

# <sup>FDA</sup> CONSUMER

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How  
Close  
To  
The  
Real  
Thing?







## Healthy Lunches for the Brown Bag Set

*Whether you pack it in a lunchbox, a briefcase or just a plain brown bag, there's no reason your lunch-away-from-home can't be healthy as well as tasty.*

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*For some people, oysters on the half shell approximate heaven. Others wake up many hours later with gastroenteritis caused by the succulent mollusks. To find out whether raw oysters, clams and mussels are safe to eat, turn to page 20.*

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Commissioner of Food and Drugs

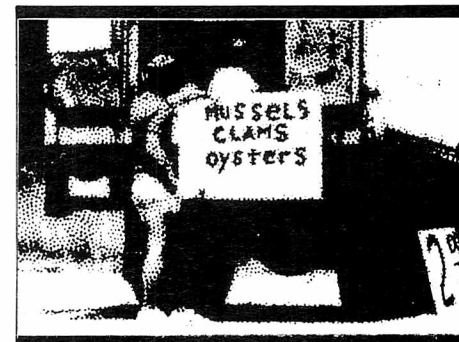
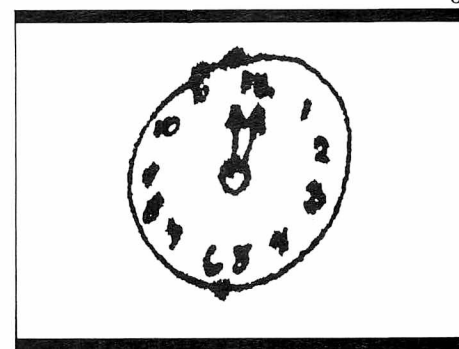
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## New Flu Vaccine

Scientists at the U.S. Centers for Disease Control have recommended that a new vaccine be used against influenza this year because last season's widespread type B flu appears to be evolving into a new strain.

Early this year, the U.S.S.R. flu strain, which was responsible last winter for the worst flu season in five years, evolved toward a new and different type B flu, known as the Ann Arbor flu. Because of this change, CDC has recommended that the 1985-86 flu vaccine not be used. The 1986-87 vaccine will protect against B/Ann Arbor plus two A strains—Chile and Mississippi—according to an update of the center's influenza immunization recommendations, published in the May 23 *Morbidity and Mortality Weekly Report*.

Vaccination programs should give first priority to people, including children, with chronic heart or lung disorders and residents of nursing homes and other chronic-care facilities, followed by otherwise healthy persons 65 or older, adults and children with chronic metabolic diseases, kidney dysfunction, anemia, immunosuppression or asthma, and children receiving long-term aspirin therapy (for juvenile arthritis, for example) who may be at risk of developing Reye syndrome if they get influenza.

Vaccination is also recommended for medical personnel who care for high-risk persons in health-care facilities and for family members and volunteers who provide such care at home.

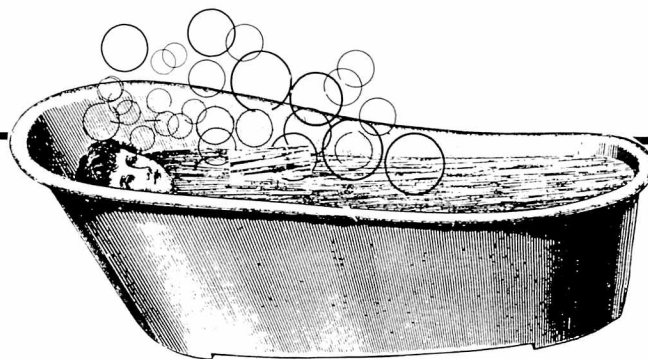
Ten thousand or more people have died in each of the 18 flu epidemics from 1957 to 1985, according to CDC. Recently, the toll has reached more than 40,000 per epidemic. Approximately 80 percent to 90 percent of the deaths from pneumonia and influenza during epidemics have occurred among persons 65 or older.

Because of the growing number of older people in the United States and because age and its associated chronic diseases are risk factors for severe influenza illness, the future toll from influenza may increase even more unless control measures, such as vaccinations, are used more vigorously than in the past, CDC warns.

(For information about other vaccinations for adults, see "Shots *Adults* Shouldn't Do Without" in the June 1986 *FDA Consumer*.)

## Warning Label on Bubble Baths

Labels on children's bubble bath products will have to warn about the risk of irritation to the skin and urinary tract from prolonged exposure or excessive use, accord-



ing to a recently published FDA regulation.

The regulation, which will go into effect June 5, 1987, applies to "foaming detergent bath products" intended for use by children. Products for use solely by adults are not included. According to the regulation, published in the June 5, 1986, *Federal Register*, the children's bubble bath products will have to include the following caution statement:

"Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness, or itching occurs. Consult your physician if irritation persists. Keep out of the reach of children."

Manufacturers may add to the last line the phrase "except under adult supervision."

The regulation was proposed in 1980, but put on hold the following year to allow time to study issues raised by the cosmetic industry.

## Food Editors' Conferences Set

New nutrition research, food labeling, food irradiation, and the safety of imported foods are among the subjects to be covered in two conferences for journalists sponsored by FDA and the U.S. Department of Agriculture. The conferences, scheduled for one-and-a-half days each, will be held in New York City Oct. 30 and 31 and in Los Angeles Nov. 13 and 14.

In addition to presentations by scientists and key policy makers from both agencies, the conferences will include exhibits and demonstrations on measuring body fat, USDA's meat and poultry hotline, and biotechnology.

The registration fee is \$50. For more information, call Gloria Logan (FDA) (202)245-6943 or Marci Hilt (USDA) (202)447-4026.

## FDA Upheld on Action Levels

The Supreme Court has ruled that FDA does not have to change its procedures for controlling some poisons that occur naturally in food. In an 8-1 decision in June, the high court overturned an appeals court ruling that would have required the agency to regulate such substances



through formal rule-making rather than by the present, more informal method. FDA currently decides between the two methods based on a variety of circumstances.

At issue was the regulation of aflatoxin, a cancer-causing mold that commonly grows on corn and other crops. FDA allows interstate shipment of corn as long as the aflatoxin level is less than 20 parts per billion. That level, called an "action level," was adopted in 1969 without public hearings or formal rule-making.

Two consumer organizations, the Community Nutrition Institute and Public Citizen, sued FDA in 1981, seeking to force the agency to adopt formal aflatoxin levels, known as "tolerances," after public hearings. The U.S. Circuit Court of Appeals for the District of Columbia ruled for the consumer groups last year saying the Federal Food, Drug, and Cosmetic Act of 1938 requires formal regulations establishing tolerances for such poisons.

Supreme Court Justice Sandra Day O'Connor, writing for the majority, said the appeals court wrongly imposed its resolution of the 1938 law's "inherent ambiguity" about the procedures for regulating food poisons.

"We find the FDA's interpretation [of the law] to be sufficiently rational to preclude a court from substituting its judgment for that of the FDA," she said.

## Interferon to Treat Rare Leukemia

Two preparations of interferon to treat a rare form of adult leukemia have been approved by FDA. This is the first commercial use in the United States of the hormone-like protein.

Interferon, a protein produced naturally by the body's cells in response to infection, was discovered in the late 1950s. Early studies of interferon to treat a wide variety of illnesses produced disappointing results, partly because supplies were limited.

It is now known that human cells contain genes for the production of several forms of interferon. These have been classified into three major types: leukocyte, or alpha, interferon—produced by white blood cells; fibroblast, or beta—produced by connective tissue cells; and immune interferon, called gamma—produced by T-lymphocytes (immune cells).

The new interferon products are of the alpha type. One product, developed by Schering Corp., Kenilworth, N.J., will be marketed under the brand name Introna; the other, produced by Hoffmann-LaRoche, Inc., Nutley, N.J., will be marketed as Roferon-A. The two companies developed their products independently, but both are produced using recombinant DNA technology in which a

gene containing the production code for alpha interferon is inserted in a harmless bacteria, which then produces large amounts of the substance identical to that produced by the human body.

The rare form of leukemia for which the interferon products have been approved is called hairy cell leukemia. So named for the hairy appearance that the surface of the lymph cells take on when infected with the disease, it accounts for about 2 percent of all leukemias. It is believed, in some cases, to be associated with the human T-cell lymphotropic virus (HTLV) family of retroviruses. The AIDS virus is another member of this family.

Conventional chemotherapy is of limited value in hairy cell leukemia. Removal of the spleen, supportive chemotherapy, and repeated blood and platelet transfusions have been the primary treatments. The mortality rate for hairy cell leukemia patients is 7 percent to 20 percent a year.

In studies involving more than 200 patients, alpha interferon produced partial or complete remission of the disease in 75 percent to 90 percent of patients. Overall, 92 to 94 percent of patients survived more than two years regardless of whether there was remission.

Alpha interferon may act directly against the tumor cells in hairy cell leukemia to prevent their growth or by stimulating the immune system. The most common adverse reaction seen in clinical trials was development of flu-like symptoms, including fatigue, fever and chills.

## FDA Panel Finds No Association Between Spermicides, Birth Defects

Studies do not point to an increased risk of birth defects from use of spermicides in vaginal contraceptives and, therefore, warning labels on such products are not warranted, according to FDA's Fertility and Maternal Health Drugs Advisory Committee.

The advisory committee's conclusions were based on a review by scientists at the U.S. Centers for Disease Control of studies that suggested an increased risk of birth defects in babies whose mothers used the products when they were already, but unknowingly, pregnant or who became pregnant soon thereafter. One study was by Dr. Hershel Jick, published by the *Journal of the American Medical Association* in 1981, and the other was by Dr. K. J. Rothman, published in the *American Journal of Public Health* in 1982.

The studies provided data on limb reduction deformities (missing fingers and toes) and Down syndrome, a chromosomal abnormality resulting in retardation and physical defects. Both occur without spermicide use, but

the studies looked at their possibly higher rate when spermicides are used at about the time of a pregnancy. The CDC review concluded that the two studies did not support a link between vaginal spermicide exposure and an increased risk of birth defects.

FDA has concurred with its advisory committee's conclusions and forwarded the recommendation against a warning label to the over-the-counter drugs division, which is completing a review of vaginal contraceptive products.

### Electrical Devices Treat Severe Scoliosis

Children with a severe form of the curved spine condition known as scoliosis may be able to avoid round-the-clock therapy or surgery through use of electrical stimulation devices recently approved by FDA.

Electric stimulation was previously available for only a single curvature, or "C" curve. But, when scoliosis involved a double curvature, or "S" curve, the patient had to wear a back brace for 23 hours a day and had an increased chance of the curve worsening and, eventually, of needing an operation.

The new devices consist of a two-channel electric stimulator, conducting cables, two sets of electrodes, conductive gel, tape patches, and a battery charger. The physician explains where to tape the electrodes on both sides of the back. Gel applied to the skin under the electrodes conducts electrical impulses to certain muscles, causing contractions that gradually correct the abnormal curves. Like the body brace, electrical stimulation must be used until the child's spine is mature.

The stimulators are not approved for use on patients who have a cardiac pacemaker. The safety and effectiveness of the devices have not been established for infants or adults or for patients with spinal structural deformities; progressive, degenerative diseases of the spine or spinal muscles; and some other medical conditions.

To learn more about scoliosis, see "When the Spine Curves" in the September 1984 *FDA Consumer*.

### CPR Techniques Revised

A national conference on cardiopulmonary resuscitation (CPR) has given a resounding endorsement to this life-saving technique, while changing slightly the way it should be administered.

"Early bystander CPR remains the most critical element in the prevention of sudden death," stated a report on the conference organized by the American Heart Association

and other medical groups. "When CPR is combined with an efficient emergency medical service and advanced cardiac support capability, the chances for survival (in cardiac arrest) average 25 percent, compared to only 5 percent when CPR and other elements are weak or missing."

The conference was held in Dallas in July 1985, and its findings and recommendations were published in the June 6, 1986, issue of the *Journal of the American Medical Association*. They appear there as standards and guidelines for using and teaching CPR and other cardiac emergency procedures throughout the United States.

The conference urged that CPR continue to be widely taught for its own value, noting also that it "penetrates the community like no other public education endeavor" and allows information about heart disease and good health practices to reach almost everyone.

The new guidelines recommend that lay (non-medical) persons be instructed in the one-rescuer technique rather than the more complicated two-rescuer method and that CPR compressions be 80 to 100 per minute rather than the 60 to 80 compressions now used. The guides also urge that emergency medical personnel learn to recognize ventricular fibrillation in the cardiac patient and how to use a defibrillator. Fibrillation is a useless twitching of heart muscle that pumps no blood; a defibrillator is an electrical device that can jolt the heart back into proper rhythm.

The conferees made a particular point that there is no evidence of any infectious disease having been transmitted through CPR among the millions of Americans who have learned or used the technique over the past 20 years.

The conference recommendations are being adopted by the American Red Cross, American Heart Association, American Hospital Association, and other organizations involved in cardiac emergencies.

(For more about CPR, see "Back from the Brink" in the February 1986 *FDA Consumer*.)

### Five Color Additives Approved

FDA has decided to permanently approve five color additives: D&C Orange No. 17, D&C Red Nos. 8, 9 and 19, and FD&C Yellow No. 6.

The decision to approve those used in drugs and cosmetics (Orange No. 17 and Red Nos. 8, 9 and 19) was based on conservative risk assessment and analysis by a scientific review panel composed of experts from five government agencies: FDA, the U.S. Centers for Disease Control, the National Heart, Lung, and Blood Institute,

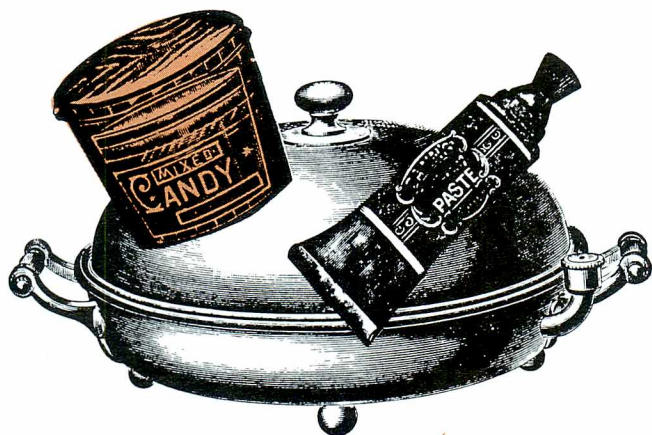
the National Cancer Institute, and the National Institute for Occupational Safety and Health.

FDA concluded that those four colors are safe and may be permanently listed (approved) for use, subject to certain conditions.

Permanent listing of FD&C Yellow No. 6 (which is used in foods, drugs and cosmetics) was based on an evaluation of scientific data that led FDA to conclude the additive is safe and does not cause cancer. The decision is based on the agency's "constituents policy," which applies when an additive as a whole is not carcinogenic, but contains carcinogenic impurities, or constituents, for which conditions may be established to ensure safe use.

D&C Red No. 37 was "de-listed" (i.e., not approved) because its sponsor, the Cosmetic, Toiletry and Fragrance Association, withdrew its request for permanent listing. No further use of this color will be permitted unless a new petition is submitted and approved by FDA.

The permanent listing of the five colors was published in the June 6 *Federal Register*.



## Monoclonal Antibody for Kidney Transplants

A monoclonal antibody to reverse acute kidney transplant rejections is the first such biotechnology-derived product to gain FDA approval for use within the body. The new product, Orthoclone OKT\*3, produced by Ortho Pharmaceutical Corporation, Raritan, N.J., was approved June 19. Other monoclonal antibodies have been used for tests outside the body, including home pregnancy tests.

Each year, about 7,000 Americans receive kidney transplants. About 60 percent require treatment to suppress the body's immune system to prevent rejection. Orthoclone OKT\*3 uses an antibody that acts against the body's

T-cells, white blood cells responsible for acute rejection of foreign tissue. In one clinical trial of the product, kidney rejections were reversed in about 94 percent of patients receiving the monoclonal antibody intravenously. In another study, it reversed rejection in 65 percent of patients who had not responded well to conventional anti-rejection therapy.

Although it is the first therapeutic monoclonal antibody, the new product is the fourth therapeutic product of biotechnology to gain FDA approval. The first three—human insulin, human growth hormone, and alpha interferon—are produced by gene splicing (i.e., putting a gene into a bacterium which then manufactures the substance). A monoclonal antibody, on the other hand, is produced by combining two types of cells: an antibody-producing white blood cell and a tumor cell, called a myeloma, which can reproduce itself endlessly.

The process, discovered in 1975 in Cambridge, England, begins with injection of a specific antigen into a mouse whose spleen produces white cells that will make antibodies against that antigen. For Orthoclone OKT\*3, the mouse was injected with human T-cells that ordinarily produce the tissue inflammation and destruction that occur in a graft rejection. These white cells are then fused with myeloma cells. The resulting combination cell, called a hybridoma, can then be mass-produced, providing an endless supply of "clone" cells that secrete an endless supply of identical antibodies.

## FDA Consumer: A Better Bargain Than Ever

The best things in life aren't *all* free. But some are a bargain anyway. Take *FDA Consumer*, for instance. The price of a one-year subscription has been reduced to \$9.50 domestic, \$11.90 foreign. The reduction comes not from any lessening of the quality of the magazine, but because of a change in pricing policies by the U.S. Government Printing Office, which sets the rates for government periodicals.

If you're not yet subscribing to *FDA Consumer*, an order form is on the back cover of this issue. Or write to *FDA Consumer*, HFI-40, 5600 Fishers Lane, Rockville, Md. 20857.

## Reprints Available

Reprints are available of the following articles from the May 1986 *FDA Consumer*: "Progress Against Breast Cancer" and "Eating Disorders: When Thinness



Becomes an Obsession.”

Reprints can be obtained from the Food and Drug Administration, HFI-40, 5600 Fishers Lane, Rockville, Md. 20857. Up to 100 copies will be provided. Negatives of reprints are also available for those organizations needing more than 100 copies.

## *Consumer Forum*

### **‘Chinese Restaurant Syndrome’**

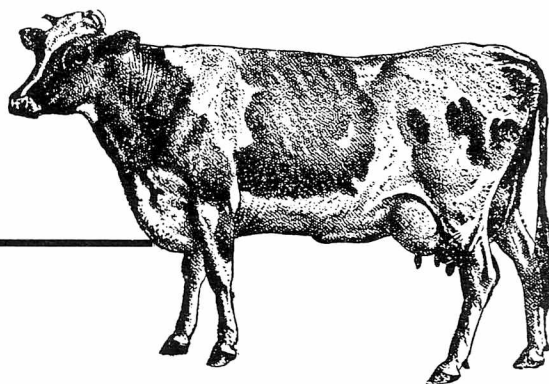
“Food Allergies: Separating Fact From ‘Hype’ ” in the June 1986 *FDA Consumer* is a timely feature. Its message is long overdue in highlighting the hasty generalizations

frequently made about “food allergy.”

However, the article goes on to identify monosodium glutamate (the popular flavor enhancer) as a known allergen. It is not. Extensive research on potential human response to monosodium glutamate has revealed no evidence of an immunologic response.

In the most recent evaluations completed in the laboratories of George Washington University Medical School’s Dr. Richard Kenney, who has been researching this area for some 17 years in self-claimed responders, it was found that hypersensitivity to monosodium glutamate could not be confirmed by physical measurement.





Response to double-blind challenges with varying levels of MSG produced such inconsistent responses that Dr. Kenney now doubts the validity of any link between monosodium glutamate and the so-called "Chinese Restaurant Syndrome."

Dr. Kenney has hypothesized that if idiosyncratic reaction to monosodium glutamate is, in fact, a real phenomenon among sensitive individuals, the mechanism is no different than that of common heartburn, which results from black coffee and spiced tomato juice, to name but a couple of offenders. The mechanism involved here is likely an irritation of the baroreceptors in the esophagus, he postulates.

In any case, the use of the word "allergy" to describe the alleged reaction to MSG is quite inappropriate.

The characterization of monosodium glutamate as an allergen implies a far more severe reaction than the transient symptoms of discomfort reported by individuals who believe they may be intolerant to monosodium glutamate.

Dr. Kenney's latest research is scheduled for publication in *Food Chemical Toxicology* imminently.

Richard E. Cristol  
Executive Director  
The Glutamate Association—United States  
Atlanta, Ga.

