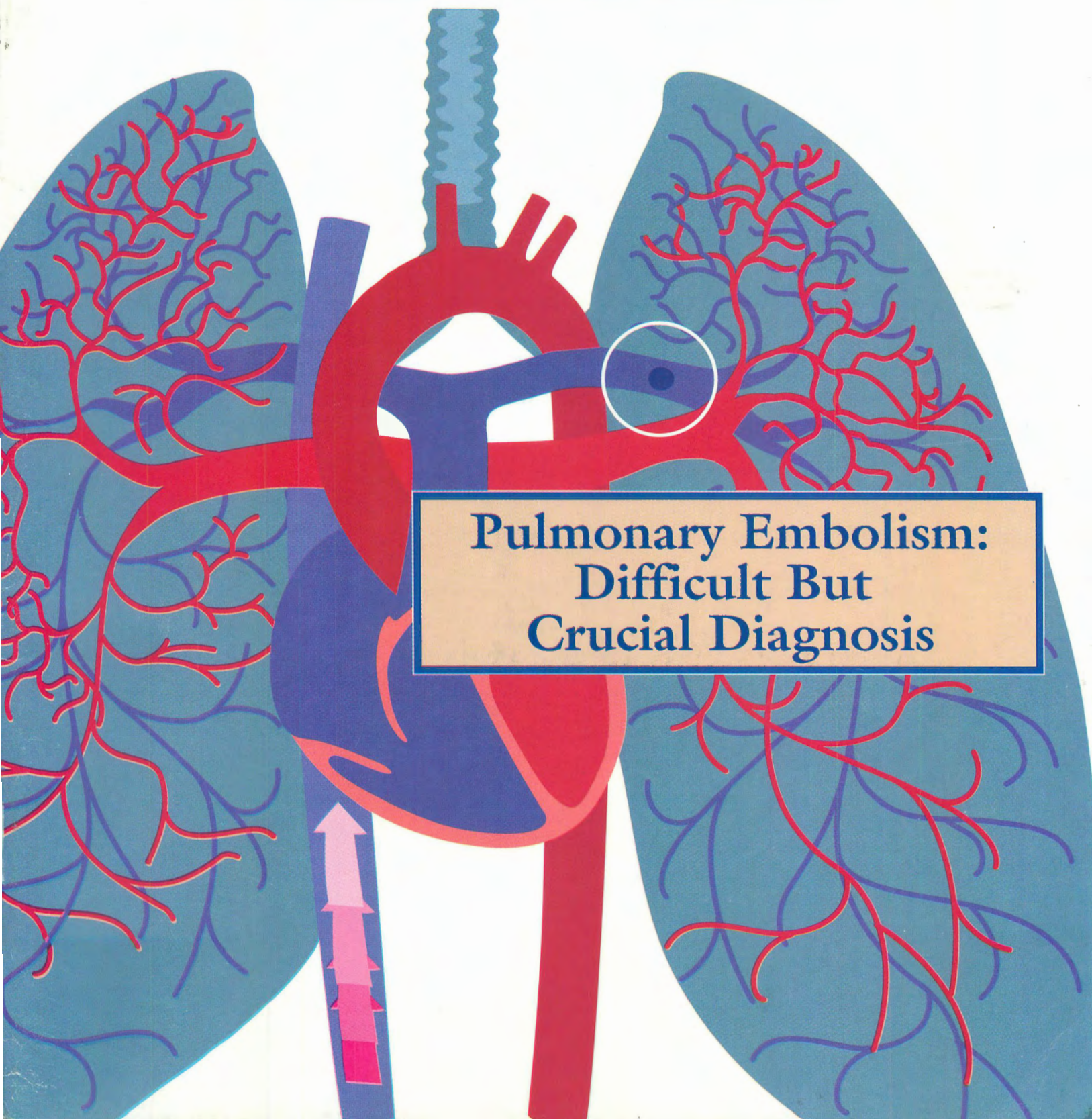


FDA CONSUMER

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

• VOL. 23 NO. 9

NOVEMBER 1989 •



**Pulmonary Embolism:
Difficult But
Crucial Diagnosis**

Natural Delight



NUTRITION INFORMATION
SERVING SIZE 1 OZ (28.4 g. ABOUT 1 CUP)
SERVINGS PER PACKAGE 7

	CEREAL	WITH 1/2 CUP VITAMINS A & D SKIM MILK
CALORIES	110	150*
PROTEIN	6 g	10 g
CARBOHYDRATE	20 g	26 g
FAT	0 g	0 g
SODIUM	230 mg	290 mg

PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCES (U.S. RDA)

PROTEIN	10	20
VITAMIN A	15	20
VITAMIN C	25	25
THIAMIN	35	40
RIBOFLAVIN	35	45
NIACIN	35	35
CALCIUM	**	15
IRON	25	25

CARBOHYDRATE INFORMATION

	CEREAL	WITH 1/2 CUP VITAMINS A & D SKIM MILK
COMPLEX CARBOHYDRATES	17 g	17 g
SUCROSE & OTHER SUGARS	3 g	9 g
TOTAL CARBOHYDRATES	20 g	26 g

GUARANTEE If you are not satisfied with the quality of this product, return ENTIRE package for replacement. PRINT your name and address on why returned, where purchased.



Louis W. Sullivan, M.D.
Secretary of Health and
Human Services

Frank E. Young, M.D., Ph.D.
Commissioner of Food and Drugs

Jeff Nesbit
Associate Commissioner for
Public Affairs

Judith Levine Willis /Editor

Jesse R. Nichols/Art Director

Michael L. Herndon/Production Manager

Carol L. Ballentine/Copy Editor

Cover Design: Zebulon Rogerson

FDA Consumer (ISSN 00362-1332) is published by the Food and Drug Administration, U.S. Public Health Service, Department of Health and Human Services. It is published monthly, except for combined issues for July-August and December-January. Use of funds for printing *FDA Consumer* has been approved by the Office of Management and Budget.

Editorial Matters

Address for editorial matters is *FDA Consumer*, Food and Drug Administration (HFI-40), 5600 Fishers Lane, Rockville, Md. 20857. Articles in *FDA Consumer* may be republished without permission. Credit to *FDA Consumer* as the source is appreciated. *FDA Consumer* is indexed in the *Reader's Guide to Periodical Literature*.

Subscriptions

Send inquiries concerning subscription problems or address changes to Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. Include mailing label from the back cover for address changes.

To keep subscription prices down, the Government Printing Office mails each subscriber only one renewal notice. To determine when you will get your renewal notice, check the number that follows ISSDUE on the top line of your mailing label. When the label reads ISSDUE003, a renewal notice will be sent. When the label reads ISSDUE000, you have received your last issue unless you renew.

To continue to receive *FDA Consumer* without interruption, please return your renewal notice promptly. If your subscription has expired, simply send your mailing label with \$12 (\$15 foreign), using the form on the back cover, to Superintendent of Documents, Government Printing Office, Washington, D.C. 20402, and your service will be reinstated.

FDA CONSUMER

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

VOL. 23 NO. 9

NOVEMBER 1989

New Information Available About AIDS Treatments 6
FDA Commissioner Frank E. Young gives details about the creation of a new computerized listing of all FDA-approved clinical trials of new AIDS therapies.

Rethinking Dining Out 8
Americans are beginning to seek the same nutritional benefits when eating out as when eating at home, and many restaurants are responding with both novel and nouvelle cuisine.

A New Look at Food Labeling 14
Do you need more information about exactly what is in frozen and canned foods? FDA wants your opinion about proposals to revise the labeling requirements for packaged foods.

Sealing Out Decay 18
Children's teeth can now be protectively "sealed" against cavities, but relatively few people are taking advantage of this process.

Pulmonary Embolism: Difficult but Crucial Diagnosis 22
Correct diagnosis is crucial to survival for persons who develop blood clots in their lungs. Doctors are aided in this tricky task by modern technology. But preventing pulmonary embolism is not only possible, it may also be the best medicine.

Of Lice and Children: Going to the Head of the Class 28
A note from the school nurse about head lice need not cause parental panic. Knowledge of this parasite's habits and proper application of prescription or over-the-counter products can help you rout the louse.

Updates	2	Investigators' Reports	33
AIDS Page	5	Summaries of Court Actions	36
Notebook	32		

← Inside Front Cover Photo:

Do you think there's a better way to give information about the contents of packaged food? FDA is soliciting consumers' opinions on this and other food labeling topics in a series of hearings in four different cities. For more information, see page 14.

Due to a printing problem, this issue was unavoidably late. We apologize for the delay.



FDA Monitoring Generics

FDA is intensifying its efforts to ensure the safety and effectiveness of generic drugs as well as fairness throughout the review process.

According to statements issued jointly in August by Louis W. Sullivan, M.D., secretary of Health and Human Services, and Frank E. Young, M.D., Ph.D., commissioner of Food and Drugs, these steps include:

- intensified surveillance of generic firms and their product approval submissions,
- creation of an independent ombudsman reporting directly to the FDA commissioner to review complaints and to ensure fairness in the processing of generic applications, and
- reorganization of generic drug approval in a new Office of Generic Drugs with new management and additional resources.

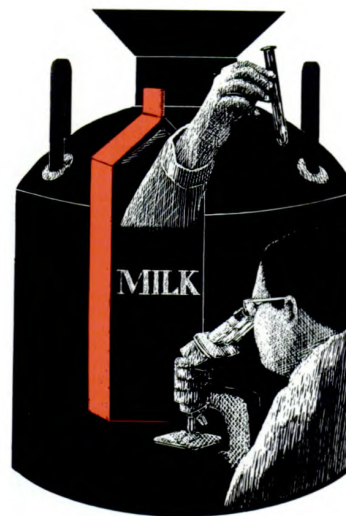
Announcement of this plan followed the discoveries that employees at two generic firms had misled FDA about batch sizes and/or samples used in their test procedures, and that generic firms had given illegal gifts to three former FDA employees.

Both Secretary Sullivan and Commissioner Young emphasized that they had no evidence that the safety or effectiveness of generic drugs had been compromised.

As part of the intensified scrutiny of generic drugs and firms, FDA is sampling the 30 most-prescribed drug products (representing about three-fourths of the U.S. generic market) and analyzing them for potency, dissolution, composition, and other specifications.

The agency is also analyzing pre-market product samples to determine whether generic drug companies have submitted valid samples in their marketing applications. Also, based on findings of potential problems, additional generic firms are being inspected to verify that products are being manufactured in accordance with FDA-approved specifications. FDA is asking contract laboratories that perform pre-market testing for generic drug firms to supply the agency with samples to affirm that product approvals by FDA are based on valid data.

In addition to these steps, FDA is conducting comprehensive inspections of the 20 leading manufacturers of generic drug products. These inspections do not result from allegations of wrongdoing; rather, the firms were selected because of their large number of approved applications for generic drugs and because the agency was able to obtain samples of their products for independent bioequivalency testing.



Dioxin and Milk Safety

FDA studies have shown that dioxin levels in milk from bleached paper cartons are extremely low and do not present a health hazard. The agency has confirmed reports that dioxin, which contains a compound known to cause cancer in animals, migrates from bleached paper cartons into the milk they contain. However, studies show that levels in these products measure well below 1 part per trillion.

If findings in test animals have a parallel in humans, FDA tentatively estimates that the lifetime cancer risk of consuming milk packaged in cartons over the next three to five years would be less than one in a million.

As FDA was testing dioxin levels in milk, the paper industry developed techniques for producing bleached paper containers that contribute no dioxin to milk and other foods they package.

"Because we now have the means to virtually eliminate even the low level of dioxin in milk from bleached paper cartons, it is prudent to do so," FDA Commissioner Frank E. Young, M.D., Ph.D., said. "However," he added, "during the short period of time it will take to complete corrective steps, milk is safe to drink."

Dioxin is chemical shorthand for a large family of compounds. The substance in milk cartons is formed from reactions between chlorine and certain materials in paper products. FDA will closely monitor the changes in paper manufacturing techniques and the levels of dioxin in milk as industry changes its production processes.

Cow Drug Reviewed

In reviewing data on the safety of milk and meat from cows treated with bovine growth hormone (also called bovine somatotropin, or BST) to boost milk production, FDA has thus far found that BST appears to be safe. During digestion in humans, the drug is broken down into inactive fragments in the gastrointestinal tract. Further, even if *injected* in humans, BST is inactive and has no effect in people.

BST has *always* been in cows' milk because it is produced naturally by the animal's pituitary gland. In cows treated with the genetically engineered version of the hormone, no more of the drug reaches the milk than the upper limits of what would occur in untreated cows.

Before BST can be approved for marketing, drug sponsors must show that their product is safe for the cow and the environment, and that residues in milk or meat from treated cows are safe for people to eat. The sponsor must also show that the drug is effective in increasing milk production. For more information on BST, see "High Tech' Comes to 'Vet Med'" in the April 1989 *FDA Consumer*.



Dipstick Urinalysis

The benefits of screening symptom-free young adults by dipstick urinalysis are outweighed by the possibilities of false positive results and complications from further, more invasive testing. Two reports by the U.S. Preventive Services Task Force appearing in the Sept. 1, 1989, *Journal of the American Medical Association* also found, however, that the quick and easy screening test may be useful to detect unsuspected urinary problems in patients age 60 or older.

In the first report, five studies showed that fewer than 2 percent of young adults with dipstick results indicating blood in the urine had a serious, treatable urinary tract disease, according to Steffie Woolhandler, M.D., and colleagues at Harvard Medical School in Boston. In four studies, fewer than 1.5 percent of young patients who tested positive for urinary protein had a treatable urinary disease. In the second report, Harvard's Richard J. Pels, M.D., and colleagues said the prevalence of urinary tract infection in asymptomatic men and women under 60 is less than 0.5 percent and 4.4 percent respectively — too low to justify screening.

Dipstick urinalysis involves dipping a chemically treated stick into a urine sample. The chemicals measure urine acidity and reveal the presence of glucose, protein, blood, and other substances that indicate bacterial infection or other bladder and kidney problems. Visits to internists alone generate more than 50 million such tests a year. And though patients pay only about \$3 per test, the annual cost to the nation of dipstick urinalysis adds up to more than \$150 million.

While recommending against general dipstick screening, the authors of both reports said that routine urinalysis may be justified for certain asymptomatic patients, such as pregnant women, diabetics, and some elderly patients. For instance, dipstick testing for blood and protein may be appropriate for people over 60 because they have a higher disease prevalence and, therefore, a higher rate of true positive results.

Also, several studies suggest that pregnant women have a higher incidence of bacteria in the urine without symptoms and, so, may benefit from screening. Moreover, treatment during pregnancy may help prevent urinary tract infections, premature deliveries, and other problems. However, Pels and colleagues caution that it is preferable that pregnant women be screened with more sensitive tests.

(For more information about urinalysis, see "Looking into the Void," in the October 1989 *FDA Consumer*.)

'Report Card' on Health Habits

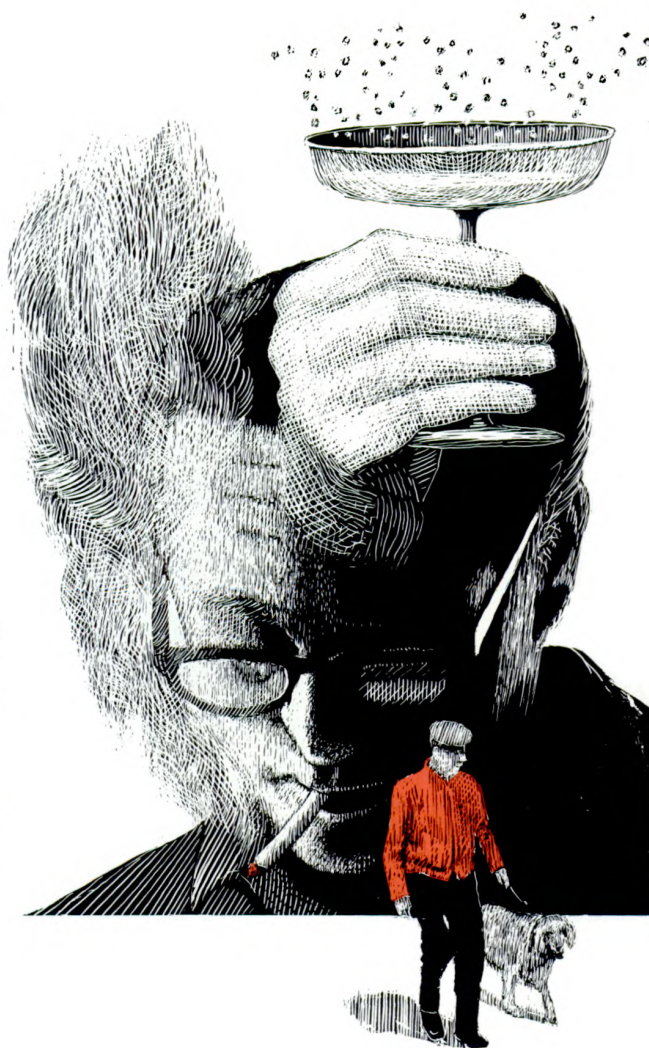
The results of an annual "report card," a survey conducted in November 1988 by Louis Harris and Associates to measure the practice of good health habits among Americans show improvement in several areas, but also point to a discouraging trend: Many Americans are still losing the battle of the bulge.

The survey reveals:

- Major progress was made in avoiding a high-cholesterol diet. Forty-eight percent of adults say they "try a lot" to avoid eating too many high-cholesterol foods—a 6 percentage point improvement over the 1987 survey. In addition, 48 percent of American households bought low-fat or low-cholesterol food products during the month before the survey, up 9 percentage points from 1987. (For more information about consumer awareness of specific nutrients, see "The Health-Diet Link: Charting a Rising Awareness," in the October 1989 *FDA Consumer*.)
- Sixty percent of adults say they never drive after drinking, and another 18 percent say they do not drink. This 78 percent figure represents a 10 percentage point increase over the level reported in 1983 and an increase of 4 percentage points over 1987.
- The proportion of American adults who frequently walk for exercise has increased 5 percentage points from the 1987 survey (52 percent compared to 47 percent), although the percentage of individuals who engage in strenuous exercise at least three times a week has changed little over the past six years.
- The proportion of adults who say they smoke cigarettes has fallen to 26 percent, the lowest smoking rate ever registered in a Harris survey that measured this trend.
- Seventy-nine percent of adult women report having a Pap smear every two years compared to 75 percent in 1987. And the proportion of women doing breast self-exams on a monthly basis increased to 51 percent, up 9 percentage points from 1987.

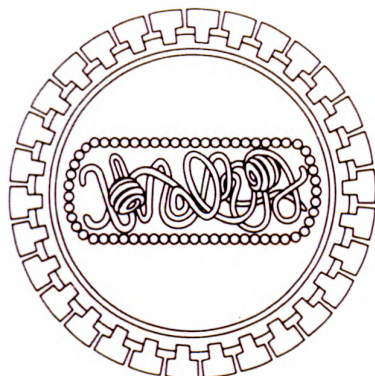
But there is also a downside to this year's survey findings.

- Sixty-four percent of American adults—the largest proportion ever—are overweight, and 20 percent of them do not think they have a weight problem.
- A greater percentage of this year's survey respondents had trouble limiting salt or sugar intake.



Known as the Prevention Index, this annual survey is the sixth conducted by the Harris organization for *Prevention Magazine*. In this year's survey, Louis Harris and Associates interviewed 1,250 randomly selected adults across the country and questioned them about 21 health-promoting activities.

Progress Reports in the Battle Against Acquired Immune Deficiency Syndrome



AIDS File Added to Bulletin Board

FDA has recently added an AIDS file to its electronic bulletin board. The file includes current AIDS-related media releases, policy documents, articles from agency newsletters, fraud information, speeches, congressional testimony, and notices of upcoming meetings.

