

FDA CONSUMER

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

• VOL. 24 NO. 2

March 1990 •

*Perspective
On Food
Biotechnology*



A black and white photograph showing a microwave crisper sleeve, which is a rectangular box with a grid pattern on its side, resting on a white plate. The sleeve is partially open, revealing a waffle inside. The sleeve is placed on a dark, textured surface, possibly a tablecloth. In the background, there are some glassware and a cup, suggesting a dining setting.

MICROWAVE
Crisping Sleeve
3.

For Microwave Use Only

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Human Services

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Acting Commissioner of Food and Drugs

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Inside Front Cover Photo:

This waffle scorched after only a few seconds' overcooking in its crisping package, which contains microwave heat susceptors. To find out why FDA is concerned about microwave problems beyond burnt food, see page 17.

FDA CONSUMER

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

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Applying biotechnology to foods is almost as old as agriculture itself. But genetic engineering has put a new spin on attempts to use biology to create or modify products.

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FDA regulations did not anticipate innovations in food packaging spawned by microwave oven technology. Now the agency is gathering information about possible migration of packaging materials into food.

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When kidneys fail to work properly, the loss of internal pollution control can be life-threatening. Today the latest in drugs, devices, and transplants are used to restore or replace the function of these essential organs.

When Teens Take Over the Shopping Cart 30

In 70 percent of homes where both parents work, or where there is only one parent, teenagers do most of the shopping. How do teens cope with this task, and what effect is it having on family nutrition?

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This issue of *FDA Consumer* is dedicated to the memory of FDA officials John F. Harty and Patrick J. Pouzar, who died in the line of duty in a plane crash in Chile last January.



'89 Orphan Grants Totaled \$2.4 Million

Efforts to develop improved therapies for rare diseases got a boost from FDA during fiscal year 1989 with the agency's awarding of \$2.4 million in research grants.

The grants were given to 20 U.S. researchers studying therapies for 15 rare diseases, including autism, graft-versus-host disease, and neuroblastoma. The therapies, called "orphan products," include drugs, biologics, medical devices, and foods marketed for medical purposes that show promise in treating rare diseases, but are not considered sufficiently profitable for manufacturers to invest in their commercial development.

Barbara Helen Herman, Ph.D., of the Children's Hospital National Medical Center, Washington, D.C., received funds to evaluate the use of the drug naltrexone in treating autistic children. Naltrexone, under the trade name Trexan, is now approved for treating heroin addiction.

Currently, there are no approved drug treatments for autism, a severe developmental disorder characterized by abnormal social relations and bizarre mannerisms, such as oddities of motor movement and speech patterns.

Georgia B. Vogelsang, M.D., of Johns Hopkins University School of Medicine, Baltimore, will study thalidomide for treating chronic graft-versus-host disease. This disease often occurs after bone marrow transplants and leads to rejection of the transplanted marrow.

James C. Sisson, M.D., of the University of Michigan in Ann Arbor, will study the use of iodine I 125 meta-iodobenzylguanidine (MIBG) in the treatment of neuroblastoma, a cancer that strikes children. For patients with advanced disease, standard chemotherapy is often unsuccessful.

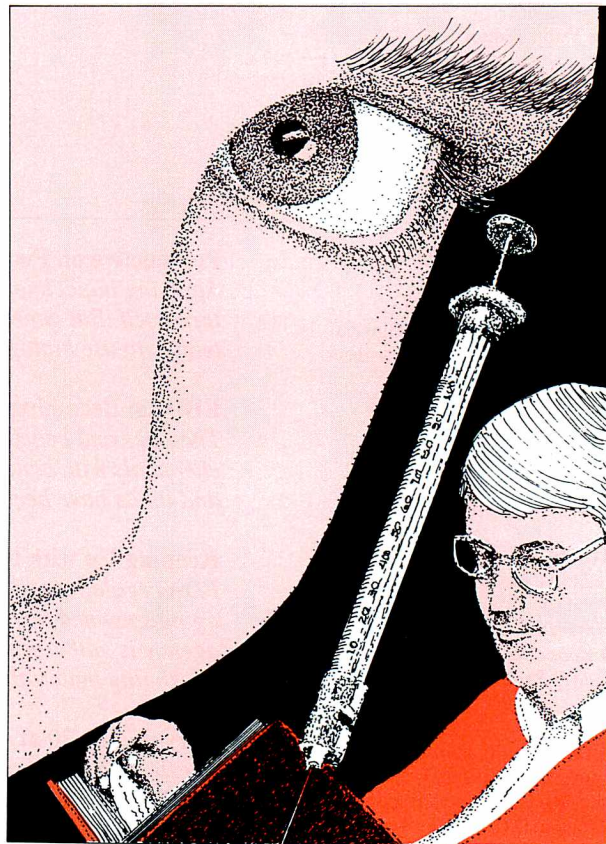
A complete list of 1989 grantees is available from FDA's Consumer Affairs Office (HFE-88), 5600 Fishers Lane, Room 16-85, Rockville, Md. 20857-1706; telephone (301) 443-5006.