*Monosodium glutamate (MSG) is a flavor enhancer that has been used for centuries throughout the world. It is especially popular in Oriental countries and in Oriental foods wherever they are prepared.*

*In some persons, MSG produces a flushed sensation of warmth and tingling over the face and upper trunk and a feeling of chest pain and tightness. Headache, nervousness, thirst, gastrointestinal problems, and other reactions have also been reported. These apparently harmless symptoms occur minutes after ingesting MSG and are usually gone within an hour. This was dubbed the "Chinese restaurant syndrome" in 1968 in The New England Journal of Medicine.*

*MSG is considered by FDA to be a safe food ingredient, but because some people are sensitive to it, monosodium glutamate must appear by name on the label of any food in which it is present. This labeling requirement was reaffirmed by the agency's advisory committee on hypersensitivity to food constituents last May 8.*

## Health Risks of Raw Milk

Although I enjoyed your April 1986 edition with its cover story, "A Closer Look at Dairy Safety," I am somewhat mystified at your exclusion of the continuing outbreak of deaths and illnesses due to raw and raw certified milk in California. FDA held hearings on this matter and concluded that there are significant health risks to consuming raw and raw certified milk.

This is a problem that has affected hundreds of people over the last few years, especially regarding infections with *Salmonella dublin*. This organism is not a benign one. Approximately 80 percent of its victims end up in the hospital and approximately one-quarter of them die. Of the total number of cases, approximately 45 percent are consumers of "certified" raw milk.

John C. Bolton, M.D.  
Mill Valley/San Francisco, Calif.

*The April article dealt with problems encountered with dairy products that were supposed to have been pasteurized and, therefore, did not discuss raw milk.*

*The Health Hazard Evaluation Board of FDA's Center for Food Safety and Applied Nutrition concluded last May that any food that receives no further heat treatment and is contaminated with *Salmonella dublin* should be regarded as a "life-threatening hazard." There are some 1,800 species of *Salmonella*, and in the past the board had classified their hazard potential as ranging from "limited-acute" to "severe-acute," depending on the age, physical condition, and susceptibility of an individual who consumed a *Salmonella*-contaminated product. But *Salmonella dublin* differs from other types of *Salmonella* because of its more traumatic effects on those it infects. As the board noted, "S. dublin attacks persons over 40 with underlying disorders, resulting in hospitalization of 80 percent of affected individuals and 25 percent mortality." Other species of *Salmonella* generally result in hospitalization "in 5 percent of affected individuals and mortality in less than 1/2 percent."*

*The classification of S. dublin as a life-threatening hazard affects regulatory actions taken by FDA, such as the way in which recalls are conducted when S. dublin is found in food. FDA's position is that people who drink raw milk—certified or not—are exposing themselves to a health risk, including the risk of exposure to S. dublin.*

# Healthy Lunches for the Brown Bag Set

by Annabel Hecht

There are dinner pails and lunch buckets; lunch boxes and box lunches; designer bags and plain brown paper bags; recycled margarine tubs and plastic totes with nests of smaller boxes shaped to hold a sandwich or a piece of pie.

No matter what the container, a midday repast brought from home has sustained generations of workers and school children who don't have access to lunchrooms or can't afford or prefer not to buy the food in those that are available. Today the practice of "brown bagging" has risen to new heights and taken on new dignity. Brown bags have, in a manner of speaking, come out of the briefcase and are appearing unashamedly on the desks of professionals and on board room tables during business lunches.

The lunch-box meal is often depicted in the comics or on television as a limp meat or cheese sandwich and a thermos of soup or coffee taken ruefully from a black box with a high humped lid. Today, however, lunch from home is turning into a gourmet treat. What goes into the box or bag is limited only by the imagination of the person who prepares it and the likes and dislikes of the one who eats it. Packing a lunch at home can have a distinct advantage—no surprises, no excess sodium or unwanted calories—if the packer packs with good nutrition in mind.

Whether it comes out of a tin box or a bag, the noon meal should be nutritious. This is particularly true for school-age children who need fuel for their rapidly growing bodies and to keep their minds alert. A hungry child is not able to concentrate on school work and often becomes restless and overactive.

Most schools do provide a hot lunch, but often youngsters don't like what is on the menu, or they buy lunch only on those days when a special favorite is served. The rest of the time they bring their noon meal from home. An estimated 3 billion lunches a year are carried by children, according to David Lyon of the Brown Bag Institute, a research marketing firm. And, for many young children, half the fun of lunch time is carrying a new lunch box decorated with cartoon characters.

A good lunch should include selections from the basic four food groups:

- A protein food such as meat, fish, cheese, eggs, nuts, dried beans, or the perennial favorite, peanut butter. Foods in

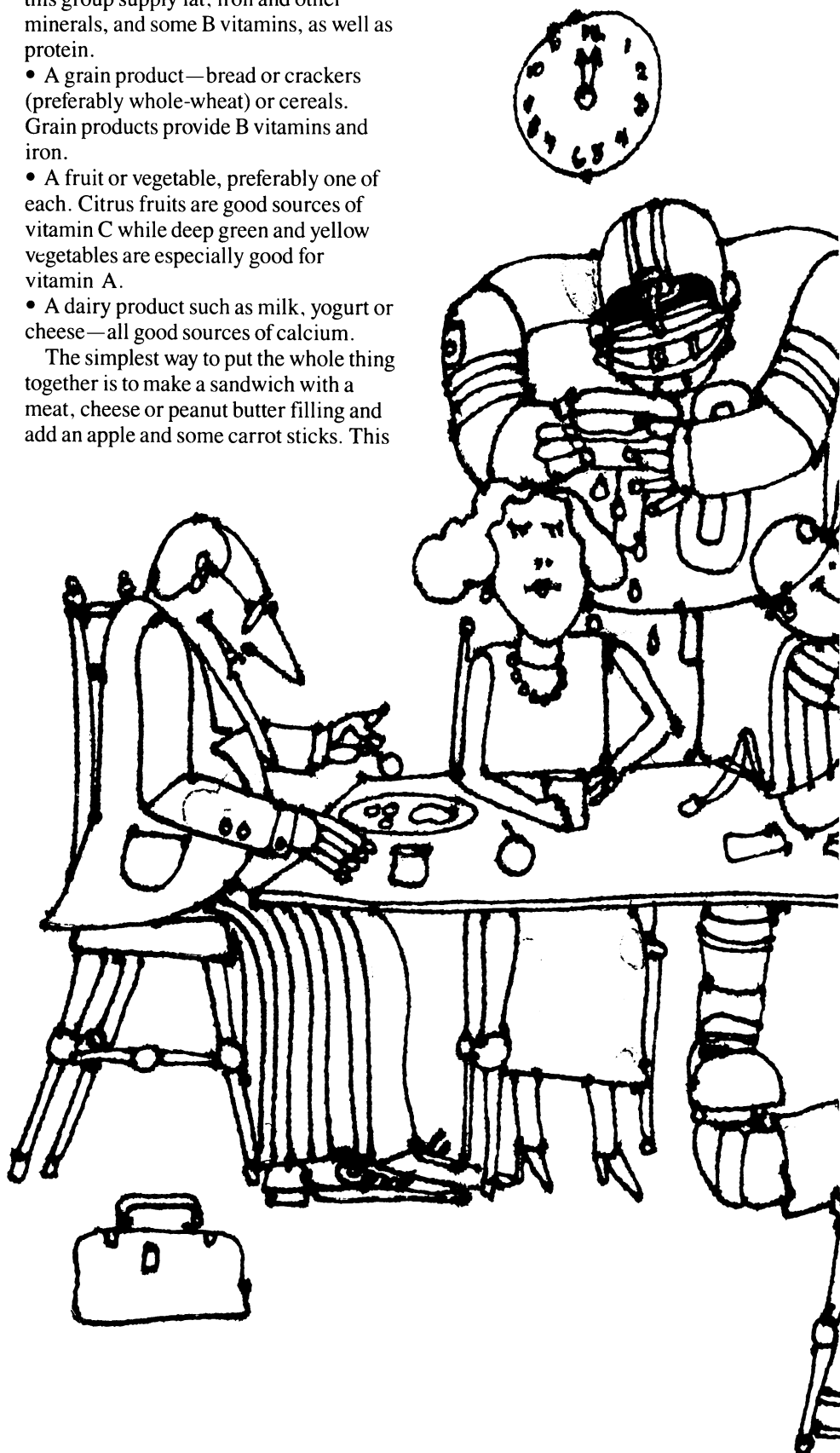
this group supply fat, iron and other minerals, and some B vitamins, as well as protein.

- A grain product—bread or crackers (preferably whole-wheat) or cereals. Grain products provide B vitamins and iron.

- A fruit or vegetable, preferably one of each. Citrus fruits are good sources of vitamin C while deep green and yellow vegetables are especially good for vitamin A.

- A dairy product such as milk, yogurt or cheese—all good sources of calcium.

The simplest way to put the whole thing together is to make a sandwich with a meat, cheese or peanut butter filling and add an apple and some carrot sticks. This





can be topped off with cookies for dessert and a beverage.

For some children, this may suffice for a time. Some will insist on the same thing day after day. But eventually even the most lovingly made sandwiches can become a bore and may well end up in the lunch-room trash can. In fact, it's a good idea to ask from time to time just what is and isn't being eaten (and why).

It isn't hard to find ideas to liven up the school lunch. Many popular women's magazines carry articles with suggestions for nutritious lunches, and a number of supermarket chains have free leaflets on nutrition and meal planning. Cookbooks, too, have sandwich recipes that aren't just for tea parties. Here are some ideas for nutritious school lunches gleaned from some of these sources:

For sandwiches, try hard-cooked eggs, chopped and mixed with mayonnaise or salad dressing. Spice them up with chopped onion, celery, green pepper, raisins or bean sprouts.

Instead of using sliced cheese, grate it and mix it with salad dressing, chopped nuts, onion or crushed pineapple.

Last night's chicken, without the high-fat skin, can be sliced or chopped and mixed with mayonnaise or salad dressing and shredded raw vegetables.

Tuna or other fish can be mixed with dressing and chopped vegetables, such as celery. (Remember, tuna packed in water has fewer calories than that packed in oil.)

Dress up plain old peanut butter with raisins, chopped nuts, bananas, apples, or pineapple, for a treat that's extra nutritious.

Go easy on the processed meats such as salami, bologna and other cold cuts. They are tasty and convenient, but may be high in salt and fat.

Protein doesn't have to come between two slices of bread. Chunks of cheese or ham, cottage cheese, a chicken wing or leg, chili or soup (in a wide-mouthed vacuum bottle, of course), and peanut butter-filled celery stalks all will fill the bill. And instead of bread, try whole-wheat or sesame crackers, home-made rolls or muffins, or pita bread, an unleavened bread from the Middle East, filled with a favorite sandwich stuffing.

Raw vegetables—carrot or celery sticks, cauliflower or broccoli florets, cucumber slices, green pepper slices—are crisp and fun to eat, especially with a home-made dip. Lettuce leaves and sliced tomatoes can serve as a salad, or be added to a sandwich just before eating.

Fresh fruits in season need little preparation. When canned varieties are used,





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## Putting a Little Punch in Your Lunch

*Almost anything goes when it comes to lunch, as long as one item is selected from each of the four basic food groups and isn't excessive in sugar, fat or sodium. Here are a few sample menus; mix them up or add any of your family favorites and enjoy.*

Chopped egg on whole-wheat bread  
Celery and carrot sticks  
Nuts and raisins  
Milk

Peanut butter mixed with chopped dried fruit or walnuts on zucchini bread  
Broccoli florets  
Yogurt with fruit  
Vegetable juice

Ham and cheese cubes  
Bran muffin  
Fresh tomato slices  
Berries  
Oatmeal cookies  
Milk

Apples stuffed with peanut butter  
Sesame crackers  
Green salad (lettuce, green pepper, cucumber)  
Unsalted sunflower seeds  
Milk

Lettuce wrapped around sliced turkey  
Sliced, buttered Boston brown bread  
Banana and plain yogurt  
Fruit juice

Chicken noodle soup  
Swiss cheese sandwich on rye bread  
Three-bean salad  
Fruit bars  
Milk

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look for those packed in their own juice or light syrup. They have less sugar than heavy syrup packs.

For some people lunch wouldn't be complete without dessert. While prepackaged puddings, fruit pies or cupcakes are convenient, they are notorious for their excessive calories. Fruits or yogurt can double for dessert. There's nothing wrong with an occasional cookie or brownie—provided the child eats the rest of the meal first.

As for the beverage, it usually is cheaper to buy milk at school. Many schools now offer low-fat milk products that contain less fat and cholesterol and fewer calories. Fruit and vegetable juices can substitute for milk if lunch includes another dairy product, such as cheese or yogurt. Some juices and fruit drinks are now available in single-serving cans or paper cartons complete with straws.

Teenagers who "brown bag" should carry basically the same things that the younger members of the family do—only more. As any mother knows who has watched the contents of the refrigerator disappear, teenagers seem to be perpetually hungry. And no wonder, for 15- to 18-year-old boys need 2,800 calories a day while 19-year-olds need 2,900. In contrast, a man over 50 should be taking in only 2,400 calories.

Girls don't need as much in the calorie department as boys, but they still should eat more than their moms and grandmothers—2,200 calories a day for 11- to 14-year-olds versus 2,000 for a woman 23 to 50 years of age and 1,800 for one over 50.

Whether or not they are consuming a healthy, well-balanced diet is usually of small concern to most teens. It isn't easy to do, but they should be encouraged to limit their intake of foods high in sugar, salt and fat (e.g., candy bars, chips and pretzels) in favor of those that are more nutritious, such as fresh fruits and raw vegetables, low-fat yogurt, and unbuttered popcorn, when they get the urge to snack.

For working adults with a creative culinary urge, almost anything can fill the brown bag. More and more offices now have small refrigerators and microwave ovens, opening up a wealth of luncheon possibilities, especially those made from leftovers. A delicious meal can be packed in a microwave-safe container, all ready for reheating. Extras such as lettuce, tomatoes, or pickles that will wilt in the microwave oven should be wrapped separately, of course.

Even when these amenities aren't available, brown bag lunches don't have to be mundane. Perk up sandwich fillings in the ways already mentioned. Fill a vacuum

bottle with chilled soups in the summer and hot ones in the winter. Instead of a sandwich, bring a fresh fruit or vegetable salad in a plastic container and enjoy it with a bran muffin, or rye or wheat crackers.

Packing the lunch does require some care, since it may be standing at room temperature for several hours before being eaten. To make sure that it doesn't turn into a gastronomic disaster, use fresh or thoroughly cooked foods and avoid those that are likely to spoil easily, such as rare roast beef and home-made mayonnaise. Don't use leftovers that have been in the refrigerator for days.

The same kitchen cleanliness rules for preparing at-home meals apply to brown-bag lunch making. Be sure that utensils, hands and work areas are clean. Wash food containers, including the lunch box itself, after each use. Don't reuse paper bags that have already carried food.

Lunch should be kept as cool as possible. Insulated lunch boxes are available, but there are other tricks a cool-headed lunch packer can use, such as freezing sandwiches in advance (they'll thaw out by lunchtime—but don't put the lettuce or tomato in before freezing them). Some sandwich fillings that freeze well are peanut butter, cheese spreads, cream cheese, sliced meatloaf, chicken and fish, and hard-cooked egg yolks. Raw vegetables and hard-cooked egg whites don't fare well in the freezer. Another trick is to prepare the fillings the night before and chill them. If there is some time before the school bus or the car pool rounds the corner, keep the whole lunch in the refrigerator until the brown bagger is ready to go.

In really hot weather, put something cold in the lunch bag—a cold drink, a small plastic refrigerator dish filled with water and frozen, or one of the new commercial freezing gels, suggests the U.S. Department of Agriculture in the publication *Safe Food To Go*. Some plastic lunch boxes have lids that can be frozen to keep foods cool for several hours. Canned drinks and some of the juices in paper cartons can also be frozen.

So, when packing lunches, remember: Keep work areas clean, use foods that are thoroughly cooked and unlikely to spoil if they are unrefrigerated for a time, make a balanced meal with nutritious foods that provide more than calories, keep them cool as long as possible, and carry your lunch box or brown bag proudly! ■

*Annabel Hecht is a member of FDA's public affairs staff.*



*'Beer'*  
Nonalcoholic  
*'Wine'*

How  
Close  
To  
The  
Real  
Thing?





***'Black Label Non-Alcoholic has just 60 calories, and a very low sodium content, attributes which satisfy current lifestyle interests in physical fitness, health, diet and moderation.'***

by Roger W. Miller

The quote above is from a press kit handed out when a national brewer recently introduced a new brand of nonalcoholic malt beverage (beer). The statement says a lot about Americans' changing attitudes about themselves, and in particular the growing concern about their drinking habits.

The concerns about alcoholic beverage consumption were demonstrated in a 1985 nationwide survey by the Roper Organization in which nearly half the people—45 percent—categorized drinking as a high risk from a health and safety standpoint.

That was up from 34 percent in 1978.

The introduction of the new nonalcoholic malt beverage is yet another example of how the marketplace responds when the public changes its mind. Since their rediscovery a few years ago, nonalcoholic malt beverages and wines have become something of a growth industry. It's not that they threaten the market for "real" beers; these impotent versions are finding a niche of their own by satisfying "current lifestyle interests."

Despite their promotion of moderation, the nonalcoholic products are not without controversy. The controversy concerns the amount of alcohol that may be in the products and whether alcoholics can safely use them as substitutes for alcoholic beverages.

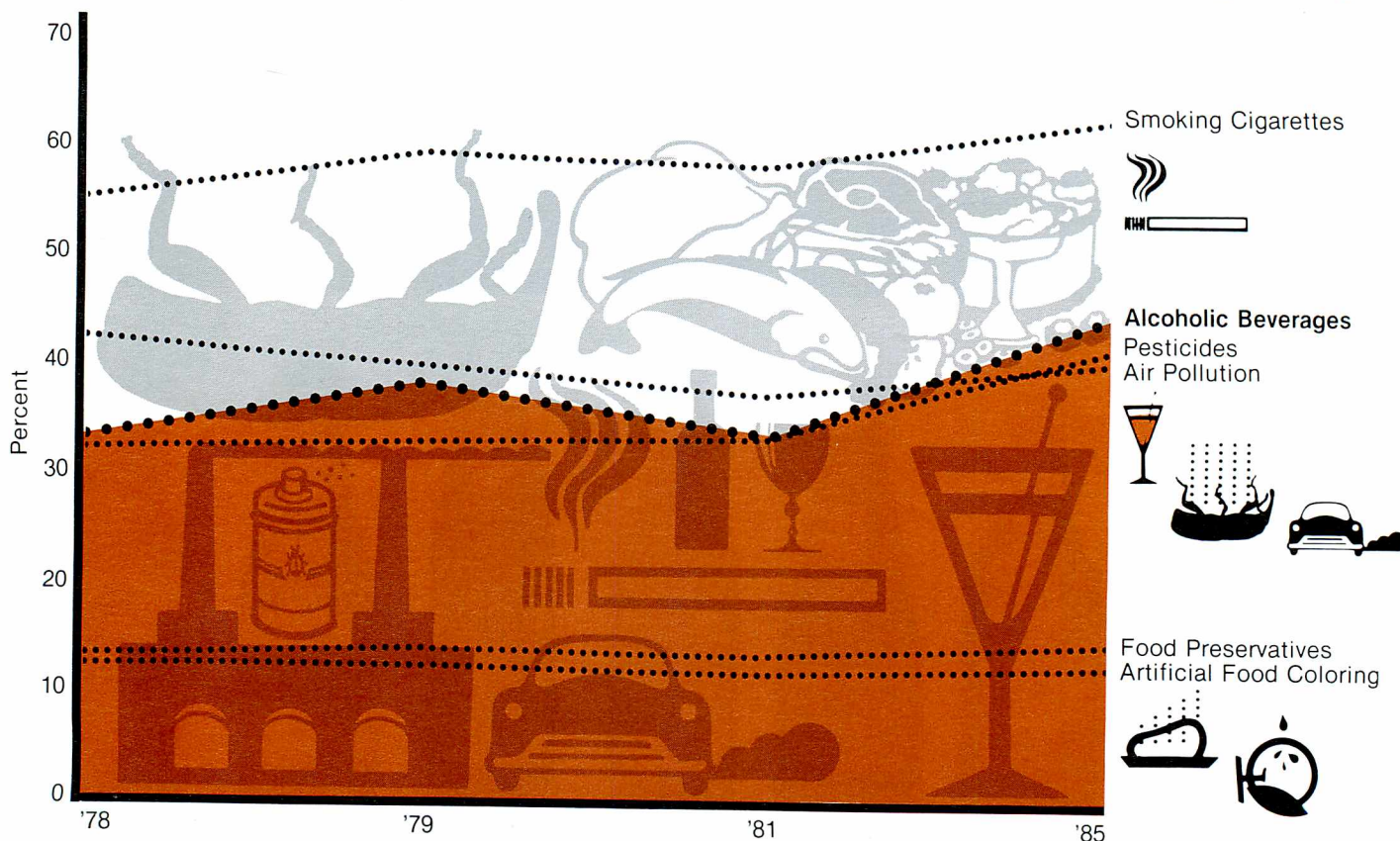
The products have less than one-half percent alcohol (by volume), compared with 4 percent for regular beer, 3 percent for light beer, and 12 percent for most wines. The nonalcoholic drinks may not be entirely free from alcohol, as there is no known process that will extract all the alcohol from an alcoholic drink. However,

one producer advertises that it makes the beer "without alcohol in the first place."