In addition to the AIDS file, the FDA bulletin board also includes all agency press releases, the *FDA Enforcement Report's* listing of recalls and legal activities, drug and device approval lists, congressional testimony, speeches by the FDA commissioner, *FDA Federal Register* summaries, and articles from *FDA Consumer*, *FDA Drug Bulletin*, and the Center for Devices and Radiological Health's newsletters.

Access to the bulletin board is available to subscribers of the ITT-Dialcom service. For subscription information, contact ITT-Dialcom representative Vicky Wheeler, 6210 Executive Blvd., Suite 150, Rockville, Md. 20852 (301) 770-4280.

Although the new AIDS file does not include a listing of AIDS-related clinical trials, that list can be obtained by calling the Public Health Service's toll-free AIDS number 1-800-TRIALS-A. (See "New Information About AIDS Treatments" in this issue.)

AZT Slows HIV Infection

A large federal drug study shows that zidovudine (also known as AZT) delays the onset of AIDS in persons who are infected with the human immunodeficiency virus (HIV) but show no symptoms. HIV is the virus that causes AIDS.

"These results provide real hope for the millions of people worldwide who are infected with HIV," said HHS Secretary Louis W. Sullivan, M.D.

The study, involving more than 3,200

volunteers, showed that individuals who took the drug developed symptoms of AIDS at half the rate of those who took a placebo (pill with no active ingredients). Scientists also discovered that low doses of AZT were as effective as high doses. With the exception of nausea, which occurred in 3 percent of the volunteers, there were no differences in side effects in those receiving the lowest dosage of the drug and those receiving a placebo.

"This study has clearly demonstrated that early treatment with zidovudine can slow disease progression without significant side effects in HIV-infected persons . . . who do not yet have symptoms," said Anthony Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases.

Announcement of the results of this study occurred shortly after the results of another major clinical study showed that zidovudine can slow the progression of symptoms in individuals with early AIDS-related complex (ARC).

The earlier study included 713 HIV-infected persons with lowered T-4 cell levels (disease-fighting white blood cells) and mild symptoms such as oral thrush (an infection of the mouth), chronic rash, or intermittent diarrhea.

Half the patients received AZT, while the other half received a placebo or dummy pill. Patients were treated over a period of 3 to 20 months. As of last July, 50 of the study participants had developed AIDS or ARC. Thirty-six of the 50 were in the placebo group and 14 were in the AZT group.

The institute stopped the study when it became apparent that zidovudine offered a clear advantage over placebo. All study participants were then given zidovudine.

Both studies were conducted with the support and collaboration of Burroughs Wellcome, Co., manufacturer of zidovudine. Zidovudine is marketed under the trade name Retrovir.



Health Talk With Dr. Frank Young

New Information Available About AIDS Treatments

*by Frank E. Young, M.D., Ph.D.
Commissioner of Food and Drugs*

Just as the war on the deadly disease AIDS has changed the face of public health in this country, so too have new developments in public health changed the scope of the battle against the disease. We've made great progress since the AIDS virus was first isolated and identified just five short years ago. Although a cure still eludes us, we now have drugs available to improve the quality of life of people with AIDS.

Zidovudine (commonly known as AZT), aerosolized pentamidine, ganciclovir, and alpha interferon have been found to be effective in treating AIDS or the serious related conditions commonly associated with the disease. But much work remains ahead of us. We must continue to investigate how these and other new products can be used most effectively against the disease.

Not long ago, clinical studies on investigational new drugs to treat AIDS were limited for the most part to large medical facilities maintained by a relatively select group of institutions. This is changing. Today, dozens of community-based trials and treatment facilities are opening up as more and more investigational drugs and biologics are developed to fight AIDS. It is hoped that this new development will make treatment available to more patients and, with the larger number of participants, speed study results as well.

As more and more trials develop, it is necessary to provide both the patient and physician with basic information about where trials are being held and how to enroll. To fill this need, on July 17, 1989, Health and Human Services Secretary Louis W. Sullivan announced the availability of the FDA component of the U.S. Public Health Service's AIDS Clinical Trial Information Service (CTIS) — a toll-free telephone listing of all FDA-recognized AIDS clinical efficacy trials. Created in response to the Health Omnibus Programs Extension Act of 1988, the CTIS enables the general public to get up-to-date information about AIDS drug and biologic trials across the country.

The creation of this new information service makes available for the first time information about privately sponsored trials. The National Institute of Allergy and Infectious Diseases (NIAID) has had an information service available with information about federally sponsored trials since last spring. Information from both services are now available through one system.

Created as a public service to people with AIDS and their families, physicians, and other concerned individuals, the data base of information on clinical trials is available by calling toll-free 1-800-TRIALS-A, Monday through Friday, from 9 a.m. to 7 p.m., Eastern time.

Callers to the service will reach a trained health information specialist who will provide information on the purpose of the product being tested, patient eligibility criteria, the name and address of the trial sponsor, and whether or not the trial is enrolling new patients. The caller can also get the name and phone number of a contact person at the company to call for more information.

The information is updated every week. Callers can elect to receive the information immediately over the phone and can have a printout of this search mailed to them in a plain envelope marked only with a return P.O. box, city and state. This will help ensure the confidentiality of the service. The name and address of the caller is deleted as soon as the information is mailed.

In addition to information regarding ongoing clinical efficacy trials, the new information service will provide similar information about products with treatment IND status. These are experimental products for life-threatening or serious diseases for which FDA allows wide pre-approval distribution. Distribution is permitted when evidence from clinical studies has shown that the drugs may be effective and do not pose unreasonable risks. One such product is erythropoietin (EPO), which was recently given treatment IND status to treat the severe anemia many AIDS patients develop while using AZT.

The creation of the CTIS was a cooperative effort of the federal Centers for Disease Control, NIAID and FDA. FDA's recently created AIDS Coordination Staff developed the data base working with these agencies, other divisions of FDA, and the pharmaceutical industry.

The Health Omnibus Programs Extension Act legislation and the information now available through the CTIS marks a change for pharmaceutical companies and the information they are required to make available about a new AIDS product before it is approved. Before this law was passed, information about efficacy trials for investigational products for AIDS was considered confidential. Now, companies must submit the required information to the CTIS within 21 days after an efficacy trial for a new AIDS product begins.

Specifically, for each new trial to test product effectiveness,



sponsors must provide information on the purpose of the experimental protocol, the patient eligibility criteria, and the location of each new trial.

In addition to the toll-free telephone number, the information on clinical trials can also be accessed through the National Library of Medicine's computer system, which is available on a subscription basis. The AIDS Clinical Trials data base (called AIDSTRIALS) is available 24 hours a day, seven days a week, except for a brief daily maintenance period. Those using the system can either have the information printed out on their own printer or request to have the information mailed to them. Information will be mailed in an envelope bearing the library's return address. Information on the computer service may be obtained by calling the library at 1-800-638-8480.

The AIDS Clinical Trial Information Service marks important progress in getting information about new drug trials to the desperately ill. There are, without a doubt, thousands of people with AIDS or infected with HIV (the virus that causes AIDS)

wishing to become enrolled in clinical trials for experimental drugs. In fact, since its inception last July, the information service has been receiving an average of over 500 calls per week. FDA is happy to join with CDC and NIAID to help bring this information to the many physicians, researchers and patients who want to be brought up to date on the availability of new therapies for AIDS and related conditions.

I believe we have finally begun to turn the corner in the war on AIDS. We are beginning to see an increasing number of new drugs that seem to have an impact on this terrible disease. As a physician and as a member of the public health community, I look forward to the day when we find a cure. At present, however, there is no cure—but there is hope. And we pledge to continue bringing information about investigational drugs to those who need it the most. FDA also remains committed to encouraging the development and marketing of new drugs that prove to be effective in fighting the disease. ■

RETHINKING EATING OUT

While decadent desserts and bulging burgers aren't yet restaurant relics, such menu items may be passing their prime. We're substituting more skinless poultry for fried chicken, lighter frozen desserts for ice cream, and bare, baked potatoes for french fries. Mayonnaise-mustard-ketchup-cheese-smothered hamburgers are being put on the back burner in favor of steamed, poached, roasted and broiled foods.

In an age where diet is increasingly linked to coronary consequences and other ailments, we're becoming more discriminating about what we eat — and that includes away-from-home foods. A 1986 Gallup Poll found 4 out of 10 consumers changing away-from-home eating habits by trying to consume more vegetables and fewer fats, meats and fried foods. A 1988 Gallup survey for the National Restaurant Association (NRA) suggests healthful

foods are a chief restaurant-patron priority: Fifty-nine percent of survey respondents rank nutritious menu items second on a list of 10 features they would like to see at restaurants.

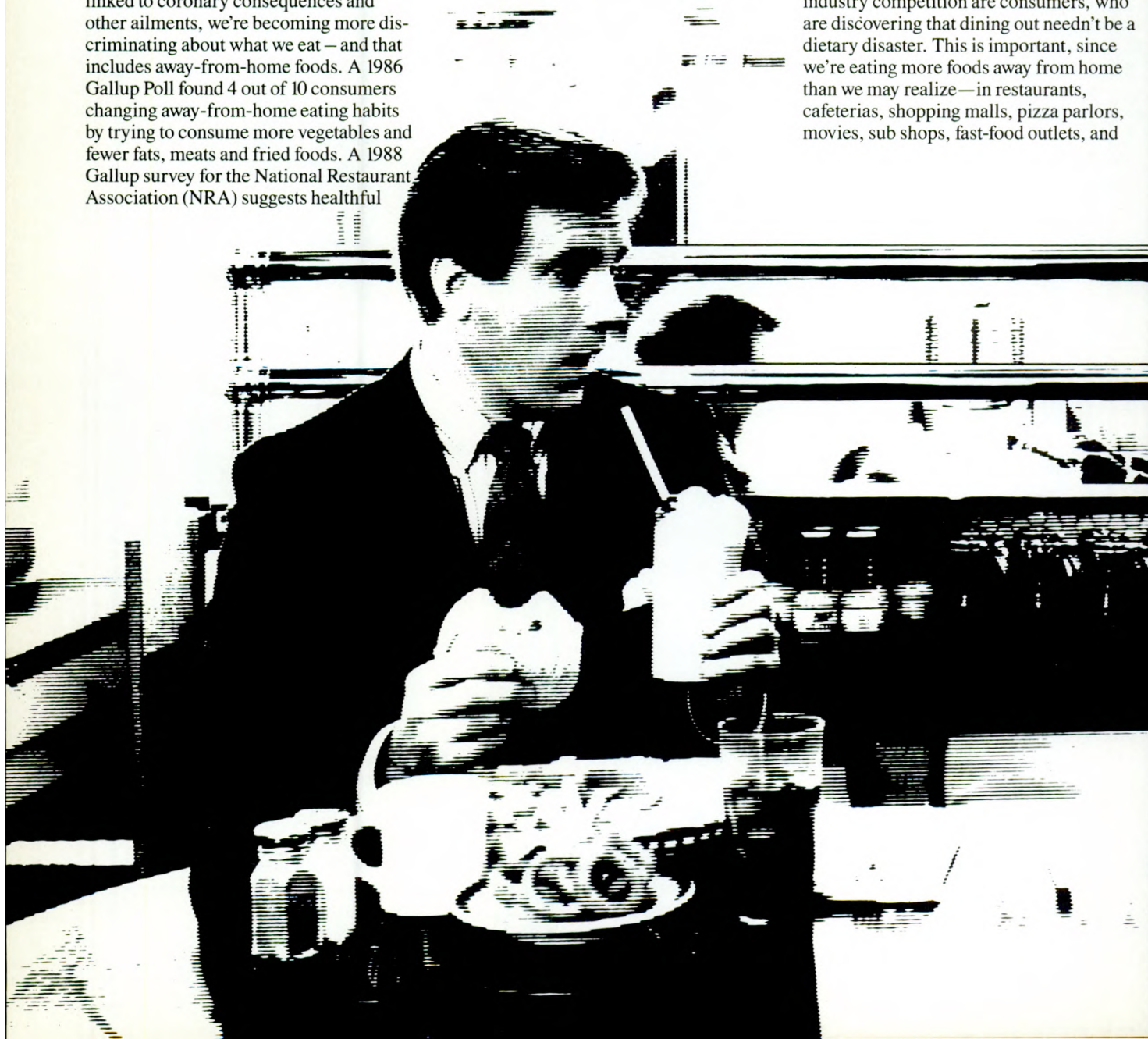
Dining out without sacrificing good nutrition is getting easier, as restaurateurs creatively cater to our fitness-food fondness. While a 1986 NRA survey found 23 percent of restaurant operators featuring health and nutrition promotions, approximately 40 percent now offer special nutri-

tional menu items lower in calories, fat, salt, and cholesterol.

"This is a highly competitive industry with very little growth right now, because the market is almost saturated," notes NRA nutritionist Claire Regan. Among efforts aimed at maintaining a competitive edge, restaurateurs are recruiting consultants to develop nutritious menu concepts.

Consumers Benefit

The biggest beneficiaries of intense industry competition are consumers, who are discovering that dining out needn't be a dietary disaster. This is important, since we're eating more foods away from home than we may realize—in restaurants, cafeterias, shopping malls, pizza parlors, movies, sub shops, fast-food outlets, and



by Cheryl A. Sweet

convenience stores. With one of every five meals eaten away from home, Americans were expected to spend \$85 million on 1989 food and beverage purchases.

We're more apt to dine healthfully during a business or social-obligation restaurant visit than during a non-routine meal for fun. The most nutritionally conscious Americans are women of all ages and older men, suggest studies.

"Age is the most important determining

factor in eating nutritionally," says Anita Owen, president of the American Dietetic Association Foundation and senior vice president for nutrition education and research for the National Dairy Council. "As people age, we realize our vulnerability to heart disease and other health problems and we're willing to listen to advice and change our behavior. You try to talk to teenagers about having a coronary in 20 years and they're not going to listen."

Requests Honored

Restaurants today are impressively receptive to special diet requests, which also increase your nutritious-meal odds. A 1986 NRA survey of restaurant operators found that nearly three-quarters of respondents will alter food preparation methods upon request. Operators are increasingly willing to cook with unsaturated fats like margarine or vegetable oil rather than butter, lard, shortening, or other saturated fats.

(continued on next page)





Dining out without sacrificing good nutrition is getting easier.

While some restaurants have separate menus for special nutritional items, others incorporate these dishes into existing menus. A potential drawback to separate menus is they may not always be presented during peak periods when waiters or waitresses are pressed for time. At restaurants where the demand for nutritious items does not warrant a special menu section, there may be a statement on the menu encouraging special requests, such as food cooked without salt or served without sauce.

Although menu information may never reach the detailed supermarket-labeling level, today's menus contain more nutritional information than ever before. Besides listing calorie, fat, sodium, and cholesterol content, many menus also describe food preparation—which is where a grasp of cooking lingo comes in handy.

Buzzwords that indicate less fat include grilled, broiled, stir-fried, roasted, poached, or steamed. Clues that selections are higher in fat include terms like battered, fried, breaded, creamed, au gratin, scalloped, hollandaise, rich, or escalloped. Few terms guarantee less sodium, and even "fresh" or "homemade" products can be fairly high in sodium, depending on the types and amounts of ingredients, including salt, used to prepare them. High-sodium terms include smoked, pickled, barbecued, marinated, Parmesan, in broth, in a tomato base, and with soy sauce, teriyaki, creole sauce, or mustard sauce.

Selecting Restaurants

Restaurants with varied menus usually offer the best nutritional options by providing the greatest flexibility in types of foods and preparation methods. Items are often prepared to order, so you can feel comfortable making special menu requests.

While cafeterias also provide diverse choices, the foods are prepared in advance and items usually cannot be made to order. Smart cafeteria eating requires exercising control over portion size and amounts of sauces, gravies and dressing.

(continued on page 12)

Eating Ethnic

Since part of the fun of eating out is sampling new cuisines, you may want to consider these suggestions for nutritious ethnic meals.

Chinese

Limit high-sodium soups and high-fat fried noodles or make other selections. If the noodles are on the table, you may want to ask the waiter to remove them to avoid temptation. Choose dishes that are boiled, steamed, or lightly stir-fried in vegetable oil, rather than sautéed. Although many Chinese dishes are salty, you can ask that sauces, such as soy, be served on the side and that monosodium glutamate (MSG) and salt not be used in preparation. Also, limit egg foo young dishes and items made with lobster sauces. These contain egg yolks and, therefore, cholesterol.

French

A good rule for French dining is "keep it simple." Steamed mussels or a salad (with dressing on the side) are fine starters, but avoid French onion soup, which is salty and may be high in calories, especially if it's topped with bread and cheese. Be wary of sauces, the heart of classic French cuisine. For example, hollandaise is made with egg yolks and butter; bechamel is made with milk, butter and flour; and bear-naise is an expanded hollandaise. Alternatives are French wine sauces and "nouvelle" sauces made without flour—the latter may still contain cream, egg yolks, butter, and plenty of calories. Since all sauces tend to be high in sodium, ask if your entree is in sauce and how that sauce is prepared. You can also ask whether the sauce can be served on the side.

Greek

If you're counting calories, you may worry that Greek food is too oily. However, Greek food is usually prepared with olive oil, which is monounsaturated and hence a desirable type of fat. To keep down calories, seek dishes made with limited amounts of olive oil. There are many acceptable choices,

such as tzatziki, an appetizer made with yogurt and cucumbers. Pita bread is low in fat, and the feta cheese in Greek salads is slightly lower in fat than many hard cheeses, but relatively high in sodium.

Italian

Pastas, an Italian staple, are a good choice for those on low-fat diets as long as they aren't filled with cheese or fatty meat, or tossed with butter or cream sauces. Linguine with white or red clam sauce is a fine pasta selection. Other lower-fat sauces include marsala, made with wine, or marinara, made with tomatoes, onions and garlic. Simply prepared chicken and fish are also good choices. Veal scallopine is usually prepared by adding fats. Italian ices are an excellent low-calorie, low-fat dessert choice.

Japanese

Although many Japanese dishes are salty, this country's cuisine is a boon to those on low-fat diets. Pickled vegetables are low in cholesterol, saturated fat, and calories. But watch out for deep-fried dishes like tempura and salty soups and sauces. Ask for sauces on the side. Look for the word "yakimono," which means broiled. Dishes with tofu, a low-fat soybean curd protein without cholesterol, are nutritious alternatives.

Mexican

Contrary to popular belief, Mexican food is not off limits to dieters. Whole grains are staples of Mexican dishes, and tortillas, made with corn and baked rather than fried, can be a welcome addition to your diet. Tomato, onion and avocado salads with fresh lemon squeezed over the top are refreshing. Shrimp or chicken tostados on unfried cornmeal tortillas are good choices. Refried beans are cooked in lard. Request cheese and sour cream served on the side, and try rice and beans: They're high in fiber, low in fat, and a complete vegetable protein. ■

— C.A.S.





From 1978 to 1985 dessert consumption at home dropped 13 percent, but rose 18 percent in restaurants.

(continued from page 10)

"Steer clear of all-you-can-eat specials because you have a tendency to eat more," advises ADA's Owen. "Go to a restaurant that offers a wide variety of choices with a la carte suggestions. Also, to avoid extra calories and fat, request that chips and salsa be removed from the table." Another calorie-cutting option: "Ask for an extra plate and split an entree with a friend, or eat only half of what's served and ask for a doggie bag. Be sure it's wrapped up before temptation hits you."

Steakhouses and fish houses generally offer fewer menu items, although diners can often order seafood prepared by methods that keep fat and calories lower, such as broiling. Different sizes and cuts of meats are often available. Preparation methods may be more limited than full-service restaurants, but special requests may be honored.