Drug from Botulism Toxin

Oculinum, an injectable form of sterile, purified botulism toxin type A, has been approved to treat two eye muscle disorders—strabismus, which may appear as crosseye or walleye, and blepharospasm, in which the eyes close involuntarily.

The product is produced from *Clostridium botulinum*. Eaten in improperly handled foods, such as home-canned vegetables, the toxin can cause botulism, an illness that can lead to paralysis and death.

In clinical studies, however, the injected form was used safely in thousands of men and women to weaken muscles that pulled an eye in or out or to reduce spasms



in muscles that pulled the eyelid closed.

In the treatment, Oculinum is injected into the muscles near the eye, but not into the eye itself. Anesthetic eye drops may be used to numb the area during injection.

The injection usually takes effect in a day or two—"turning off" the injected muscle—and may help for about three months. The treatment may be repeated. The most common side effects are drooping eyelids or eye irritation.

About 60,000 to 80,000 operations are performed each year to correct crossed eyes. Blepharospasm affects only 3,000 to 5,000 Americans, but it may make simple tasks—such as reading or walking across a room—difficult to nearly impossible.

The treatment was developed by Alan B. Scott, M.D., an ophthalmologist at the Smith-Kettlewell Eye Research Foundation in San Francisco. The product is manufactured by Oculinum Inc. of Berkeley, Calif., and will be marketed by Allergan Pharmaceuticals, a division of Allergan, Inc., of Irvine, Calif.

FDA encouraged the product's development by giv-

ing it "orphan" drug status in 1984. The National Eye Institute, part of the National Institutes of Health, supported Scott's research.

First in New Class Of GI Drugs Approved

FDA has approved the first "acid pump inhibitor," one of a new class of drugs for limited use in patients who have certain serious gastrointestinal diseases.

Taken once a day as a delayed-release capsule, the new drug, Losec (omeprazole, MSD), was approved last September for short-term treatment of confirmed severe erosive esophagitis and of symptomatic gastroesophageal reflux disease (GERD) in patients responding poorly to conventional care. In GERD, stomach acid backs up into the esophagus to cause ulcers, erosions or scarring. Symptoms include chronic heartburn, acid backup into the mouth, painful or difficult swallowing, or coughing. The drug is not for use for heartburn without erosive or poorly responsive GERD.

The drug also is approved for long-term therapy when patients have unusually high acid secretion—as occurs with Zollinger-Ellison syndrome, an extremely rare ulcer condition with severe, often disabling pain and diarrhea.

Two-year rat studies with Losec showed a dose-related increase in stomach tumors called carcinoids. Examination of stomach tissue from humans on short-term treatment did not reveal cancer risk, but the labeling warns that further human data are needed to rule out the possibility of an increased risk from long-term therapy. This potential risk limits other uses of the drug at this time.

Unlike current ulcer treatments, Losec inhibits the stomach's "acid pump," which is the final step in the production of acid into the stomach. Losec was developed by AB Astra of Sweden and is being marketed in the United States by Merck Sharp & Dohme.

Some Imported Glassware Hazardous

Several patterns of imported glass tableware sold last spring at Macy's, Nordstrom's, and several other department stores in California, New York, and the Northeast may contain dangerously high levels of lead that can leach into food. The patterns are "Crackle Rim," "Murrina Clear," "Cracked Gold," and "Murrina Transparent Silver" collections of dinner plates, soup plates, bowls, stemware, vases, and ashtrays. Some of these patterns may also be sold as the "Orofolio" collection.

Consumers who purchased any of this glassware should immediately stop using it and return it to the store where purchased. Eating off these products or even handling them could cause acute abdominal pain, vomit-

ing, and diarrhea in adults and children, or central nervous system damage in fetuses and small children.

Lead leached from samples reached levels higher than 16,000 parts per million (ppm). (Currently, safe levels for ceramic products range from 2.5 to 7 ppm. An FDA proposal now is calling for lowering the allowable limit to 0.1 ppm for some items.)

FDA discovered the problem during a routine inspection of a shipment that arrived at the San Francisco port. Other shipments were sent to the New York port. The glassware was manufactured by SI-AN di Cioni & Busoni of Florence, Italy, and sold to various U.S. companies. R.H. Macy Company and other retailers have taken the glassware off their shelves and posted warnings of the danger to alert customers who had purchased the products.

Leukemia Drug Under Treatment IND

Patients who are seriously ill with chronic lymphocytic leukemia and can't be helped by standard therapies now have access to a new experimental orphan drug, fludarabine phosphate. The drug is given intravenously on an outpatient basis.

FDA recently granted "treatment IND" (investigational new drug) status to fludarabine phosphate for wider use before complete safety and effectiveness information is available.