The small traces of alcohol make the labeling of the beverages an issue. Under current regulations, beers (malt beverages) and wines qualify as nonalcoholic if they contain less than 0.5 percent alcohol. But does even that much alcohol threaten an alcoholic who tries to use the drinks as a substitute for real beer and wine?

One-half percent alcohol in a drink is hardly considered sufficient to bring on drunkenness. According to a consultant's report to the Federal Trade Commission, James M. Schaefer, Ph.D., director of the Office of Alcohol and Other Drug Abuse Programming at the University of Minnesota, estimated that "in order for the average, healthy, 160-pound individual to sense the cognitively registered alcohol induced reactions, 8 to 11 five-ounce 'nonalcoholic' wine drinks at .5 percent would need to be consumed within 10–15 minutes." And he adds: "The social aspects of drinking 8 to 11 nonalcoholic drinks in rapid succession would be con-

## Degree of Risk Perceived by Consumers About Certain Health, Safety Items ("High Risk")



Percent of consumers who perceived the item as a high risk. Source: Roper Organization





sidered abnormal behavior in most social circles."

However, even small amounts of alcohol may induce an alcoholic to return to his or her old habits, some experts fear. Kenneth Warren, Ph.D., director of the Office of Scientific Affairs, National Institute on Alcohol Abuse and Alcoholism, fears that an alcoholic who turns to nonalcoholic "beer" and "wine" to stay on the wagon "may not have a long-term prognosis of a favorable outcome." But, he adds, it's too early to tell, as no studies have been done in the area.

*Consumer Reports* magazine, which tested two imported nonalcoholic malt beverages for alcohol content and found they contained 0.06 and 0.28 percent alcohol, quotes Walter Murphy, former executive director of the National Council on Alcoholism as saying: "We just don't know what level of alcohol could trigger an alcoholic episode. I can't imagine why anyone would want to take the risk."

The University of Minnesota's Schaefer addressed the "relapse" potential in his report to the FTC, noting that the minute amount of alcohol in these beverages may not be as great a concern as psychological factors involved in drinking substitutes that are so similar to the real thing.

"There is no clear evidence that the 'nonalcoholic' drink would be a more likely source for a 'slip' than any other drink that tasted and smelled familiar," Schaefer said, "or any other evoked inner feeling, 'just like the good old days.'"

"In physiological terms the ethanol [alcohol] content of one to eight such drinks in an hour would provide no detectable blood alcohol response and would be the equivalent of a mild carbohydrate or a mild sugar load on the digestive system," according to Schaefer's report. "But the psychocultural dimension of relapse is more than mere chemistry. It involves challenges in the softer world of words and meanings."

The controversy surrounding the label-

ing of nonalcoholic beverages leads to a bureaucratic thicket involving not only the FTC, but also the Food and Drug Administration and the Bureau of Alcohol, Tobacco and Firearms (ATF) of the U.S. Treasury Department. ATF has a policy that permits the use of the words "non-alcoholic" and "alcohol-free" to describe wine and malt beverages of less than 0.5 percent alcohol. ATF also requires that the qualifier "contains less than .5 percent alcohol by volume" accompany any use of the word nonalcoholic.

"Nonalcoholic" has been the term used for over a half century to describe non-alcoholic malt beverages with less than 0.5 percent alcohol. Government and industry officials think it should continue to be, and ATF maintains that the addition of the language "contains less than .5 percent . . ." will aid those who are trying to avoid even such small amounts of alcohol. (ATF also does not permit the use of the word beer to describe, on labels or in advertising, malt beverages of less than one-half percent alcohol.)

FDA, which regulates de-alcoholized wine, agrees with the use of the term "nonalcoholic" despite the half-percent maximum because a number of foods, including some soft drinks, have traces of alcohol in them. But FDA objects to the term "alcohol-free" because it implies that all alcohol has been removed when that may not be the case.

Just how good are the nonalcoholic beverages from aesthetic and social standpoints? Many of those who've tasted them rate them as acceptable and maybe more. The nonalcoholic malt beverages may offer a slightly different beer taste, but it is a beer taste nevertheless and many drinkers get accustomed to it. Further, those partial to the beverages tell of regular beer drinkers accidentally getting a nonalcoholic brew at a party or poker game and never noticing the difference.

From a social perspective, the nonalcoholic beverages permit the user to allow

others to think that he or she is imbibing right along with them.

To date, the sales of nonalcoholic beverages have hardly amounted to more than a drop in the old beer bucket, and some industry analysts say that they don't expect much more to happen. ATF says that sales of domestically produced non-alcoholic malt beverages were 388,460 barrels (of 31 gallons each) in the year ending Sept. 30, 1983. The next year it climbed to 522,541 barrels, and for the year ending Sept. 30, 1985, slightly increased again, to 536,540 barrels. Those figures compare with annual sales of regular beers of more than 180 million barrels. However, those figures include only domestically produced brews, and a number of nonalcoholic malt beverages are imported from England, Canada, Germany and Switzerland.

The G. Heileman Brewing Co. of La Crosse, Wis., which calls itself the largest producer of nonalcoholic malt beverages in the world, reports that growth in sales of nonalcoholic brews has been in the double-digit area and continues to climb. Its Kingsbury brand, which has been advertised in *USA Today*, is the nation's No. 1 seller, the firm says. Last year, sales of that brand were up 43 percent to 2.3 million cases (about 167,000 barrels). Kingsbury nonalcoholic is produced in breweries in five cities. Heileman, which is the nation's fourth largest brewer, has three other brands of nonalcoholic brew.

A few years ago, an eastern brewery advertised its regular alcohol content beer as "the one beer to have when you're having more than one." Moussy, a Swiss nonalcoholic import, advertises as "the beer to drink when you choose not to drink." These wallop-less brews might also be touted as "the one beer to have when you're having none." ■

*Roger W. Miller, director of FDA's communications staff, has been known to have more than one nonalcoholic brew.*



# FDA Gets Ready for The 21st Century

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**W**hen Dr. Frank Young became FDA commissioner two years ago, he immediately set the agency to work on an "Action Plan" to prepare FDA for "the challenge of the 21st century." After months of meetings among FDA officials and with countless groups from outside the agency, the 64-page plan, with its 10 major goals, was made public in July 1985. (See "FDA 'Plan for Action'" in the Updates section of the October 1985 FDA Consumer.)

No time was wasted in starting to implement the plan's recommendations, which covered such areas as speedier review of new drugs and medical devices while improving the quality of those reviews, strengthened post-marketing surveillance of FDA-regulated products, and increased public awareness of health fraud, among others.

What does this Action Plan mean to American consumers in terms of improved public health? FDA Consumer editor Bill Rados met with Dr. Young to find out, and to see how the plan is faring in the real world of conflicting priorities and limited budgets. The interview follows.

**Q.** What made you decide FDA needed a plan for the future, and how did you go about accomplishing it?

**A.** Basically, the need for a plan emanated from experience that I've had in the past helping other organizations, such as the University of Rochester's medical school, reach their fullest potential. FDA is the most important consumer protection agency in the world, so we developed a program that acknowledged that "Here is a very strong agency," and asked "What can we do to renew it to prepare it for the 21st century; to prepare it for the enormous changes in technology in the fields of drugs, medical devices, foods, animal husbandry, radiation protection, and the other areas that we deal with?"

At the turn of the 20th century, FDA was mainly looking for filth and other gross contamination of the products we regulate. At the turn of the next century, we are going to be concerned with regulating food and drug manufacturing done mainly by automation, with computer systems that will monitor body functions and help assess the effectiveness of new therapeutics. We're already beginning to see high-technology medical devices, such as the artificial heart and other replacement

organs. These technological changes in the health-care industries and in the health professions will change the Food and Drug Administration markedly; there will be a vast shift in focus for FDA's responsibility.

To prepare us for this new frontier in medicine, we've put together a plan that is not a Frank Young plan but is an agency plan, with teams of agency people that met with individuals from outside the agency and brought together a concerted view of where FDA should be headed. There's a true renewal from the grass roots up.

**Q.** What has been the most difficult part of the Action Plan to implement?

**A.** I think the most difficult part was to convince all of us, me included, that a federal agency can not only plan but can implement its plans. The average view of government planning is that the product is "The Plan." And when "The Plan" is developed it's simply put on a shelf where it gathers dust. Nothing is implemented. Getting those outside the agency to believe that we were serious about not only developing a workable plan but then implementing it as well—that was the most difficult part.

But the outside world now knows that we're committed to action. Our constituents are beginning to watch the Action Plan and to judge its success. In less than two years most of the plan will be virtually completed. Particularly important in the implementation of the plan was the development of APRES [Action Plan Reporting and Evaluation System], initiated under the leadership of [Deputy Commissioner] John Norris and [Associate Commissioner for Planning and Evaluation] Jake Barkdoll.

**Q.** Two of the most important goals in the plan are to speed up the review processes for new drugs and for medical devices. This has been attempted many times in the past. What's different about the Action Plan that makes you think that this time we'll succeed?

**A.** There are three things that are different this time. First, the plan to improve the approval process was built by the agency—it's an agency plan. It's not someone else's goals to improve the process, imposed from without. It's the work and cooperation of the people within FDA that are going to make the difference.

Second, we're implementing important managerial changes. We will put in tracking programs to look at input and output of approval applications, for example. In fact, in the medical device area, the Center for Devices and Radiological Health is already doing a spectacular job of this, and the analysis clearly shows the dilemma we have: Workload—in terms of the number of applications for FDA approval of new devices—going up, and resources—in terms of employees to review the applications—going down. How do you deal with that? Well, part of that is a management approach. In medical devices, we've begun a tracking system and determined where redundant reviews can be abolished





***"The need for [the Action Plan] emanated from experience I've had helping other organizations . . . reach their fullest potential."***

and the process streamlined. In all of the previous fiscal year, 37 pre-market approvals were accomplished; in the first eight months of the fiscal year after the managerial changes were in place, there were 48. And the number of overdue supplemental applications is dropping considerably.

Those accomplishments have happened not because the commissioner put them in place but because people down in the "trenches" really feel that this is important. The Center for Devices and Radiological Health, under the leadership of [Center Director] John Villforth, [Deputy Director] Jim Benson, and [Director of Device Evaluation] Kshitij Mohan, demands a great deal of performance from its device reviewers, but there is very high morale in this group and they know how much they're accomplishing. Being able to measure progress is of key importance because problems can then be identified and the system changed.

Similarly, the Center for Drugs and Biologics has made significant improvements in the area of generic drug application review, under the management of [Center Director] Dr. Harry Meyer, [Deputy Director] Dr. Paul Parkman, James Morrison [deputy director, Office of Drug Standards], and Dr. Marvin Seife [director, Division of Generic Drugs]. In fact, the center is now well under the statutory time limit for reviewing applications for generic drugs. One of the Action Plan goals was to complete the review within 180 days—as the law requires. We now have 95 percent of the applications approved or disapproved in 140 days. In the area of new drug approvals we're counting on the leadership of Dr. Robert Temple [director of drug research and review] and Dr. James Bilstad [deputy director for medical affairs, Office of Biologics Research and Review].

While the management issues are important, these kinds of changes alone are insufficient. So, as a third point, we need to shift resources, first to the highest priority areas and then to other priority areas. Of course, the commissioner can only move resources at the margin. In fact, the total number of personnel that I've reassigned is less than 100 out of 7,000. But when you can provide 20 new people to device evaluation to assist the approval process because they're doing such a spectacular job, that sends a signal that we are committed to getting the job done. And when we can allot more positions to drug approval—approximately 40 new medical reviewers next year—that sends a signal. We just need more people in these areas to get the job done.

But that does produce some problems: It is difficult to manage our resources so that we don't disadvantage other parts of the agency or create the feeling that the work being done in those other areas is not important, because, of course, it is important. The Action Plan is a renewed commitment to certain goals; it's not a substitute for sustained commitment to excellence across the broad range of FDA's responsibilities.

**Q.** *Are there not limits as to how fast scientists can perform the reviews?*

**A.** We are not in any way going to sacrifice the quality of our reviews in determining the safety and effectiveness of these drugs and devices. Our problem is that our reviewers haven't been able to even get to the applications. The 25-month average approval time doesn't mean that someone's working on the application for 25 months; we simply don't have the resources to be able to get to it fast enough. The combination of additional resources, better facilities, and better management that the Action Plan



***"The average view of government planning is that the product is 'The Plan.' And when 'The Plan' is developed it's simply put on a shelf where it gathers dust."***

calls for is going to make a real difference. But these are long-term solutions. There is no "quick fix" that will address these complicated concerns immediately.

Not only do we need to improve our part of the review process, but the drug and medical device manufacturers have a role to play, too, in making sure their approval applications are well prepared so our reviewers don't have to waste time wading through a hodgepodge of poorly presented data.

Imagine an application for approval of a new drug in excess of 100,000 pages. It would be twice as tall as I am. And you're the FDA reviewer, and the manufacturer wheels it into your office and says "Good luck, review it." Well, as that reviewer, you may know that the company was just packaging that thing together to send it off to you as quickly as possible and it may not be well quality-controlled. When I was teaching, I wanted an essay of three pages from my students, so I did the following: I gave a clear instruction. Then, when I received a longer essay, I ripped off the first three pages, threw the rest away, and graded only the first three pages. I only needed to do that once.

Regrettably, FDA sends out a signal: "We want a well-organized application" and then reviews anything that comes in the door. So we need to give a better signal of what we expect, and if it doesn't get done we'll send it back. In fact, I want to be on the loading dock when we send some of those poor-quality applications back. The company's CEO [chief executive officer] only needs to receive one application back because of improper preparation before his staff is going to get the message.

But there's still another ingredient that I can't stress enough: We need people who are both active scientists and reviewers. The scientist/reviewer will be able to

examine the application from his or her position as a practitioner of state-of-the-art science. It was possible to approve alpha interferon within six months, as we did recently, because the person reviewing the application was an expert on interferon. At that point it's going to be easier to assess the risks. It's going to be easier to understand the nuances. So we've got to have an environment where our reviewers can go to national meetings, where our reviewers can be involved when necessary in clinical teaching, and where they can be involved when necessary in research.

**Q.** *Besides interferon, are there other drugs or devices that show the progress that's been made in speeding up FDA's review process under the Action Plan?*

**A.** I can give you a few examples. The HTLV-III antibody test for screening blood for antibodies to AIDS took approximately 10 weeks. The lithotripter—a device to remove kidney stones without surgery—was approved in less than a year. This was possible, as with the AIDS blood test, largely through very active interaction between the reviewer and the sponsor of the application.

Another example would be the approval of 30 new chemical entities [brand new types of drugs] last year, including ribavirin for respiratory syncytial virus, and human growth hormone produced by genetic engineering: Major accomplishments. But we must focus on the quality of the approval process rather than merely counting numbers.

**Q.** *While we're hoping to get products to the market more quickly, we're also working to see that they're watched more closely once they are approved. What's being done to improve our surveil-*



***“We’ve been in the emergency mode since the beginning of January.”***

*lance capabilities?*

**A.** Because of the relatively small number of people that participate in clinical trials, you just can’t have a process of approval that will catch every problem with a new product before it gets out on the market. Therefore, the Action Plan calls for, and we have implemented now, post-market surveillance in every part of the agency.

Of course, surveillance is of no use if the reports we receive aren’t investigated promptly. So the Center for Drugs and Biologics over the past three years has decreased the backlog of unanalyzed reports about adverse reactions to drugs from many months to two weeks under the able leadership of Dr. Gerald Faich [director of epidemiology and biostatistics]. That adds an important layer of safety because only about 5,000 patients, at the most, are studied with a particular drug before it is approved; only about 1,000 with a new medical device. Once approved, these products are used on hundreds of thousands or millions of people. So we need to know if there are any rare or unanticipated adverse reactions, and we need to know as rapidly as possible so we can take corrective action.

Before the Action Plan, we didn’t have a post-market surveillance system for foods; we now have one. A new regulation for post-marketing surveillance of medical devices is in effect now, as well. Just last year, for example, we were able to identify problems with apnea monitors [devices used to check infants for lack of breathing during sleep]. A few children were injured and one died, regrettably, because the wires that attached the monitor to the baby could be directly plugged into the wall outlet by mistake. Because we have a post-market surveillance system for medical devices such as these monitors, we rapidly

learned about that problem and the industry made important changes that eliminated the hazard.

**Q.** *How is the Action Plan faring as it comes up against the real world of budget constraints? Is this going to cause shifts in priorities?*

**A.** It has been important that we had the Action Plan at a time of diminishing resources because we have been able to use it as a budget plan as well. Because it is an Action Plan that is agency policy, fully supported by [Department of Health and Human Services] Secretary [Otis] Bowen, it has been transformed from solely a programmatic plan to a budget document as well. So our budget requests are made with the Action Plan’s priorities in mind. The Action Plan gave FDA a way of saying “We need resources for this particular approach.”

Thus we were able to recommend to the Administration that we should consider user fees [charged to drug companies to review their marketing approval applications]. Those fees—if special authorizing legislation is enacted by Congress—would enable us to add a substantial number of individuals to the agency for product approval. It’s a good approach, in my opinion, because the beneficiaries of the application approval should, in part, pay for it. Many other countries—Sweden and Switzerland, to mention just two—have user fees. User fees would add additional revenue to FDA to improve the drug approval process. As I have emphasized repeatedly, more personnel are required for drug review.

**Q.** *FDA has recently been involved in handling tampering emergencies involving Tylenol and several other drugs. How does this kind of emergency response*





***"The 25-month average approval time doesn't mean that someone's working on the application for 25 months; we simply don't have the resources to be able to get to it fast enough."***

*affect our ability to do our routine business of reviewing new drugs and devices and so forth?*

**A.** We've been in the emergency mode since the beginning of January. But there is no impact of the emergency activities on the drug and device review process or some of our other standard operations, such as post-market surveillance, because different people are involved. Even though our expenditures on investigating consumer complaints have doubled this year, we do have a small amount of dollars in a special emergency fund provided by Congress for meeting emergency needs, and we have been approved for a half million dollars to cover our emergency operations thus far this year. We will undoubtedly continue to have expenses and we will determine whether we have additional fiscal needs.

The primary difficulty that we face is that a portion of our field forces has not been able to do routine inspections, and that's a real problem for us. In fact, the lack of routine inspections can affect our ability to deal with emergencies when they do occur. For example, we were able to know that a recall of Gerber's infant food was not necessary at the time of the reported glass incidents, because we had just inspected Gerber's plants. We knew from the start that the quality control was satisfactory and that we were dealing with tampering at the site of purchase rather than a failure in manufacturing practices. But if we don't do those routine inspections, then at a time of emergency we won't have the data we need. We believe that the combination of good manufacturing practice inspections and emergency actions undertaken under the leadership of Paul Hile [former associate commissioner for regulatory affairs, who retired June 30] has really served the American

public well this year.

**Q.** *Let's move on to quackery, another one of your major concerns, and, again, a question of resources. How can the agency realistically devote its attention to quackery where, in many cases, there is no direct threat to health and when we have so many competing demands on our resources, from product tampering to drug review?*

**A.** FDA works best if it can form constituencies amongst a wide variety of groups and can then use its enforcement and education tools most appropriately. In the case of health fraud we feel that we can amplify our actions through the involvement of a large number of groups and through public education. We've used the Pharmaceutical Advertising Council to design an education program with us, for example. The focus on education has been highly effective and still less resource-intensive for FDA than other more enforcement-oriented methods.