At pizza parlors, sub shops, and fast-food restaurants, special menu requests are minimal or nonexistent. Despite nutritional strides, many fast-food restaurant menu items have large amounts of fat or salt. For instance, most fast-food breakfast sandwiches—combinations of eggs, cheese and meats between muffins, biscuits or croissants—derive more than half their calories from fat. Sodium levels in many foods are also steep at fast-food outlets. While the Food and Nutrition Board of the National Academy of Sciences has set a safe and adequate range of 1,100 to 3,300 milligrams per day, some single fast-food items contain 1,000 milligrams or more of sodium.

Some fast-food eating tips: Order sandwiches plain and hold the sausage and bacon. "The rule is the plainer the better," says Stephanie Wood, a dietitian at the Mayo Clinic in Rochester, Minn. "If you're going to have a hamburger, stay away from the super-deluxe, which has more fat and calories." Additionally, look for salad bars where you can make your own meal. Use salad dressings, sauces, and other toppings sparingly, to avoid the extra calories and fat. Limit dishes with



cream sauces, and select more greens and vegetable items. Try baked potatoes with vegetable or yogurt toppings.

Despite a growing nutritional awareness, our behavior lags behind well-meaning intentions. "There's a big difference in what people say they want and what they do," remarks NRA's Regan. Most of us haven't managed to reduce our fat intake to 30 percent of our total daily calories—a recommendation of both the American Heart Association and the National Cancer Institute. Our food selections when eating out seem to differ from at home. The Market Research Corporation of America found that home red meat consumption declined more than 11 percent from 1981 to 1986, but increased by just over 1 percent in restaurants. Another survey by that organization found that from 1978 to 1985 dessert consumption at home dropped 13 percent, but rose 18 percent in restaurants.

"Americans want it both ways," says Owen. "Being human beings and enjoying food, people are eating prudently all week, and when they go out to a restaurant a couple times a month, they like to splurge. It appears that Americans seem to view home as a place for simple-to-make or healthful foods, but once away from home, it becomes acceptable to satisfy the desire for forbidden foods."

Challenges for Chefs

While consumers rethink dining-out behavior, chefs are confronting challenges on their own—trying to maximize nutrition without compromising taste. Today's emphasis on nutrition in culinary schools is helping chefs achieve that delicate balance.

"When I went to school 15 years ago, we had one course on nutrition and then it was never mentioned again," says Robert Briggs, a chef and instructor at the New York-based Culinary Institute of America. "It's easy when you make something that doesn't taste quite good enough to doctor it up by throwing on some more salt or



Americans who make small changes in what they eat can make a major difference in their overall health.

adding some more fat. It's a little more difficult to think of other ways to season and preserve flavor. Chefs are now learning nutritional innovations that are being practically applied."

One such innovation in California finds chefs adopting a no-fat, hot-rock cooking method. Thinly sliced, skewered raw meat, fish and vegetables cooked on a slab of hot granite are eaten plain, dipped in sauce, or wrapped in soft flour tortillas. The availability of more menu items made with grains reflects another dining-out trend. Once restricted to health food stores and natural food restaurants, whole-grain products that don't drive up fat and calorie content and that add fiber are moving into mainstream restaurants.

Towards the Year 2000

More than just a fad, surveys suggest our appetite for healthful foods is here to stay. An NRA 1988 study of food service in the year 2000 predicts nutritional concerns will continue to be critical to menu development. Menu items with fewer calories are expected to be commonplace, with chefs able to achieve rich flavors without the addition of extra fat and salt.

Among the host of food-technology developments on the horizon are two new fat substitutes, Simplesse and Olestra, under review by the Food and Drug Administration for marketing approval. Foods manufactured with these products would have taste and texture characteristics similar to those of their regular counterparts but with fewer calories. Also, Cornell University scientists are working to refine a commercially feasible process that would remove up to 90 percent of the cholesterol and reduce saturated fat in milk with little change in the taste. Similar to the process used to decaffeinate coffee, the process might also be used to produce a variety of other low-cholesterol dairy products such as butter, cheese and ice cream. Also on the biotechnology drawing boards: specifications to genetically alter cholesterol in animals to produce red meat



with less cholesterol.

Despite benefits associated with healthful eating, some experts worry that we're becoming a society of food fanatics.

"There's a tremendous conflict being set up," says Molly Gee, of the American Dietetic Association. "We're trying to eat a variety of good foods and cut the fat, but there's the notion that when you cross the line of eating for good health, you're going to be deprived. Many of us look at food today from a risk-avoidance perspective."

Observes Gee: "I think we've lost sight of common sense. People are so concerned about what they eat that they immediately think food is going to hurt them. We must look at the total diet—not at whether one food or another is going to cure or kill us. The pendulum has to swing back in the middle so we think of food as a pleasurable experience."

Rather than embrace sweeping diet revisions, Americans who make small changes in what they eat can make a major difference in their overall health, according to a new public education program sponsored by the U.S. Department of Agriculture. "Eating Right . . . The Dietary Guidelines Way," encourages variety, balance and moderation in food consumption by following USDA's seven dietary guidelines for Americans. The first two guidelines suggest eating a variety of foods that provide enough essential nutrients and calories to maintain a desirable weight; the other five describe characteristics of good eating, recommending eating an adequate amount of starch and fiber and avoiding too much fat, sugar, sodium, and alcohol.

Despite less control over how foods are prepared when we eat out, the secret to maintaining an away-from-home nutritional edge lies in exercising control over restaurant food choices, and over how much we eat. Sensible, slight eating adjustments can improve nutrition both at home and while dining out. ■

Cheryl A. Sweet is a free-lance writer in Phoenix, Ariz.

A New LOOK

At Food Labeling

by Dale Blumenthal



If a frozen pizza is 12 inches in diameter, weighs 20 ounces, contains 1,604 calories and 4,320 milligrams of sodium, and one serving is 5 ounces and contains 401 calories and 1,080 milligrams of sodium, did the slice you ate at lunch contain more, less, or the same amount of calories and sodium as the manufacturer's recommended serving size? Is that a lot of sodium or relatively little? Is the number of calories marked so you can compare brands? Did your slice of frozen pizza contain more or less cheese than the same size slice from a competing brand — or from the chain pizza restaurant down the street?

Questions like these have prompted the Food and Drug Administration to take a new look at food labels.

Federal laws governing food labeling have remained essentially unchanged since 1973, when FDA launched the first drive to develop labels that give consumers information about nutrients. At that time, the agency adopted nutrition labeling rules permitting — and in some cases requiring — foods to be labeled for their nutritional content.

Renewed interest in food labeling has followed recent studies and government reports, such as the *Surgeon General's Report on Nutrition and Health* and the *National Academy of Sciences' Report on Diet and Health*, linking diet to the risk of developing certain diseases. Public interest groups, such as the American Heart Association and the American Cancer Society, stress the importance of diet to health, and consumer groups advocate food labels that are more informative and easier to read.

Some food manufacturers are using food labels to promote the supposed health benefits their products may offer by virtue of containing certain components (such as fiber) or containing smaller amounts of certain substances (such as sodium). Although traditionally not permitted by FDA, some argue that these health messages are beneficial to consumers when supported by scientific evidence.

New regulations have responded to some of these concerns. For example, a 1984 rule required that sodium content be included in nutrition labeling and defined the terms "sodium free," "low in sodium," and "reduced sodium." A 1986 proposal would define the terms "cholesterol free," "low in cholesterol," and "reduced cholesterol" and require that both cholesterol and fatty acid content be included in nutrition labeling whenever a claim is made that a product is low in cholesterol or saturated fats.

FDA now is considering a major overhaul of the regulations that describe food labeling policy. This stems from Americans' heightened concern about diet, and from new methods of food production, processing, packaging, and distribution technologies. The FDA announcement published in the Aug. 8, 1989, *Federal Register* (vol. 54, no. 151) alerts consumers and industry to the issues the agency plans to consider in revamping the food label.

FDA will be holding a series of four hearings in late 1989. These hearings will provide a forum for public comments and suggestions on the following subjects:

Nutrition Labeling

FDA is seeking public comment on whether the current nutrition label requirements should be changed.

Under the 1973 regulation, nutrition labeling is required only if a nutrient is added to a food or if a nutrition claim is made about a food. Nutrition labeling is optional for all other packaged foods. Currently, about 61 percent of products regulated by FDA bear nutrition labeling. More than half of these labels have been adopted voluntarily by the manufacturer.

When nutrition labeling is provided, manufacturers must include the following information: serving size, number of serv-

ings per container, caloric content, protein, carbohydrate and fat content in grams, sodium in milligrams, and vitamin A, vitamin C, thiamine, riboflavin, niacin, calcium and iron content expressed as a percentage of the U.S. Recommended Daily Allowance (U.S. RDA). Vitamins D, E, B₆, B₁₂, folic acid, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, potassium, and copper may also be stated as percentages of the U.S. RDA.

In addition, manufacturers may voluntarily include information about fatty acid composition (saturated and polyunsaturated) and cholesterol content. If a label claim is made about any of these nutrients, or if any are added, they must be included in nutrition labeling. All nutrient values are listed per serving.

FDA seeks public comment on whether the current nutrition label requirements should be changed. If changes in the agency's labeling regulations are adopted, other questions arise, such as:

- **What foods should have nutrition labeling?** Nutrition labeling is now voluntary for most foods. Should it be made mandatory for most foods? Should foods that make insignificant nutrition contributions, such as spices, coffee and condiments, be exempted? If so, what should be the criteria for determining exemptions?

- **What about fresh fruits and vegetables?** If nutrition labeling is required for traditionally nonpackaged foods, how could this information best be provided? Should nutrient information be based on average values in published data bases?

- **More than 41 percent of food dollars are now spent on foods eaten away from home. Should nutrition labeling requirements be extended to restaurants and other food service establishments? As menus and recipes may vary from location to location and from day to day, how could this be accomplished?**

- **What nutrients should be declared in the nutrition label?** Are there currently required nutrient declarations that could become optional (such as B vitamins)? Should declarations of other food components (such as fatty acids, cholesterol and fiber) be required?

- **Should nutrient amounts continue to be declared according to the amount in a serving?** A principal issue is how to determine serving size. Initially manufacturers chose large serving sizes to show large amounts of vitamins and minerals. However, now that consumers are more aware that some food components, such as fat and sodium, are associated with chronic diseases, some manufacturers are defining servings to be smaller in size. These changes become a problem when serving sizes for similar items differ and when manufacturers claim multiple servings in containers that are the size of a typical single serving. For instance, a manufacturer might state that a traditional single-serving container holds 1.4 servings. Who should determine serving sizes — manufacturers (as now), FDA by regulation, or manufacturers following criteria established by FDA?

Nutrition Labeling Format

The form, as well as content, of nutrition labeling is at issue. FDA regulations specify that nutrition information should appear as columns of figures.

However, from surveys it conducted in 1978 and 1982, FDA has learned that many consumers believe the current system is too inflexible, too complex, and too difficult to understand. (See "For Food Labels, Better Read = Better Fed" in the October 1982 *FDA Consumer*.) Many people want labels that tell them — at a glance — whether a particular food is high or low in a nutrient or food component.

- **What is the best format for the nutrition label?** Twenty years ago, when FDA developed the food label, many nutritionists felt it was very important to provide consumers with information about vitamins and minerals, which are referred to in terms of their RDA. This concern is reflected in the current format of food labels,

Present Nutrition Label

(Minimum Required)

Nutrition Information Per Serving	
Serving Size	1/4 pizza
Servings per Container	4
Calories	240
Protein	9g
Carbohydrate	35g
Fat	7g
Sodium	640mg
Percentage of Recommended Daily Allowances (U.S. RDAs)	
Protein	20%
Vitamin A	15%
Vitamin C	8%
Thiamine	8%
Riboflavin	10%
Niacin	10%
Calcium	10%
Iron	6%

which list the percentage of RDAs for vitamins and minerals.

Today public health officials, nutritionists, and consumers are most concerned about saturated fat, cholesterol, and sodium. However, the suggested intake of these macronutrients is not expressed in the same way as for micronutrients.

The National Academy of Sciences, the American Heart Association, and the National Heart, Lung, and Blood Institute all recommend that less than 30 percent of total daily calories should come from fat, and less than 10 percent of total calories should come from saturated fat. Should amounts of nutrients like saturated fat, calcium, and fiber be expressed in terms of quantitative dietary recommendations?

Should a new nutrition label use only the current numerical approach for measuring nutrients? Or would a pie or other form of chart showing the percentage of fats, carbohydrates and protein

in a serving size also be helpful for consumers? Should certain nutrition components be highlighted?

FDA invites ideas for types of label formats that would help clarify label information. The agency also is considering whether it is necessary for all foods to provide exactly the same information on all nutrients or whether manufacturers might have flexibility in using nutrition label formats.

Ingredient Labeling

Currently, packaged foods containing two or more ingredients must list the ingredients in descending order of predominance by weight.

• ***Should "and/or" labeling for fats and oils be revised?*** With the current labeling, it is often difficult to know whether a product contains a certain fat or oil. If fats or oils are not the predominant ingredient, manufacturers may list, in combination, fats or oils that may be in the product. For instance, an ingredient label for cheese-flavored corn chips may read: "whole grain corn, vegetable oil (contains one or more of the following: cottonseed, soybean, peanut, corn, partially hydrogenated soybean, or partially hydrogenated cottonseed), dehydrated cheddar," followed by a listing of the rest of the ingredients in order of predominance by weight.

This rule allows manufacturers to take advantage of shifting prices for the various fats and oils without requiring them to revise the label each time the fat or oil ingredient is changed. Some groups feel the "and/or" labeling exemption should be revoked because it undermines the U.S. Department of Agriculture/Department of Health and Human Services dietary guidelines for Americans, which recommend that people eat less saturated fats.

Others suggest modifying the exemption so that "and/or" labeling would be used only when fats and oils are of like nutritional value (such as using "and/or" for similar polyunsaturated vegetable oils, but not for alternating use of saturated and polyunsaturated vegetable oils). Another option would be to modify the exemption so that it would apply only when the fat or oil content is a minor portion of the food product or when nutrition labeling (including fatty acids) is provided.

• ***Should major ingredients be listed by percentage instead of by predominance according to weight?*** Some people feel that percentages are needed to tell consumers more about the amount of an ingredient in a product. This may be expensive for industry, however. Whenever a manufacturer slightly changes the percentage of an ingredient, the food label also will have to be revised. And, by revealing percentages of ingredients, manufacturers may reveal their formulations to competitors.

Description of Food

Naming a food in a way that accurately describes its characteristics and that does not deceive the consumer would seem to be a fairly straightforward task. However, how to do this has become controversial in recent years.

Congress has given FDA authority to set standards of identity through the Federal Food, Drug, and Cosmetic Act. Food standards define the required ingredients in certain traditional foods, such as bread, milk and cheese, and if a product does not meet the applicable standards, it must be labeled as "imitation" or called by a different name.

However, the current procedures for setting or amending standards are cumbersome and time-consuming. (It took almost a decade to adopt the peanut butter standard.) In addition, advances in technology and nutrition are constantly redefining what is

Food Labeling Issues at a Glance

Nutrition Labeling

- Should nutrition labeling be voluntary or mandatory?
- What foods should be exempt from nutrition labeling?
- What food components and nutrients should be required to be declared in nutrition labeling?
- Should FDA establish serving sizes and, if so, what criteria should be used?

Nutrition Labeling Format

- Are there terms on the nutrition label that are not readily understandable?

- If the nutrition label is revised, should the numerical approach be changed to a pie graph or scale of adjectives?
- Should the order in which nutrients are listed be changed?
- How should information be provided on small cans and on unpackaged foods?
- Should FDA and/or industry conduct consumer testing before making any changes in the food label format?

Ingredient Labeling

- Should the existing order of predominance labeling be bolstered by a

requirement that major ingredients be listed by percentage?

- Should the agency's current "and/or" labeling regulations for fat be modified?
- Should ingredient labeling be expanded to include spices, colors and flavors?
- Should there be ingredient labeling for "fast food"?

Description of Food

- Should the current method of naming foods be changed?
- Should any changes be made in how FDA prescribes use of descriptors?

Health Messages

- How should FDA revise or rewrite the 1987 health messages proposal? ■

desirable in a food. For instance, the cheese standards established many years ago require a certain level of fat. To be called "cheddar cheese," a product must not contain less than 50 percent milk fat. However, fat is no longer valued as an ingredient, and manufacturers wish to produce cheddar cheeses with lower fat content for consumers who desire them.

To give manufacturers relief from the dilemma of either complying with an outdated standard or having to use the somewhat pejorative term "imitation," FDA has adopted two regulations. Under the first, the "imitation" policy, a food that resembles a standardized food need not be labeled as an imitation if it is not nutritionally inferior to the food it resembles and if it bears a name that will distinguish it from that food (for instance, "mozzarella cheese substitute" would use different ingredients but be nutritionally equivalent to mozzarella cheese).

Under the second regulation, FDA may assign "common or usual names" to describe particular types of food for which no standard has been set (for example, the common or usual name of shrimp cocktail is "shrimp cocktail, contains X% shrimp"). These names are adopted by a less time-consuming procedure than standard setting.

In addition, some manufacturers have begun to adopt the current practice of placing statements on their labels that describe their products as "light," "low in salt," and "reduced fat." To bring some order to the marketplace and to ensure that consumers are not misled, FDA—on a food component by food component basis—is developing a series of descriptors for use on food labels.

• **Does the system of food standards have any continuing value for the 1990s?** If nutrition and ingredient labeling are revised to provide more information to consumers, will there still be a need for standards of identity? Do the tight recipe specifications and inflexibility of standards put new products at a disadvantage? Are consumers less willing to try products described as substitutes?

Health Messages

Manufacturers have begun to add health messages to the labels. Some cereal box labels state that the fiber in the cereal may help prevent some kinds of cancer; labels on products containing unsaturated oils may inform consumers that lowered consumption of saturated fats has been linked to lower rates of heart disease, and labels on milk cartons may promote calcium for prevention of osteoporosis.

FDA traditionally has viewed these health-related messages as drug claims, meaning that foods making these claims would be regulated as drugs. However, manufacturers have expressed a desire to promote products that are healthful, and consumers want information to help them select such foods. FDA issued a proposed regulation in 1987 that would permit health claims in certain products. The agency requested public comment. Comments submitted showed an extreme divergence of opinion about the proposal. Therefore, FDA is interested in gathering further comments on options for resolving the problem.

• **Is food labeling an appropriate vehicle for disseminating health-related dietary information about specific diseases?** If so, what guidelines should be used for evaluating whether the health message is false or misleading and what scientific information should be necessary to support the claim? Could the use of health messages on food labels invite problems, such as overfortification of foods with nutrients so that "positive" claims could be made? How should health claims on food packages make reference to the nutrition label information on the package? Should health messages be required to meet certain standards?

