlier.

If you're running a fever above 100 F,

or if your upset stomach symptoms are severe or continue for more than a day or two, consult your doctor, who may recommend one of the many OTC products available for these problems.

Rash Action

Because rashes can be caused by so many different things—including allergies, funguses, and poison oak or ivy—it's often best to get a doctor's opinion about what's causing your rash before treating it.

There are topical OTC products that you apply directly to the skin available specifically to treat poison ivy and oak. Some of these products contain calamine, which protects the skin, and benzocaine, which dulls the pain or itching. Other products contain an antihistamine or hydrocortisone, which relieve itching. Antihistamine creams, such as Benadryl, and hydrocortisone products, such as Cortaid and Caldecort, can also be used for rashes from allergies and insect bites, but you shouldn't use them for more than seven days without seeing a doctor.

Another type of skin problem, pimples or acne, can also be treated with topical OTC products. Many of these lotions (such as Clearasil products and Oxy-5 and -10) contain benzoyl peroxide in strengths of 2.5, 5, or 10 percent. It's best to try the lower dosage level first, to keep your skin from getting too dry.

FDA is currently taking another look at the safety data for benzoyl peroxide as part of its ongoing review of OTC drugs.

Other products (including some Clearasil and Oxy products) contain sulfur, sulfur combined with resorcinol, or salicylic acid. (There is no known association between Reye syndrome and the use of topical acne products containing salicylates.) If your face doesn't clear up while using these products, or if your skin gets overly dry or breaks out in a rash, contact your doctor.

Expert Advice

These are just a few of the types of products available over the counter. Their number and uses can be confusing to adults and teens alike. Before buying any product you haven't already used, it's best to read the labeling and, if possible, ask the pharmacist how the product works and what it should be used for. And, if still in doubt, check with your doctor. ■

Judith Levine Willis is editor of FDA Consumer.



PANTOTHENIC ACID
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U.S. Recommended Daily Allowances

Infants (0–12 mo.)	Children (1–3 years)	Adults and Children 4 Years +	Pregnant or Nursing Women
3 milligrams	5 mg	10 mg	10 mg

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

This article is the 13th and last in a series giving essential facts and figures on different vitamins.

Pantothenic acid is a B-complex vitamin.

Functions: Involved in release of energy from carbohydrates, metabolism of fats, and synthesis of steroid hormones and other vital substances.

Sources: Milk; beef, pork and poultry; legumes; some fruits and vegetables, including strawberries, dried fruit, avocados,

mushrooms, potatoes, and succotash; whole-grain cereal products.

Deficiency: Pantothenic acid deficiency has not been recognized in humans, and it is unlikely to occur in the U.S. population.

Excess: No effects have been reported. ■

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



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

■ **A children's immunization hot line**, part of the National Immunization Campaign sponsored by Children's Action Network and the American Academy of Pediatrics, offers free information on children's immunization needs. Call toll-free: (1-800) 525-6789.

■ **The pros and cons of the Canadian Health Care System** are discussed in a report by the General Accounting Office titled "Canadian Health Insurance, Lessons for the United States." For up to five free copies, write the GAO, P.O. Box 6015, Gaithersburg, Md. 20877, or call (202) 275-6241 and ask for report number HRD-91-90.

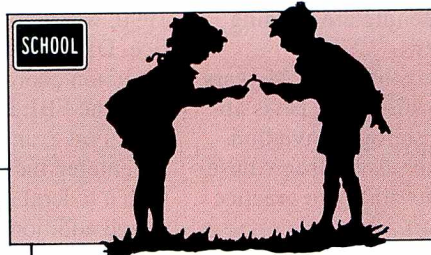
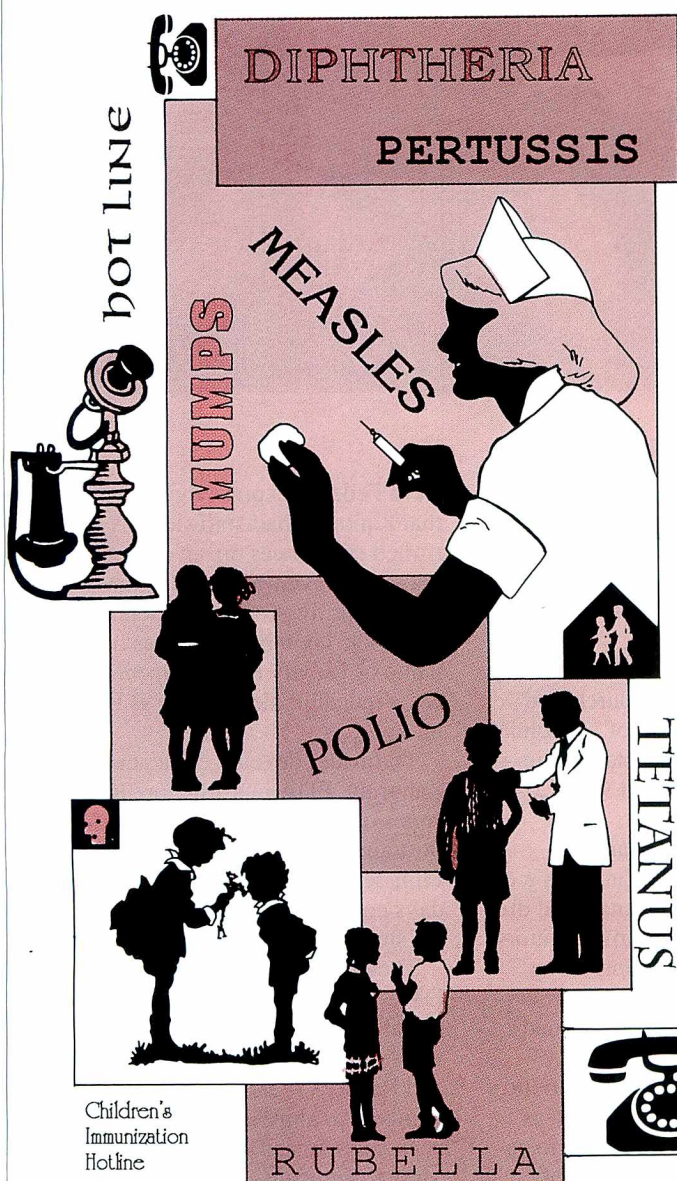
■ **Baby bottle tooth decay** is the focus of a prevention program sponsored by the Dental Disease Prevention Activity at the national Centers for Disease Control. Call (404) 639-1833 for information on how to begin a program in your community.

■ **Financially strained trauma centers** are examined in a General Accounting Office report titled "Trauma Care, Lifesaving System Threatened by Unreimbursed Costs and Other Factors." For up to five free copies, write the GAO, P.O. Box 6015, Gaithersburg, Md. 20877, or call (202) 275-6241. Ask for report number HRD 91-57.