Health fraud is a disease, and education of consumers is one of the best remedies because it primarily serves as "preventive medicine." It helps the customer to avoid being cheated.

**Q.** *Let's talk about risk assessment, particularly with regard to cancer-causing substances in the food supply. Do you believe that the agency in the past has been too cautious, too conservative, perhaps, in regulating hazardous substances and now we need to move in the other direction?*

**A.** In the past when the agency has acted in the field of risk assessment, it has always attempted to use the best scientific knowledge available. But problems with risk assessment began to



***“The bottom line is that the Action Plan is designed to help the most significant consumer protection agency be ready for the 21st century.”***

occur as our scientific capabilities improved. For example, in 1958, when the food safety amendments were enacted, we could detect hazardous substances in food at the level of 1 part per thousand or 1 part per 10 thousand. We can now assay down to 1 part per trillion—an enormous degree of sensitivity.

It has been an evolutionary change. Now we realize that we need to examine the risk of food additives in view of the sensitivity of our current analytical methods. Thus, we can analyze substances in such great detail, and we’re finding a large number of carcinogens. But sometimes the level is so small that a substance provides essentially no risk to people. To address that situation, we began to enunciate our *de minimus* policy, which essentially says that the law does not deal with trifles. This still leaves the Delaney clause [which bans the addition of cancer-causing substances to the food supply] fully intact, but states that a risk of cancer over a lifetime of one in a million from a particular substance constitutes a risk that’s so very low as to be insignificant.

There’s no question that these are complex issues, and we need a better public understanding of these concepts. One of the roles of a magazine like *FDA Consumer* is to participate in such public education.

**Q.** *To a public that may not be familiar with the details of how FDA works, with the milestones and other things associated with the Action Plan—What’s the bottom line for them? How does this plan pertain to their own better health?*

**A.** The bottom line is that the Action Plan is designed to help the most significant consumer protection agency be ready for the 21st century. In that sense, we

are renewing our pledge to protect the public health. After all, 25 cents of every consumer dollar is spent on products regulated by FDA, and this agency has to be able to ensure that the drugs and medical devices the public depends on are safe and effective and that the food we consume is wholesome. The renewal of that pledge to carry out our fundamental mission of public health protection is what the Action Plan is all about. It focuses our energies on public health actions. ■





# Weighing the Risks of the Raw Bar

by Carol Ballentine

The day after a women's club luncheon in Old Westbury, N.Y., 14 of the members began to feel extremely unwell. Their symptoms—nausea, vomiting, diarrhea, chills—spoke strongly of food poisoning as the cause. The New York State Health Department was notified and, after some medical sleuthing, the culprit was identified as raw littleneck clams the women had eaten.

Only four days earlier, on Nov. 22, 1984, eight people had dined on raw clams at a restaurant in nearby Eastchester, N.Y., and then had developed similar symptoms. And in a little over a week, three more people would fall ill after eating at a restaurant in Syosset, N.Y.; again the food they would have been better off not eating was raw clams.

In all cases, the ailing individuals were advised to receive gamma globulin injections immediately to prevent getting hepatitis A, a prolonged viral illness that can be contracted by eating contaminated shellfish. Severe cases of hepatitis A can cause liver damage and, sometimes, death.

The three incidents in New York state are not isolated outbreaks. Reports of viral illness caused by eating shellfish (defined here as edible clams, oysters and mussels), and particularly raw shellfish, are steadily increasing, and the Food and Drug Administration and state shellfish regulatory agencies are concerned.

Many shellfish lovers are worried, too. Recent newspaper and magazine articles, prompted by a medical journal report last spring on illnesses due to eating oysters and clams in New York in 1982, have consumers wondering if eating raw—or even steamed—shellfish is too risky. FDA shellfish experts feel that caution *is* advised, and people with certain health problems should, indeed, avoid uncooked shellfish. But for most healthy individuals who take a few prudent steps, there's no need to totally shun the raw bar.

Since 1925, when the first national shellfish sanitation guidelines were developed by the Committee on Sanitary Control of the newly created National Shellfish Sanitation Program (a triumvirate of FDA, state agencies and industry), bacterial illnesses caused by bacteria in shellfish—such as cholera and typhoid—have been declining steadily. No documented cases of typhoid fever, once the most common shellfish-borne disease, have been reported due to eating shellfish since 1954. But in the 1960s, hepatitis A virus moved into the limelight as a shellfish pathogen. From 1960 through 1963, over 1,000 people were diagnosed with hepatitis A illness after eating oysters and clams.

In 1980, another virus appeared on the scene to make life miserable for raw bar devotees. The Norwalk virus was first identified in 1968 during an outbreak of gastroenteritis linked to drinking water in Norwalk, Ohio. But in 1980, the virus was found in oysters that had sickened six people in Florida.

Initially, the virus, which causes transient flu-like symptoms, was not thought to be a significant cause of shellfish-borne illness. But in March 1986, *The New England Journal of Medicine* described 103 outbreaks of shellfish-caused gastroenteritis due to this virus, in which 1,017 people became ill

in 21 counties in New York state between May 1 and Dec. 31, 1982. The shellfish had been caught off the coast of several northeastern states. (In November of that year, there was also an outbreak in Louisiana in which 472 people became ill and 25 percent of the state's shellfish harvesting beds had to be closed.)

*The New England Journal* article said, "Although recent shellfish-associated outbreaks have not reached the epidemic proportions of 1982, outbreaks in several northeastern states during 1983, 1984 and 1985 (including 59 outbreaks resulting in 888 documented cases within New York state alone) demonstrate that the problem is continuing. Until effective control measures are developed, the public should be warned that consumption of raw clams and oysters poses a risk of enteric [intestinal] illness, particularly Norwalk-like gastroenteritis."

Even as the article was being written, the shape of shellfish regulation was changing. The Food and Drug Administration was overseeing the first revision of the National Shellfish Sanitation Program *Manual of Operations* in over 20 years. The first part, "Sanitation of Shellfish Growing Areas," was published in June; the second part, "Sanitation of the Harvesting and Processing of Shellfish," is still in draft form and must be approved by the Interstate Shellfish Sanitation Conference (a voluntary organization of shellfish-producing states, FDA, the shellfish industry, and the U.S. Commerce Department's National Marine Fisheries Service).

The revised guidelines are an attempt to clarify and strengthen existing regulations—for shipping and storing shellfish, among other things—and create uniformity from state to state. The guidelines stress, for example, that shellfish must be traceable to their source from the moment they are harvested from a bay, river or other estuary to when they end up in a restaurant or market. This is vital, says J. David Clem, chief of FDA's Shellfish Sanitation Branch, "otherwise you might end up condemning the shellfishing waters in an entire area or state to control an outbreak." Each container of shellfish must have a tag or label, approved by the appropriate state shellfish control agency, that bears the information necessary to trace the shellfish both to a specific area and a particular harvester. When state inspectors check containers of fresh or fresh-frozen oysters, clams or mussels in markets, they will thus be able to verify if the shellfish came from approved waters. If the mandatory information is not present, they can have the shellfish removed and destroyed.

The increase in viral illness caused by shellfish has led to increased concern about the monitoring of the waters from which the shellfish come. (See "For Oyster and Clam Lovers, the Water Must Be Clean" in October 1984 *FDA Consumer*.) The safety of these waters, called growing areas, is determined largely by the level in the water of two groups of coliform bacteria, including fecal coliform bacteria (found in the intestines of mammals). If these bacteria are abundant, it means that sewage is present and that there may be disease organisms both in the water and in the shellfish (shellfish obtain nutrients by filtering them from water—thus they also take in any pathogens in the water, such as



*Roadside stands and trucks selling shellfish may have bargain prices, but they don't always have the safest shellfish. FDA advises consumers to buy oysters, clams and mussels only from reputable dealers.*



bacteria and viruses, which don't necessarily hurt the shellfish but may cause illness in humans).

Badly contaminated growing areas are restricted from shellfish harvesting. In areas of less contamination, shellfish may still be harvested, as long as they are subsequently purified, under permit, in holding tanks for several days before they are sold, a process called depuration. If Part II of the revised shellfish guidelines is accepted by the Interstate Shellfish Sanitation Conference, guidelines for depuration will be changed to require monitoring of different critical factors affecting the speed with which shellfish are cleansed. These factors include the salt content and temperature of the water, the way in which the shellfish are loaded into the tanks, and the species involved.

The revised guidelines have lowered the level of fecal coliform bacteria that must be present before growing waters are declared restricted. And the frequency with which growing waters need to be surveyed has been increased.

But many scientists feel that the use of coliform indicator organisms for determining the sanitary quality of shellfish growing areas is not good enough. In an editorial accompanying *The New England Journal* article, Dr. Herbert L. DuPont, an infectious disease expert with the University of Texas Health Science Center, urged that methods be developed to test specifically for viruses. "Studies have shown that the absence of fecal coliform bacteria in harvesting areas is an inadequate indicator of safety from virus contamination among shellfish," DuPont said. Also, he said, methods that purify shellfish of bacteria probably are not adequate to rid them of viruses.

FDA's Clem agrees that fecal coliform bacteria are poor indicators for measuring the health hazard posed by viruses, but there is no suitable substitute, he says. FDA is planning to review research reports on different organisms, such as viruses and bacteriophages (viruses that attack bacteria), that could be used to indicate the sanitary quality of shellfish growing waters. The most promising of these "indicator organisms" will be selected for further study.

But shellfish regulators agree that viruses in shellfish are an unresolved problem. Depuration is criticized because some scientists believe it is not as effective in cleansing shellfish of viruses as it is in negating bacteria. And cooking appears to be less effective in killing viruses than bacteria.

Because most of the recent illnesses have involved raw shellfish, some experts, including University of Texas' Dr. Dupont, say that eating raw shellfish is a risky business. The New York State Health Department has advised consumers to cook all shellfish before eating.

But FDA feels that such advice is unwarranted and, besides, the agency is skeptical that mere cooking alone will provide absolute protection to shellfish lovers. "Toxins and some pathogens won't necessarily be killed by cooking," says FDA's Clem. He points out that steamed clams, for instance, are usually judged to be done when the shells open, which happens after about a minute. But it takes four to six minutes of thorough cooking to kill most viruses. In England there was a case in which consumption of cockles (an edible bivalve mollusk common in Europe) caused hepatitis A—even though the cockles had been steamed first and

then boiled for four minutes. In any case, even if consumers do cook their oysters, mussels or clams at a high enough temperature (about 212 degrees Fahrenheit) and for a long enough time to kill any lurking virus, the food may be too tough to be worth eating at that point.

FDA does recommend, however, that people with certain health conditions cook their shellfish. Individuals with cancer, diabetes, liver disease, chronic gastrointestinal disease, or any condition resulting in impaired immunity should avoid raw shellfish, but not because of possible viral contamination. The bacterium *Vibrio vulnificus*, a natural inhabitant of coastal waters, can cause infections that lead to blood poisoning in people with these health problems. The mortality rate from *Vibrio vulnificus* infections for these people is 40 percent, according to the American Medical Association. Luckily, infections from *Vibrio vulnificus* are rare, and the bacteria are killed more quickly by cooking than viruses, so even those individuals with the risk factors can still indulge in a bowl of oyster stew or clam chowder.

Most oysters, clams and mussels being harvested are clean and safe to eat. Unfortunately, there is no way to tell which shellfish do harbor bacteria or viruses. Just because a clam or oyster looks and smells—and even tastes—all right doesn't mean it is free of contaminants, says Clem. A dish of raw oysters might well delight a person's palate one night and keep him awake the next with diarrhea and vomiting.

To guard against shellfish-borne illness, FDA advises consumers to buy shellfish only from reputable sources—definitely not off the back of a truck or from a roadside stand. Labels on the containers should identify the waters from which the shellfish were harvested.

Most cases of gastroenteritis caused by shellfish contaminated with bacteria or viruses usually clear up by themselves in 24 to 48 hours. But anyone with severe, persistent diarrhea and vomiting should see a physician.

Consumers who do get sick from eating clams, oysters or mussels should immediately notify their local health department and FDA regional or district office by phone (the offices are listed in the government section of the local white pages). This helps FDA assess the extent of the current risks from eating shellfish and to identify waters from which contaminated shellfish are being taken, either because they are being harvested from misclassified waters or because they are being bootlegged from condemned areas by unscrupulous harvesters (see "The Cop on the Boat, Tightening the Net Against Unsafe Shellfish," in the February 1986 *FDA Consumer*).

Meanwhile, FDA and the other members of the Interstate Shellfish Sanitation Conference continue to explore and develop better methods for ensuring shellfish sanitation. Purification methods are being improved, new ways to detect contaminants are being developed, and enforcement against illegal harvesting is increasing. Perhaps someday, viral epidemics caused by eating shellfish will go the way of typhoid fever, and people will only be able to read about them in history books. ■

*Carol Ballentine is a member of FDA's public affairs staff.*

# A Primer on High Blood Pressure

by Evelyn Zamula

Back in 1969 a group of volunteers permitted themselves to be fitted with a device that recorded their blood pressure at five-minute intervals as they went about their normal routines. Depending on what they were doing, it was found that their blood pressure showed wide swings during a 24-hour period. Activities such as sitting down, sleeping and doing mental work caused a drop in blood pressure. Driving a car caused a slight rise, exercise a greater rise, sexual intercourse a still greater rise. The researchers noted that during the course of the experiment, every person, even those with normal blood pressure, had what could be considered a high blood pressure reading at one time or another.

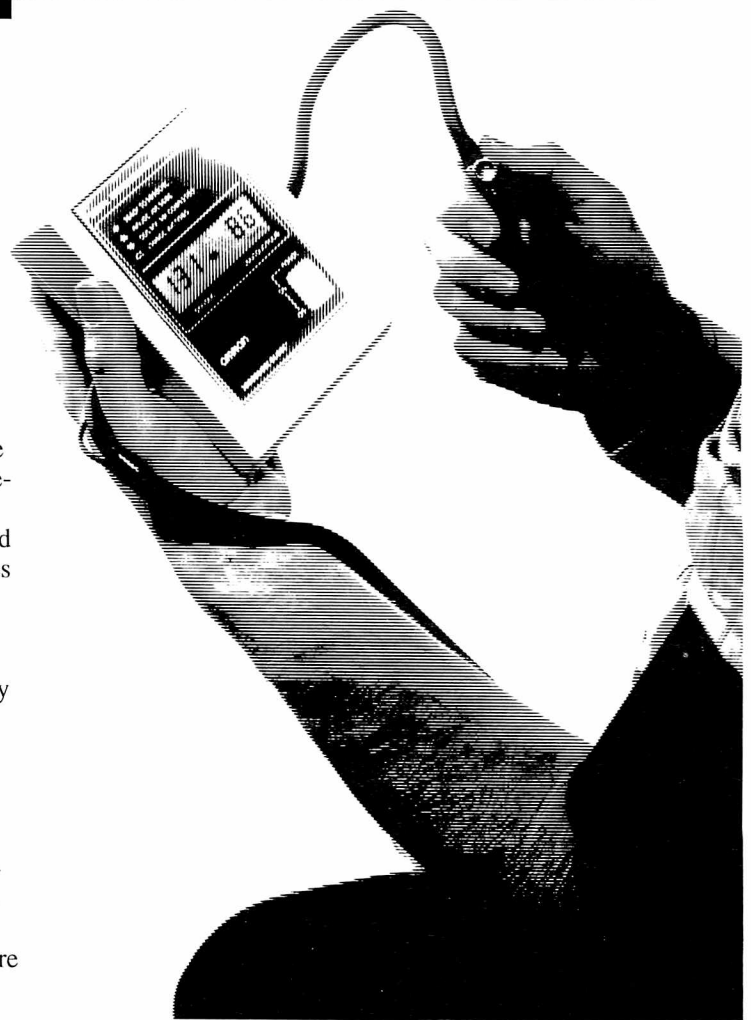
One subject with normal blood pressure, a physician on the hospital staff, got the extra treatment. As he was standing at the bedside of a patient, a nurse jabbed a pin in his buttock. Not surprisingly, his blood pressure jumped abruptly in response to the pain.

The body can take these temporary elevations of blood pressure in stride. Trouble begins when blood pressure goes up and stays up. That's when life expectancy goes down. Besides being the leading cause of stroke, high blood pressure can damage the heart, brain, kidneys and arteries. It increases the risk of heart attacks, congestive heart failure, and kidney failure. Even moderately elevated blood pressure can be dangerous, especially when combined with other risk factors, such as high cholesterol and obesity. A report on a Johns Hopkins University study that has followed over 1,000 medical students for 37 years found that "young adults with mild to moderate high blood pressure, high cholesterol levels, a hypertensive father or a weight problem are likely to face their 40s and 50s with heart disease and high blood pressure."

High blood pressure, also known as hypertension, is the most common circulatory disorder among human beings. With a few exceptions, such as in some of the South Sea Islands and remote parts of Brazil and Africa, it occurs all over the world, mostly in middle-aged or elderly men and women. It is estimated that as many as 60 million Americans have hypertension. Nearly half of all Americans who reach the age of 74 develop high blood pressure.

Blood pressure is the pressure exerted by blood on the artery walls. It is expressed as a larger number (systolic) over a smaller number (diastolic), for example, 120 over 80. What this means is that when the heart contracts to pump out blood to the arteries (systole), its force can drive a column of mercury up a tube to a height of 120 millimeters, designated mm Hg. When the heart is relaxed between beats and filling with blood (diastole), the column of mercury drops to 80 mm Hg, the diastolic reading.

The device used to measure blood pressure is called a sphygmomanometer. The word comes from the Greek *sphygmos*,



meaning pulse, and *metron*, meaning measure. The device consists of an inflatable cuff that is wrapped around the upper arm, a rubber bulb that is squeezed to pump air into the cuff, and a device (often a tube of mercury, sometimes a dial or an electronic reading device) that measures air pressure in the cuff.

A more accurate way to measure blood pressure involves inserting a catheter into an artery. The catheter is connected to a device that records the blood pressure as an electronic signal. For obvious reasons, this is not frequently used.

When blood pressure is taken with the sphygmomanometer, the examiner also uses a stethoscope to listen to the sounds within the artery. After inflating the cuff tightly enough to momentarily stop the flow of blood in the arm, a valve is opened and the air in the cuff gradually released. With the stethoscope placed below the cuff, the examiner listens for a distinct, thumping sound that blood makes when the air pressure is relieved and the blood flow resumes. The instant the examiner hears this sound, he or she notes the level of the mercury column; this is the systolic pressure. As more air is released from the cuff and blood once again flows freely through the artery, the thumping sound disappears. The pressure at the moment all sounds disappear is the diastolic pressure.

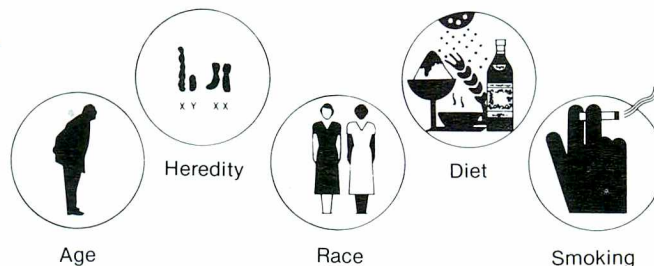
Newer devices use blood pressure cuffs plus digital readouts or electronic devices. Many use microphones or other sensing devices instead of a stethoscope. All properly calibrated instruments give reasonably accurate blood pressure readings. Their convenience and low cost make it easy for everyone to check his or her blood pressure.

(Continued on page 27)



## Stepped-Care Approach to Drug Therapy for Hypertension

When dietary changes and other efforts, such as stopping smoking, fail to adequately control high blood pressure, drug therapy is the next step. The chart below, from the National Institutes of Health, shows the "stepped-care" approach, which begins with the smallest dosage of the drugs with the fewest side effects, moving on to higher doses or other drugs if the hypertension is still not under control.



### Step 1

Begin with less than a full dose of a thiazide-type diuretic (e.g., hydrochlorothiazide, triamterene) ➡

OR

Begin with less than a full dose of beta blockers (e.g., propranolol hydrochloride, timolol maleate) ➡

Proceed to full dose if necessary and desirable.

### Step 2

If Blood Pressure Control Is Not Achieved:

Add a small dose of an adrenergic inhibiting agent (e.g., methyldopa hydrochloride)

OR

Add a small dose of a thiazide-type diuretic

Proceed to full dose if necessary and desirable.