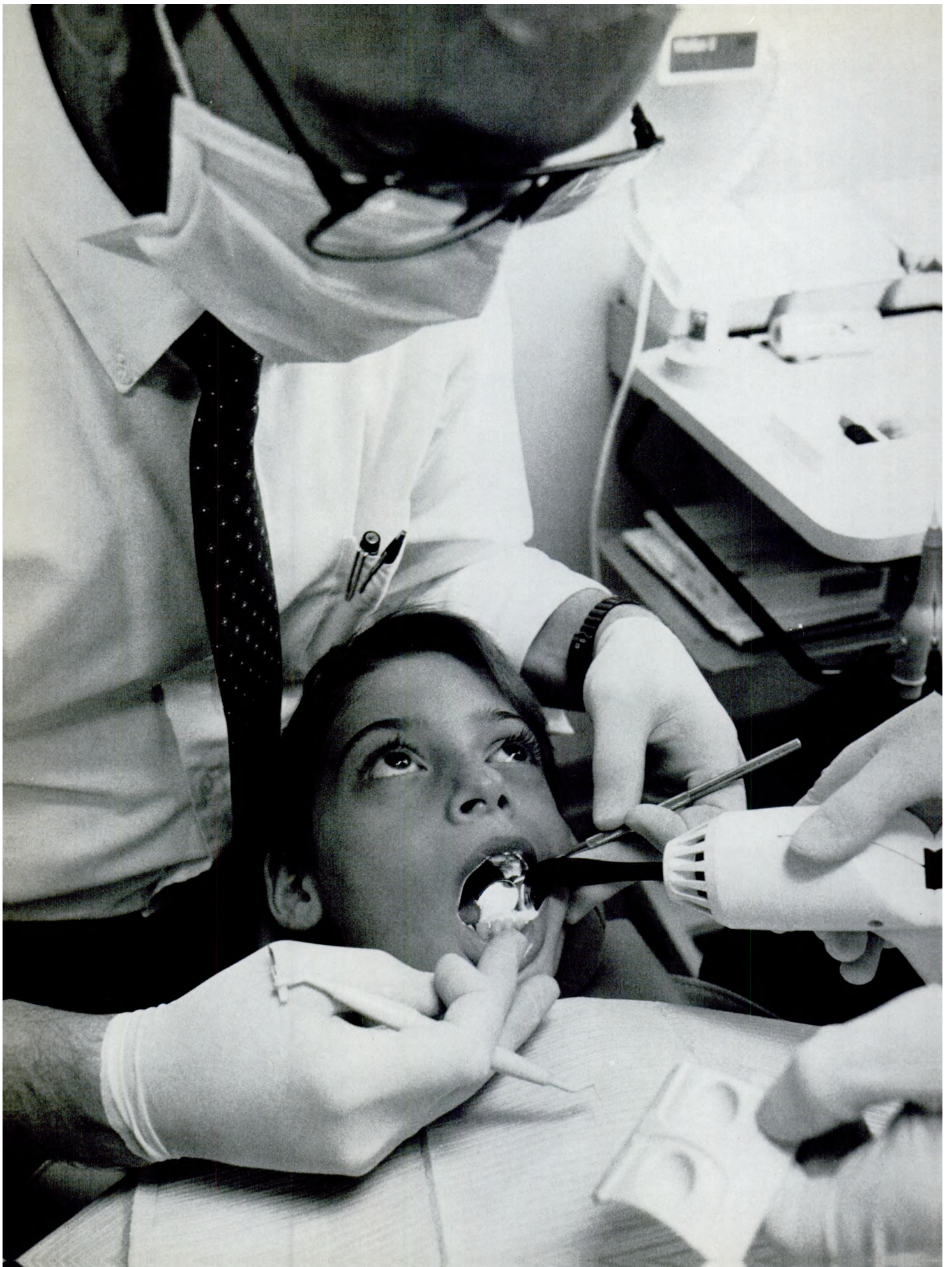
The Hearings

The first food labeling hearing was scheduled for Chicago on Oct. 16. Other hearings will be held in San Antonio on Nov. 1, in Seattle on Dec. 7, and in Atlanta on Dec. 13. These hearings will provide a forum for comments from consumers, industry, and health professionals. For more specific information about times and locations, call (301) 443-3170, or write to Food Labeling, c/o Office of Consumer Affairs, FDA (HFE-88), Rockville, Md. 20857.

FDA Commissioner Frank E. Young, M.D., Ph.D., will preside at the meetings and is especially interested in learning what people feel are the most important questions. If you would like to comment but are unable to attend a hearing, submit written comments on Docket No. 89N-0226, by Jan. 5, 1990, to Dockets Management Branch (HFA-305), Room 4-62, 5600 Fishers Lane, Rockville, Md. 20857.

The call now is for people to attend the hearings, submit comments, and make their views heard so that their opinions can play a part in the formulation of the food label for the future. ■

Dale Blumenthal is a member of FDA's public affairs staff.



Sealing Out Decay

by Jeffrey P. Cohn

Imagine being able to protect your children's teeth from decay instead of both you and they having to undergo the stress and discomfort often associated with getting teeth filled. Imagine that such protection is available now from your regular dentist.

Sound too good to be true? Well, the good news is that your children's teeth most at risk of cavities can be protected by a sealing process that is safe, effective, and relatively inexpensive. Moreover, today's sealants are long-lasting, easily applied, and can virtually eliminate the kinds of cavities kids get most often.

The bad news, however, is that sealants have been underused. Many in the general public have not known they are available, and health insurers and other third-party payers often have not reimbursed for them. Fortunately, though, more dentists are beginning to encourage patients to use sealants. People are also becoming aware of them through public education programs, and more insurers are beginning to include sealant coverage in their dental policies.

"We have the means today to prevent most tooth decay," says Preston Littleton Jr., D.D.S., deputy director of the National Institute of Dental Research (NIDR) in Bethesda, Md. "We'd like to see dental sealants adopted on a much broader scale than they have been so far."

Dental sealants were conceived in the 1950s, developed in the 1960s, and brought into general use in the early 1970s. They are mixtures of the same bisphenol and methacrylate chemicals used in most white dental fillings. The sealants, which are applied as a liquid, may be clear or tinted.

Sealants' protective qualities derive from the barrier they form on the chewing surfaces of molars and premolars. A thin, plastic coating seals the teeth surfaces, preventing food particles from becoming trapped in pits and fissures where individual tooth-brush bristles often cannot reach.

Pits and fissures occur naturally on the chewing surfaces of molars and premo-

lars. Shaped like deep river valleys or rock crevices, they increase the surface area available for grinding food before it is swallowed. Those of concern are the particularly deep and narrow ones at the bottom of larger, more rounded crevices.

Smooth-surface teeth (incisors and canines) do not require sealants because they lack the surface irregularities of molars and premolars. For the former, fluorides and regular brushing remain the best preventive dentistry. But not even topical fluorides can completely stop pit and fissure cavities.

Dental sealants are best applied when permanent molars erupt, usually at ages 6 to 8 and 12, although they can be used effectively later too, according to Louis Ripa, D.D.S., professor and chairman of children's dentistry at the State University of New York's School of Dental Medicine at Stony Brook.

Children are more likely than adults to get cavities, Ripa explains, because they typically eat more sweets than adults usually do. Also, newly erupted molars are more susceptible to and develop decay faster than other teeth. In fact, more than 80 percent of cavities today occur on the chewing surfaces of molars and premolars, Ripa says.

Benefiting from Sealants

How many children could use sealants? NIDR surveys have found a nationwide decline of 36 percent in dental cavities among school-age children. While in 1979-80, the per child average was 4.8 decayed, missing or filled teeth, by 1986-87, this had decreased to 3.1. Nevertheless, Ripa says, nearly all children would benefit from sealants.

The reason: While 97 percent of 5-year-olds have no decay in their permanent teeth, the percentage falls to 15 percent by age 17, according to John Bogert, D.D.S., executive director of the American Academy of Pediatric Dentistry (AAPD), who agrees with Ripa that the overwhelming

majority of school-age children should get sealants.

Michael Roberts, D.D.S., NIDR deputy clinical director says, "Dentists cannot absolutely predict who will get cavities and who will not. If I guess wrong, the child will get decay. If I have to err, I would rather err on the side of preventing decay, and sealants can't hurt."

In Ripa's opinion, however, not all teeth require sealing, nor do all children need to have their teeth sealed. If the pits and fissures are not deep and narrow and if they do not catch the hooked tip of the dentist's metal explorer, he says, perhaps they should be left unsealed.

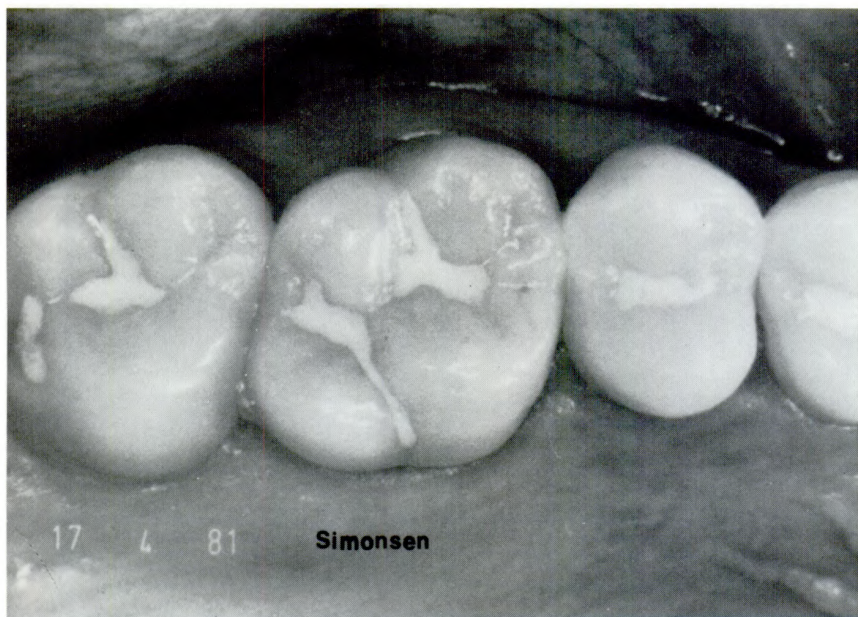
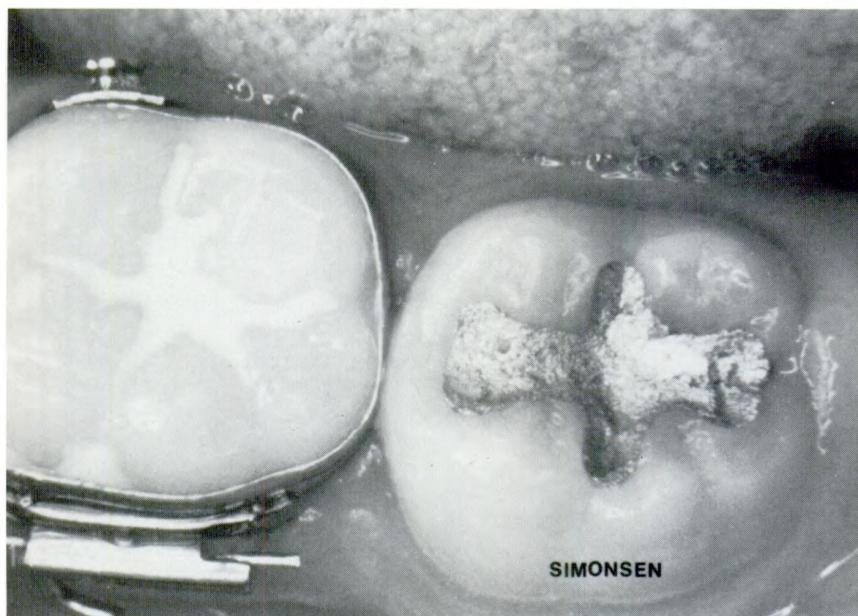
"It calls for the dentist's best professional judgment," Ripa explains. "The profession may one day agree that all teeth should be sealed," he says, "but that is not the current consensus among dentists."

"It's individually determined on a patient-by-patient and tooth-by-tooth basis," adds AAPD's Bogert.

Roberts also urges sealing the primary molars of children under 5. "Baby molars stay in the mouth from age 2 or 3 until 12, when they are replaced," he says. "These teeth are very susceptible to decay." Roberts concedes that getting young children to cooperate long enough to apply sealants is difficult. Thus, he says, sealants probably will continue to be used primarily on older children.

At the other end of the age scale, most dentists and dental groups recommend sealing teeth only through age 17. But, Ripa says, given the increasing number of cavities dentists see in older teens and young adults, perhaps they would benefit from sealants, too. By the mid-20s, though, most people have had most of the cavities sealants are designed to prevent.

Before sealants are applied, the teeth to be sealed are first cleaned, then etched using a mild, 30 to 50 percent phosphoric acid solution. The acid creates many small, microscopic pores in the teeth. The liquid sealant flows into the pores, aided



In the top photo, the permanent molar on the left was sealed for five years and needed no restorations, but the one on the right, which came in later and was left unsealed, needed an amalgam filling.

These permanent teeth (bottom photo) are shown with sealants, three years after they were originally sealed.

(Photos by Richard J. Simonsen, D.D.S.)

by a small brush, and becomes bonded to the teeth. If left unsealed after etching, by the way, the pores would remineralize and naturally fill in.

Sealing Process

Applying sealants causes no pain, Bogert says. Patients might experience an unpleasant taste, but would feel nothing except their teeth being cleaned, the brush applicator, and maybe a little liquid. Afterwards, patients might feel the sealant when they bite down, especially at first, but after a few days it would feel like any other tooth surface.

"The beauty of sealants is they are non-invasive, require no drilling or anesthetic, and do not interfere with normal chewing," Bogert says.

Moreover, the process of applying them is quick, typically taking 7 to 10 minutes a tooth, and relatively inexpensive. While the price varies from city to city and from dentist to dentist, sealants usually cost from \$7 to \$26 for a single tooth. That is about half the cost of filling a single cavity.

Additionally, Bogert says, if the teeth remain sealed, "you probably will never need a filling" for the surfaces of sealed teeth. Sealants are virtually 100 percent effective in preventing pit and fissure cavities, he adds, noting: "Sealants are the most effective preventive tool dentists have except for fluorides. Together, they can virtually eliminate cavities."

Indeed, Ripa says, numerous scientific studies have found that dental sealants can reduce cavities up to 99 percent for the two years after being applied, up to 85 percent after three years, and up to 62 percent after four. How much protection occurs depends on whether a chemical activator is used to harden the sealant, the skill of the dentist (or, in some states, hygienist) applying them, and whether the sealants are replaced if they begin to deteriorate.

The key, he adds, is good etching, keeping the tooth enamel contamination-free and, most important, maintaining a completely dry tooth until the sealant has hardened.

Sealants may eventually wear down with chewing, and the bond between them and teeth can break down in the mouth's moist environment. But while early sealants usually lasted no more than a year or so, most now remain good for four years, and many last much longer, Bogert says. Still, they should be checked periodically and

replaced when necessary.

In addition to being beneficial, sealants are also among the safest of dental materials, according to Robert McCune, D.D.S., associate dean of the Washington University School of Dental Medicine in St. Louis. They are made of chemically inert materials, and there have been no known cases of illness or injury caused by their use. "Once they harden, sealants are just a piece of plastic stuck on a tooth," McCune says.

FDA regulates dental sealants as medical devices under the Food, Drug, and Cosmetic Act. The agency has found no side effects or safety problems with their use either, says Gregory Singleton, D.D.S., the dental officer in FDA's office of device evaluation.

Previously, though, many dentists worried that any bacteria or an early, undetected cavity sealed into a tooth would continue to decay under the sealant. Studies have shown, however, that any decay inadvertently sealed into a tooth will get no worse than it was before sealing, Ripa says. That's because the cavity-causing bacteria would be sealed off from their food source, thus halting the cavity's progress. If the sealant is dislodged later, the cavity might develop further or the tooth might become susceptible to decay again, but no more so than had the sealant never been applied.

Unfortunately, sealant use among American children is low. A 1986-87 nationwide survey sponsored by NIDR found only 7.6 percent of almost 40,000 school children examined had one or more teeth sealed. "We were surprised by the findings," NIDR's Littleton says.

The findings were especially unexpected given the acceptance sealants have received from almost every dental and public health group. The American Dental Association first approved a commercial sealant in 1972 and then accepted sealants in general in 1976. A 1983 National Institutes of Health (NIH) consensus conference called sealants a "safe" and "highly effective means" of preventing cavities. And former Surgeon General C. Everett Koop declared: "The greater use of sealants would lead to an improvement in the public's health, as well as reduce the future need for dental care."

If sealants are safe, beneficial, cheap and widely approved, why have so few children had their teeth sealed? There are no good answers, say numerous dental

officials and observers, but there are a number of possible explanations.

Bogert says that while they are no longer new, sealants have been heavily promoted only since the 1983 NIH consensus conference. He adds that some dentists, remembering the low lifetimes and poor reliability of early sealants, are reluctant to try the new ones.

Another reason: Relatively few health insurance plans cover dental sealants. Many dentists are reluctant to advise parents to have their children's teeth sealed if the parents' insurance will not reimburse the cost, Bogert says. The American

Most dentists and dental groups recommend sealing teeth only through age 17.

Academy of Pediatric Dentistry and other groups are urging insurers to offer sealant coverage. To some extent most now do, Bogert says, but only about 1 in 5 of their policies contain the coverage.

Increase Seen

Still, some signs indicate sealant use may be going up. The number of dentists applying sealants rose, according to published surveys, from 38 percent in 1978 to 52 percent in 1984. More recently, 85 percent of 1,330 Michigan dentists responding to a 1988 University of Michigan mail survey said they use sealants. But only 22 percent of them said they applied sealants to more than 20 percent of their patients' teeth.

At the same time, Janet Brunelle, an NIDR statistician and co-director of the 1986-87 survey, reports that slightly more 8-, 9- and 10-year-olds (about 11 percent) had at least one tooth sealed than did younger (6.5 percent at age 7) or older (5.5 percent at 17) children. Brunelle says that is "a good sign" sealant use may be increasing because in years ahead more older children will have sealed teeth and more younger ones will get sealants as they get older.

Meanwhile, several state health departments—assisted by the National Institute of Dental Research, U.S. Centers for Dis-

ease Control, American Dental Association, and others—have launched programs to promote more widespread use of sealants. Perhaps the most far-reaching is in Ohio, where a statewide poll conducted earlier this year found only 15 percent of those surveyed had heard of sealants and could correctly state their purpose.

Together with the state dental society, the Ohio Department of Health began a pilot program in Cincinnati in February 1989 that features public service announcements on television and radio, billboard ads, brochures and posters, letters to dentists, and news media and academic journal articles. The Ohio Department of Health has also promoted the distribution of videos on sealants developed by the Columbus (Ohio) health department.

Earlier, the Ohio Department of Health awarded grants to local health departments in eight cities to increase the number of disadvantaged children who get sealants. Under the grants, dentists examine second- and sixth-graders in public schools who have returned signed consent forms. Those who need sealants get them on the spot from hygienists. Some 10,000 to 12,000 children a year now receive sealants through this program, up from 2,000 in 1984, when it started.