■ **"Residues in Foods 1990,"** a report summarizing pesticide levels in foods, is now available as a reprint from FDA. For a free copy, contact Norma J. Yess, FDA, Division of Contaminants Chemistry, HFF-420, 200 C St., S.W., Washington, D.C. 20204.

■ **Radon research projects** funded by the U.S. Department of Energy are summarized in a 294-page book available to the public. Titled *Radon Research Program, FY-1990*, the publication costs \$31 and is available by writing to the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Va. 22161, or by calling 1-800 553-NTIS. Ask for reference number DE-91009356.

■ **A list of photosensitizing drugs**, called "Medications that Increase Sensitivity to Light: A 1990 Listing," is available free from FDA, Center for Devices and Radiological Health, HFZ-114, 5600 Fishers Lane, Rockville, Md. 20857. Ask for HHS Publication FDA 91-8280.





Physician Convicted in Steroid Distribution

by Dori Stehlin

In the first conviction of a physician for steroid trafficking under the Anti-Drug Abuse Act of 1988, a federal jury recently found a Harrisburg, Pa., urologist guilty of 11 felony counts of illegally distributing anabolic steroids and controlled substances.

Anabolic steroids are synthetic derivatives of testosterone, a male sex hormone. They are approved for limited use in treating some debilitating diseases. Steroids are being misused, however, by athletes and body builders who hope to develop stronger, more muscular bodies. The Anti-Drug Abuse Act prohibits distributing anabolic steroids for any use other than the treatment of a disease in accordance with a physician's orders.

Last June, in the U.S. District Court for the Middle District of Pennsylvania, a jury convicted George T. Zahorian III of four counts of distributing anabolic steroids to a weight-lifting coach who was working as an undercover government informant, three counts of distributing large quantities of Schedule III and IV controlled substances (drugs of abuse subject to FDA and Drug Enforcement Administration regulations) to the same informant, and four counts of distributing anabolic steroids to four professional wrestlers.

The jury also found Zahorian's multi-million-dollar office-condominium subject to forfeiture to the United States. The terms of the forfeiture are pending further judicial review.

Zahorian faces a maximum of 44 years in prison and a \$3 million fine. He is appealing the anabolic steroid conviction on the grounds that the Anti-Drug Abuse Act interferes with his ability to practice medicine as he sees fit.

Law enforcement officials first learned of Zahorian's activities from a weight-lifting coach in Virginia. Virginia state police had arrested the coach in August 1987 for falsifying codeine prescriptions,

and, as part of an informal arrangement with Virginia authorities, he agreed to work as an undercover informant for the Dauphin County (Pa.) Drug Task Force. (Zahorian's medical office is located in Dauphin County.)

Four times between October 1989 and March 1990 the informant purchased thousands of dollars worth of anabolic steroids and controlled substances, including Valium and Tylenol with Codeine, from Zahorian.

After the final buy, on March 27, 1990, which took place at Zahorian's office, Dennis Degan, FDA's national drug diversion coordinator, and investigators from the FBI, Dauphin County Drug Task Force, and Postal Inspection Service entered the doctor's office, armed with a federal search warrant. They seized additional quantities of anabolic steroids and controlled substances, as well as records and other documents relating to the doctor's distribution of drugs.

Included among the seized records

were Federal Express receipts indicating that Zahorian had sold steroids and controlled substances on several occasions between November 1988 and March 1990 to professional wrestlers, including Roderick Toombs, who goes by the stage name of Rowdy Roddy Piper, and Richard Vigneault, also known as Rick Martel.

To further develop evidence against Zahorian, FDA investigators Karles Jones of FDA's Wilmington resident post and Michael Rashti of the agency's Philadelphia district office spent eight days combing the doctor's patient files for steroid prescriptions.

They turned over their findings to Dave Kaszubski, FDA's assistant national drug diversion coordinator. Kaszubski tallied up the results of Jones' and Rashti's search and compared those numbers to shipping records that had been subpoenaed from drug wholesalers Moore Medical Corp., New Britain, Conn., and Shery-Wolins Co., Long Island, N.Y. He found that although



Zahorian had purchased 49,700 tablets and 8,800 intravenous doses during the two years covered in the indictment, he wrote prescriptions that added up to only 700 tablets and 532 doses.

At the four-day trial, which began on June 24, Piper, Martel, and three other professional wrestlers, Brian Blair, Daniel Spivey, and Billy Graham, all testified that they had purchased steroids

and controlled drugs from Zahorian.

While Zahorian admitted that the wrestlers were telling the truth, his attorney argued that the doctor was simply treating patients who wanted a competitive edge. In the case of the informant, Zahorian's attorney argued that the informant intimidated Zahorian into selling him steroids. The informant denied the allegation.

The wrestlers were not charged because during the time covered in Zahorian's conviction, using steroids was not a federal crime. A recent change in the law makes possession and use a federal crime with penalties of up to one year in prison and a \$100,000 fine.

Dori Stehlin is a staff writer for FDA Consumer.

Firm Fined in Illegal Animal Drug Sales Scheme

A New Jersey corporation and one of its former managers will pay close to half a million dollars in fines for importing and distributing unapproved animal drugs.

The fines are the culmination of four years of detective work by agents of the National Animal Drug Investigation Team, a special unit of the Food and Drug Administration that hunts down smugglers, distributors and users of illegal animal drugs.

The team's efforts have thus far led to the conviction of 36 individuals and six corporations.

Helm New York Chemical Corporation, located in Piscataway, N.J., was fined \$400,000 after pleading guilty last June to one count of conspiring to violate the federal Food, Drug, and Cosmetic Act and Customs law, and one count of violating the Food, Drug, and Cosmetic Act.

Three of the firm's former managers, George Peter Filipiak, Jerry Silberman, and Lars Peitersen, have also pleaded guilty to federal offenses involving the illegal distribution of animal drugs. On July 12, Filipiak was fined \$50,000, given a two-year suspended sentence, and placed on three years' probation. On Sept. 6, Silberman was fined \$10,000, given a three-year suspended sentence, and placed on three years' probation.

The sentences were handed down in the U.S. District Court for the District of New Jersey by Judge Alfred Wolin (who sentenced Helm New York and Silberman) and Judge Maryanne Trump Barry (who sentenced Filipiak).

Peitersen is awaiting sentencing.

Helm New York, a subsidiary of Helm AG in Germany, is an international broker of drugs and chemicals. The New York firm imports large quantities of raw animal drugs, such as antibiotics, and then sells them to animal drug manufacturers. The manufacturers use the raw drugs to formulate animal drugs in various forms, such as injectables, tablets, and medicated feeds, which they sell to farmers or distributors of veterinary products.