Additional substitutions may be made at this point.\*

### Step 3

If Blood Pressure Control Is Not Achieved:

Add a vasodilator\*\* ➡

### Step 4

If Blood Pressure Control Is Not Achieved:

Add guanethidine monosulfate

\*An angiotensin-converting enzyme inhibitor (e.g., captopril) may be substituted at step 2, step 3 and step 4 if side effects limit use of other drugs or if other drugs are ineffective.

\*\*Hydralazine, or minoxidil for resistant cases.



# Preventing High Blood Pressure

Given the potentially serious consequences of high blood pressure and the long and often difficult battle in treating this insidious disease, the best alternative for those who are at special risk is clearly prevention.

Many factors determine whether an individual develops high blood pressure. Age is one. Generally, blood pressure rises with age, often beginning as early as the 30s. The younger the age at which hypertension begins, the greater the danger if it is left untreated. People in their 30s with blood pressures around 150/100 have five times the chance of dying in the next 20 years as those with normal pressures. Those over 50 who have had normal blood pressure all their lives have a good chance of retaining normal diastolic blood pressure, although systolic pressure is apt to go up with age in many cases because of hardening of the arteries and other reasons.

Dr. Edward Roccella, director of the National High Blood Pressure Education Program, says: "The risk of stroke increases with a rise in the systolic and/or diastolic pressures. We have clinical evidence that lowering diastolic pressure is of significant value. Now we are doing a study on elderly people who have high systolic, but normal diastolic pressures. We hope to find out whether lowering isolated systolic pressure is of value."

Heredity plays a part, too. A person is more likely to develop the disease when one or both parents have had it. There is probably no single gene that determines whether one's blood pressure will be high or low, but rather several genes. How one responds to environmental factors, such as sodium, is probably an inherited factor.

Blacks develop high blood pressure at twice the rate of whites. Black males appear to be especially at risk. Many theories have been advanced for this greater incidence, and all of them may contain part of the answer. Perhaps some blacks have a hereditary predisposition to high blood pressure. Diet may play a role, because historically blacks in America

have tended to eat foods high in sodium and saturated fat—both of which can contribute to hypertension. In black women, obesity appears to be a strong factor in hypertension. Black women from 35 to 55 are almost twice as likely to be overweight as white women.

Though males develop high blood pressure earlier than females, the disease is about evenly divided between the sexes. Under the age of 50, males have both higher systolic and diastolic pressures than women; with those 50 and older, more women have higher readings. Younger women may develop high blood pressure in the last months of pregnancy, a condition called pre-eclampsia. If not treated, it can be dangerous to both mother and child.

Obviously, people can't do much about their age, heredity, race or sex. But other factors can be controlled. Diet is one of the most important. For the obese, simply cutting calories to reduce weight is often the most effective way to reduce blood pressure. Excess poundage adds to the heart's work, because there's more tissue to be supplied with blood. Although thin people can have high blood pressure, too, hypertension is more common among the overweight.

Since many Americans eat too much salt, and it's impossible to predict who will develop hypertension because of too much sodium, eating less salt is a smart idea for everyone, even when blood pressure is normal.

Though sodium occurs naturally in most foods (exceptions include sugar and edible oils), most of what we consume is added in processing, cooking, or at the table. (Salt is 40 percent sodium, and a teaspoon of salt contains about 2,000 milligrams of sodium.) The average American may consume 7,000 milligrams a day, although 1,100 to 3,300 is considered a safe and adequate daily amount.

In addition to eating less salt, doctors may recommend a diet lower in saturated fats and cholesterol and higher in fiber. Besides helping to delay the beginnings of atherosclerosis, eating less fat usually causes weight loss, as fats are the most significant source of calories. There is also evidence that consumption of saturated fats is directly associated with a rise in blood pressure, regardless of the patient's weight.

Dietary fiber appears to have the opposite effect. Some researchers have noted that vegetarians and other people who eat a great deal of fiber have lower blood pressure than those who don't. They theo-

rise that not only does a diet high in fiber reduce blood cholesterol levels, but it may also reduce diastolic blood pressure.

The doctor may also advise drinking less alcohol. Although a small amount of alcohol produces only a fleeting rise in blood pressure, many people who drink larger amounts—three or more drinks daily—are often hypertensive. In the Framingham study, a decades-long study of residents of a Massachusetts town, researchers have found that hypertension greater than 160/95 was twice as prevalent among persons drinking more than 60 ounces of ethyl alcohol (the average glass of wine, mixed drink, or can of beer contains one-half ounce of alcohol) each month as among those drinking less than 30 ounces. Although scientists are not sure how alcohol affects blood pressure, some believe that it may cause the arterioles to constrict. When drinking stops, blood pressure levels normally decline. Alcoholic drinks are also high in calories, an important point to remember if it's necessary to lose weight.

Physicians may ask their hypertensive patients to avoid caffeine. Just two or three cups of coffee each day can raise both the systolic and diastolic pressure of normal people an average of 10 or more mm Hg. The rise may last up to three hours.

Besides dietary changes, other changes in lifestyle may be in order. Physicians may advise patients to stop smoking—even a couple of cigarettes a day may cause a temporary rise in blood pressure. Hypertensive women should not use oral contraceptives, especially those who smoke or are overweight. No one with high blood pressure should take (without consulting a doctor) over-the-counter drugs containing phenylpropanolamine (also known as PPA and found in some cold, allergy and diet medications), caffeine (found in some analgesics, diuretics and stimulants), or other medicines that increase blood pressure. Regular exercise and avoidance of stress are also recommended.

If all this advice sounds familiar, it is. It's the same advice that's given to preserve good health in general. Since excess weight is the most important risk factor associated with high blood pressure, reducing should be a top priority. And it can't hurt to cut down on salt and saturated fats in the diet, increase consumption of fiber, and moderate the intake of caffeine. In fact, some scientists believe that changes in the diet are essential for those who wish to prevent the development of high blood pressure or alleviate it once it occurs. ■



(Continued from page 24)

Normal blood pressure for people under 18 is below 120/80. Since blood pressure often goes up with age, a reading up to 140/85 is considered normal between the ages of 18 and 50. When the figures go above 140/90, the pressure warrants a trip to the doctor.

Besides putting a strain on the kidneys and arteries, high blood pressure strains the heart, which has enough to do keeping us alive. Although the heart pumps out only two or three ounces of blood with each contraction, it does this 60 to 80 times a minute when at rest, or more than 100,000 times a day, for roughly 2,000 gallons of blood—an astonishing effort for an organ about the size of two clenched fists and weighing from 11 to 16 ounces in adults (though it becomes larger and heavier with age). Any resistance that the blood flow meets on its way through the arteries will add to the heart's labor, making it pump harder to get blood to every organ and tissue in the body. That extra effort results in a rise in the blood pressure.

Researchers have found several mechanisms that cause high blood pressure. One of the causes involves the tiny arteries, called arterioles, that conduct blood from the larger arteries to the capillaries. (Capillaries are minute blood vessels that connect the arterioles to the smallest veins, or venules.) Arterioles play a key part in regulating blood pressure. Normally the walls of these millions of arterioles are equipped with a layer of muscle cells that enables them to open up or contract as needed. If more blood is required for digestion, the arterioles in the intestines will open up, while those that feed muscles in the arms or legs, for example, will constrict. All this is beautifully and automatically controlled via chemicals sent out by the nervous and endocrine systems.

The body has a built-in protective reflex that tries to keep the blood pressure at the same level all the time, so that all the tissues and organs receive an adequate supply of blood. However, in some people the muscle cells of the arterioles tighten up and stay tightened, causing the heart to pump much harder to get the blood through to the capillaries. Why arterioles constrict abnormally is not known, but high blood pressure is the result.

Another cause of hypertension is atherosclerosis, or hardening of the arteries, a condition in which fatty plaque builds up on the inside of arterial walls, causing resistance to blood flow. Here again the heart must exert itself to push the blood through the narrowed arteries. The resulting high blood pressure further injures the arterial walls and worsens the atherosclerosis.

Excessive salt consumption contributes to some, but not all, cases of hypertension. At a recent FDA conference on women's health issues, Dr. Harriet Dustan, an authority on hypertension from the University of Alabama at Birmingham School of Medicine, stated: "It's a widely held belief in this country that the amount of salt we eat is responsible for the essential hypertension which affects about 25 percent of the population. This is not true. Maybe only about half of the hypertension that exists is salt-sensitive."

Actually, the villain in hypertension is the sodium in salt. The sodium-hypertension connection has been proved by many animal and human studies. Sodium is an essential nutrient, but people require only a tiny amount of salt—about one-tenth of a teaspoon a day—to meet their needs. Many Americans get several times that amount. Most people excrete the excess in the urine, but some can't handle the excess. When they eat extra salt, more water is drawn into the circulation, adding to the volume of blood to be pumped. The result is hypertension.

While tightened arterioles, atherosclerosis and salt-sensitivity lead to high blood pressure in some people, in most of those with

hypertension, the cause remains a mystery. High blood pressure with no known cause is called essential or primary hypertension and it's the kind over 90 percent of Americans with high blood pressure have. Hypertension due to some other condition or disease is known as secondary hypertension. When children and young people have high blood pressure, it is usually secondary. Causes of secondary hypertension include kidney disease, adrenal tumors, narrowing of the aorta, inflammation of the arteries, or other serious conditions.

Especially dangerous is malignant hypertension, where readings can exceed 200/130. Often this condition is discovered completely by accident—like less serious cases of high blood pressure—because it usually causes no symptoms or discomfort. (About half the people found to have high blood pressure say they didn't know they had it.) Malignant hypertension is so severe that a doctor can detect it by simply looking into the eyes. Extremely high blood pressure causes the eye's arterioles, the only blood vessels that can be seen directly, to hemorrhage (leak blood). In some cases the optic nerve also swells, a particularly ominous sign. Immediate hospitalization is required to lower the blood pressure. Malignant hypertension can cause irreversible kidney damage, brain swelling, and impaired vision, sometimes blindness. Before antihypertensive drugs were developed in the 1950s, about half of those with malignant hypertension died within six months after diagnosis, and 90 percent within a year.

Malignant hypertension is seen less and less frequently in Western societies, because high blood pressure is treated before it gets to that stage. How it's treated depends on the severity of the disease. Many doctors agree that those with diastolic pressures from 85 to 90 should try a non-drug regimen first—changes in diet and increased exercise, for example—because drugs usually have to be taken for life.

When other efforts fail and drugs are necessary to lower the blood pressure, some doctors use a stepped-care program (see chart), beginning with a small dose of an anti-hypertensive drug with the least risk of side effects. If blood pressure is not lowered satisfactorily, they'll increase the dosage, or they'll add or substitute one drug after another in gradually increasing doses until pressure is lowered, or until side effects become unbearable or the maximum dose of a drug is reached. For people with mild hypertension, the doctor will usually try a particular drug for two or three months before stepping up to the next level.

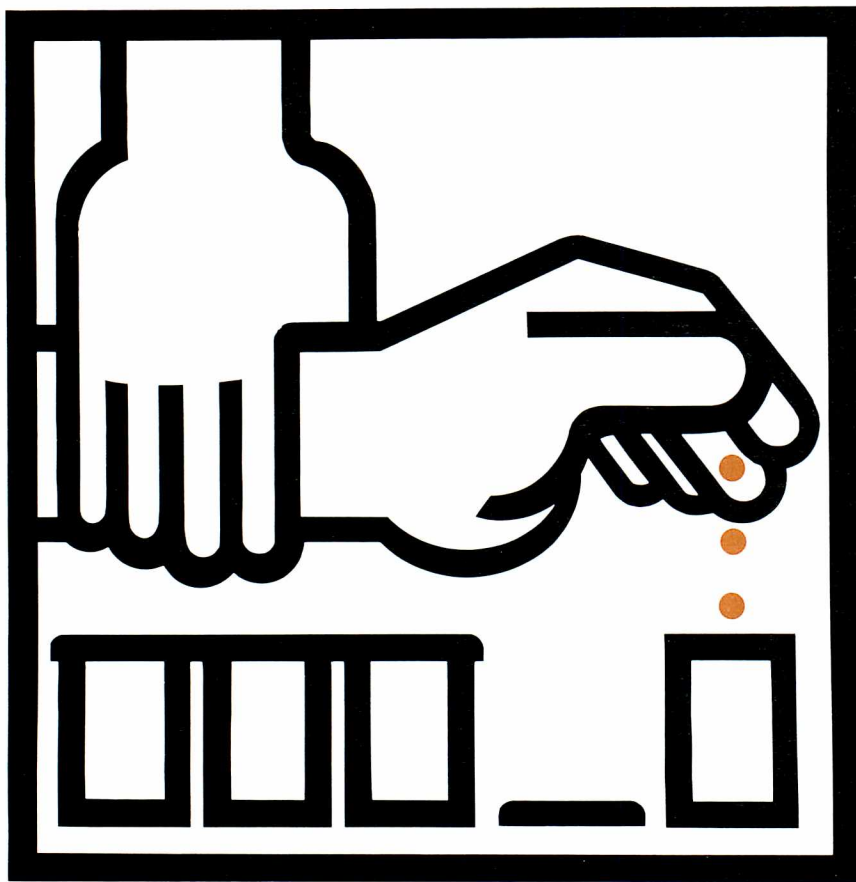
The most commonly used drugs in the first step are the diuretics, which stimulate urination. By causing excess fluid and sodium to leave the body, diuretics reduce the volume of blood and thus lower blood pressure. (Since potassium, an essential mineral, is also washed out of the body along with the sodium, doctors may prescribe potassium supplements for some people on diuretics.) Other doctors may use beta blockers as a first step (more commonly in Europe) or prescribe them along with diuretics. Beta blockers are drugs that slow the heart rate, thereby lessening its work.

If diuretics and beta blockers don't lower pressure sufficiently, doctors may add adrenergic-inhibiting agents, which work like beta blockers, or vasodilators, which relax and open up blood vessels, including constricted arterioles. Some of the newer medications—called slow channel calcium entry blockers—prevent calcium in the body from constricting blood vessels.

With rare exceptions, nothing cures hypertension, so whatever course is prescribed—dietary changes or drugs—will have to be followed for life. ■

*Evelyn Zamula is a member of FDA's public affairs staff.*

# Tamperings, False Reports Bring Arrests, Jail



The arrest of Edward Arlen Marks last May 29 for allegedly tampering with over-the-counter drug capsules should serve as a reminder that tampering with consumer products—or even falsely reporting tampering—is a federal crime. And, as a number of people who have tried it have learned, it's a crime that doesn't pay.

Marks is the erstwhile stockbroker trainee who is charged with putting rat poison in Contac, Dietac and Teldrin capsules and planting them in stores in Houston and Orlando, Fla., March 19 and 20, 1986. Using the name "Gary," he allegedly telephoned the manufacturer, Philadelphia-based SmithKline Beckman Co., newspapers, and radio and TV stations claiming he wanted the firm to withdraw all over-the-counter capsule medications. Marks allegedly hoped to make a killing on the stock market when SmithKline's stock price dropped as a result of his misdeed.

It was Mark's unusually large purchase of "put" options on SmithKline shares that led authorities to link him to the poisoned capsules. Law enforcement officials charge that a fingerprint on one of the drug packages confirmed the link. (A "put" option gives the holder who thinks a stock price will fall an opportunity to bet on the decline and make potentially enormous returns. As it turned out, the stock did not drop as Marks had expected.)

If convicted, Marks faces up to a \$50,000 fine and 10 years in prison. Had serious injury resulted, he could have been fined as much as \$100,000 and been given a 20-year sentence. If a death had occurred, he could have been given a similar fine and possibly life in prison.

Marks was not the first person to be charged under anti-tampering laws. In fact, the first federal conviction under the



anti-tampering laws, passed after seven deaths in Chicago from cyanide-laced Tylenol capsules in 1982, was in Pueblo, Colo., in 1984. It was the result of an investigation that began early that year after a man called a grocery chain and said he had put cyanide in the store's products. He demanded \$500,000, but was caught by the FBI before he could collect the extortion money. He was fined \$5,000 and given five years probation after he pleaded guilty.

Unfortunately, after each tampering incident—whether it involves a drug product, baby food, or Girl Scout cookies—there has been a rash of copycat tamperings or false reports of tampering, often inspired by a desire to get attention or a real intent to cause harm to others. Making up stories about tampering is just as much a crime as an actual tampering, as a number of people have learned, the hard way. The following list illustrates the kinds of offenses that have occurred just this year:

Two women were arrested in Louisville, Ky., March 3 for falsely reporting a pin in baby food.

In nearby Sellersburg, Ind., on March 4, a 17-year-old was turned over to juvenile authorities because of an alleged false report of a pin in a cupcake.

A young woman who reported glass in baby foods March 14 in Galesburg, Ill., was arrested for filing a false report. Police said she told them she wanted to "get attention."

Two 12-year-old girls in Duluth, Minn., admitted March 17 that they put glass in baby food after hearing news reports of similar tamperings. They were not charged.

A mother was arrested in April in Sampson County, N.C., on a charge of felonious child abuse when she deliberately fed bits of wire to her infant using baby food as a

vehicle. The child had been hospitalized Feb. 27 because of injuries from the wire.

A Waterbury, Conn., woman who reported cutting her mouth on a razor blade embedded in a chocolate Easter bunny was arrested April 10 and charged by police for falsely reporting the incident. (If convicted, she faces up to a \$25,000 fine and five years in prison.)

Putting pins and staples in packages of cookies as a "joke" led to the arrest of a teenager in Lafayette, Ind., March 19. The girl was not formally charged because she did not sell or give the cookies to others.

A Jacksonville, Fla., woman who reported finding staples in Girl Scout cookies was arrested April 9 on charges that she lied when she told authorities she did not place the staples in the cookies herself. After later admitting she did it as a prank, the woman was charged by the FBI with "knowingly communicating false information that a consumer product had been tainted"—a federal offense under the tampering laws.

Last March, an Idaho Falls man told an employee of a TV station that he had poisoned Skippy peanut butter in local supermarkets. The story was false, but the consequences were all too real. Indicted by a federal grand jury on April 9, he was tried, convicted and sentenced to five years in prison June 4.

Extortion, a crime under any circumstances, is also covered under the tampering laws. A man claiming responsibility for the death of a Peekskill, N.Y., woman who took cyanide-laced Tylenol capsules last February tried to extort \$2 million from the manufacturer of Tylenol, Johnson & Johnson Products, Inc., New Brunswick, N.J. He was caught and charged with extortion under the anti-tampering laws. He pleaded guilty to lesser charges related to the threat,

according to the U.S. attorney for the District Court in White Plains, N.Y., and was sentenced to three-and-a-half years in jail, to be followed by three years probation. (In fact, even though he claimed responsibility, the man was not guilty of the actual tampering. The person responsible is still at large.)

In Nashville, Tenn., a court sentenced a 62-year-old man to three months in a halfway house and four-and-a-half years on probation after he pleaded guilty Aug. 29, 1985, to attempting to extort \$100,000 from a grocery store by threatening to put cyanide in the store's food. The man pleaded guilty as charged Aug. 29, 1985.

An Atlanta restaurant chain's corporate officials helped the FBI catch a man who said he would poison patrons of the restaurant with cyanide and arsenic unless he was given \$650,000. The thwarted extortionist was sentenced to 40 years in prison.

Regrettably, there are no clues yet in the cases of the seven deaths in 1982 from cyanide-laced Tylenol capsules in Chicago, the single death in Yonkers, N.Y., last February, or the two deaths from Extra-Strength Excedrin capsules that had been tampered with in the Seattle area.

The Proprietary Association, a trade organization of manufacturers of over-the-counter drug products, has established a toll-free hotline to collect tips on tampering-related crimes. The number is 1-800-222-3081.

The association also is offering rewards totaling \$1 million for information leading to the arrest and conviction of anyone responsible for drug tampering cases. The rewards, of up to \$300,000 for each incident, cover drug tampering cases dating back to the seven Chicago poisonings in 1982. ■

—Annabel Hecht and Mike Shaffer

# Women's Health: On Avoiding The Nursing Home

by Bill Rados

Noting that three out of four nursing home patients are female, a top U.S. health official recently urged women to take steps when they are young to prevent the illnesses that require long-term care later in life.