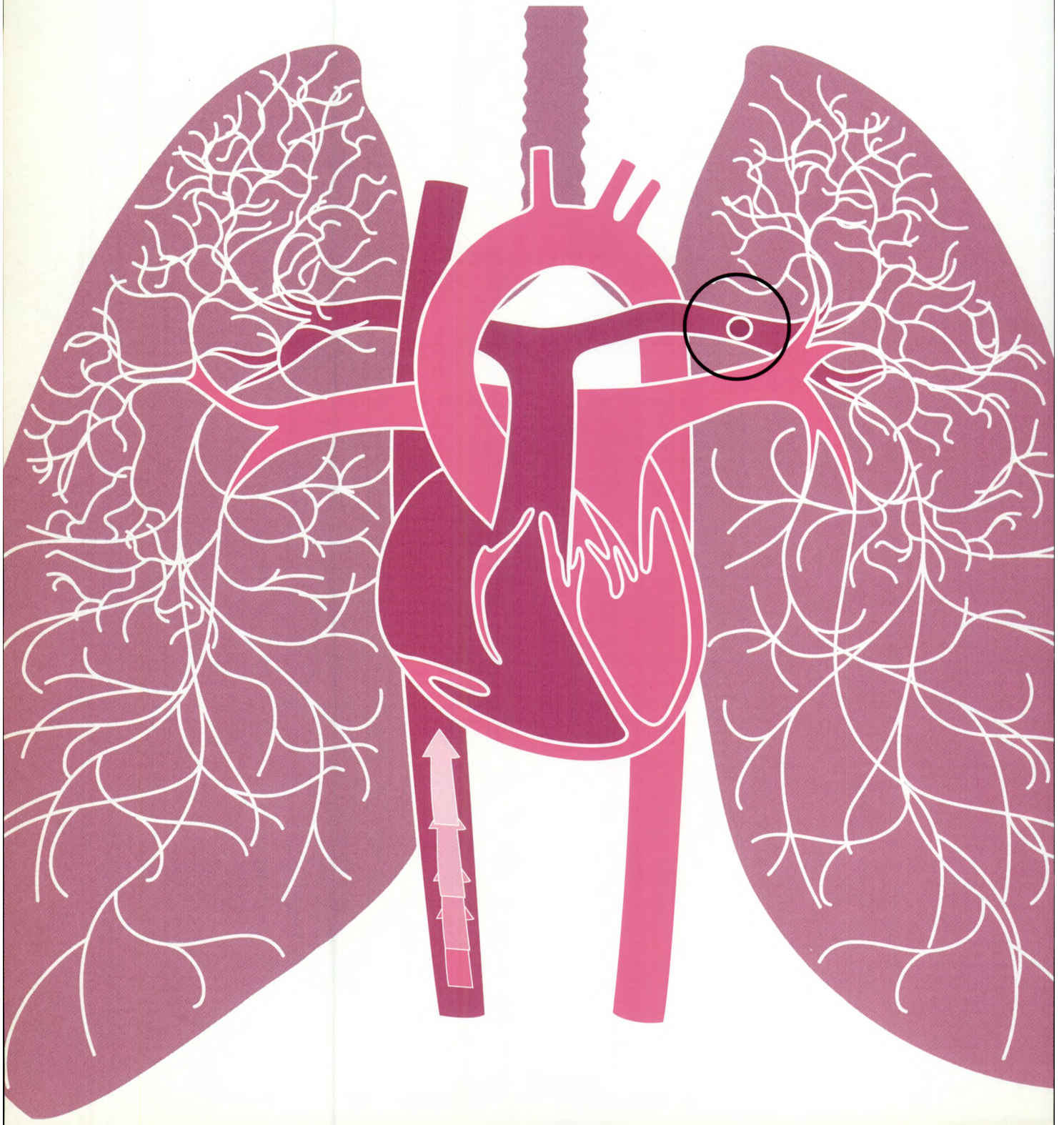
"We are trying to make more people aware of sealants, to get them to ask their dentists about sealants, and, through school-based programs, to reach those kids who are unlikely to get dental care in a private office," says Mark Siegal, D.D.S., chief dental officer in the Ohio Department of Health. Similar programs are under way in Massachusetts, Utah, and other states.

It is just such programs that give NIDR's Littleton hope that sealant use is rising. "I think the momentum is rolling in the right direction," he says. "We are doing a better job of getting our message across. I'm optimistic that we can at least double the number of kids with sealed teeth in the next decade."

Stony Brook's Ripa agrees. He says dentistry is a profession committed to prevention, pointing to longstanding support of using fluorides in drinking water, toothpaste and mouthwashes to help prevent cavities. "If some dentists are looking for something to do," Ripa says, "sealants are it." ■

Jeffrey P. Cohn is a free-lance writer in Washington, D.C.

Pulmonary Embolism:



Difficult But Crucial Diagnosis

by Evelyn Zamula

An 86-year-old man sails through gallbladder surgery like a champ, only to die a week later of a blood clot in the lung.

After completing long airplane flights in cramped economy class seats, two healthy, middle-aged physicians develop blood clots in the lung — within days of the flight in one case and a few weeks later in the other.

On New Year's Day, a 40-year-old bartender watches three consecutive bowl games on television while lying on the sofa and then goes right to bed, spending over 40 hours in a horizontal or near-horizontal position. Next day he is hospitalized with a blood clot in the lung.

A 16-year-old breakdancer is admitted to the hospital with a swollen right arm and chest pain. His doctors discover a blood clot in the lung.

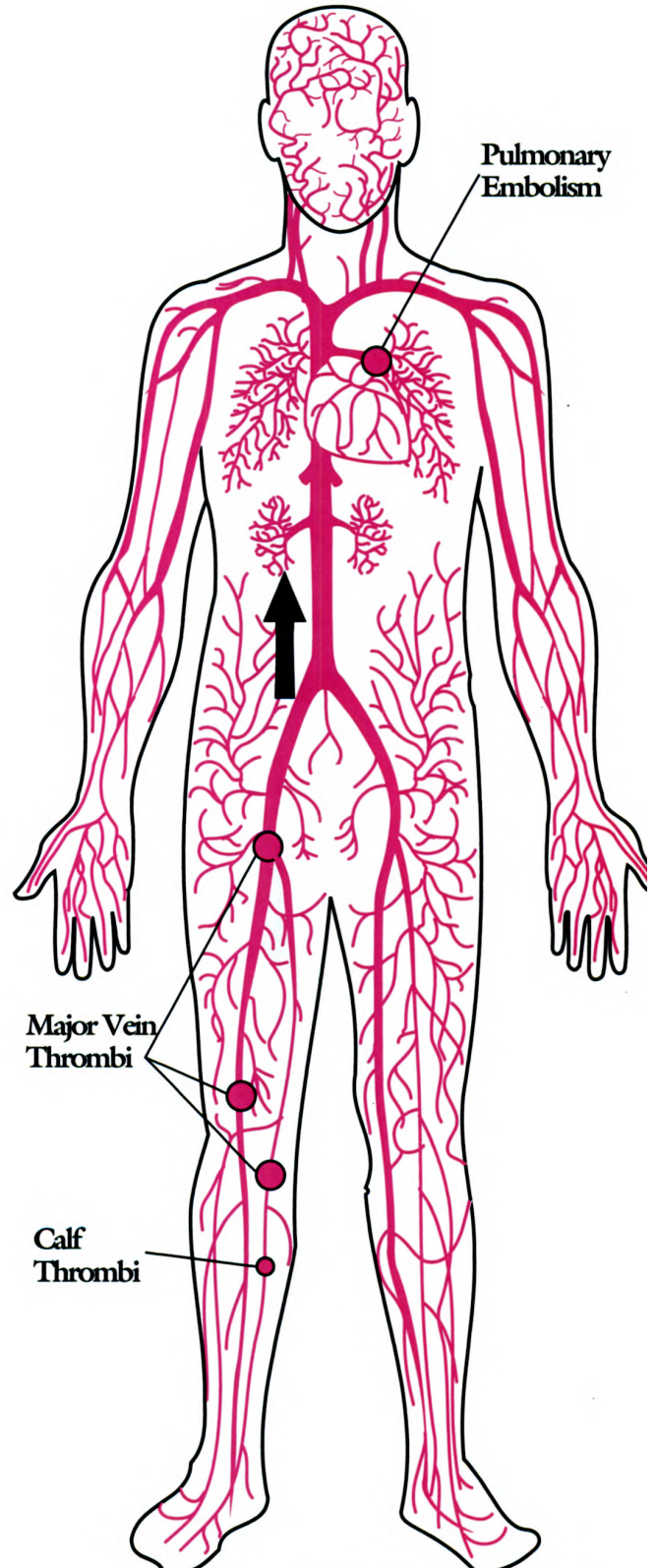
A 45-year-old U.S. senator and prospective candidate for the presidency develops a blood clot in the lung while recuperating from surgery to repair a weak spot in a brain artery.

* * * * *

With the exception of the octogenarian, all these people were correctly diagnosed and treated, and thus survived. They were the lucky ones. Each year there are about 630,000 cases of pulmonary embolism (the medical term for a blood clot that plugs the arteries supplying blood to the lungs) in the United States, and approximately 70,000 people die within an hour of their first symptoms. Of the 560,000 patients who survive longer than one hour, approximately 70 percent, or about 400,000, are misdiagnosed. Since about a third of this group dies, it is estimated that correct diagnosis and therapy could save more than 100,000 lives each year.

A blood clot in the lung is not formed there, but elsewhere in the body, a fact that puzzled doctors for centuries. The mystery was solved in 1845 when Rudolf Virchow, the German physician known as the father of pathology, described how the clot formed in a leg vein, then flowed with the venous blood up to the right side of the heart where it was pumped to the lungs.

Further research proved him correct. About 95 percent of the time, clots that end up in the lungs develop in the large vein deep inside the muscles of the leg and pelvis. (Only about 1 to 2 percent originate in the upper extremities, usually in young, healthy men following strenuous exercise or activity. The breakdancer, for example, developed a blood clot in the arm he used for balancing and spinning.) A deep vein clot is not to be confused with blood clots that form on atherosclerotic plaque in arteries and block the flow of blood to the brain, causing a stroke, or to the heart, causing a heart attack. Nor are the affected veins the superficial leg veins that are visible under the skin, the ones that commonly become enlarged and twisted, or varicosed.



Women who use oral contraceptives, especially those who smoke, are also more likely to develop this condition.

Virchow's Triad

Virchow also postulated that three underlying conditions in the body, afterward called Virchow's triad, contributed to the formation of a vein clot. The first of these conditions, injury to a vein wall, can be caused by inflamed valves in the deep leg veins, an indwelling catheter, an injection or accident, or by other problems.

Normally, when a blood vessel is injured, a clot (thrombus) forms at the injured site to prevent further blood loss. Over a period of days or weeks, the blood vessel heals itself and the clot gradually dissolves. In certain instances, though, the blood clot doesn't stick to the damaged vein wall, but breaks away (or fragments of it break away) and is carried to the lungs via the bloodstream, causing pulmonary embolism. (A thrombus that breaks loose and travels is called an embolus.)

The second of Virchow's risk factors is sluggish blood flow. The circulatory system needs some help to get the venous blood back up to the heart against the force of gravity. (In very tall people, the blood must rise as high as five feet.) To keep the blood flowing in one direction, most leg veins are equipped with valves that prevent blood from flowing backward (reflux). Breathing in and breathing out creates a partial vacuum that also helps send the blood upward. More assistance comes from another quarter—the muscles of the legs, especially calf muscles, pump blood towards the heart by squeezing the deep veins in the leg during exercise and activity.

When the body is inactive, blood may stagnate in the veins (medically this is called venous stasis). Thickening and slowing of the blood flow tend to make the blood clot more readily. This condition may occur when people are bedridden because of a heart attack or congestive heart failure, are immobilized in a cast, or are recuperating from burns or surgery, especially orthopedic or prostate surgery. Stroke victims run as high as a 75 percent risk of developing deep vein clots in a paralyzed leg.

Virchow's third risk factor is blood that becomes hypercoagulable (prone to clot excessively). Normally, circulating blood stays fluid through a kind of balancing act between clotting promoters and clotting inhibitors. If the clotting promoters increase, or if the activity of the clotting inhibitors decreases, the result may be blood that clots too readily.

People especially vulnerable to this hypercoagulable state are those who have cancer, blood diseases such as polycythemia vera (characterized by an increase in red blood cells), some inherited diseases, and chronic ulcerative colitis. Women who use oral contraceptives, especially those who smoke, are also more likely to develop this condition. A rise in hormone levels may cause blood to coagulate more readily in pregnant women, who are five times more likely to develop deep vein clots than nonpregnant women in the same age group. Women who have just given birth are at increased risk if they are obese or have varicose veins, or if they've had deep vein clots or pulmonary embolism in the past.

Finding a Clot

Obviously, there would be fewer deaths from pulmonary embolism if deep vein clots were treated with drugs before they

(continued on page 27)

People at High Risk for Pulmonary Embolism

1

People immobilized for long periods due to illness or accidents

2

Congestive heart failure patients

3

Those with tumors, especially certain cancers of the GI tract

4

Postsurgical patients

5

Pregnant women

6

Women over the age of 30 using oral contraceptives

7

Patients with intrinsic vein disease

8

Those with certain blood disorders

9

Chronic obstructive lung disease patients

10

The obese

An Ounce of Prevention

Keeping deep vein clots from forming is the best way to prevent pulmonary embolism, since most deaths due to the disease occur before treatment can begin. In individuals with predisposing factors (see accompanying article), low-dose heparin may be given under the skin before and during certain surgical procedures—usually elective abdominal, pelvic and chest surgery—and is continued until the patient is up and about. The same treatment may be used in individuals who are recuperating from a heart attack, major burns, or acute paralysis, and in some bedridden patients who have cancer and vein diseases or who are obese. Since anticoagulant drugs interfere with the clotting process throughout the body and may cause bleeding, patients must be carefully watched.

Intermittent pneumatic compression of the legs is also used on high-risk patients to prevent blood clots from forming. A plastic sleeve is fitted over each calf and inflated with air at regular intervals. Compression usually begins with surgery and continues until the patient can walk.

Patients at lesser risk are encouraged to get on their feet as soon as possible—ordinarily the day after surgery or childbirth. People who aren't allowed out of bed for a few days are usually told to move their feet and legs in bed as much as they safely can. Bending the knees and straightening the legs, contracting the muscles in the calf, pressing the balls of the feet against the footboard of the bed repeatedly, are some easy exercises that lower the risk of clot formation.

Healthy, active people don't usually have to worry about pulmonary embolism. Traveling, however, especially when sitting nearly immobile for long periods, has its dangers. For example, in a letter to *The Lancet* (Aug. 27, 1988), two doctors reported that over a three-year period at Heathrow Airport,

an estimated 18 percent of 61 sudden deaths in passengers traveling long distances were due to pulmonary emboli. They advise air travelers not to smoke, as smoking thickens the blood, and recommend drinking plenty of non-alcoholic liquids to counteract the dehydrating effects of low humidity in the air cabins. Frequent walks around the plane will keep blood from pooling in leg veins and feet from swelling.

Other exercises that can be done in place are moving the feet up and down, toe-wiggling, and extending the lower legs. Contracting the muscles in the stomach and buttocks encourages blood flow in the pelvic veins, while deep breathing increases the flow of blood to the upper part of the body. Though the risk of blood pooling is slight in the upper extremities, people whose hands swell should do reaching exercises, or open and close the fingers occasionally.

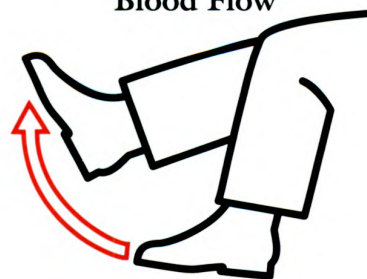
The same goes for long trips in other vehicles. Walking up and down the train, or stopping the car occasionally to stretch the legs, helps the circulation. Wearing restrictive clothing in general is not sensible, but it is especially important to forego tight girdles or panty hose on the road, as they may act as tourniquets to the upper legs. If the doctor has advised wearing elastic stockings in the past, they should be worn while traveling.

People in sedentary jobs need to ambulate as well as eat during lunch hour, while devoted TV fans should make a habit of moving about during commercials and other dull spots.

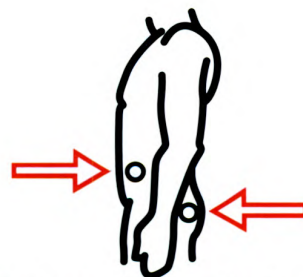
Since there's not much we can do about some of the ills that are visited upon us, it's wise to do all we can about the ones we can prevent. The body requires activity to keep itself in good condition, and that's not really asking much. ■

—E. Z.

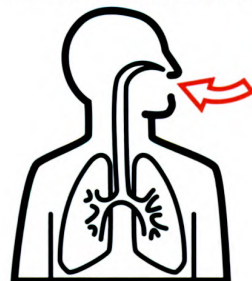
Simple Exercises to Encourage Venous Blood Flow



Extend your lower legs



Contract the muscles in your abdomen and buttocks



Breathe deeply



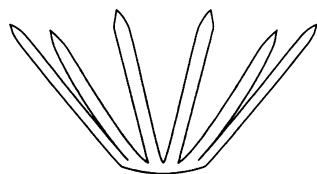
Stretch your arms



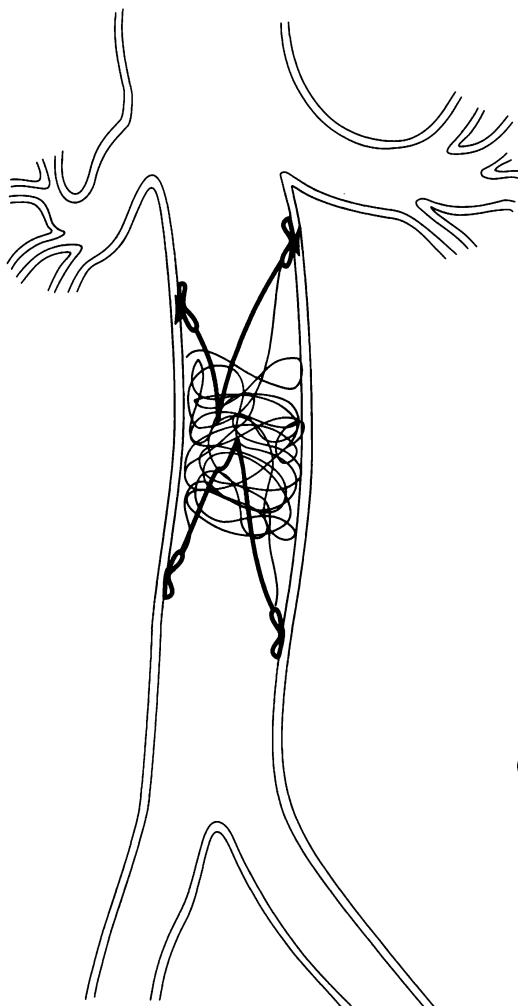
Close and open your hands

Physicians have another ace up their sleeves for those who can't be anticoagulated or who have had complications from previous anticoagulation.

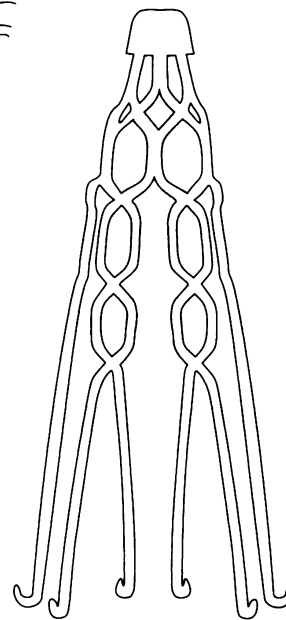
Three Different Blood Filters



Umbrella



Bird's Nest



Greenfield

(continued from page 24)

broke loose and traveled to the lungs. Unfortunately, they don't always make their presence known. About half the people with deep vein blood clots have no symptoms. When symptoms do occur where the clot was formed, they may include slight swelling of the leg or calf, tenderness, cramp-like pain, chills, fever, a bluish discoloration of the skin in the area, and prominent superficial veins.

When deep vein clots are suspected, the best diagnostic test is a venogram. After a radiopaque contrast material is injected into a vein in the foot, the leg area is X-rayed. Clots show up as dark spots in the veins. Other tests, not as conclusive as a venogram, are available for those who are allergic to the contrast material.

Since it's important not to dislodge deep vein clots—and to prevent new ones from forming—people whose tests are positive may be hospitalized for a few days in bed with feet elevated and treated with blood thinners (anticoagulants) and painkillers. Anti-embolism elastic stockings, which function as a form of pressure on the leg veins, may be worn to aid circulation.

If untreated, about 50 percent of deep vein clots will travel to the lungs, where they cause death in about 10 percent of the cases, according to A.G. Turpie, M.D., and Jack Hirsch, M.D., writing in the October 1984 *Hospital Medicine*. Small emboli in the lungs may cause no symptoms at all. A large embolus can cause death within seconds if it lodges in the fork of the pulmonary artery where it divides into branches to each lung. More commonly, however, embolism is accompanied by shortness of breath, sometimes with wheezing, abnormally rapid and shallow breathing, anxiety, and restlessness. Other symptoms that may appear include chest pain, coughing up blood, rapid heartbeat, dizziness, fainting, and occasionally fever.