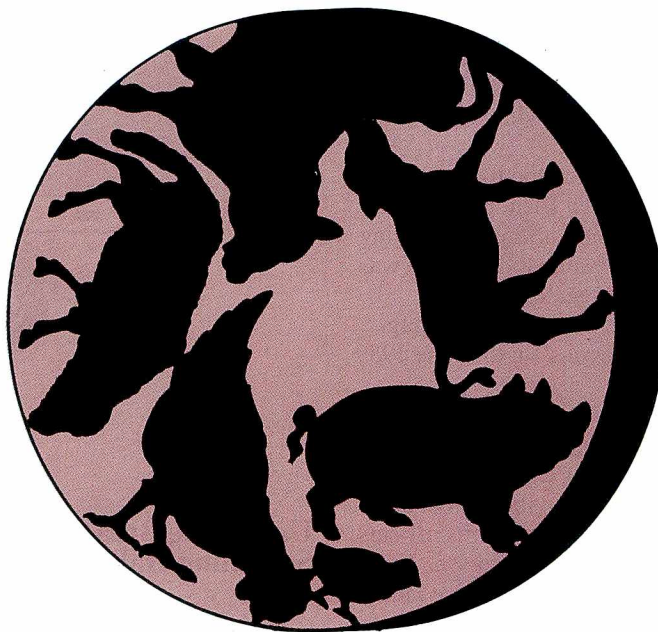
Before a drug manufacturer can process raw animal drugs, it must first provide FDA results of controlled studies that the agency reviews to determine if the finished product is safe and effective. Further, the manufacturer must demonstrate that it has adequate facilities in

which to produce the drug. Firms that can produce such data are given FDA approval to process certain raw animal drugs. Companies that do not meet FDA's standards are not allowed to purchase and handle raw animal drugs, and therefore drugs processed in these facilities are considered illegal.

FDA is placing considerable emphasis on stopping the trade in illegal animal drugs. These products may not only be ineffective, but dangerous. Animal drugs that are not manufactured according to FDA standards may leave toxic residues in the meat of animals, as well as milk or eggs.

The animals that receive these drugs may develop abscesses, go into shock, or die.

FDA became aware of Helm New



York's illegal activities in 1986 when an employee of Custom Feed Blenders of Fort Dodge, Iowa, alerted the agency that unapproved raw animal drugs were being handled at the facility. (Custom Feed Blenders did not have FDA approval to handle the raw animal drugs.)

In January of that year, FDA agents raided Custom Feed Blenders and seized a quantity of unapproved raw animal drugs. A significant amount of the drugs had been supplied by Helm New York, the agents discovered.

(In 1989 Jeff Engel, the former manager of Custom Feed Blenders, pleaded guilty to three felony offenses involving the distribution of animal drugs. He was fined \$10,000 and sentenced to six months in prison. See "Snaring Smugglers of Animal Drugs" in the June 1989 *FDA Consumer*.)

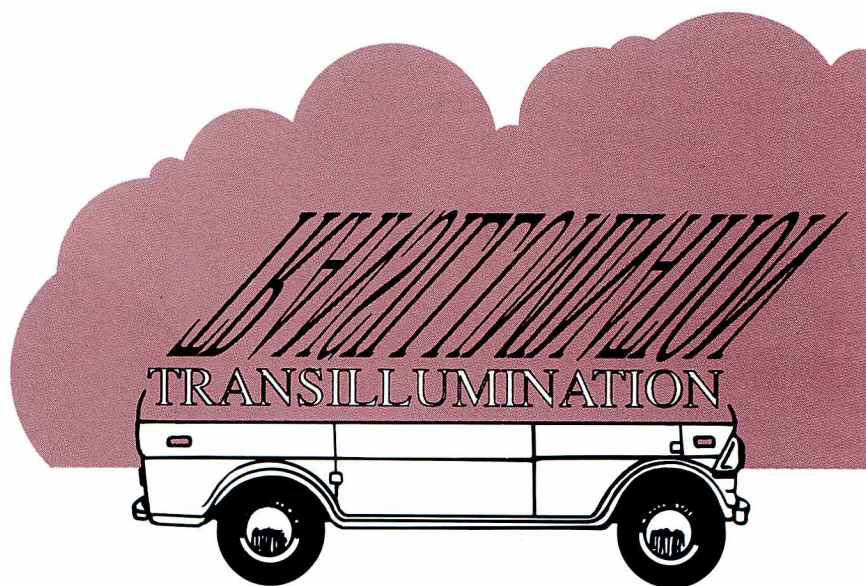
Following the raid on Engel's facility, FDA's Animal Drug Investigation Team, located in the Kansas City District Office, began focusing on the activities of Helm New York and three of its officers: Silberman, Filipiak and Peitersen. The team's investigation revealed that Helm New York imported raw animal drugs into the United States under the pretense of selling them to firms that had FDA approval to handle such drugs. Helm would then ship the drugs to Custom Feed Blenders instead.

Investigators also found that the firm imported drugs into Canada. Engel would then arrange to have the drugs smuggled into the United States.

In December 1990, Helm New York and Silberman were indicted by a federal grand jury for the Northern District of Iowa, in Cedar Rapids. Their cases, as well as Filipiak's, were later transferred to New Jersey at the defendants' request.

Peitersen's case is being handled in the U.S. District Court for the Northern District of Iowa, in Cedar Rapids.

The Justice Department's Office of Consumer Litigation is coordinating the prosecutions.



Unreliable Breast Cancer Screening Halted

A Markesan, Wisconsin-based company that used an unapproved method of breast cancer screening, called transillumination, was shut down for public health violations and its equipment seized by U.S. marshals.

In the spring of 1990, Mobile Clinics of Tomorrow Inc. advertised its transillumination services in the local newspapers. An advertisement in *The Portage Daily Register* promoted the procedure in large block letters as "mammography screening," describing it as a "non x-ray, painless, and rapid breast screening technique" priced at \$55. Company representatives then traveled by van to small communities in south-central Wisconsin, offering the transillumination screening.

Transillumination involves shining light in the red and near-infrared spectrum through the breast to illuminate its interior structure. The image of the

breast tissue produced can be examined on film or video monitor.

FDA's Obstetrics and Gynecology Devices Advisory Panel recently concluded, however, that transillumination is not an accurate or effective means of breast examination, alone or together with other techniques, for the following reasons:

- Transillumination is not accurate enough to serve as a reliable breast screening method.
- The technique cannot detect tumors smaller than 1 centimeter in diameter. Even larger tumors are more difficult to detect if they are near the chest wall or in women who have dense breast tissue.
- The method cannot distinguish whether increased vascularity (blood vessels) indicates possible cancer, is usual for certain areas of normal breast structure, or is related to benign breast conditions or internal bleeding that occurs after recent biopsy.
- Transillumination is also an extremely complex process requiring considerable

expertise that is not always readily available.