Women also should help in finding alternatives to long-term institutional care, the high cost of which is "shocking," said Don M. Newman, undersecretary of health and human services. He said that, because of a lack of coverage by private health insurance or Medicare, two-thirds of those who enter nursing homes spend all their assets within three months.

Newman made the remarks at the National Conference on Women's Health last June 18 in Bethesda, Md. The conference was sponsored by FDA and the Public Health Service Coordinating Committee on Women's Health Issues.

"Becoming immobilized through stroke, hip fracture, heart disease, or any other acute condition—immobilized to the point that we can no longer get around by ourselves, feed ourselves, or dress without help—is a terrible thing to consider," Newman told the audience of some 600 specialists in women's health. "While it is true that some preventive health measures can be taken by the elderly, we must start educating women about what they can do before they get too old to avoid the severe disabilities we see among the elderly today."

Noting that women today live an average of eight years longer than men, Newman called this longevity "a mixed blessing." Though women don't have as much acute illness as men, they suffer more chronic ailments that require intensive long-term health care, he said. While most of the elderly live in their own homes, those most ill and dependent—29 percent of the long-term care

population—reside in institutions such as nursing homes. And 75 percent of those patients are women, Newman said.

"The average nursing home patient is a woman, approximately 84 years old, who has at least six chronic conditions and two acute conditions, and has no one close to her who can any longer take care of her," he said. "Chances are she was admitted . . . because she suffered a stroke or a fall—perhaps a hip fracture—from which she did not recover well enough to manage the everyday tasks of taking care of herself. Or she may have become seriously disabled by Alzheimer's disease, or urinary incontinence," a leading cause of admission to nursing homes even though it is treatable and preventable, according to the undersecretary.

The need to prevent these illnesses is all the greater given the high cost of nursing home care, which can be upwards of \$25,000 a year, Newman said. Between 1972 and 1984 the national bill for nursing home care quadrupled to \$32 billion annually and is expected to soar to \$82 billion by 1990. Yet there is "virtually no health insurance coverage for long-term care," he said, adding that even Medicare, the national health insurance for the elderly, does not cover such expenses. So most of the bill is paid from the pockets of the elderly and their families, or by Medicaid, which will pay "after a person has become impoverished by the costs." According to Newman, not only do two-thirds of those who enter nursing homes spend all their assets within three months, but also approximately half of all people in nursing homes are on Medicaid.

"The devastating costs of long-term nursing care are everyone's problem, and all of us—families, the health-care system, government financing programs, and private sector financing institutions—must respond to the challenge to find solutions," Newman urged. "We need to encourage a sense of mutual responsibility between the public and private sectors, especially with regard to catastrophic and long-term care. So that in 25 years when the baby boomers are approaching 65, there will be long-term care choices that they, their families, and the nation can afford."

By the year 2030 one out of five Americans will be over 65, Newman predicted, and "most of the very old will be women. They will face the highest risks of the severe physical and mental disabilities that can rob women of their independence and well-being."

Yet many elderly women are able to preserve their good health. "Of the 8 million elderly Americans who live alone, 80 percent are women," Newman noted. "Their average age is 75, and most of them report that their health is good. With proper attention to diet, exercise, preventive health measures, and generally healthy lifestyle, women will probably continue to live healthier, longer lives than men."

One disabling condition that women can take steps to avoid is osteoporosis, caused by a loss of calcium from the bones. Newman said that the 210,000 hip fractures that occur each year in the United States, most of them in women, "account for a very large number of women's admissions to nursing homes, and for many can initiate a severe decline. Twenty percent of those who do not recover normal function after a hip fracture die within a year," he said.

Yet, "this terrible disability among elderly women can be prevented," he stressed, explaining that "one strategy to prevent fractures is through estrogen replacement therapy, calcium and regular exercise."

"Estrogen replacement therapy, using low doses, is highly effective in preventing osteoporosis in postmenopausal women,"

*Before his appointment last April as undersecretary of the Department of Health and Human Services, Don M. Newman held positions in state government in Indiana and with the National Governors' Association. Before his government service, he owned and operated two pharmacies, in Mishawaka and South Bend, Ind. He received a bachelor of science degree in pharmacy from Purdue University, a master's in business administration from Indiana University, and a doctor of laws degree from Georgetown University.*





according to the health official. (For more on estrogen therapy, see "Estrogen Effective Against Osteoporosis" in the Updates section of the July-August 1986 *FDA Consumer*.)

As for the other facets of the strategy to prevent osteoporosis, Newman noted that a consensus panel convened in 1984 by the National Institutes of Health recommended that in addition to estrogen replacement, middle-aged women should consume between 1,000 and 1,500 milligrams per day of elemental calcium and undertake a program of modest weight-bearing exercise, such as walking. (See "Osteoporosis, Calcium and Estrogens" in the November 1984 *FDA Consumer*.)

Strokes are another frequent cause of nursing home admissions among women, Newman said, noting that the rate of strokes among older women is higher than that for older men. But here, too, preventive steps can be taken. "Since women are more likely than men to practice good health and nutrition measures," according to the undersecretary, "the rewards in stroke prevention are there" for women who:

- avoid cholesterol-rich foods,
- keep their blood pressure at normal levels,
- stop smoking,
- exercise regularly,
- decrease their salt intake,
- watch their weight, and
- avoid stress.

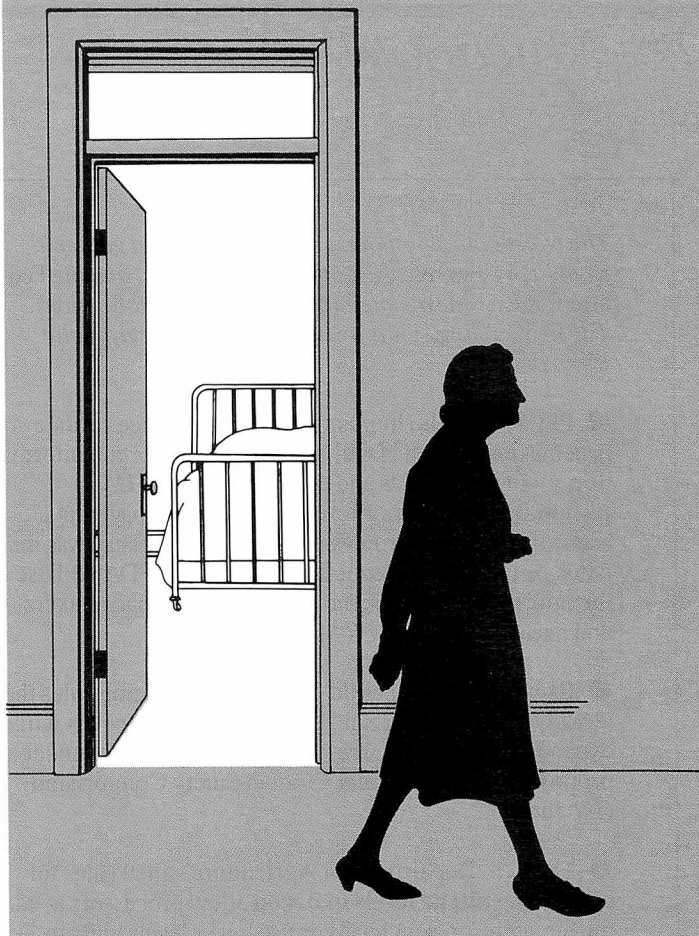
(For more on stroke and its prevention, see "Stroke: Fighting Back Against America's No. 3 Killer," in the July-August 1986 *FDA Consumer*.)

Newman told the many health educators in the audience that osteoporosis and stroke are two areas well-suited for health promotion. "The women's health movement has been telling women from the very beginning to take charge of their health: Get the information you need to make good decisions, work in partnership with your doctor, and ask the right questions. It seems to me that you have some exciting opportunities here to promote solid, sure health practices and, in doing so, to make some real inroads against two of the most terrible threats to the self-sufficiency of older women," Newman said.

However, he cautioned, "there is one area where prevention and health promotion have gone awry; where . . . women's good sense about their health has taken a dive"—smoking and lung cancer. He predicted that "death rates for women from lung cancer will soon overtake deaths from breast cancer," noting that deaths among women from lung cancer have risen 600 percent in the past 30 years, "most of it due to smoking." He advised that "men and women have a lot of good things to learn from each other, but cigarette smoking is not one of them."

Smoking carries other health risks besides cancer, Newman stressed. Women who smoke, for example, have two to four times the risk of heart attack as nonsmoking women. "Are women going to throw away their leading edge in longevity by dying 'like men' from lung cancer and heart disease? If this happens, women will not have come such a long way after all," he said.

Although stroke, heart disease, osteoporosis and other conditions can often be prevented by healthy diet and lifestyle, Newman noted that there is still too little known about one condition—Alzheimer's disease—to say how to avoid it. "Of the 2.5 to 3 million Americans who suffer the debilitating effects of Alzheimer's, most—again, because they live to age 80 or beyond—are women. One in three women over the age of 80 is at risk," Newman said. "In fact, Alzheimer's disease may be the leading cause of admission to nursing homes." Yet Newman said



that the degenerative brain disease "is not a natural consequence of aging," although more research is needed to determine how it occurs and how it might be prevented.

While healthy living early in life can help keep many women—and men—out of nursing homes in their later years, society must still find other ways of providing long-term care for the elderly who need it, according to Newman. "The nation's long-term care system must be restructured," he said. He pointed to new programs by the states to provide care through adult day-care centers, home health services, and self-care programs in wellness and accident prevention. "These experiments in providing care in the home and community are crucial to assessing the cost effectiveness of various long-term care alternatives. And cost effectiveness is a major issue in long-term care," he said. "I think the private and public sectors together will figure out ways to pay for long-term care; ways that won't deplete an individual's or a family's economic resources, or force taxpayers to pay exorbitantly for the care the elderly need."

Newman also discussed the work of an advisory committee appointed earlier this year by Secretary of Health and Human Services Dr. Otis R. Bowen to find ways to pay for long-term health care and catastrophic illnesses. The committee, composed of government and private sector members, is particularly examining how financing through private insurance can be more widely used. It "will look very closely at how private financing mechanisms improve the quality of life and dignity of the individual, how they strengthen, not deplete, the resources of the family, and how they contain federal expenditures and assure . . . cost effectiveness," Newman said.

*Bill Rados is editor of FDA Consumer.*



# The Notebook

*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 large public libraries.*

■ Physicians who implant, remove or replace cardiac pacemakers and leads will have to provide certain information about the patients and the devices to an **FDA pacemaker registry** or lose their Medicare payments, according to a rule proposed in May. The registry was mandated by the Deficit Reduction Act of 1984. FDA will use the information to track the performance of pacemakers and pacemaker leads (FR May 6).

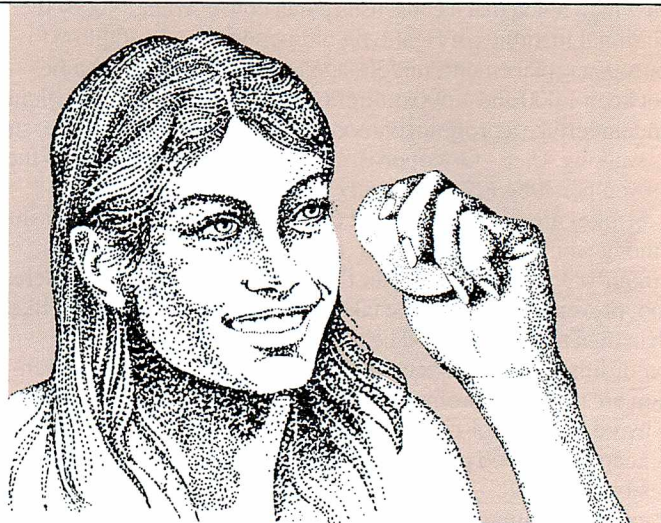
■ Exemptions from **child-resistant packaging** rules that already apply to Alka-Seltzer and Alka-Seltzer Plus will be expanded to include Extra-Strength Alka-Seltzer, under a proposal by the Consumer Product Safety Commission (FR June 17).

■ The U.S. Department of Agriculture's final rules for controlling **nitrite levels in bacon** allow processors to add nitrites at the present levels or use lower levels with an approved quality control program. The process used will determine how often nitrosamines—potentially cancer-causing substances produced from nitrites—will be monitored (FR June 16).

■ FDA and the Department of Health and Social Security of the United Kingdom have signed an agreement recognizing each other's inspections as official evidence that **medical device** manufacturers have complied with **good manufacturing** practices. This is the first such agreement with any country in the medical device area.

■ The drug **dronabinol—synthetic tetrahydrocannabinol (THC)**, the psychoactive substance in marijuana—has been put in Schedule II of the U.S. Controlled Substances Act, but THC is still in the strictest schedule (Schedule I) of the international Convention on Psychotropic Substances. The Drug Enforcement Administration warns that anyone holding a DEA registration for Schedule II drugs who dispenses or prescribes dronabinol outside the approved use associated with cancer treatment except in a recognized research program can lose that registration (FR May 13).

■ Advertising claims for **Stri-Dex Triple Action Pad** ingredients were found "marginally acceptable," but could deceive consumers by making a brand-to-brand superiority comparison, concluded a panel of the National Advertising Review Board. The manufacturer, Sterling Drug Inc./Glenbrook Laboratories Division, agreed not to use competitors' names in future ads for its acne medication. The ads had been challenged by the makers of Oxy-10 and



Clearasil, who objected to effectiveness and superiority claims in Stri-Dex ads. The NARB review panel was convened when the original dispute could not be resolved by the National Advertising Division of the Council of Better Business Bureaus.

■ The Federal Trade Commission has modified a 1970 order with American Home Products Corp. by removing some restrictions on advertising for **Preparation H** (used to treat hemorrhoids) and allowing use of any claims "FDA has tentatively approved." The firm asked to be allowed to make all ad claims recommended in a monograph proposed by the advisory panel on OTC anorectic drug products (FR June 5).

■ **Medical device approvals:** The Caridex **Caries Removal System**, produced by the National Patent Development Corporation, New Brunswick, N.J. The system is used with conventional dental instruments to remove dental caries where the applicator tip of the device can directly contact the carious lesion, thus reducing the amount of drilling (FR May 2).

The GammaDab [125] **Alpha-Fetoprotein Radioimmunoassay Kit** for use as an aid in the detection of fetal open neural tube defects. The kit is produced by Travenol-Genentech Diagnostics, Cambridge, Mass. (FR June 17).

■ The Committee on Safety of Medicines of the United Kingdom has recommended that **aspirin** no longer be given to feverish children under 12, unless specifically indicated, because of a possible link with **Reye syndrome**. In a June 10 letter to health professionals, the committee said the pharmaceutical industry is voluntarily withdrawing children's aspirin from the market and advising parents not to give aspirin to children under 12. By early 1987, adult aspirin labels will warn against giving aspirin to children. British studies indicate the age of onset of Reye syndrome is lower than in the United States; 93 percent of cases in Great Britain are in children under 12, while in the United States cases have occurred in youths up to the age of 19.



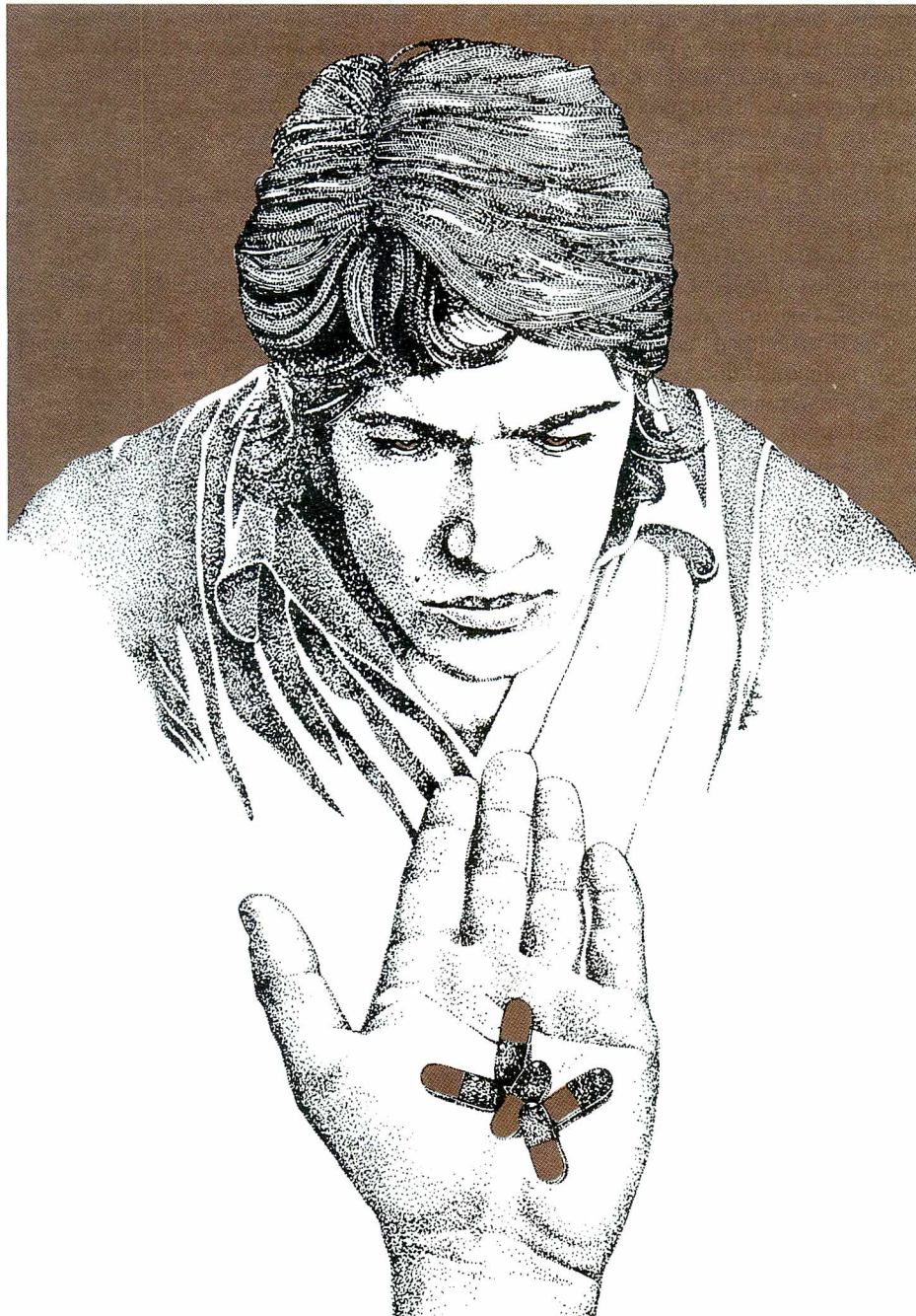


## Shutting Down a Major Source of Deadly 'Look-Alike' Drugs

Everyone knows the sale of illegal drugs is big business. The sale of *fake* illegal drugs is also widespread, and it poses a public health hazard of its own to unsuspecting users.

Now a big bite has been taken out of the big business in bogus drugs, as FDA has

shut down one of the major suppliers of phony "uppers" and "downers" to American teenagers and other users. While the pills weren't really amphetamines, Quaaludes or barbiturates—as they were made to appear—the youngsters who bought and used them, thinking they were the real thing, were still taking a big—even deadly—risk.



The sale of these so-called "look-alike" drugs has been a major problem for several years. The products contained a combination of ingredients that, sold separately and taken in the proper doses, are safe and legal over-the-counter medications: caffeine, ephedrine and phenylpropanolamine (PPA). All three have some stimulant activity; ephedrine and PPA are often marketed—individually—as decongestants for cold and allergy sufferers. But these drugs were being illegally sold in combination without the usual ingredient or caution labeling, to teenagers who thought the pills were street drugs such as "speed" or "ludes."

Taking large doses of these seemingly "harmless" drugs may cause injury or even death. What is more dangerous is that youngsters who get used to taking large doses of look-alikes to get "high" may some day take the same amount of real amphetamines or sedatives, with fatal consequences.

One company that saw the potential for huge sales of look-alikes was Midwest Pharmaceuticals Inc.

The firm began business operations in Council Bluffs, Iowa, in 1980. Its business was entirely telephone and mail-order sale of capsules and tablets containing the three stimulants, obtained mainly from Gemini Pharmaceuticals in Nesconset, N.Y. Robert Liebert was the firm's first president; Steven F. Sommers took over the reins as president in 1984.