Since its symptoms imitate the symptoms of so many other chest and lung diseases, pulmonary embolism is often difficult to diagnose. Just as syphilis was known as the "great masquerader" in the past because of its ability to mimic other diseases, so pulmonary embolism is the medical mimic of our times. Its symptoms can be confused with pneumonia, heart attack, inflammation of the membrane lining the wall of the abdominal and pelvic cavity (peritonitis), inflammation of the sac that contains the heart (pericarditis), asthma, acute bronchitis combined with emphysema, lung cancer, and even an anxiety attack. Thomas A. Neff, M.D., chief of pulmonary service, Denver General Hospital, comments: "It is always essential to think of pulmonary thromboembolism [pulmonary embolism] in any acute, obscure, and, especially, serious lung disease."

Jan M. Orenstein, M.D., professor of pathology, George Washington University School of Medicine, and the director of the autopsy service at George Washington University Hospital, says: "Pulmonary emboli are a relatively common finding at autopsy, usually unsuspected and frequently the cause of death. We often find emboli in the lungs of the elderly, the obese, heavy smokers, and those with diabetes, but the most common underlying condition is heart disease."

Orenstein's observation is borne out by the results of a large multi-institutional study published in 1987. In all cases of pulmonary embolus identified at autopsy that caused or significantly contributed to a person's death, 46.8 percent were not diagnosed before death. "The autopsy is the only sure means of determining the incidence of pulmonary emboli. This is true for many problems in medicine," says Orenstein.

Physicians have a number of tests to help diagnose pulmonary embolism. Some tests are used to rule out other diseases; for example, an electrocardiogram will often distinguish between a heart attack and a pulmonary embolism. Other tests are more specific. Lung scans—which can show lung areas that are not receiving enough blood because of blockage by a clot—and measurement of the amount of oxygen in arterial blood are the most reliable screening tests. Pulmonary arteriography, a more invasive procedure, is performed when the diagnosis is in doubt. A flexible catheter containing a contrast material is passed into the pulmonary artery while the technician takes X-ray pictures. Emboli and obstructed pulmonary arterial branches can be seen on the X-ray screen.

Treatment

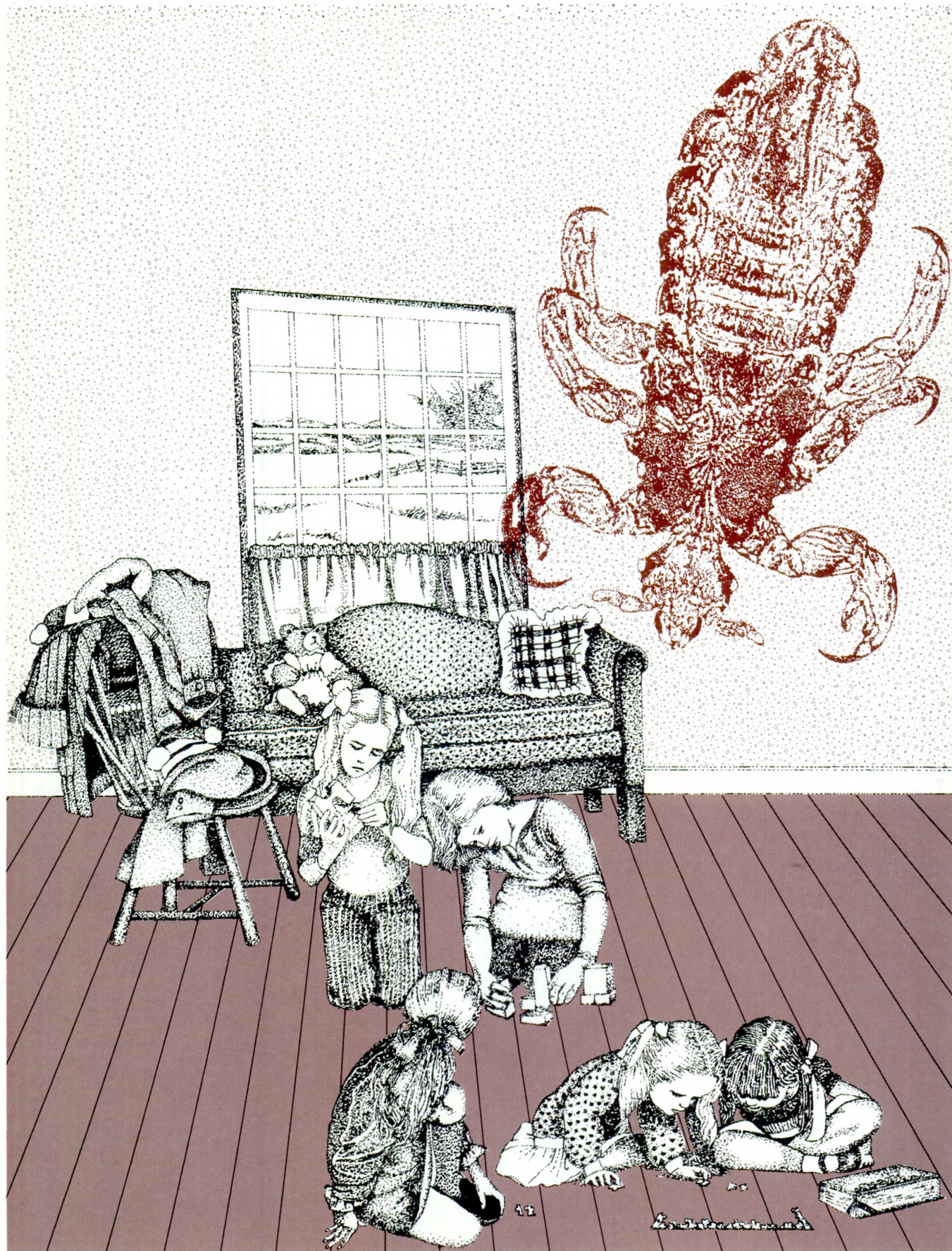
Even though most blood clots resolve spontaneously in several days or weeks, once a diagnosis of pulmonary embolism has been made, patients are given anticoagulant drugs, usually heparin, through the vein for 7 to 10 days to prevent new clots from forming. After leaving the hospital, anti-clotting treatment may be continued at home with warfarin, which can be taken by mouth, for three to six months. Both prolonged sitting and standing, which encourage the pooling of blood in leg veins, should be avoided during this period. Because warfarin can cause birth defects, women who must be on prolonged or continuous anticoagulant therapy are advised against becoming pregnant.

Patients who have a dangerously large pulmonary embolus or who are at risk for recurring emboli and are in unstable condition because of poor pulmonary circulation are often given newer drugs—streptokinase, urokinase, and a genetically engineered drug called tissue plasminogen activator, or tPA. Given through the vein, these drugs actually dissolve clots, sometimes in a matter of hours. (Streptokinase and urokinase have been approved by FDA for the treatment of pulmonary emboli; FDA has approved tPA for dissolving blood clots that obstruct coronary arteries and cause heart attacks, but it is sometimes also used to dissolve lung clots.) These drugs are not used as frequently as heparin, because they can cause severe bleeding complications.

Physicians have another ace up their sleeves for those who can't be anticoagulated or who have had complications from previous anticoagulation. A small device called a filter can be inserted into the inferior vena cava, the large vein that leads directly into the heart. This device permits the flow of blood but traps any emboli that travel up from the leg or pelvic veins. The trapped clots gradually self-destruct. One of those most frequently used is the Greenfield filter, a stainless steel wire device that resembles an umbrella without the cloth cover. In April 1989, FDA approved another clot-catching device, the bird's nest filter, a tangle of wires that looks exactly like its name. Because filters can be inserted through a catheter introduced into a vein using local anesthesia, they provide safe and effective protection against pulmonary emboli without surgery.

Tests can confirm the diagnosis of acute pulmonary embolism in a patient who doesn't have the typical symptoms of the disease, and, in many cases, the disease can be effectively treated. The trick, however, is to suspect and diagnose the condition in the first place. ■

Evelyn Zamula is a free-lance writer in Potomac, Md.



OF LICE AND CHILDREN

Going to the Head of the Class

by Theresa A. Young and
Judith Levine Willis

"Oh, honey, another note from the school nurse," you sigh. "What is it this time, a vaccine shot, toothache, ear infection? What on earth could be wrong with you now! . . . Will you please sit down, honey, and stop that scratching!"

You open the tightly sealed envelope and read:

Dear Parent/Guardian:

Upon inspecting your child's head today it was discovered that he/she has a lice infestation. It is necessary to exclude him/her from school until adequately treated.

YOUR CHILD MAY RETURN TO SCHOOL AFTER SHE/HE HAS BEEN TREATED.

Sincerely,

Principal & School Nurse

* * * * *

The head louse, technically known as *Pediculus capitis humanus*, is by no means a new nuisance. The insect has been an unwelcome companion to humans probably from the beginning, as have its close relatives, the body louse and the pubic or crab louse (see accompanying article). But head lice infestations seem to be on the rise in recent years as almost any parent of an elementary school-aged child can tell you.

A parent's first reaction to head lice is often revulsion, sometimes accompanied by a sense of shame due to the misperception that head lice only live on "dirty" people. In truth, the only thing that the presence of head lice tells about children is that they've been around other kids with head lice.

Head lice are parasites about the size of a small ant. They get their nourishment by sucking small amounts of blood from humans. Their favorite feeding area is the scalp behind the ears and at the nape of the neck. Their feeding and sucking activity is responsible for the itching that is so frequently the first hint of infestation.

Left untreated, rash and infection can occur. In severe cases, the lymph glands in the neck may swell. Although usually confined to the head, head lice sometimes also set up shop in beards, eyebrows and, rarely, eyelashes.

Though they don't fly, lice are quite adept at getting from head to head, especially when those heads are close together. Good hygiene is always an admirable goal, but a clean head of hair is no guarantee that they won't invade. Because children play so closely together, often in large groups, lice have an easy time traveling from child to child. Cases of lice seem to increase in the winter, possibly because kids are inside and close together, sometimes sharing hats, combs and, consequently, "cooties," as kids sometimes call them. The creepy critters can live up to two to three days apart from the body and, in closets where clothes hang close together, may hop from hat to scarf. They also may be lurking on the headrest of a school bus seat, just waiting to get aboard an attractive head. (The stitchings of those upholstered headrests can hide the tiny gray-white lice eggs called nits.)

How to Spot Lice

It's easier to spot the nits than the lice themselves. And, because nits are dandruff in appearance, they are easier to see on brunettes than on blonds. To distinguish them from dandruff or hair spray, pick up a strand of hair close to the scalp and pull your fingernail across the area where the whitish substance appears. Dandruff (or hairspray) will come off easily, but nits will stay firmly attached to the hair. If you look real hard, you may be able to see the bugs themselves on the back of the head and around the ears.

Once you have discovered head lice on one family member, all other members of the family, as well as close friends, should be checked. Also, look for lice or their nits in fabrics of stuffed toys, upholstered furniture, and bedding.

Routing the Louse

Both over-the-counter (OTC) and pre-

scription shampoos are available to get rid of head lice. OTC anti-lice shampoos, which are not to be confused with medicated shampoos to treat dandruff and similar problems, contain two pesticides: pyrethrums, derived from chrysanthemum plants, and the chemical piperonyl butoxide. These shampoos should be left on the hair 10 minutes. The hair should be towel-dried, and nits should be removed using a special comb or tweezers (included in some OTC product packages). Remember to give the hair a second application after 7 to 10 days even if you see no signs of lice. People who are allergic to ragweed should only take these products under a physician's direction. Pyrethrums can cause asthma, allergy symptoms, and even severe, potentially life-threatening allergic reactions in sensitive individuals.

There are two types of prescription products to help rout lice. One is a shampoo containing the chemical lindane. The other is a cream rinse that contains permethrin, a chemical form of the pyrethrums found in the OTC products.

Lindane shampoos must be applied to the hair for four minutes. The nits are then removed in the same way as for OTC products. A second application is usually not required. Though it's good at getting rid of the varmints, lindane in large doses can be toxic to the human central nervous system so that care—and the guidance of a physician—is especially important when treating babies. It should not be used for premature infants or by people who have had seizures. Pregnant women should seek the advice of their physicians before using lindane products on themselves and should wear rubber gloves if they must apply them to others' hair.

The cream rinse containing permethrin is applied after shampooing with a regular shampoo and towel-drying the hair. It should be left on the hair 10 minutes before rinsing off. Usually, only one application is necessary. Combing the nits out is not required, although some parents may prefer to do this anyway for aesthetic reasons. Like the OTC products, the cream rinse should not be used by anyone allergic

(continued on page 31)

Several over-the-counter shampoos are effective in killing lice and their nits. Instructions for their use should be carefully followed.



Anti-lice sprays should not be used on people, but are useful in making sure that household items are free of lice.



You Say You Itch Somewhere Else?

Body lice (*Pediculus humanus corporis*) and pubic lice (*Phthirus pubis*) are pesky parasites closely related to the head louse.

Fortunately, the body louse is relatively rare in this country. It thrives in unsanitary, overcrowded living conditions and historically has been common in military, refugee and concentration camps, prisons, and overcrowded city dwellings. It can carry organisms that cause diseases such as epidemic typhoid fever. This critter lives and deposits its eggs in clothes, bedding, and other personal articles and then hops aboard a human when it needs a feed.

The body louse has figured in a number of history's main events. The story goes that after Archbishop Thomas à Becket was assassinated at Canterbury Cathedral in 1170, the penitential hair shirt he never removed was found to be

swarming with lice. And the term “cootie” is said to have originated in the trenches of World War I as a nickname for the body louse that was all-too-familiar to so many of the soldiers.

Body lice usually go their own way when living conditions are improved. Thus, today they are a rarity in most



Artist's sketch of a crab louse, magnified about 32 times, grasping a human hair.

developed areas of the world.

Pubic lice are transmitted by close—usually sexual—contact. Also called crab lice, or simply “crabs,” pubic lice seen close up resemble a crab, with two grasping “arms” in front. They live on the human body where the hair is coarse—mostly in the pubic area and armpits. The infested area frequently becomes itchy and, as with head lice, a rash often results. Like head lice nits, the whitish eggs of the pubic louse are firmly attached to the hair shaft. The lice may look like small scabby crusts, or they may appear as small bluish spots on the skin. Sometimes infested people may notice louse excretions—minute brown specks—on their underwear.

Along with other sexually transmitted diseases (STDs), “crabs” seems to be enjoying a resurgence, especially among those in their teens and 20s. Therefore, people who find they have pubic lice would be wise to be examined for other STDs.

The same products that get rid of head lice will also do away with crab lice. ■

(continued from page 29)

to chrysanthemums or pyrethrums.

With either the OTC or the prescription products, directions for the specific shampoo or cream rinse you're using should be carefully followed. It's a good idea to place a clean towel across the forehead to keep the medication from dripping into the eyes. (If accidental contact with eyes occurs, flush with water. If irritation develops, discontinue use and consult your physician.) Be sure to apply a generous amount, sufficient to thoroughly cover all the hair. With the shampoos, wet the hair thoroughly, until a good lather forms.

In the rare case of lice infestation of eyebrows and lashes, a physician should be consulted. Shampoo should not be used around the eyes. Petrolatum products may help get the lice out of these areas, or the physician may have to remove them with forceps.

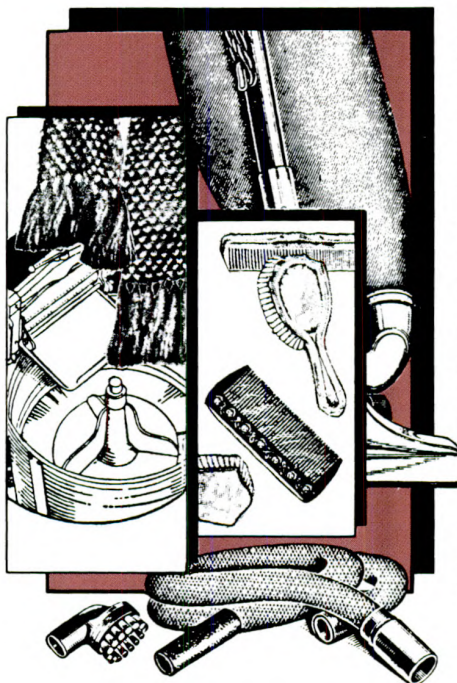
Beyond Shampooing

Now that you've gotten rid of them, you don't want the nasty nuisances to come back, do you? To prevent reinfestation, the following may be helpful:

- **Make sure all family members and friends of the infested person have been closely scrutinized for signs of lice. If any**

of them appear to have lice, make sure they are treated.

- Wash *all* clothing and bed linens used by the infested members of your family in *hot* water and place in a hot dryer for at least 20 minutes. If this cannot be done, place the linens and clothing into an airtight bag for two weeks. Dry cleaning also kills lice and nits.



- Vacuum backs of chairs, pillows in living and bedroom areas, mattresses, car seats and headrests, and rugs that might be in contact with infested hair. *Empty the vacuum bag* (if it is the paper disposable sort, discard the bag). There are some OTC sprays for disinfecting furniture and bedding. They contain insecticides that are *not* suitable for humans or animals, so be careful not to confuse them with the products that are for human use.
- Disinfect combs, brushes, sports helmets, and other objects that come in contact with the head by soaking in medicated shampoo or very hot soapy water.
- Recheck all family members and friends 7 to 14 days and 21 to 28 days after initial treatment to be sure lice have not reappeared (eggs that remain after treatment will hatch in 7 to 14 days).

Though discovering that your child has head lice is no picnic, neither is it cause for panic or shame. The problem is shared by a good portion of the American school population and can be controlled by vigilance and appropriate treatment. ■

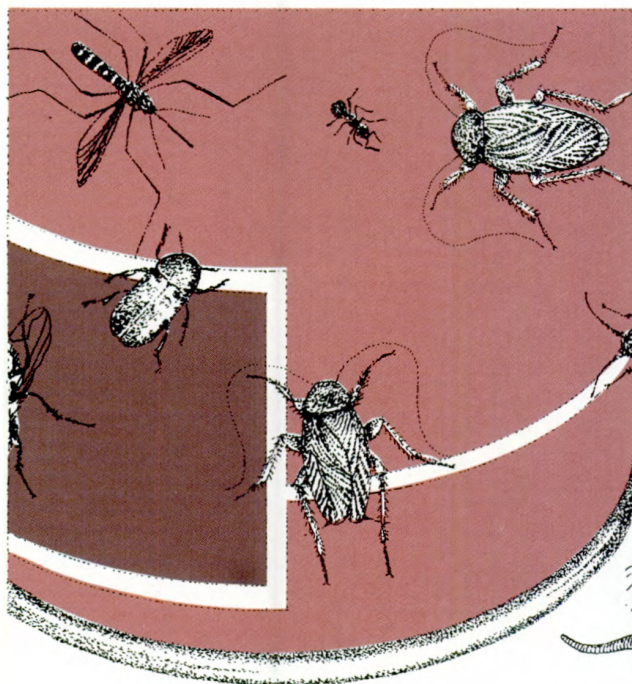
Theresa A. Young is an FDA consumer affairs officer with the Philadelphia district. Judith Levine Willis is editor of FDA Consumer.



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 public libraries.

■ A revised guide to FDA compliance policy, "**Reconditioning of Foods Adulterated Under Section 402(a)(4)**," is available for \$10.95 from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, Va. 22161. Order NTIS number PB-89-217806 (FR Aug. 7).



■ December 6 is the deadline for comments on possible changes on **labels** of FDA-regulated **food** products. Comments should be sent to the Dockets Management Branch (HFA-305), FDA, 5600 Fishers Lane, Rockville, Md. 20857. For more information, see "A New Look at Food Labeling," in this issue (FR Aug. 8).

■ FDA scientists have developed monoclonal antibodies and a new purification method that may help other scientists develop an improved acellular **pertussis vaccine**. Information and materials are available from the Dockets Management Branch (HFA-305), FDA, 5600 Fishers Lane, Rockville, Md. 20857 (FR Aug. 23).