In June 1990, local public health officials in Wisconsin reported Mobile Clinics to the Radiation Protection Section, Division of Health (DOH), Wisconsin Department of Health and Human Services. DOH began an investigation and located the van parked in a shopping center in Portage. Upon questioning, the staff (an x-ray technician and a nurse) provided documentation on the transillumination process and equipment published by the equipment manufacturer, Lintronics International, based in Plantation, Fla.

DOH consulted with the National Cancer Institute, national Centers for Disease Control, and FDA. NCI and CDC both stressed the ineffectiveness of the transillumination process, and FDA said that the device could not be legally marketed as comparable to or as a substitute for mammography.

On Aug. 6, 1990, Tom Garvin, investigator and x-ray auditor in FDA's Milwaukee resident post (Minneapolis district), inspected Mobile Clinics of Tomorrow.

"After reading the promotional literature obtained during the inspection and subsequent investigations of the companies," he says, "I realized that the process was in no way effective and that there could be possible health fraud involved. At this time, the company [Mobile Clinics] was attempting to sell the transillumination product to local firms in the Milwaukee area for use in 'Worksite Breast Screening Programs' for employees, and I felt action was necessary."

On Dec. 7, 1990, at FDA's request, U.S. marshals seized the van and equipment in Markesan, Wis. The seizure was based on violations of the federal Food, Drug, and Cosmetic Act, including misbranding the product, distributing inadequate instructions for its use, and failing to notify FDA before marketing.

Garvin, the U.S. marshal, and several local police agencies found the van, with the equipment inside, parked unattended at the corporate president's home. The device and accompanying literature were placed in custody of the U.S. marshal.

Garvin's Aug. 6 inspection of Mobile Clinic revealed that about 60 women in four Wisconsin towns (Appleton, Pardeeville, Princeton, and Portage) had the transillumination procedure. The state's health department prepared releases for print and broadcast media, urging these women to contact the Wisconsin Department of Health and to get proper examinations through the standard procedure, radiographic mammography.

At the time of the seizure, Mobile Clinics of Tomorrow was attempting to sell the device to an x-ray firm in Milwaukee.

Mobile Clinics of Tomorrow consisted of a group of four investors. No legal action was taken against them.

FDA continues to investigate the possible distribution of the company's transillumination devices for similar use in other states.

Wrong Flora in Micro-Flora

A California firm that manufactured a product to aid in digestion went out of business after an FDA investigation showed bacterial contamination of some of the product.

The Micro-Flora Corporation of Camarillo, Calif., advertised its Micro-Flora liquid product as "a concentrated liquid form of viable organisms designed to assist in the replacement and maintenance of favorable intestinal bacterial growth."

The product consisted of a liquid growth medium seeded with *Bacillus laterosporus* bacteria. These bacteria live in the intestinal tract and replace and maintain intestinal bacterial growth, leading to more efficient digestion, elimination of toxins, and restoration of destroyed intestinal flora.

In March 1990, officials from the Canadian Health and Welfare Department informed the Canoga Park resident post of FDA's Los Angeles district office that analysis of a sample of Micro-Flora liquid from lot #0522, obtained from a consumer, showed contamination with *Klebsiella pneumoniae* bacteria.

Exposure to *Klebsiella pneumoniae* can lead to an acute infection of the respiratory tract. This can be very dangerous and is often fatal to young children and the elderly.

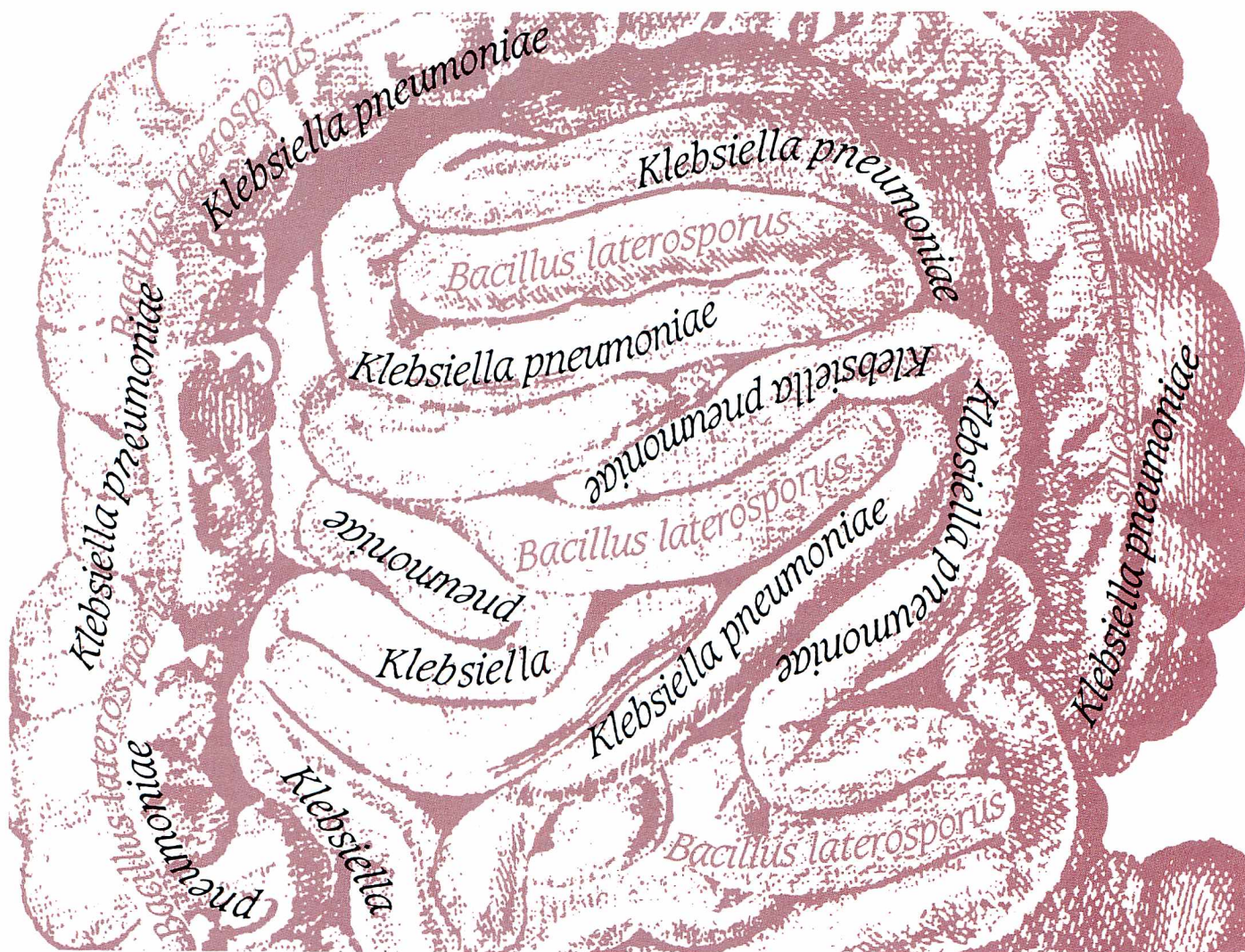
The liquid was labeled for treatment of ill-defined digestive upsets, as well as gastrointestinal cancer, inflammatory bowel disease, diverticulitis, and other digestive afflictions.