The company's wares were advertised in motorcycle, drug-oriented, or "adult" magazines such as *Stag*, *Iron Horse*, *High Times*, and *Hustler*. The ad copy called them "legal body stimulants" and "sleep aids," but pictures of the capsules and tablets, along with descriptive captions in product flyers, suggested they were something quite different. Names such as "black mole" (pronounced "mollie"), "white mole," ".357 Magnum," "20/20," and "mini-pink heart" are associated with controlled substances sold as illegal street drugs rather than legitimate OTC products.

Business boomed for Midwest Pharmaceuticals. Records obtained in 1984 showed the firm was distributing an average of more than 750,000 doses a day, assuming six-day-a-week sales. Midwest's customers bought the 100-, 250-, or



1,000-dose bottles and repackaged the drugs in smaller quantities for resale; for example, to high school students who thought they were amphetamines, Quaaludes, or barbiturates. A Lincoln, Neb., school official would later testify that Midwest's products were found in the possession of junior and senior high school students in that community.

Midwest's products also have been found in the possession of high school students in Maryland and in drug raids in Illinois and California.

Because of the seriousness of this situation, many states passed legislation dealing with look-alike drugs. Iowa's Imitation Controlled Substances Statute went into effect July 1, 1982. Midwest Pharmaceuticals packed up and moved across the Missouri River to Omaha, Neb., on June 30. When Nebraska's Imitation Controlled Substances Statute became effective on May 23, 1985, Midwest moved back to Council Bluffs.

FDA banned drug products with the triple combination of caffeine, ephedrine and PPA in August 1982. Despite an advisory letter that went to all known manufacturers and distributors of look-alikes, Midwest continued selling the triple-combination products.

In November 1982, FDA effected the first seizure of Midwest's products, on the basis that the triple combinations were unapproved new drugs. The seizure at the Omaha facility netted federal authorities 1,242,000 doses. All ended up in a local landfill.

Not to be deterred, Midwest then began to obtain and sell look-alikes with double combinations of caffeine, ephedrine or PPA. In November 1983, FDA announced a ban of double-combination look-alikes and so advised Midwest and other distri-

butors. On Nov. 29, U.S. marshals, at FDA's request, seized 18,940,000 doses of the two-ingredient look-alikes at Midwest's facility. Another half million doses were surrendered to investigators from FDA's Omaha office. Again the drugs ended up in a landfill.

An inspection of the firm early in 1984 revealed that it was still in the look-alike business, but now the tablets and capsules contained only one ingredient, usually ephedrine or caffeine. FDA investigators collected samples of products made to resemble different street drugs. Many were identical to the double-combination drugs seized the year before.

In April 1984, FDA sought a court order to seize 24,150,800 doses plus 15 pounds of a white powdery substance, marketed as incense, but resold by various customers as cocaine. The agency charged that the drugs were imitations of other drugs and therefore were misbranded and subject to seizure. This was the first time the agency had used this provision of the Federal Food, Drug, and Cosmetic Act in a case involving OTC look-alike drugs. The agency also sought an injunction to prevent Midwest Pharmaceuticals from selling look-alike drugs.

The firm claimed that the term "imitation" is unconstitutionally vague and that the drugs weren't counterfeits of controlled substances because of differences in markings and in any event they were legal because the original containers had truthful labels and the drugs could be used legally. The case came to trial in February 1986 in the U.S. District Court for the District of Nebraska.

After a two-and-a-half-week trial, Judge Lyle E. Strom ruled that the products were indeed imitations. Most looked virtually the same as controlled substances even

though the markings were different. Products don't have to be identical to be imitations, Judge Strom said; that is the distinction between counterfeit and imitation.

Judge Strom also noted that Midwest Pharmaceuticals marketed the same dosage (i.e., 200 milligrams of caffeine) in many different sizes, colors and shapes with no reasonable explanation or justification for this variety of dosage forms, unless the products were designed to imitate controlled substances or illegal drugs.

Midwest's marketing scheme was designed to appeal to people's perceptions that the products are illegal, the judge said. The firm's ads appeared in various subculture magazines, rather than legitimate trade journals, he noted, and showed pictures of the products but didn't say what was in them, a clear indication that they were being marketed on the basis of appearance alone.

The judge also found that the drugs were being "passed off" as illegal street drugs. Two of Midwest's former customers testified that the practice had been endorsed and encouraged by the firm, and on some occasions the firm's president had sold the products as controlled substances himself.

On April 1, Judge Strom ruled that the drugs in question were imitations and thus misbranded. Midwest Pharmaceuticals and its officers were ordered to stop selling the look-alike products or any identical or similar drug products using marketing techniques such as providing a certain dosage in numerous forms or advertising solely on the appearance of the product.

The drugs seized in 1984 are in the custody of U.S. marshals while Midwest Pharmaceuticals appeals the court's decision.

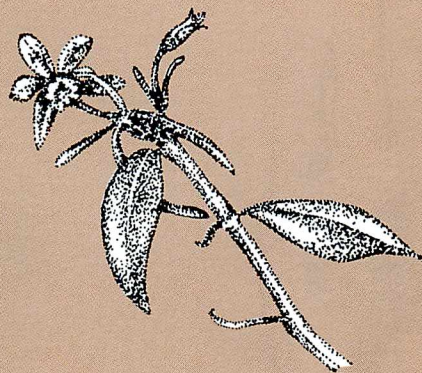
—Annabel Hecht

## Imitation Vanilla Recalled

*What's in a name? That which we call a rose by any other name would smell as sweet.*

From *Romeo and Juliet* by William Shakespeare.

Shakespeare may have been right about a rose but, according to FDA, a product named vanilla must be vanilla. If not, there's trouble, as Akron, Ohio's Bickford Laboratories, Inc., learned when it began marketing an imitation as the real thing.



What's in vanilla? FDA requires that real vanilla be made from the vanilla bean. Bickford's product was not. Vanilla also must be at least 35 percent ethyl alcohol. Bickford's product was not—a flagrant omission, since the label actually stated, "Contains no alcohol, sugar, salt." The firm was in further violation of the law when it claimed, incorrectly, that the product was made from "oils of natural herbs, vegetables, fruits" and when it failed to list the true ingredients: propylene glycol, vanillin and ethylvanillin (which are synthetic products), helio-



tropin and water.

The Florida Department of Agriculture, which had analyzed the so-called "vanilla" being sold in that state, tipped off FDA's Orlando district office on Oct. 14, 1985, and Orlando promptly notified the Cincinnati district office about the situation. In a follow-up inspection, FDA confirmed that the product did not comply with the law. As a result, at FDA's request, the Ohio State Department of Agriculture issued an embargo, stopping sales of the product.

In cooperation with FDA and the U.S. Attorney's Office, Bickford Laboratories subsequently recalled all stock from its distributors. The firm plans to bring the embargoed products into compliance by relabeling them under FDA's supervision and to the satisfaction of the U.S. attorney. Meanwhile, Bickford is marketing new bottles of its imitation vanilla with interim stick-on labels that, while unattractive, do correct the labeling violations.

## Irresistible Fake Honey Scam Sours with Jail Sentence

A Mississippi man who pleaded guilty in 1984 to selling phony honey and maple syrup couldn't resist the temptation to continue his sweet scam. Now, instead of paying his fine and mending his ways, he's serving three years in prison.

Oliver Anthony of Philadelphia, Miss., and a co-defendant, Dewey Garland Clark, had been indicted by a federal grand jury on 13 criminal counts for selling flavored and colored glucose and corn syrup labeled as honey, sorghum and maple syrup. The products were sold at premium prices throughout the United States.

FDA first investigated the scheme in 1978 and later seized the phony products in Texas, Oklahoma, Kentucky, Washington, Indiana, Louisiana and other locations. (See "Two Charged with Scheming to Dilute Honey" in the May 1983 *FDA Consumer*.)

Anthony and Clark pleaded guilty in 1984 in the U.S. District Court for the Southern District of Mississippi to a reduced number of charges. Clark was fined \$10,000 and Anthony \$20,000, and both were placed on probation for four years.

Clark paid his fine and has since met the terms of probation. However, Anthony paid only \$3,000 of the \$20,000 and con-

tinued to pack and ship the phony products.

When FDA investigators found Anthony's products appearing again in interstate commerce, they asked Judge Dan Russell, who had imposed the earlier sentence, to revoke Anthony's probation. The judge agreed and ordered Anthony to begin serving a three-year sentence on June 20.

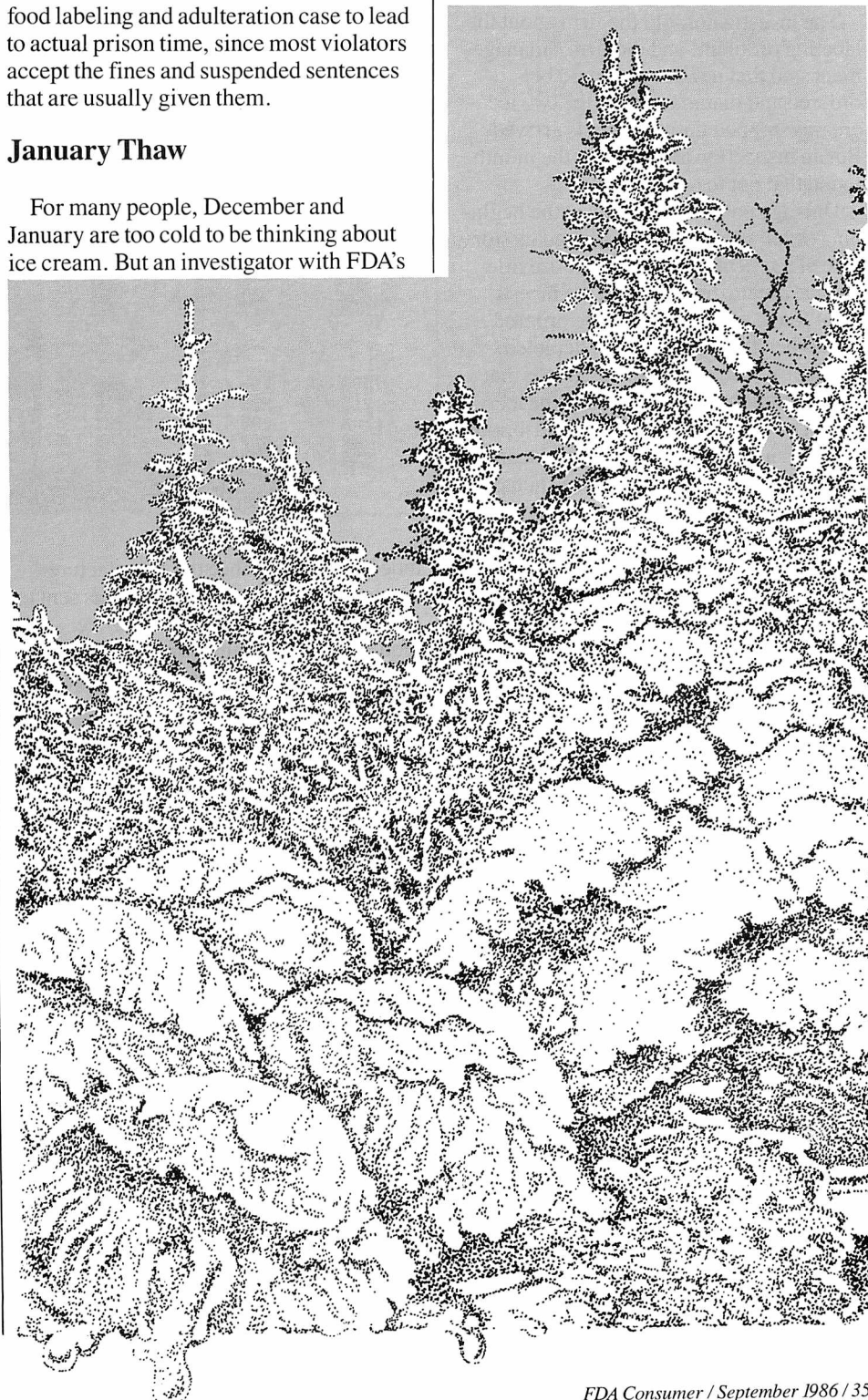
FDA officials note that it is unusual for a food labeling and adulteration case to lead to actual prison time, since most violators accept the fines and suspended sentences that are usually given them.

## January Thaw

For many people, December and January are too cold to be thinking about ice cream. But an investigator with FDA's

New Orleans district office spent a lot of time looking at containers of the cold confection in those months and didn't like what he saw. The result was the destruction of some 1,400 gallons of ice cream, due to improper and potentially unsafe labeling.

The firm that had the investigator's attention was Super Ice Cream Suppliers in Metairie, La., which distributes ice cream to about 140 retail stores in five



states. During the first inspection, two days before Christmas 1985, the investigator noticed that the firm was using FD&C Yellow No. 5 in two flavors of ice cream—butter pecan and eggnog—but the coloring was not listed on the labels. As many as 100,000 people in the United States are allergic to Yellow No. 5, which is why FDA requires that the color be listed on the labels of foods, drugs and cosmetics that contain it.

The investigator told the firm about the labeling problem, and the firm's management said that new labels would be ordered and manufacture of the two ice creams stopped until the labels arrived. But an inspection at the end of the month found that not to be the case.

During another inspection at the beginning of January, the firm changed its story. One of the firm's managers, whose title was ice cream director, told the investigator that new labels would be ordered only when the old ones were depleted.

The ice cream director suggested that placards might be placed above the ice cream counters of the various distribution outlets but refused to divulge the location of the stores. When asked when such placards might be distributed to the stores, she said "a week or two."

That wasn't good enough. At the agency's request, state health authorities placed the ice cream under embargo. The district office asked a federal court judge to have the ice cream seized, but before that could be done, the firm asked for the embargo to be lifted and destroyed the ice cream, valued at about \$4,500. The violation, in effect, was allowed to melt away.

## Pharmacy with Drug Complaint Not Just Your Corner Drugstore

FDA receives complaints about defective products from people in many places, even famous places. For instance, the agency recently got a call about a decongestant drug with directions that recommended too high a dosage, posing a possible hazard for some users. Any such complaint would prompt the agency to investigate, but this caller happened to be the chief pharmacist at the White House.

The call came in to FDA's Medical Products Quality Assurance Staff in its Rockville, Md., headquarters on Oct. 31, 1985. Within hours, the staff collected a sample of the product and determined that the dosage instructions on the label were

indeed too high. Since the manufacturer was located in New York, word was sent to the agency's Brooklyn district office requesting an investigation.

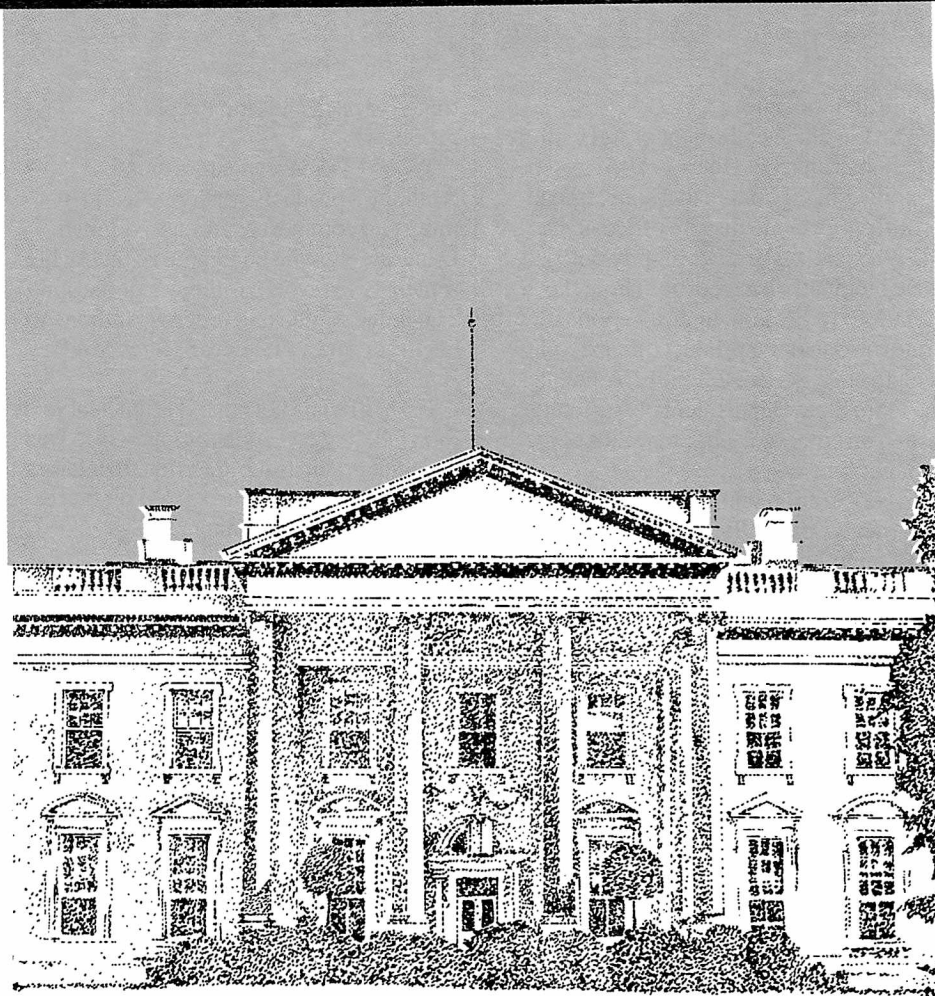
A Brooklyn investigator inspected the manufacturer, LNK International, Inc., of Hauppauge, N.Y., and found that the problem was not a labeling or printing error; rather, the firm had made a mistake in determining the correct dosage. LNK formulated the drug, pseudoephedrine hydrochloride, in 60-milligram tablets. Dosage directions stated, "Adults and children over 12 years of age: 2 tablets every 4 hours." Accordingly, a patient might take six doses in a 24-hour period of 120 milligrams each, or a total of 720 milligrams, and believe this to be quite safe. However, an FDA advisory panel for over-the-counter drugs recommends only 240 milligrams as a day's maximum. FDA determined that the labeling's potential for causing an overdose presented a moderate health hazard for people with certain medical conditions—that is, overdosing could aggravate diabetes, high blood pressure, and some other diseases. The nervousness and tremors that might occur in healthy people would probably lead to

their reducing the dosage or discontinuing the medication altogether.

LNK manufactured the drug solely for the Department of Defense (DOD), which shipped supplies nationwide and overseas. It turned out that LNK had made only one shipment: to DOD's Mechanicsburg, Pa., depot. But from Mechanicsburg, the drugs had found their way to a number of government installations, including 1600 Pennsylvania Avenue in Washington, D.C. On Nov. 6, FDA informed LNK, DOD, and the White House pharmacist of the health hazard assessment. That same day, LNK made arrangements with DOD to correct the problem. They agreed that DOD would contact all the locations that had received the drug, requesting that they return all unopened bottles to LNK for relabeling and replacement. Opened bottles were to be destroyed.

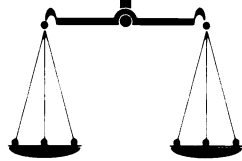
FDA's Brooklyn office monitored the recall.

*—This small sample of reports from the field was prepared by Annabel Hecht, Carol Ballentine, Dixie Farley, Theresa Hoog, Herman Janiger and Richard Thompson.*





# 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.

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

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

## SEIZURE ACTIONS

### *Foods/Poisonous and Deleterious Substances*

**PRODUCT:** **Pepper, black, whole, and ground black pepper**, at Brooklyn, E. Dist. N.Y.; Civil No. 85-3883.

**CHARGED** 10-24-85: While held for sale, the articles contained the added poisonous and deleterious substance *Salmonella* microorganisms—402(a)(1).

**DISPOSITION:** Consent—authorized release to Victoria Packing Co., Brooklyn, N.Y., for bringing into compliance. (F.D.C. No. 64716; S. No. 85-393-069 et al.; S.J. No. 1)

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

**PRODUCT:** **Beans, lima, dried**, at Norfolk, E. Dist. Va.; Civil No. 85-662-N.

**CHARGED** 9-24-85: When shipped by FCX, Inc., Statesville, N.C., the article, which was intended to be rehydrated, repackaged and sold for human consumption (and which was labeled "California Grown Fancy Quality Seed Beans . . . 9-84"), had been held under insanitary conditions—402(a)(4).