■ Draft policy statements prepared by FDA's Center for Veterinary Medicine concerning exclusivity, withdrawal periods, substitution of active ingredients, and labeling for **generic animal drugs** are available from the Dockets Management Branch (HFA-305), FDA, 5600 Fishers Lane, Rockville, Md. 20857 (FR Aug. 28).

■ FDA has increased the amount of **mineral oil** that can be added to increase flexibility in the **manufacture of rubber articles**, such as conveyor belts, that are intended for repeated use in contact with food during its processing (FR Aug. 29).



Two Veterinarians Guilty In Antibiotic Case

by Marian Segal

Two California veterinarians pled guilty last April to illegally dispensing an animal prescription antibiotic.

Wesley A. Jacobs and Santokh Singh Takhar, owners of the Hilmar Animal Hospital in Hilmar, Calif., admitted to three counts of misbranding and selling chloramphenicol to dairy farmers in California. The antibiotic has never been approved in the United States for any use in food-producing animals.

Chloramphenicol is approved for treating bacterial infections in dogs. The drug is also approved for human use to treat some eye and ear infections. Use of the drug in humans, however, has been associated with the development of aplastic anemia, an often fatal condition in which the body is unable to produce certain blood cells. It is thought that the disease could develop in susceptible individuals exposed to residues of the drug in milk or meat from animals that have been treated with chloramphenicol. Disease development is not related to either the level or the duration of exposure to the drug residues in food.

Chloramphenicol was effectively banned for use in food animals in March 1984 when FDA sent a letter to approximately 42,000 veterinarians warning that "A comprehensive enforcement program by federal and state authorities will continue until diversion of chloramphenicol to food animal use ceases."

The letter was prompted by evidence of widespread misuse of the drug in food-producing animals and the well-established link of the drug's toxic effect in humans.

In July of that year, FDA's Chicago district office notified the agency's San Francisco district office that in March 50 kilograms of chloramphenicol powder had been shipped to Hilmar from Schuyler Laboratories in Rushville, Ill. On July 13, FDA investigator Robert Anderson visited Hilmar to interview Jacobs about the drug. Jacobs told Anderson that he had run out of chloramphenicol powder in May and had no more solution on hand. He claimed

he was no longer making or selling chloramphenicol products, and that the animal hospital was not dispensing the drug except occasionally in tablet form for the treatment of cats and dogs.

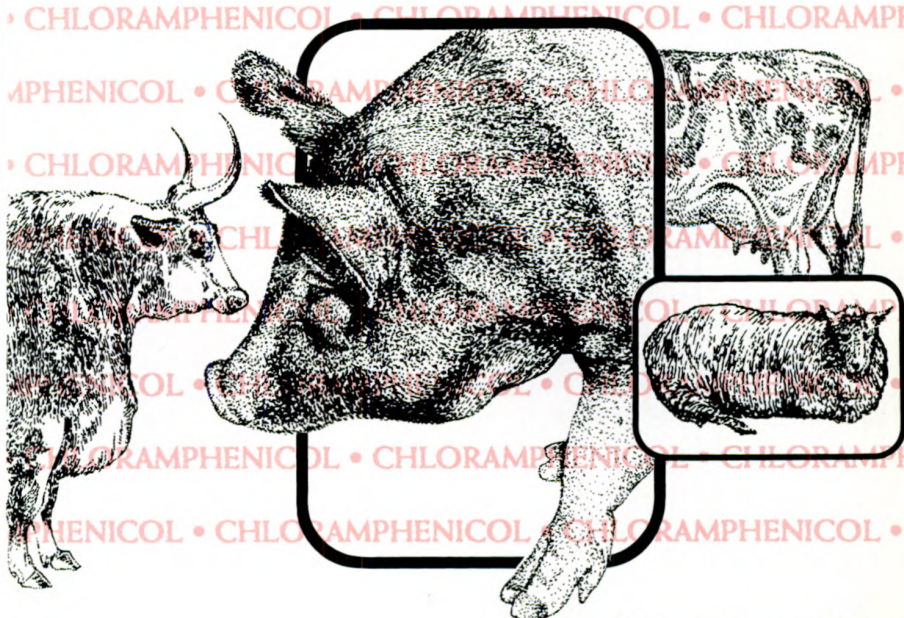
A month after Anderson's visit, a former Hilmar employee contacted FDA's Sacramento resident post to notify the agency that Jacobs' statements to Anderson were not true. She said that chloramphenicol solution, labeled as "sterile water," was on hand during Anderson's investigation, and chloramphenicol powder was stored at Jacobs' residence. The employee claimed she had continued making chloramphenicol solution for the clinic until she left the firm in early August, and that the solution was being sold under the name "Bemacol."

She also said that both veterinarians had read Crawford's March 1984 letter and were aware of the legal status of chloramphenicol. (This had not been the first notice to veterinarians warning against the use of chloramphenicol in food-producing animals. As early as January 1975, a letter went out from FDA to veterinarians stating that "chloramphenicol residues in animal tissue makes that food contaminated under the Food, Drug, and Cosmetic Act . . . and the interstate shipment of such a food

product a prohibited act." The letter went on to say that "Our [FDA's] General Counsel has interpreted this to include animals moving to slaughter . . . as food that is already in interstate commerce. Therefore, you or your client could be subjected to legal action in the event it is shown that you have contributed to the shipment of contaminated food in interstate commerce.")

On Sept. 12, 1984, Anderson and Henry Maher, another investigator from FDA's San Francisco district office, conducted a second inspection of Hilmar. This time, confronted with the information given by his former employee, Jacobs admitted that he had lied to Anderson on July 13. With Jacobs' permission, Anderson and Maher reviewed sales and farm visit records from July 1 to Sept. 12, 1984, and documented 33 sales of Bemacol—both over-the-counter at the clinic and directly to farmers at visits to their dairies. Jacobs admitted to recommending and selling Bemacol for use in dairy cattle and calves. He further admitted knowing it was illegal to manufacture chloramphenicol solution and that his firm sold the product without the FDA-required warning label: "Not for use in animals raised for food production."

Also during the inspection, Anderson discovered chloramphenicol solution on a



shelf marked "sterile water." He returned to Hilmar on Sept. 14 and Dec. 12, 1984, to witness the destruction of chloramphenicol collected from dairies.

FDA requested that the Department of Justice prosecute Jacobs and Takhar and, on June 26, 1986, a federal grand jury charged the two men with three counts of selling chloramphenicol for use in food animals, in violation of the Food, Drug, and Cosmetic Act. Jacobs was also charged with making false statements to the government.

The trial began in Fresno, Calif., on Feb. 10, 1987, with the defendants claiming that they were using chloramphenicol solely in their practice of veterinary medicine and that they did not receive proper legal notice stating that FDA was excluding the use of the drug from its extra-label use policy. (This policy states that regulatory action will not ordinarily be considered when a drug is used for other than the labeled use, provided carefully defined criteria are met. The policy also states, however, that certain drugs—including chloramphenicol—may not be used in food-producing animals under any conditions.)

At the beginning of the second trial day, Anderson, testifying for the government, was asked to identify a document marked GX 100. He identified it as a copy of his handwritten notes of his visit to Hilmar Animal Hospital on Sept. 12, 1984.

Asked to make sure all the pages were there, Anderson looked through the notes and said, "It looks like at least one page has been left out here. They are complete except for one page."

The presiding judge, Edward Dean Price, immediately then said, "Okay. They will not be used. I will entertain a motion to dismiss." The defense attorney moved to dismiss, and Judge Price ruled that "The motion is granted on the basis of misconduct of government counsel." The alleged "misconduct" was failure to make available to the defendant all written material on which the prosecuting attorneys rely.

Within two minutes after the dismissal, Anderson and the government's counsel discovered that the document was, in fact, complete. The attorney immediately informed the court clerk of the error and asked that the jury be reassembled since the jurors had not yet left the building.

Judge Price refused, instructing the government counsel to file a motion for reconsideration. The government did so later that day, but the motion was denied two weeks later.

But it wasn't "case closed" quite yet. The Department of Justice appealed the dismissal and the allegation of prosecutor misconduct and, on Aug. 31, 1988, obtained a reversal by the Court of Appeals for the Ninth Circuit in San Francisco. The appellate court found that the district judge had abused his discretion in dismissing the case and granted a new trial before a different judge.

On April 10, 1989, just one day before the new trial was to begin, Jacobs pled guilty to two counts of misbranding a drug after its shipment in interstate commerce and Takhar pled guilty to one count of misbranding, charges on which they had been indicted almost three years earlier. As this issue of *FDA Consumer* went to press, the veterinarians were awaiting sentencing.

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

Twilite Glow

It was strictly business that sent two of FDA's Los Angeles district investigators out on the town to one of that city's discotheques. And sure enough, they did not dance the night away.

Electrooptics specialist James A. Roseboro and consumer safety officer Robert Nicol visited the Twilite Club after the agency's Center for Devices and Radiological Health received a complaint that the audience at the club was being exposed to laser beams. (Under the Radiation Control for Health and Safety Act, FDA is responsible for ensuring that people are not exposed to hazardous levels of radiation from lasers and other radiation-emitting products such as microwave ovens and X-ray machines.)

In June 1988, FDA had granted the owners of the club, RNB Corporation, a variance allowing them to operate a laser light show. The terms of the variance included detailed safety requirements to ensure the public would not be exposed to laser radiation greater than Class I. (FDA standards divide laser products into four broad classes based on the intensity of the

radiation light in the laser beam and its potential for injuring people.)

Laser radiation from Class I products is not known to injure health. Radiation from Class II products can cause eye damage. Class III laser products can cause burns from direct exposure to the beam or its direct reflection off a shiny surface, such as a mirrored wall or ball. Class III is divided into Class IIIa and IIIb. Lasers in Class IIIa pose a hazard to the eyes even with an exposure time of less than a quarter of a second. Radiation from Class IV lasers can cause severe burns from

direct or reflected exposure, even when the beam is scattered or diffused.)

The FDA standard limits laser products for display or entertainment purposes—such as those used in discos or rock concerts—to Class IIIa. Manufacturers of Class IIIa projectors are required to include with their products instructions for their safe assembly, operation and maintenance. The instructions must contain clear warnings concerning precautions that will ensure the public is not exposed to laser radiation greater than Class I. FDA may grant a "variance"



allowing the use of even more powerful lasers—including Class IV products—if it can be ensured that the public will not be exposed to hazardous levels of laser light.

The safety requirements were spelled out in the variance approval letter FDA sent to RNB Corporation's president, Brian Y. Park. In that same letter, FDA requested that Park confirm that certain safety checks would be done before each laser show. Park did not respond to the request, nor did he respond to follow-up letters FDA sent on Sept. 7 and Oct. 27, 1988, and Jan. 10, 1989—the last by certified mail requesting return receipt.

So when the Center for Devices and Radiological Health was told that patrons of the Twilight Club were being irradiated by reflections of high-power laser beams through rotating mirror balls, Roseboro and Nicol were dispatched to investigate. They arrived at the club Saturday evening, Feb. 18, 1989, around 8 p.m. and observed the light show for several minutes before presenting their credentials to Park, along with a Notice of Inspection.

Roseboro then inspected the laser projection system and interviewed Park and the club's disc jockey, who operated the system. The system featured a Class IV laser for projection effects and a Class II laser used for beam alignment. Roseboro found several deficiencies in the operation and configuration of the system that violated the variance and might expose patrons and employees of the club to laser radiation exceeding Class I.

Roseboro gave Park a written list of his observations and discussed them with him. They included the following:

- The projector housing had been removed, allowing possible access to laser radiation greater than Class I.
- Laser beams were projected out into publicly accessible areas, allowing exposure to laser radiation greater than Class I.
- The power supply was located in a place that could not be accessed without the operator being in almost direct contact with laser radiation above Class I.

Park immediately stopped the laser projection system and promised, through a written affidavit, not to restart it until all the deficiencies were corrected. The citation report was sent by facsimile to FDA headquarters, and on Feb. 24, 1989, Roseboro delivered to Park notification that his variance was withdrawn.

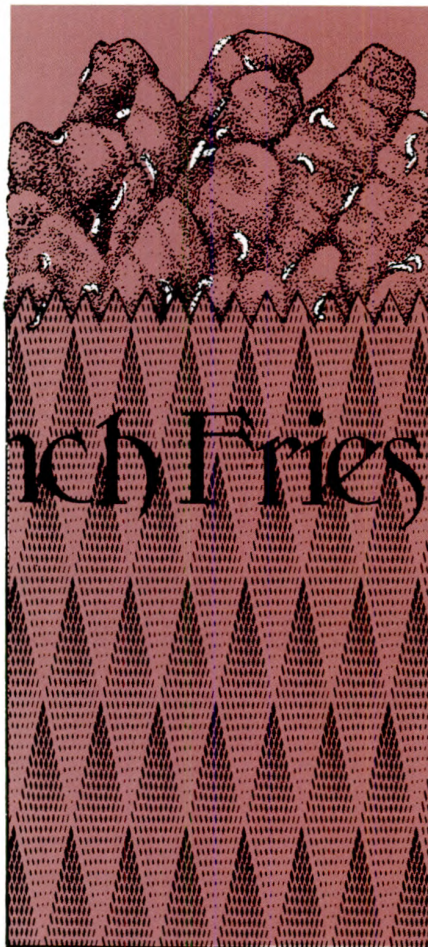
No injuries from exposure to the club's laser display were reported.

Potatoes and Maggots

Bags of french fries mixed with maggots led to a court injunction ordering a Spokane, Wash., food company to stop operating until it cleaned up its plant.

Last April, when FDA's Seattle district office investigator Robert Williams inspected Produce Supply Company, which prepares and distributes potato products and salad mixes to restaurants in Idaho and Washington state, he found:

- live flies and maggots in decomposing potato residue lining the processing equipment for hash brown potatoes,
- maggots along the wall behind the potato cutters,
- live flies and maggots next to the french fry cutters,
- maggots under the base of the conveyor belt that transports french fries to the



packaging station,

- live flies and maggots in the spinning basket used to process salad ingredients.

At FDA's request, on June 20, 1989, the U.S. District Court for the Eastern District of Washington entered a consent decree of permanent injunction against Produce Supply Company's president, John R. Cooper, and his father, Harry R. Cooper, the firm's recently deceased chairman of the board. The injunction required John Cooper, whose responsibilities include sanitation and pest control, to stop production until he could ensure the plant's cleanliness.

(Usually, when preparing a consent decree, reconditioning of adulterated products is listed as an option. However, in requesting the injunction against Produce Supply Company, FDA stressed that "with the conditions reported in this firm, reconditioning should not be considered under any circumstances.")

According to John Foret, FDA assistant to the director, division of regulatory guidance, "the maggot-ridden food processed at Produce Supply Company was filthy and could not possibly be made fit for human consumption."

The April investigation of the firm was the third since January 1988. After the first two inspections, both conducted a year ago last January, FDA notified the Coopers in writing of their sanitation violations and requested from them a list of measures they were taking to clean up the plant.

FDA's repeated requests urging voluntary compliance were unsuccessful until, according to Christopher Rezendes, FDA Seattle district supervisory investigator, "we got their attention" with the injunction in June.

One month later, the company had installed new ceilings and walls, replaced all its food processing equipment with new stainless steel machines, hired a pest control agent, and developed a sanitation program calling for cleaning the plant daily. FDA followed the firm's progress with a comprehensive inspection on July 21.

It took what Rezendes calls "one of the quickest injunctive actions ever processed by FDA," but Produce Supply Company completely turned around its sanitation standards and is back in business.

— This small sample of reports from the field was prepared by Dale Blumenthal, Marian Segal, and Gordon Scott.



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/Contamination, Spoilage, Insanitary Handling

PRODUCT: Cumin seeds, coriander powder, moth (brown) beans, split toordall, and chili powder, at Brooklyn, E. Dist. N.Y.; Civil No. 88-2545.

CHARGED 8-15-88: While held by Maya Overseas Food, Inc., Brooklyn, N.Y., the articles had been held under insanitary conditions—402(a)(4).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65497; S. No. 87-423-272 et al.; S.J. No. 1)

PRODUCT: Flour, at Atlanta, N. Dist. Ga.; Civil No. C84-646A. **CHARGED** 3-29-84: When shipped from Alton, Ill., the article contained rodent filth and had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Pursuant to a consent order, Maplehurst Deli-bake South, Inc., Bakery Distributors, Atlanta, Ga., the possessor of the article was granted an extension of time to file a claim and an extension to file an answer. The possessor's claim asserted its belief that certain undetermined portions of the article were unadulterated. Subsequently, the claimant filed an answer denying the charges. Meanwhile, the claimant's counsel advised that the shelf life of the article was due to expire shortly. Ultimately, pursuant to a consent decree of condemnation, the article was destroyed. (F.D.C. No. 64249; S. No. 84-376-251; S. J. No. 2)

PRODUCT: Flour, at Pine Bluff, E. Dist. Ark.; Civil No. PB-C-88-570.

CHARGED 10-5-88: While held by River Delta Dist. Co., Pine Bluff, Ark., the article contained bird filth and had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 65534; S. No. 88-519-797; S.J. No. 3)

PRODUCT: Rice, at Seattle, W. Dist. Wash.; Civil No. C 88-1073.

CHARGED 8-18-88: While held for sale by Beacon Market, Seattle, Wash., the article contained insect filth and had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65520; S. No. 88-501-287; S.J. No. 4)

PRODUCT: Sesame seed, at College Park, N. Dist. Ga.; Civil No. 1:88-CV-2042-ODE.

CHARGED 9-14-88: When shipped by Robertson-Johnson Warehouses, Inc., Orlando, Fla., the article, labeled "Sesame Seed TICA . . . Texas Intl. Commodities Assoc. Inc. Brownsville, Texas . . . Product of Columbia," contained insect filth and had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 65531; S. No. 88-565-180; S.J. No. 5)

PRODUCTS: Sugar, and other food stocks, at San Lorenzo, Dist. Puerto Rico; Civil No. 87-0843(JAF).

CHARGED 7-2-87: While held by Juan A. Selles, Inc., San Lorenzo, Puerto Rico, the articles had been held under insanitary conditions—402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 65213; S. No. 87-512-803 et al.; S.J. No. 6)

PRODUCT: Tempura batter mix, rice, dulse powder, and other food stocks, at Fort Lauderdale, S. Dist. Fla.; Civil No. 85-6209.

CHARGED 3-13-85: While held by Vitality Distributors, Inc., Fort Lauderdale, Fla., all of the articles had been held under insanitary conditions, and the named articles contained insect filth—402(a)(3), 402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 64531; S. No. 85-333-706 et al.; S.J. No. 7)

Foods/Economic and Labeling Violations

PRODUCT: Horseradish preparation, Tulkoff's White, at Indian Trail, W. Dist. N.C.; Civil No. C-C-85-65-P.

CHARGED 2-1-85: When shipped by Tulkoff's Horseradish

Products Co., Inc., Baltimore, Md., the article had had potatoes substituted in part for horseradish—402(b)(2).

DISPOSITION: Default—authorized donation to a charitable institution. (F.D.C. No. 64496; S. No. 85-482-810; S.J. No. 8)

PRODUCT: Horseradish preparations, five seizure actions, at Gahanna, S. Dist. Ohio, Shreveport and Monroe, W. Dist. La., El Paso, W. Dist. Texas, and Peabody, Dist. Mass.; Civil Nos. C 2-85-22, CV 85-319-S, CV 85-0318-M, EP-85-CA-19, & 85-0350-C.

CHARGED 1-18-85, 2-4-85, 2-4-85, 1-18-85, & 1-12-85: When shipped by Tulkoff's Horseradish Products Co., Inc., Baltimore, Md., the articles had had potatoes substituted in part for horseradish—402(b)(2).