Canadian authorities recalled the product in Canada in March 1990 and requested that FDA's Los Angeles district office investigate further.

Canoga Park resident post investigator Ronald Koller investigated the distributing firm, located in Camarillo, Calif., that month and obtained samples of the product for testing. Laboratory analysis confirmed that lot #0522 was contaminated with *Klebsiella* bacteria.

The analysis also revealed that a second lot (#0573) was not only contaminated with *Klebsiella*, but also lacked *Bacillus laterosporus*, the active ingredient of the product. FDA issued a class I recall of both lots of Micro-Flora liquid on June 22, 1990. (A class I recall means that there is a reasonable probability that use of or exposure to the product under recall could result in serious adverse health consequences or death.) Canadian health officials also recalled lot #0573.

Investigator William Teachworth and microbiologist Richard Ruby, both from the Canoga Park resident post, had conducted a follow-up investigation in May 1990 of the bottler, Cosmetic Development Systems in Newbury Park, Calif., and the manufacturer, John McConville and Associates of Valencia, Calif., to determine the origins of the contamination.



The source was found to be the manufacturer. Upon learning that the product was contaminated, McConville voluntarily destroyed his ongoing production of bacteria culture for shipment to Micro-Flora.

On Aug. 31, investigators Ronald Koller and Marvin Walker of the Canoga Park resident post met with Micro-Flora officials at their office and warehouse in Camarillo, where they were to witness the dumping of all frozen and returned stock of lots #0522 and #0573.

When they arrived, however, Micro-Flora's president, Boyd J. O'Donnell, told them that new information obtained by the corporation proved that the Micro-Flora liquid had not been contaminated with *Klebsiella*. Furthermore, according to Koller, O'Donnell said he was planning to sue FDA and would not destroy the product because he intended to use it as evidence. All further matters, he claimed, would be handled by his attorney. O'Donnell refused to allow inspection and asked the investigators to leave.

The investigators obtained a warrant for inspection and returned to the Micro-Flora warehouse on Sept. 20. They discovered that lot #0573 had been destroyed, but lot #0522 was still in the warehouse.

The scene at the firm was one of "turmoil," according to Koller. O'Donnell told the investigators that the stockholders of the company had decided to vote him out and that he was no longer acting president. He said he was in the process of vacating the office and claimed that the interim president was Tevis Morrow of Colorado.

The investigators then contacted Morrow, who acknowledged that he was interim president, but said that his primary position was that of president of Boulder Nutrition, a distributor of Micro-Flora. Morrow said he had no knowledge of the *Klebsiella* contamination of Micro-Flora liquid and could not give the investigators any information about the product, but that he would try to cooperate fully

with the agency.

On Sept. 27, Morrow contacted the Canoga Park resident post and informed the investigation team that O'Donnell was involved in litigation with the company stockholders over control of company assets, which were frozen because the company had no product to distribute. He also said he would permit FDA to oversee destruction of the contaminated lot.

On Nov. 26, Koller and officials of the California Food and Drug Administration supervised the voluntary destruction of 3,467 16-ounce containers of Micro-Flora liquid, lot #0522, valued at \$70,000.

The Micro-Flora Corporation ceased operation immediately following the destruction of the liquid.

—This small sample of reports from the field was prepared by Tom Cramer and Raja Mishra.

Summaries of Court Actions



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

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

SEIZURE ACTIONS

Food/Contamination, Spoilage, Insanitary Handling

PRODUCTS: **Cashew kernels, blanched**, at Jersey City, Dist. N.J.; Civil No. 90-877.

CHARGED 3-2-90: When shipped from Nutracker Snacks, Inc., Billerica, Mass., the article labeled "Blanched Cashew Kernels . . . Produce of India . . . Packed By The Kerala State Cashew Development Corporation Ltd Quilon India" contained insect filth—402(a)(3).

DISPOSITION: Consent—authorized release to SLD Commodities, Inc., Port Chester, N.Y., for salvaging. (F.D.C. No. 65830; S. No. 90-598-516; S.J. No. 1)

PRODUCT: **Flour**, at Norfolk, E. Dist. Va.; Civil No. 87-459N. CHARGED 7-23-87: While held by Norfolk Noodle Factory, Norfolk, Va., the article contained rodent filth and had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent decree authorized release under bond of the article to the dealer for salvaging. The claimant failed to complete bringing the article into compliance within the 30 days prescribed by the bond because the decree provided that the claimant could not bring the article into compliance until the claimant's premises had been rendered clean and suitable for the storage of food and the premises had been found to be inadequate due to potential rodent entries, clutter and rodent filth. The government moved for forfeiture of the claimant's \$10,000 penal bond. Upon the consent of the claimant and its manager, the bond was forfeited, and the flour was destroyed at the expense of the claimant. (F.D.C. No. 65235; S. No. 87-441-837; S.J. No. 2)

PRODUCT: **Teas, spices, canned mushroom pieces and stems, Oriental pasta products, candy, and other imported food stocks**, at Sacramento, E. Dist. Calif.; Civil No. 89-0520 LKK-JFM.

CHARGED 4-12-89: While held by Warren Trading, Inc., Sacramento, Calif., one lot of tea labeled in Chinese as "Chinese Tea" contained rodent filth; and all of the articles had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—authorized release to dealer for salvaging. (F.D.C. No. 65654; S. No. 89-541-065 et al.; S.J. No. 3)

Food/Economic and Labeling Violations

PRODUCT: **Anchovy fillets, canned**, at Buffalo, W. Dist. N.Y.; Civil No. 91-0024A.

CHARGED 1-15-91: When shipped by Rubinelli, Inc., Cicero, Ill., the article labeled "Dell'Alpe . . . Fillets of Anchovies . . . Dist. by Dell'Alpe Food Prod. Rubinelli, Inc., Cicero, Ill" had had olive oil substituted in part for anchovy fillets (i.e., some cans contained more than 50 percent olive oil)—402(b)(2).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66005; S. No. 90-471-353/4; S.J. No. 4)

Drugs/Human Use

PRODUCT: **Vaginal suppositories**, at Flagstaff, Dist. Ariz.; Civil No. 90-0324 PCT-WPC.