**DISPOSITION:** Consent—authorized release to Krisp-Pak Co., Inc., Norfolk, Va., for salvaging. (F.D.C. No. 64714; S. No. 83-360-856; S.J. No. 2)

**PRODUCT:** **Candies, chocolate-coated, and carob-coated**, at Seattle, W. Dist. Wash.; Civil No. C-83-1590.

**CHARGED** 11-15-83: While held by Northwest Candy, Inc., Seattle, Wash., who used interstate components to manufacture the

articles, the articles had been prepared and packed under insanitary conditions—402(a)(4).

**DISPOSITION:** Default—ordered destroyed. (F.D.C. No. 64131; S. No. 84-335-721 et al.; S.J. No. 3)

**PRODUCT:** **Clams, chopped, canned**, at Vineland, Dist. N.J.; Civil No. 85-482.

**CHARGED** 1-30-85: When returned from St. Louis Park, Minn., to the distributor, Chincoteague Seafood Co., Inc., Chincoteague, Va., and reshipped to Vineland, N.J., the article (labeled "Cape Cod Brand Chopped Surf Clams . . . Dist. by Chincoteague Seafood Co., Inc. . . . Chincoteague, Va.") was unfit for food because it contained decomposed clams and because it was in swollen cans—402(a)(3).

**DISPOSITION:** Consent—authorized release to Venice Maid Co., Vineland, N.J., for salvaging. (F.D.C. No. 64465; S. No. 85-499-538; S.J. No. 4)

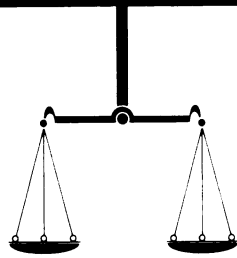
**PRODUCT:** **Mushroom stems and pieces, canned**, two seizure actions, at Seattle, W. Dist. Wash.; Civil Nos. C-85-0137 and C-85-0139.

**CHARGED** 1-24-85: When imported, the articles (labeled "House of Excellence Mushrooms Pieces and Stems . . . The People's Republic of China . . . Distributed by Shafer-Haggart Ltd.") were unfit for food, since the articles contained miscellaneous extraneous material (e.g., human hair, wood, straw-like fragments, sand, and pieces of plastic and metal)—402(a)(3).

**DISPOSITION:** The articles were claimed by Shafer-Haggart, Ltd., Vancouver, Canada, who denied the charge. Upon motion of the claimant, the court authorized post-seizure sampling of the articles. Acme Food Sales, Seattle, Wash., also filed a claim to the articles; but, upon consent of the other parties, Acme withdrew its claim.

Consent decrees of condemnation authorized release of the articles to the remaining claimant for the purpose of destruction, but exempted from destruction and ordered the complete release of those cans bearing nine specified lot numbers which were different from the originally sampled lot numbers. Then, in order to reduce the cost of the claimant's bond, the consent decrees were amended so that the articles which were to be destroyed were not to be released to the claimant; but the government was to undertake the destruction of those articles, with the costs of destruction to be borne by the claimant. Ultimately, 42 cases of the cans bearing the nine specified lot numbers were released; and a total of 1,362 cases of the articles were destroyed. (F.D.C. Nos. 64475 and 64476; S. Nos. 85-463-281 et al.; S.J. No. 5)

**PRODUCT:** **Rice, and other grocery stocks**, at Adel, M. Dist.



Ga.; Civil No. 86-17-VAL.

**CHARGED 2-14-86:** While held by Adel Grocery Co., Inc., Adel, Ga., the articles were held under insanitary conditions—402(a)(4). **DISPOSITION:** Consent—authorized release to the dealer for salvaging. (F.D.C. No. 64850; S. No. 86-436-445 et al.; S.J. No. 6)

**PRODUCT: Salmon, canned,** at Anacortes, Wash.; Civil No. C-84-697.

**CHARGED 6-19-84:** When shipped by Annette Island Packing Co., Metlakatla, Alaska, the article (some cans unlabeled and some cans labeled “Whitney’s Alaska Chum (Keta) Salmon . . . Distributed by Whitney-Fidalgo Seafoods, Inc., Seattle, Wash.”) had been prepared, packed and held under insanitary conditions (visible can-seam defects and inadequate closure of can lids)—402(a)(4).

**DISPOSITION:** Consent—authorized release to the shipper for salvaging. (F.D.C. No. 64295; S. No. 84-399-366 et al; S.J. No. 7)

#### *Foods/Economic and Labeling Violations*

**PRODUCT: “Sorghum” syrup,** at Forest Park, N. Dist. Ga.; Civil No. C-84-2599A.

**CHARGED 12-27-84:** When shipped by Dennis McBride, Section, Ala., the article (labeled “Tennessee [sic] River . . . Pure Sorghum . . . Dennis McBride Section, AL.”) had had the substance corn syrup wholly or in part substituted for sorghum syrup—402(b)(2); the article’s label falsely represented that the food consisted wholly of sorghum syrup when the food contained corn syrup—403(a)(1); and the article failed to conform to the definition and standard of identity for sorghum syrup, because the article was made with syrup from a source other than sorghum cane—403(g)(1).

**DISPOSITION:** Consent—ordered constructively destroyed by delivery to charitable institutions for use only. (F.D.C. No. 64450; S. No. 85-301-316; S.J. No. 8)

**PRODUCT: Tomatoes, canned, unlabeled, and stocks of unlabeled cans, jars and bottles of other foods,** at Abington, W. Dist. Va.; Civil No. 83-0376-A.

**CHARGED 8-16-83:** When shipped by various shippers from outside of Virginia, the article lacked labels containing the following: the name and place of business of the manufacturer, packer or distributor; a quantity of contents statement; and the common or usual name of the food—403(e)(1), 403(e)(2), 403(i)(1); some of the articles, which were fabricated from two or more ingredients, lacked labels stating the common or usual name of each ingredient—403(i)(2); and some of the articles for which there were definitions and standards of identity lacked label designations, the name of the food, and, as required, the common names of optional ingredients—403(g)(2).

**DISPOSITION:** The articles were claimed for Discount Foods, Inc., Abington, Va., by William W. Venable, president, who also filed an answer denying the charges. The government moved for summary judgment.

The claimant contended that the firm had been misled because it had been previously inspected without being advised that it was in violation, that it has been selected out, that the law was not being administered equally, and that it was impossible for the claimant to comply with the law. The court said that, since the government had shown that the canned food was unlabeled and had been offered for sale, the only legal issue was whether the seized food had been in interstate commerce. Since the claimant’s president admitted interstate commerce as to some of the foods and since his answer stated that the government’s allegations of interstate commerce were “neither admitted nor denied,” the allegations were treated as admitted. Accordingly, the court granted summary judgment to the government.

The claimant filed a notice of appeal. However, the claimant withdrew its appeal. Ultimately, because of the deteriorated condition of the articles, the articles were ordered delivered to a local institution for feeding to livestock only. (F.D.C. No. 64060; S. No. 83-395-061 et al.; S.J. No. 9)

#### *Vitamins/Special Dietary Foods*

**PRODUCT: Dietetic ketchup, jellies, and dressings,** at Wood Ridge, Dist. N.J.; Civil No. CV-85-12.

**CHARGED 1-3-85:** When shipped by William J. Elwood, Inc., Copiague, N.Y., the ketchup failed to conform to the standard of identity for ketchup since it contained the nonnutritive sweetener saccharin—403(g)(1); the jellies failed to conform to the standard of identity, since they contained saccharin and failed to declare such optional ingredient on the label—403(g)(2); and the dressing labels lacked the common or usual name of each ingredient, since saccharin was not declared—403(i)(2); and all of the articles lacked the required statement “Use Of This Product May Be Hazardous To Your Health. This Product Contains Saccharin Which Has Been Determined To Cause Cancer In Laboratory Animals”—403(o)(1).

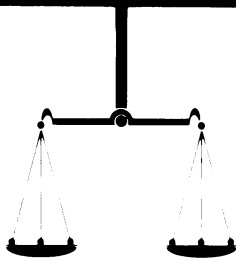
**DISPOSITION:** The articles were claimed by the shipper, who denied the charges. After some discussion between the parties, the government filed a motion for summary judgment. A consent decree of condemnation authorizing the release of the articles to the claimant was filed. Subsequently, the claimant failed to post the required bond; and, because the articles were more than a year old, the claimant found it impractical and economically unfeasible to repackage and relabel the articles. Accordingly, a consent decree ordered the articles destroyed. (F.D.C. No. 64453; S. No. 85-367-331 et al.; S.J. No. 10)

#### *Drugs/Human Use*

**PRODUCT: Triaprin-DC acetaminophen, salicylamide & dihydrocodeine bitartrate combination capsules,** at Gravette, W. Dist. Ark.; Civil No. 86-5004.

**CHARGED 1-16-86:** While held by Dunhall Pharmaceuticals, Inc., Gravette, Ark., who manufactured the article using interstate components, the article was a new drug without an effective





approved New Drug Application—505(a); and the article's labeling lacked adequate directions for use, and the article was not exempted due to its new drug status—502(f)(1).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64816; S. No. 86-493-834; S.J. No. 11)

PRODUCT: **Up Time tablets**, at Los Angeles, C. Dist. Calif.; Civil No. 84-8527-MRP (Mcx).

CHARGED 11-2-84: While held by APC Industries, Los Angeles, Calif., who was manufacturing the article using interstate caffeine, the article (labeled "Up Time 100% Organic The Natural Nutritional Energy Booster . . . Vitamin C . . . Algae . . . Caffeine . . . Distributed by Up Time, Calabasas, CA") was a new drug without an effective approved New Drug Application—505(a); and the article's labeling lacked adequate directions for use and was not exempt because of the article's new drug status—502(f)(1).

DISPOSITION: The article was claimed by Up Time, Inc., Calabasas, Calif., who denied the charges. The claimant served a request for the production of documents and written interrogatories on the government. The government moved for and obtained an order allowing the government to obtain a representative sample of the seized article. Ultimately, a consent decree ordered the article destroyed. (F.D.C. No. 64408; S. No. 84-354-886 et al.; S.J. No. 12)

PRODUCT: **Zelaforte tablets**, and **KH-3 tablets**, at San Ysidro, S. Dist. Calif.; Civil No. 83-1279-JLI(M).

CHARGED 7-13-83: When shipped by Casa Campana, Bremen, Germany, the articles (labeled "Zellaforte plus dragees . . . Cellaforte plus dragees . . . Procaine hydrochloride (H3) . . . a therapeutic agent that contains a large number of well-tried and clinically proven active ingredients . . . Anstelt für Zellforschung . . . Vaduz . . . Liechtenstein" and "K.H.3 Schwarzhaupt Procaine-Hemateporphyrin Product for Revitalization and Regeneration . . . Schwarzhaupt . . . Cologne . . . Germany") were new drugs without effective approved New Drug Applications—505(a); and the articles were merchandise which might not be entered for transportation and exportation pursuant to 19 U.S.C. 1553, even under bond, because such merchandise was prohibited both for importation and exportation—304 and 19 U.S.C. 1553.

DISPOSITION: The articles were claimed by Almacenes Donley, Inc., Tijuana, Mexico, who denied the charges due to lack of "sufficient information to either admit or deny" the allegations. As an affirmative defense, the claimant also stated the following: that, at the time of the seizure, the claimant was neither a consenting party nor privy to any illegal act; that the drugs were not being transported in interstate commerce; and that the drugs' transportation was international only.

The government moved for summary judgment. The matter came on for a hearing before the court. The claimant failed to appear or to oppose the government's motion. The court found for the government, condemned the articles, and ordered them destroyed. (F.D.C. No. 64174; S. No. 83-307-083; S.J. No. 13)

### *Drugs/Veterinary Use*

PRODUCT: **Amino Acid large-volume-parenteral solution with preservatives**, and **Sodium Iodide 20% large-volume-parenteral solution with preservatives**, at St. Paul, Dist. Minn.; Civil No. 4-85-622.

CHARGED 5-3-85: When shipped by Quality Plus Products Co., Inc., Fort Dodge, Iowa, the articles (labeled "Amino Acid Solution . . . Manufactured for Vedco, Inc., Overland Park, KS . . . Dosage And Administration Cattle: . . . Sheep and Swine . . . Horse" and "Sodium Iodide 20% . . . Manufactured for Vedco, Inc., Overland Park, KS . . . As An Expectorant in Cattle and Horses") were new animal drugs, and no approvals of New Animal Drug Applications were in effect with respect to the articles' uses or intended uses—501(a)(5).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64592; S. Nos. 85-499-436/7; S.J. No. 14)

PRODUCT: **Chloramphenicol oral solution**, at Frederick, W. Dist. Okla.; Civil No. 84-1738 (R).

CHARGED 7-13-85: While held by D&K Vet Supply (Karl W. Meyer), Frederick, Okla., the article was a new animal drug, and its use or intended use (in beef cattle) failed to conform to the approved New Animal Drug Application for the drug—501(a)(5); and the article's labeling lacked adequate directions for use and was not exempted, because the article was neither in the possession of a person lawfully distributing veterinary drugs nor was it to be sold only to or on the order of a licensed veterinarian—502(f)(1).

DISPOSITION: The articles were claimed by the dealer. Subsequently, a consent decree of condemnation and permanent injunction was entered.

The consent decree authorized release of the article to the dealer for bringing into compliance. The decree also perpetually enjoined the alleged violation and enjoined the defendant from offering for sale any interstate prescription veterinary drug or offering for sale in interstate commerce any prescription veterinary drug, unless and until a number of specified conditions were met, including the following: documenting the sale of every prescription veterinary drug; inventorying all such drugs; and registering as a drug distributor with the State Board of Pharmacy. (F.D.C. No. 64311; S. No. 84-363-156 et al.; S.J. No. 15)

PRODUCT: **Chloramphenicol powder, in bulk drums**, at Rushville, C. Dist. Ill.; Civil No. 84-3372.

CHARGED 9-10-84: While held by Schuyler Laboratories Inc., Rushville, Ill., which had been selling the article to veterinarians, who lacked New Animal Drug Applications although they used the article in food-producing and other animals, the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to the article's use and intended use—501(a)(5).

DISPOSITION: The article was claimed by the dealer; and the charge was denied. Subsequently, a consent decree of condem-



nation authorized release of the article to the dealer for bringing into compliance with the law. However, the claimant did not avail itself of the opportunity to bring the article into compliance. Accordingly, upon motion of the government, the article was ordered destroyed. (F.D.C. No. 64355; S. No. 84-384-291 et al.; S.J. No. 16)

**PRODUCT: Cyanocobalamin injection, lidocaine HCl injection, and other drugs for injection,** at Fort Collins, Dist. Colo.; Civil No. 85-C-1131.

**CHARGED 4-23-85:** While held by American Veterinary Products, Inc., Fort Collins, Colo., who manufactured the articles using interstate components, the circumstances used for the articles' manufacture and processing failed to conform with current good manufacturing practice—501(a)(2)(B).

**DISPOSITION:** The manufacturer claimed 21 lots of seized drugs but did not claim 14 other lots of seized drugs. Subsequently, the claimant sought to withdraw its claim and disclaimed any interest in the articles. Ultimately, a default decree ordered the articles destroyed. (F.D.C. No. 64540; S. No. 85-318-329 et al.; S.J. No. 17)

### CRIMINAL ACTIONS

**DEFENDANT: Quality Packaging, Inc., and James A. Mozingo,** president, Hayward, N. Dist. Calif.; Criminal No. 84-0208 MAG.

**CHARGED 7-17-84:** (Count 1) medium shelled peanuts, (Count 2) medium Virginia shelled peanuts, (Count 3) jumbo shelled Spanish peanuts, and (Count 4) sunflower seeds were held under insanitary conditions in buildings accessible to rodents and were contaminated with filth—402(a)(3), 402(a)(4).

**DISPOSITION:** Guilty plea by corporation to all counts—\$4,000 fine. Guilty plea by individual to Counts 1 and 2—\$2,000 fine, but judgment suspended, and probation for one year with special condition. (F.D.C. No. 63249; S. No. 80-252-902; S.J. No. 18)

**DEFENDANTS: Walco International, Inc., and Raymond M. Cerniga, D.V.M.,** president, Porterville, E. Dist. Calif.; Criminal No. CR-F-84-174-REC.

**CHARGED 9-27-84** by a grand jury: That, when DES implants were shipped to (Count 1) Amarillo, Texas, (Count 2) Guymon, Okla., (Count 3) Mountain View, Calif., from Amarillo, Texas, (Count 4) Yuma, Ariz., (Count 5) Yuma, Ariz., (Count 6) Somerton, Ariz., (Count 7) Hugo, Okla., (Count 8) Felt, Okla., (Count 9) Hugo, Okla., (Count 10) Hugo, Okla., (Count 11) Amarillo, Texas, (Count 12) Rocky Ford, Colo., (Count 13) Leoti, Kan., (Count 14) Leoti, Kan., (Count 15) Longview, Texas, (Count 16) Gilmer, Texas, (Count 17) Gilmer, Texas, and (Count 18) Lindale, Texas, the DES implants were new animal drugs and an approved New Animal Drug Application was not currently in effect with respect to the use and intended use of the DES implants—501(a)(5).

**DISPOSITION:** The defendants pleaded not guilty. The defendants moved for the government to disclose a number of discovery materials. At a hearing before the court, certain discovery requests were agreed upon by the parties; and some discovery requests were taken under submission.

As to the latter requests, the court subsequently ruled as follows: that the pre-trial disclosure of unaccepted offers of immunity was not required; that, in connection with certain deletions in FDA reports (which had been voluntarily supplied to the defendants by the government), and which deletions related to observations of witness agents disclosable in accordance with local practice under the Jenks Act, the unadulterated reports were to be provided two weeks before the trial date, because the government had agreed to provide its witness list and written statements of its witnesses two weeks before the trial date; and that the individual defendant's request for pre-trial discovery of transcripts of the 21 U.S.C. 305 hearings (which were alleged to be material to a defense of selective prosecution) was not granted (even though there was a *prima facie* showing that others similarly situated had not generally been prosecuted), because he had asserted only that he was selected for prosecution because he had the most to lose and had not asserted any of the grounds explained in *U.S. v. Choate*, 619 F.2d 21, 23.

The defendants made a number of motions to dismiss the indictment. However, the case came on for trial before court and jury. The jury returned a verdict of guilty against the corporation on all counts, but found that the individual was **not guilty**. The corporation was fined \$9,000. (F.D.C. No. 63560; S. No. 80-181-525 et al.; S.J. No. 19)

### INJUNCTION ACTIONS

**DEFENDANTS: Rosa Food Products Co., Inc., and James L. Foti,** president, at Philadelphia, E. Dist. Pa.; Civil No. 84-0966.

**CHARGED 2-27-84** in a complaint for injunction: That, at the defendants' warehouse in Philadelphia, Pa., pasta, cheese, figs, and other foods were held under insanitary conditions; that some of the articles contained insects (pasta products, cheeses and figs), some contained mold (figs), and other articles (canned goods) were unfit for food due to rusted, corroded and swollen cans; that FDA inspections disclosed a number of insanitary conditions; and that the defendants had been warned on a number of occasions—402(a)(3), 402(a)(4).

**DISPOSITION:** A consent decree of permanent injunction enjoined the complained of violations, and enjoined any warehousing of interstate foods unless and until a number of conditions were met. These conditions included the cleaning and renovation of the warehouse and the certification by an expert that the defendant's warehousing methods, facilities and controls would ensure freedom from contamination. In addition, all foods on hand were to be examined, analyzed if necessary, and, if contaminated, destroyed or otherwise brought into compliance. (Inj. No. 1059; S. No. 84-365-634 et al.; S.J. No. 20)



# TO PREVENT TOOTH DECAY:

## *Use Only Water at Bedtime*

You can protect your child's teeth from baby bottle tooth decay:

- If you must give your baby a bottle at bedtime, fill it only with water.
- Never allow your child to sleep with a bottle containing milk, formula, fruit juices, or other sweet liquids.
- Start regular dental checkups for your child by age 2 to 3. If you notice that your child has dental problems before then, take your child to the dentist at once.
- If your child needs a bottle for comfort, fill it with water or use a clean pacifier; *never* dip the pacifier in any sugary liquid such as honey or syrup.
- If your child's drinking water is not fluoridated, ask your dentist or physician about prescribing fluoride drops or tablets.
- After each feeding, clean your baby's teeth and gums with a damp washcloth or gauze pad.

For more information ask your dentist or physician or contact:  
National Institute of Dental Research, National Institutes of Health,  
Bethesda, Maryland 20892.