DISPOSITION: Defaults—ordered destroyed. (F.D.C. Nos. 64478, 64480, 64487, 64490, 64492; S. Nos. 85-357-701, 85-383-277, 85-383-277, 85-466-464, 85-388-964; S.J. No. 9)

PRODUCT: Mozzarella and scamorza cheeses, at Easton, E. Dist. Pa.; Civil No. 86-3494.

CHARGED 6-13-86: While held by Crivellaro & Sons, Easton, Pa., the articles had been prepared under insanitary conditions—402(a)(4); and the articles failed to conform to the definition and standards of identity for scamorza and mozzarella cheeses because the articles had not been prepared from pasteurized milk—403(g)(1).

DISPOSITION: The articles were claimed by the dealer, who denied the charges, except for the allegations that scamorza and mozzarella standards required that such cheeses be prepared from pasteurized milk and that the articles had not been so prepared. Subsequently, a consent decree authorized release of the articles to the claimant for the sole purpose of destroying the articles. The consent decree also required that FDA be notified about the claimant's receipt or assembly of pasteurizing equipment for cheese production, and enjoined the defendant from manufacturing or distributing in interstate commerce any cheese prepared from unpasteurized milk when regulations required such cheese to be prepared from pasteurized milk. (F.D.C. No. 64907; S. No. 86-445-368 et al.; S.J. No. 10)

Drugs/Human Use

PRODUCT: Analgesic preparations, adhesive bandages, swabs, toothpaste, and other drug, device and cosmetic stocks, at Augusta, Dist. Maine; Civil No. 87-0120-B.

CHARGED 4-24-87: While held for sale after the dealer's warehouse had been flooded by the Kennebec River, the drugs and devices had been held under insanitary conditions—501(a)(2)(A); the drugs had been held under circumstances that failed to conform with current good manufacturing practice—501(a)(2)(B); and the cosmetics had been held under insanitary conditions—601(c).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 65186; S. No. 87-417-524 et al.; S.J. No. 11)

PRODUCT: Gland concentrate & lysine tablets for herpes, black currant oil capsules, evening primrose oil combination capsules, and comfrey & herbs combination tablets for hair care, at Chicago, N. Dist. Ill.; Civil No. 88 C 8851.

CHARGED 10-18-88: When the capsules (labeled "Royal Oak . . . Oil of Black Currant . . . Capsules . . . Superon Natural Vitamins, Chicago, Ill." and "Capsules . . . Unsaturated Fatty Acids Vitamin E with Oil of Evening Primrose . . . Linolenic Acid . . . encapsulations incorporated, Newark, New Jersey") were shipped by Encapsulations, Inc., Newark, N.J., and while the comfrey & herbs combination tablets were held for sale, those articles contained non-conforming food additives (e.g., comfrey leaves)—402(a)(2)(C); the gland concentrate tablets were intended for the treatment of herpes and were a new drug without an effective approved New Drug Application; and the labeling of the gland concentrate tablets was false and misleading in representing the article for herpes when there was no scientific evidence to establish the safety and efficacy of the drug for herpes—502(a).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65459; S. Nos. 88-503-358 & 88-503-360 et al.; S.J. No. 12)

PRODUCTS: Gly-otic HC hydrocortisone otic solutions, Glycort HP triamcinolone acetonide dermatological gel, and Episel selenium sulfide lotion, at San Antonio, W. Dist. Texas; Civil No. SA 88 CA 0890.

CHARGED 8-26-88: While held by Heran Pharmaceuticals, Inc., San Antonio, Texas, who was manufacturing the articles, the articles were new drugs without effective approved New Drug Applications—505(a); and the labels of the articles lacked adequate directions for use, and the articles were not exempt due to their new drug status—502(f)(1).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65297; S. No. 86-363-487 et al.; S.J. No. 13)

PRODUCT: Pentylenetetrazol elixir, at Mayflower, E. Dist. Ark.; Civil No. LR-C-82-629.

CHARGED 8-30-82: When shipped by National Pharmaceutical Mfg. Co., Baltimore, Md., or others, the article, labeled "Gevrex Elixir . . . contains Pentylenetetrazol . . . Distributed by Artex Laboratories, Inc., Little Rock, Ark. . . Mfg. by National Pharmaceutical Mfg. Co., Baltimore, Md.," was a new drug without an effective approved New Drug Application—505(a).

DISPOSITION: An answer to the complaint was filed by Artex Laboratories, Inc., Little Rock, Ark., in which the firm stated that it was the owner of the article, and that it expected that a New Drug Application would be approved for the article. The firm also prayed that the article "be held pending this application." The government

filed a motion for judgment on the pleadings because the firm failed to contest the charge, and it was therefore deemed admitted. The government also noted that there was no record of a New Drug Application for the article, that no application was near approval, and that all other such pentylenetetrazol products had been removed from the marketplace, either through voluntary action or through judicial proceedings. Meanwhile, the action was scheduled for trial. Subsequently, the court granted the government's motion for judgment on the pleading, condemned the article, and awarded costs to the government against the firm. However, the court was inclined to await the decision on a pending New Drug Application for the article, if there was such an application pending. The court ordered the firm to submit a letter to the court describing in detail the status of its application. Subsequently, the article was destroyed. (F.D.C. No. 63794; S. No. 82-341-488; S.J. No. 14)

PRODUCT: Transdermal appetite reduction kits (consisting of a bottle of a liquid, adhesive bandages, and a labeling insert), at Fort Lauderdale, S. Dist. Fla.; Civil No. 88-6865.

CHARGED 11-9-88: While held by Patch Technology, Inc., Fort Lauderdale, Fla., who was marketing the kits, which contained interstate adhesive bandages, the kits were new drugs without an effective approved New Drug Application—505(a); and the kits lacked adequate directions for use for the kits' intended purpose—502(f)(1).

DISPOSITION: Default—ordered forfeit and disposed according to law, including delivery of 50 representative samples to the Department of Health and Human Services for demonstration, training and enforcement purposes. (F.D.C. No. 65535; S. No. 88-334-160; S.J. No. 15)

Drugs/Veterinary

PRODUCT: Ampicillin in bulk, other bulk drugs, and various dosage-form drugs, at Ossian, N. Dist. Iowa; Civil No. C 87-2042.

CHARGED 6-3-87: While held by Ossian Veterinary Clinic, Ossian, Iowa (who was preparing dosage-form drugs from interstate bulk drugs), bulk ampicillin, bulk amoxicillin, and dosage-form articles manufactured from those bulk drugs were new animal drugs and no approval of a New Animal Drug Application was in effect for the use and intended use of such articles—501(a)(5); and the labeling of all of the articles lacked adequate directions for use—502(f)(1).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65166; S. No. 87-495-654; S.J. No. 16)

PRODUCTS: Medicated feeds, at Okeechobee, S. Dist. Fla.; Civil No. 88-14153.

CHARGED 8-31-88: While held by Hector Feed Mills, Okeechobee, Fla., who had manufactured the articles using interstate com-

ponents, the strength of the articles (which were labeled "Agro-Mix H. F. Broiler Starter [or "High Fat Broiler Finisher"] LCR Medicated . . . Active Drug Ingredient Lincomycin . . . Monensin . . . Roxarsone . . . Manufactured For: Agro Tech International [or "Manufactured by Hector Feed Mills A Subsidiary of Agro Tech International, Inc.]" . . . Miami, Fla.) differed from their represented strengths—501(c); the circumstances used for the articles' manufacturing and processing failed to conform with current good manufacturing practice regulations—501(a)(2)(B); the labeling of the articles was false and misleading because the drug concentrations differed from those declared on the labels—502(a); and the labeling for the articles lacked adequate directions for use, because the labels lacked a caution statement regarding ingestion by species other than poultry—502(f)(1).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65494; S. No. 88-515-590 et al.; S.J. No. 17)

PRODUCT: Medicated premixes, and medicated feed supplement for cattle, at Waterloo, N. Dist. Iowa; Civil No. C 87-2041.

CHARGED 6-3-87: While held by Zander Feed, Inc., Waterloo, Iowa, the articles (which had been labeled "Rucco Pro-Tex Vitamin & Mineral Premix [or "A D E 15 Mineral & Vitamin Premix" or "A D E 15 Vitamin & Mineral Supplement"] for Cattle Medicated . . . Ethylenediamine Dihydroiodide . . . Rucco Feeds, Inc . . . Cedar Falls, Iowa," and which had been manufactured using interstate ethylenediamine dihydroiodide) were new drugs without effective approved New Drug Applications—501(a)(5); and the labeling of the articles lacked adequate directions for use—502(f)(1).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65183; S. No. 87-525-841 et al.; S. J. No. 18)

PRODUCT: Potassium penicillin preparation for veterinary use, at Benson, E. Dist. N.C.; Civil No. 88-461-CIV-S.

CHARGED 6-1-88: When shipped by PBC Enterprises, Northvale, N.J., the article was a new drug without an effective approved New Drug Application—505(a); and the circumstances under which the article had been manufactured, processed, packed or held did fail to conform with current good manufacturing practice regulations—501(a)(2)(B).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65460; S. No. 88-537-518 et al.; S. J. No. 19)

PRODUCT: Pro-Tec veterinary powder, at Bel Air, Dist. Md.; Civil No. H-88-3324.

CHARGED 11-4-88: When shipped by Pro-Tec Pet Health, Pleasant Hill, Calif., the article, which was labeled "Protec Body Guard Food Supplement . . . Pro-Tec Pet Health Division of Protein Technology . . . Pleasant Hill, CA," and was accompanied by a brochure reading "Pro-Tec . . . Nutrition Plus . . . For Skin, Coat & Flea Problems," was a new animal drug and no approved New

Animal Drug Application was in effect—501(a)(5); and the article's labeling was false and misleading because of claims for skin allergies, for improving physical condition (i.e., animal's skin, coat, body odor, appearance, alertness, vigor, energy, response, and endurance), and for the formation of collagen—502(a).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65546; S. No. 88-549-671; S.J. No. 20)

Medical Devices

PRODUCT: **Colonic irrigator kits, and components**, at Crestwood, N. Dist. Ill.; Civil No. 88 C 4129.

CHARGED 5-11-88: The articles, which were assembled and labeled by the Wood Hygienic Institute, Crestwood, Ill., and which were accompanied by labeling reading (kit insert) "One Complete Unit Includes The Following: . . . total cost is \$200.00," and (instruction booklet) "Basic Instructions . . . Read and Understand . . . Before Giving or Getting a Colonic . . . self application home use," were manufactured in an unregistered establishment and no notice of intent to market the device had been provided—502(o); the labeling of the articles lacked adequate directions for lay use because such directions could not be written for the articles' intended purpose—502(f)(1); the labeling lacked adequate warnings against dangerous and unsafe use—502(f)(2); and the articles were dangerous to health when used as directed—502(j).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65429; S. No. 88-505-441; S.J. No. 21)

Cosmetics

PRODUCT: **Canthaxanthin tablets**, at Blaine, W. Dist. Wash.; Civil No. C87-1282M.

CHARGED 9-16-87: While held for sale after manufacture by Doshire, Inc., Chicago, Ill., the article, which was labeled "Tan Without Sun—original French formula . . . Miami Tan . . . Distributed by . . . Laboratoire Organique Inc. Calgary, Alberta, Canada," contained the nonconforming color additive canthaxanthin—601(e).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65258; S. No. 87-420-749; S.J. No. 22)

CRIMINAL ACTIONS

DEFENDANTS: **International Nut Corp., Gregory Hintlian**, president, and **Aram H. Hintlian**, treasurer, Lowell/Billerica, Dist. Mass.; Criminal No. 88-165.

CHARGED 6-7-88: When shipped to Hayward, Calif., Worthington, Ohio, Jessup, Md., Roanoke, Va., Westport, Conn., Chesapeake, Va., Portland, Maine, and Norfolk, Va., cashew nuts labeled "Nutcracker Salted Cashew Halves (counts 1 & 3) [or "Whole Cashews" (counts 2 & 4)] . . . International Nut Corp.,

Lowell, Massachusetts," and "Nutcracker Salted Fancy Whole Cashews (counts 5, 6, 7 & 8) . . . International Nut Corp., Billerica, Massachusetts," contained insect filth and/or mold—402(a)(3).

DISPOSITION: Guilty pleas by corporation to all counts and by individuals to count 8. Corporation fined \$1,000 on each of counts 1-3 and \$5,000 on each of counts 4-8 for a total fine of \$28,000. Each individual fined \$5,000. (F.D.C. No. 64767; S. No. 84-377-872 et al.; S.J. No. 23)

INJUNCTION ACTIONS

DEFENDANTS: **Joe H. Butler and Linda Butler, t/a Tarheel Kennel Supplies**, Colfax, M. Dist. N.C.; Civil No. C-84-627-G.

CHARGED 7-6-84 in a complaint for injunction: That the defendants were retail mail-order distributors of nonprescription and prescription veterinary drugs but were not registered for the retail sale of veterinary prescription drugs; that the defendants sold veterinary prescription drugs (such as mebendazole powder, tetracycline hydrochloride capsules, and diethylcarbamazine tablets) to lay persons without veterinarians' orders; that, because the defendants were not lawfully engaged in the sale of prescription drugs, such drugs were not exempt from the requirement of adequate directions for use and such drugs lacked adequate directions for use—502(f)(1); that, in addition, the defendants were labeling and selling levamisole hydrochloride for the treatment of whipworms, roundworms, hookworms, and heartworms in dogs (uses not generally recognized by scientific experts as safe and effective); that such drug was a new animal drug and no approved New Animal Drug Application was in effect for such unapproved uses—501(a)(5); that the defendants were aware that their actions were in violation of the law; and that they had a long history of disregard for the law.

DISPOSITION: A consent decree permanently enjoined the defendants from the complained-of violations; and the defendants were enjoined from dealing in any interstate veterinary drug unless and until a number of specified conditions were met, including the establishment of files documenting veterinarian prescriptions for sales of prescription veterinary drugs, and the registration of the defendants under state law to engage in veterinary drug operations. (Inj. No. 1074; S. No. 82-195-598 et al.; S.J. No. 24)

DEFENDANTS: **Thomas E. DeWitt, t/a Wholesale Kennel Supply Co.**, Siler City, M. Dist. N.C.; Civil No. C-84-335-D.

CHARGED 4-20-84 in a complaint for injunction: That the defendant was a retail over-the-counter and mail-order distributor of nonprescription and prescription veterinary drugs, but was not registered as required by state law; that the defendant was labeling and selling the veterinary drug levamisole hydrochloride for the treatment of heartworm in dogs (a use not generally recognized by scientific experts as safe and effective) and such drug was a new

animal drug and no approved New Animal Drug Application was in effect for such unapproved use—501(a)(5); that the defendant was repacking and labeling levamisole hydrochloride and the defendant's labeling lacked the name and place of the manufacturer, packer or distributor and lacked an accurate quantity of contents statement—502(b); that the defendant was selling, not only the levamisole hydrochloride, but was selling diethylcarbamazine citrate to lay persons without veterinarians' orders; and, because the defendant was not lawfully engaged in the sale of prescription drugs, such drugs were not exempt from the requirement of adequate directions for use and such drugs lacked adequate directions for use—502(f)(1); and that the defendant was aware that his actions were in violation of the law and had been warned that his activities should cease.

DISPOSITION: Consent decree of permanent injunction enjoined the defendant from the complained-of violations, and enjoined him from dealing in any interstate veterinary drug unless and until a number of specified conditions had been met, including the establishment of files relating to every sale of a prescription veterinary drug, the registration of the defendant under state law to engage in veterinary drug operations, and the statement in the defendant's mail-order catalog of each advertised product's active chemical ingredient, each product's prescription or over-the-counter status, and the species of animal that the product was intended to treat. (Inj. No. 1035; S. No. 82-195-598 et al.; S.J. No. 25)

DEFENDANTS: **Harris H. Jorgensen (t/a Jorgensen Midwest, Base Mix Center, Jorgensen Feed, Jorgensen Livestock, and Midwest Seed Service), and Bernie L. Nicklaus Jr., manager, Shell Rock and Dike, N. Dist. Iowa; Civil No. 87-3136.**

CHARGED 10-18-87 in a complaint for injunction: That Harris H. Jorgensen manufactured and distributed animal feeds and raised and sold livestock (primarily hogs) at Dike and Shell Rock, Iowa; that Bernie L. Nicklaus Jr., the manager of some of Harris H. Jorgensen's operations, performed his duties at Shell Rock, Iowa; that, at the defendants' facilities, they received and processed feed components, including seeds (such as corn and soybeans) that had been treated with pesticides such as captan and carboxin; that such pesticide-treated seeds were used to manufacture animal feeds which were subsequently fed to food-producing animals; that some of such seeds and some of such animal feed components had been shipped in interstate commerce and some of the food-producing animals were ultimately slaughtered and distributed in interstate commerce; that the defendants' captan-contaminated and carboxin-contaminated animal feed contained the nonconforming food additives captan and carboxin—402(a)(2)(C); that FDA inspection established that a large volume of apparently pesticide-treated seed corn and soybeans was on hand, that treated corn arrived during the inspection, and that treated seeds were being roasted, ground, and incorporated into animal feeds; that FDA analysis documented that

captan was present in seed corn, roasted seed-corn feed component, and in finished feed at levels significantly exceeding those permitted by law; and that FDA analyses established that carboxin was present in roasted soybean feed component and in finished feed, although no carboxin was permitted in animal feed components or finished feed.

DISPOSITION: A consent decree of permanent injunction enjoined any act with respect to any interstate animal feed which resulted in adulteration with captan, carboxin, or other pesticide. The defendants were also enjoined from offering for sale any animal, including hogs, whether or not directly for slaughter as food, unless and until a number of specified conditions were met, and were enjoined from manufacturing, processing, using, or distributing any animal feeds unless and until any of their feeds or feed components that might be adulterated were reconditioned, destroyed, or diverted to non-food use under FDA supervision. (Inj. No. 1184; S. No. 87-497-866 et al.; S.J. No. 26)

DEFENDANTS: **Kontron, Inc. (a division of Hoffmann-La Roche's subsidiary Kontron International S.P.A., and Abraham Massouda, president, Everett, Dist. Mass.; Civil No. 87-2371-C.** **CHARGED** 9-26-87 in a complaint for injunction: That, at their plant in Everett, Mass., the defendants produced, packed, labeled, stored, and distributed in interstate commerce intra-aortic balloon ("IAB") catheters to assist the human heart under stress conditions (e.g., cardiogenic shock, impending infarction, and high-risk cardiac surgery); that such IAB catheters are "critical devices" under 21 CFR 820.3(f); that FDA inspections revealed serious violations of good manufacturing practice regulations—501(h); that the defendants had failed to furnish reports regarding device malfunctions and possible involvement in serious injuries or deaths; that two of the defendants' five models of IAB catheters had been shipped in interstate commerce without first furnishing required FDA pre-market notices; that, despite a number of FDA inspections and warnings, the defendants had continued to manufacture and distribute such catheters.

DISPOSITION: A consent decree enjoined the defendants from the complained-of violations and enjoined the production and distribution of devices unless and until specified conditions had been met, including the following: the establishment of specified methods, facilities and controls; the compliance with specified reporting requirements; the certification of an expert as to current good manufacturing practice; and the examination of all devices on hand and the destruction or bringing into compliance of any violative devices.

Subsequently, a modification of the consent decree of permanent injunction permitted the defendants to resume operations concerning finished IAB catheters made from bladders manufactured after the date of the modified decree upon a number of specified conditions. (Inj. No. 1166; S. No. 86-418-723 et al.; S.J. No. 27)

Play It Safe

If there's the slightest chance that a child or teenager has a viral illness such as chicken pox or the flu do not give aspirin. Use of aspirin with these illnesses in persons younger than 20 has been associated with the onset of Reye syndrome, a rare but sometimes fatal condition.



WARNING: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome, a rare but serious illness reported to be associated with aspirin.