CHARGED 3-3-90: When shipped in interstate commerce, the article labeled "Yeast Gard . . . Homeopathically Prepared Suppositories . . . Active Ingredients: Pulsatilla . . . Candida . . . distributed by Lake Pharmaceutical, Inc., . . . Mission Viejo, CA." was a new drug without an effective approved New Drug Application—505(a); the article's labeling falsely and misleadingly claimed that the article was safe and effective in the treatment of vaginal yeast infections and that the article was a homeopathic preparation—502(a); and the article's labeling lacked adequate directions for use, since the conditions for which it was offered were not amendable to self diagnosis and treatment by laity and since the article was an unapproved new drug—502(f)(1).

DISPOSITION: The article was claimed by Lake Pharmaceutical, Inc., Mission Viejo, Calif., who denied the charges and, in a counterclaim, challenged FDA's interpretation of 201(g)(1)(A) as applied to homeopathic drugs. The claimant sought declaratory judgment that FDA's interpretation was unlawful, unreasonable, arbitrary, and capricious. The claimant stated that, although the facts clearly established that the article was a homeopathic drug, it had taken action to remove FDA's doubts by requesting the *Homeopathic Pharmacopeia of the United States (HPUS)* to specifically list two of the article's ingredients, *Nosodes Candida albicans* and *Candida parapsilosis*, in the *HPUS*. [The article's third ingredient, *pulsatilla*, was already the subject of an existing *HPUS* monograph].

Pursuant to stipulation of the parties, it was agreed that the government had additional time to file its answer to the counterclaim. The claimant served a request for the production of documents on the government. Meanwhile, an FDA advisory committee recommended approval of certain other drugs for the self-treatment of vaginal yeast problems, saying that data showed such problems could be safely and adequately self-treated by the laity.

Subsequently, pursuant to stipulation of the parties, the government's complaint and cause of action and the claimant's counterclaim were dismissed. (F.D.C. No. 65756; S. No. 89-566-837; S.J. No. 5)

Drugs/Veterinary

PRODUCT: Various veterinary drugs (**Save-A-Tail, Mil-Lax, Pig Survival Kit, ProBiotic Vitamin Pak, Mother Milk Additive, and E-Z Laxative**), at Manson, N. Dist. Iowa; Civil No. C90-3035.

CHARGED 7-17-90: While held by Ag America, Inc., Manson, Iowa, who had manufactured the articles using interstate components, all of the articles (except the Vitamin Pak and the Mother Milk Additive) were new animal drugs, since no approval of a New Animal Drug Application was in effect for those drugs—501(a)(5); the labels of the ProBiotic Vitamin Pak and Mother Milk Additive lacked adequate directions for their intended use—502(f)(1); and all of the articles had been prepared in an unregistered establishment—502(o).

DISPOSITION: Consent—authorized release to the manufacturer for reconditioning or destruction. (F.D.C. No. 65883; S. No. 90-552-981 et al.; S.J. No. 6)

Medical Devices

PRODUCT: **Pocketdoc electromagnetic field generator & components**, at Minden, Dist. Nev.; Civil No. CV-R-83-002-BRT.

CHARGED 1-6-83 and amended 6-25-84: The labeling of the device (manufactured by Igon, Inc., Minden, Nev., and accompanied by labeling reading (insert) “Pocketdoc . . . Induces a low level of Vaso-dilation around the area being treated . . . Minden, NV” and (leaflets) “It’s small . . . It’s Q-U-I-E-T It Works! . . . ‘Pocketdoc’ . . . Igon, Inc. Manufacturing . . . Minden, Nevada,” and “Relief From Pain Without Drugs . . . Pocketdoc”) contained false and misleading claims to induce a low level of vasodilation, to have been proven very successful for the pain of arthritis, migraine, bursitis, backaches, etc., and to be beneficial for asthma, ileus (sic), stiff or painful joints, hemorrhoids, painful muscles, stomach cramps, migraine, arthritis, whiplash, backache, bronchial (sic), headaches, nervous tension, insomnia, and aches or pains—502(a); the device’s labeling lacked adequate directions for use and was not exempted—502(f)(1); and the article was dangerous to health when used in the manner prescribed, recommended or suggested in the labeling, in that the termination of the use of drugs several hours before using the device was indicated, which termination (in the case of drugs such as digitalis, coumarin or insulin) would impose a severe hazard to the patient—502(j). **DISPOSITION:** The article was claimed by SGR, Ltd., Minden, Nev., who denied the charges. The government served written interrogatories on the claimant. The claimant served written interrogatories on the government. Various extensions of time for the completion of discovery were granted. Meanwhile, various changes in the status of the claimant were made. An extension of time to file settlement papers was granted to the government. Subsequently, an amended complaint for forfeiture and injunction was accepted for filing by the court as a condition precedent to the acceptance of the parties’ consent decree of condemnation and injunction.

Ultimately, a consent decree of condemnation of the article and permanent injunction against certain corporate officers was filed. The decree ordered destruction of the devices and the destruction of the promotional material used for the devices. Also, Royce Sullivan and Anne Sullivan, as individuals and corporate officers of Igon, Inc., SGR, Ltd., and Igon Corp., were enjoined from directly or indirectly making any claim for devices intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals, where: (a) such claim in the labeling is false or misleading in any particular; (b) such claim fails to provide adequate directions for use, unless exempted; (c) such claim fails to provide adequate warnings regarding the safe and effective use of the device. (F.D.C. No. 63922; S. No. 82-390-882; S.J. No. 7)

PRODUCT: **Snake Doctor electroshock device**, at Greenville, W. Dist. Ky.; Civil No. C90-0098-0 (CS).

CHARGED 5-25-90: The article (which was labeled “Snake Doctor, J&K Industries, . . . Claremore, OK” and was accompanied by labeling reading “Snake Doctor . . . A Life Saver Manufactured Solely to Apply The Electronic First Aid Treatment for Poisonous Insect And Snake Bites . . . J&K Industries”) was a class III device, and no approved application for pre-market approval was in effect—501(f)(1)(B); the article’s labeling contained false and misleading claims for insect and snake bites in man and other animals—502(a); its labeling lacked adequate directions for its intended use—502(f)(1); and the required pre-marketing notification had not been submitted—502(o).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 65869; S. No. 90-581-375; S.J. No. 8)

PRODUCT: **Ster-O-Lizer sterilizers for surgical instruments, in-process sterilizers, and sterilizer components**, at Salt Lake City, Dist. Utah; Civil No. C-86-0486G.

CHARGED 6-5-86: The articles, which were being manufactured by Ster-O-Lizer Manufacturing Co., Salt Lake City, Utah, were manufactured, packed and stored under circumstances that failed to conform with regulations—501(h); labeling of the articles lacked adequate directions for use and the articles were not exempt—502(f)(1); and the articles were not included in a required list and were not the subject of a required notice prior to marketing—502(o).

LITIGATION: Tim Themy-Kotronakis, president of Halogenic Products Corp. (Ster-O-Lizer Mfg. Corp) filed an answer containing motions to dismiss the action and for a speedy disposition of the action, as well as a counterclaim for damages against the government. That answer also stated that the seized articles were property belonging to lien holder Lonnie R. Fausset. The government moved to strike such answer-motion-counterclaim on the ground that there was no party with a lawful claim to the articles. Upon the appearance of government counsel and Themy, the court denied the government’s motion since amendments were to be forthcoming. Subsequently, Themy, as president and sole stockholder of Halogenic and Ster-O-Lizer, filed an amended answer denying the charges. Themy, asserting that the property belonged to him, filed a motion to vacate the seizure. Fausset, as

lien holder, filed a motion for the release of the seized property.

The government opposed the motions to vacate the seizure and to release the seized property; and the court denied such motions. After FDA inspected Themy's place of business and after lengthy discussion with Themy, the government made it clear that injunctive relief against Themy and his operations would be sought because of activities related to the seizure complaint's allegations. Thereupon, Themy moved to withdraw his claim to the articles and to strike his pleadings, on the grounds that he did not wish to pursue his claim and had no further interest in the proceedings. The government opposed Themy's motion, and Themy filed a request for a hearing on his motion. Before setting a date for a hearing, the court granted Themy's motion to withdraw.

The government moved for an order to show cause for contempt for violations of the seizure warrant, and also moved for reconsideration of the order granting Themy's motion to withdraw his claim. The court issued an order to show cause for contempt. After a hearing on all pending motions, the court denied the government's motion for reconsideration, but granted leave for the government to file an amended complaint and to add additional parties. The court also presently found no basis for contempt; but, in light of the circumstances, the court ordered the following: that a search be made of the premises of Ster-O-Lizer, Inc.; that an accounting be made of the inventory and devices at the plant; and that a report be made to the court of the accounting.

CHARGED 7-27-87, amending the complaint for seizure and requesting seizure of additional articles and an injunction against **Halogenic Products Co.** (t/a Ster-O-Lizer Manufacturing Co.) and **Tim Themy-Kotronakis**, president, Salt Lake City, Utah: That the additional articles of device were violative under 501(h) and 502(o) as charged above; that, in addition to seizure allegations, the defendant firm and its president manufactured, processed, packed, labeled, stored, and distributed in interstate commerce certain surgical instrument sterilizers and accessories, including Models MD-200, MD-201, and the Endoscope Sterilizer for use in sterilizing disposable and non-disposable instruments such as catheters, syringes, endoscopes, and instruments made of stainless steel, glass, rubber, ceramic, and fabric; that the defendants violated and continued to violate the law by shipping such adulterated and misbranded devices in interstate commerce—501(h) and 502(o)—and by adulterating the devices while held for sale after the interstate shipment of the devices' components; that FDA inspections revealed that the defendant's firms had no quality assurance program, failed to have in place essential quality control systems, and had numerous significant deviations from good manufacturing practice.

FINAL DISPOSITION: After the defendants answered the amended complaint and some discovery was conducted, the government moved for summary judgment. The claimant/defendants cross-moved for summary judgment in their favor. The parties then entered into a stipulation. Pursuant to the stipulation, the claimant/defendants admitted the allegations of the amended complaint, "thereby withdrawing any denials in the Answer . . . except that the claimant/defendants continue to deny the Amended Complaint's allegation that the Ster-O-Lizer MD-200 is a medical

device." The parties also agreed that whoever prevailed on that single medical-device issue would be granted judgment in favor of the prevailing party.

The court ruled in favor of the government. The court first found that FDA could bring a litigated enforcement action to stop device misbranding and adulteration before it was determined in an administrative proceeding that a product was a device. As to the defendants' argument that the surgical instrument sterilizer was not a device within the meaning of 201(h) because it did not directly come in contact with patients, the court ruled that the direct contact argument had been rejected by the Supreme Court in *United States v. An article of Drug, Bacto-Unidisk*. The district court said that it "considered that the defendants' sterilizer, like the disc in *Bacto-Unidisk*, plays a significant role in healing and preventing disease in man." The court concluded that FDA's inclusion of surgical instrument sterilizers within its device jurisdiction was rational, particularly in light of the purposes of the Food, Drug, and Cosmetic Act and the reasonable conclusion that instrument sterilizer devices were of equal importance to the treatment of patients as the surgical instruments themselves. Accordingly, the court condemned the seized articles.

As to the need for an injunction, the court noted that the defendants had: failed five FDA GMP inspections, failed to heed a regulatory letter, and failed to bring their devices into compliance with the law. Accordingly, the court ordered that an injunction should issue.

The defendants objected to the government's proposed judgment and decree of condemnation and injunction as to a number of particulars. Ultimately, the court issued a decree of condemnation and injunction, approved as to form by both parties. The decree condemned the seized articles, but authorized their release under bond to the claimant and, if the articles were not brought into compliance, ordered their destruction. The defendants were enjoined from the complained-of acts and enjoined from the interstate distribution of any such devices unless and until a number of conditions were met, including the establishment of good manufacturing practice, the certification by an expert that the defendants' plant was in compliance, and the bringing into compliance of all devices or device components or their destruction. (F.D.C. No. 64895; S. No. 86-378-942 et al.; S.J. No. 9)

CRIMINAL ACTIONS

DEFENDANT: **David S. Wong**, manager of a noodle factory, Norfolk, E. Dist. Va.; Criminal No. 88-21-N.

CHARGED on or about 3-7-88: That the defendant unlawfully paid \$200 to an FDA consumer safety officer for the purpose of supplementing his salary—18 U.S.C. 209.

DISPOSITION: Guilty plea; \$2,000 fine, special confinement at defendant's expense for two months, and probation for one year. (F.D.C. No. 65321 WD; S.J. No. 10)

INJUNCTION ACTIONS

PRODUCT: **Angs Beansprout, Inc., t/a Angs Bean Sprout Co.,**

and **Michael E. Yeung**, marketing director, and **Rosana Chin**, production director, Seattle, W. Dist. Wash.; Civil No. 89-1113 WD.

CHARGED 7-27-89 in a complaint for injunction: That the defendants had been engaged in holding interstate beans and in processing, preparing, packaging, and distributing bean sprouts; that such beans and bean sprouts were prepared, processed, packed, and held for sale under insanitary conditions—402(a)(4); that FDA inspections revealed insanitary conditions throughout the defendant's facility (including spider, insect and rodent activity), as well as mold, mildew and rust; that FDA and the Washington State Department of Agriculture inspections established a history of sanitation control problems related to the design, construction, and lack of sanitation in the food processing facility, and demonstrated the defendants' unwillingness and reluctance to maintain a sanitary food manufacturing facility.

DISPOSITION: A consent decree of permanent injunction enjoined the complained-of violations, and enjoined the production and distribution of any food from the defendants' facility unless and until a number of specified conditions were met, including the elimination of all insects, spiders, worms, slugs, rodents, and other vermin, the thorough cleaning and renovation of the facility, certification by a qualified expert of an adequate sanitary control program, the examination of all goods on hand for filth, and the destruction or otherwise bringing into compliance of all contaminated food. (Inj. No. 1217; S. No. 88-502-843 et al.; S.J. No. 11)

DEFENDANTS: **International Hydron Corp.**, its division **American Hydron**, and **Martin M. Pollak**, corporate officer, Woodbury, E. Dist. N.Y.; Civil No. 87-2129.

CHARGED 9-24-88 in a complaint for injunction: That the defendants manufactured and distributed the OfficeTint System to eye-care practitioners for use in tinting soft contact lenses; that the system included an article for tinting, packets of tint, tint fixtures, and a scope; that the incorporation of a color additive into a soft contact lens required FDA pre-market approval prior to the release for sale of the tinted soft contact lenses, even though the lenses had been approved by FDA before they had been tinted; that, through the defendants' labeling and promotion of the OfficeTint System and accessories, the defendants caused eye-care practitioners to adulterate soft contact lenses—501(f)(1)(C); that the defendants had refused to permit an FDA inspection, had argued that the OfficeTint System was not a device subject to FDA regulation, and had represented that, rather than respecting FDA's request to cease further distribution, the firm was distributing OfficeTint System nationally. Despite the defendants' submission of safety and effectiveness data and request that FDA review such data, the defendant's counsel had twice refused to have FDA consider such data as a pre-market approval submission; and, notwithstanding FDA requests to cease distribution of OfficeTint System devices and extensive communication between the defendants and FDA, the defendants had continued to cause the adulteration of soft contact lenses by means of OfficeTint System devices.

DISPOSITION: The defendants filed an answer to the complaint for injunction. Thereafter Allergan, Inc., a wholly owned subsidi-

ary of SmithKline Beckman Corp. acquired the corporate defendant, renamed the successor corporation **Allergan Hydron, Inc.**, retained **Martin M. Pollok** as president of the renamed corporation, and eliminated American Hydron as an identifiable entity. Such successor defendants, without admitting the truth of the complaint's allegations, entered into a consent decree of permanent injunction that enjoined the interstate distribution of the OfficeTint System unless and until a number of conditions were met, including the approval of a pre-market device application or an investigational device exemption, notification of all known purchasers or current users, and retrieval of all OfficeTint Systems. (Inj. No. 1145; S. No. 86-330-515 et al.; S.J. No. 12)

DEFENDANTS: **Life Products, Inc.**, and **Wayne Richard Apple**, president, Boulder, Dist. Colo.; Civil No. 86-F-87.

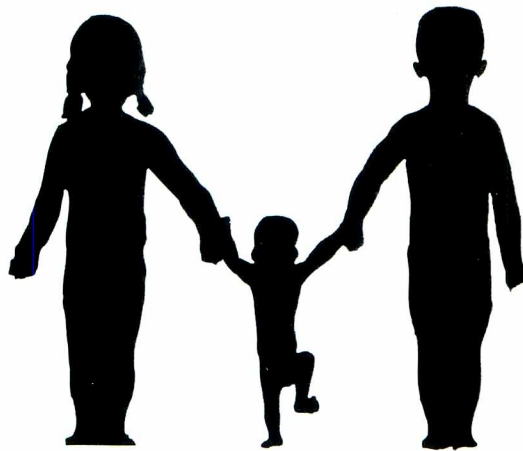
CHARGED 1-17-86 in a complaint for injunction: That the defendants manufactured, packed, stored, and distributed in interstate commerce portable volume ventilators, including models LP3, LP4, LP5, and LP6; that such devices were critical, life-sustaining breathing systems used primarily to treat patients with compromised breathing capacities; that the circumstances for the manufacture, packing and storage of the devices failed to conform with the good manufacturing practice regulations—501(h); and that the defendants were well aware that their activities were in violation of the law.

DISPOSITION: A consent decree of permanent injunction enjoined the complained-of violations and enjoined the manufacturing, packing, labeling, or holding of interstate device components and the interstate distribution of devices unless and until the defendants met a number of conditions, including the following: establishing good manufacturing practices; providing FDA with certification by a qualified expert that specified good manufacturing practice requirements had been met; notifying FDA within 30 days of the sale, transfer of ownership, or any change in the corporate structure of Life Products, Inc.; obtaining FDA approval for release of specified devices or components or for their destruction if not brought into compliance; and, under government supervision, performing all FDA recalls that the defendants voluntarily undertook. Subsequently, Aequitron Medical, Inc., purchased the corporate defendant subject to the consent decree of injunction, agreeing to be bound as a defendant to the extent it carried on the business of Life Products, Inc. (LPI). Aequitron transferred certain of LPI's manufacturing assets to Minnesota and sought to transfer the balance of LPI's assets to Minnesota. Accordingly, Aequitron sought and, upon joint motion of the parties, was granted an amended decree of injunction. The amended decree deleted language concerning "the defendants' plant . . . at . . . Boulder, Colorado" and added a provision terminating the decree after two years when no FDA action had been indicated and limiting the decree only to ventilators and ventilator components and to no other medical devices. Ultimately, upon joint motion of the parties—no FDA actions having been indicated during the prescribed two years—the consent decree of permanent injunction was terminated and vacated. (Inj. No. 1117; S. No. 85-379-161 et al.; S.J. No. 13)

Dr. Sullivan Says . . .

B e c a u s e W e A l l C a r e . . .

Have Children Vaccinated



Check this list for what your children need and when.

- ☐ **2 months old—DTP, Polio, Hib**
- ☐ **4 months old—DTP, Polio, Hib**
- ☐ **6 months old—DTP, Hib (if your doctor recommends)**
- ☐ **12 months old—Hib (if your doctor recommends)**
- ☐ **15 months old—DTP, Polio, Measles, Mumps, Rubella, Hib (if your doctor recommends)**
- ☐ **5 years old—DTP, Polio, Measles, Mumps, Rubella**
- ☐ **15 years old—Tetanus, Diphtheria**

For more information, contact:

- The local health department
- A community health center
- The visiting nurses association
- A doctor



**You CAN Make
a Difference!**

A Message from Dr. Louis Sullivan, Secretary, U.S. Department of Health and Human Services