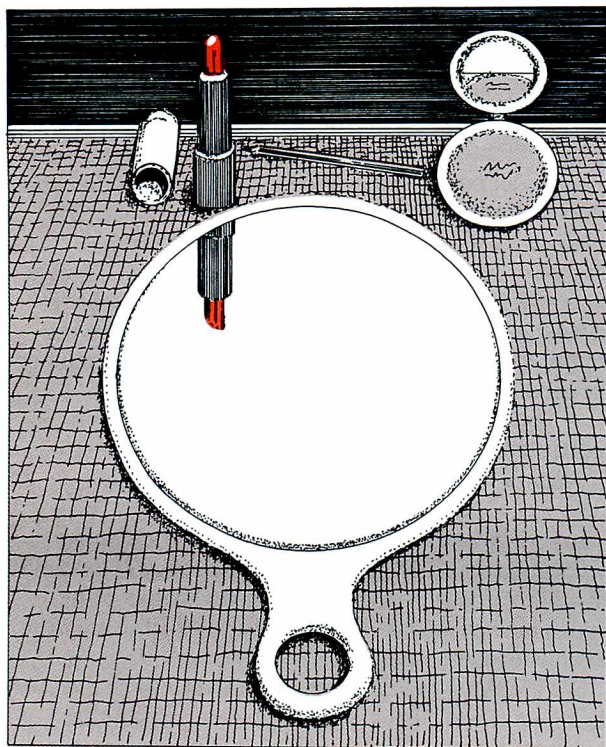
Chronic lymphocytic leukemia is the most common adult leukemia in the United States, occurring mainly in the elderly. Progressive and sometimes fatal, the disease causes abnormal white blood cells to build up in the lymph system and associated organs—including the bone marrow, blood, liver, spleen, and lymph nodes.

In clinical studies, fludarabine phosphate seems to inhibit the cancer cell growth. Current treatments—chemotherapy with drugs such as chlorambucil and cyclophosphamide, alone or with prednisone—help many patients but are not cures, and the disease often worsens.

Fludarabine phosphate is made by Triton Biosciences Inc. of Alameda, Calif. The National Cancer Institute will distribute the medication through qualifying physicians without cost under its Group C designation program. For more information, patients can call 1-800-4-CANCER, and physicians can call the institute's Cancer Therapy Evaluation Program at (301) 496-5725.

Organisms in Cosmetics

When trying out different shades of lipsticks, blushers, or eye shadows in the cosmetic department, you may be giving yourself more than a bright new look. FDA investigators have analyzed 2,461 shared-use cosmetic testers displayed at store beauty counters. Five



percent contained high amounts of bacteria, yeasts or molds.

Risk of infection often increases with the microbial count, and a high level of contamination suggests that a product may not contain the preservatives necessary to prevent organism growth. So, in this preliminary study, FDA scientists identified cosmetics that contained microorganisms at densities of 10,000 or more colony-forming units per gram. At least 43 of the products analyzed "appear to be inadequately preserved," FDA concluded.

In addition, some of the cosmetics contained organisms that can be hazardous in small amounts. For instance, *Pseudomonas aeruginosa*, which appeared in one sample of mascara, can cause blindness if the delicate cornea of the eye is scratched with a contaminated mascara applicator. *Staphylococcus epidermidis*, found in 27 products, may cause conjunctivitis or blepharitis (an inflammation of the eyelids).

Seven of the 60 different organisms found in the cosmetics may cause infections in healthy persons. Twelve are opportunistic organisms that may be especially dangerous for chronically ill persons or for those with broken skin or cuts. One or more of these 19 disease-causing organisms were found in 96 samples.

FDA plans to follow up on the cosmetic products that showed contamination to see if the same products purchased sealed also are contaminated.

Acidophilus Capsules Recalled

Vitamin Specialties brand acidophilus capsules with lot number 069296 on the package have been recalled. Some of the bottles in this lot contain capsules of stannous fluoride mixed in with the acidophilus capsules. (The stannous fluoride capsules are slightly smaller than the acidophilus.)

Ingestion of high levels of stannous fluoride can cause convulsions and sickness. Five of the capsules in the recalled lots, containing approximately 784 milligrams each of stannous fluoride, could be fatal for an adult; 1 milligram could be lethal to a small child. (Toothpaste with stannous fluoride is safe because it contains only low levels of the compound.)

Last fall, after two consumers complained of vomiting and flu-like symptoms after using the acidophilus-labeled products, FDA initiated an investigation and discovered stannous fluoride capsules in the bottles.

FDA suggested that purchasers return the capsules to their place of purchase or destroy them. Manufactured by Vita-Pure, the capsules were packed and distributed by Vitamin Specialties Co. of Wyncote, Penn., to 22 retail stores in New York, New Jersey, and Pennsylvania. The firm said that 140 mail-order customers also were notified of the recall.

Pesticide Report

More than 96 percent of the fruits, vegetables, grains, dairy and other products analyzed by FDA in 1988 either contained no residues of pesticides or the levels found were well below legally permitted limits, according to the agency's latest annual pesticide monitoring report.

The report is based on FDA's analysis of 18,114 domestic and imported food samples, a 25 percent increase over the number tested in 1987. Samples included foods from all the states and Puerto Rico, along with products from 89 foreign countries.

The report describes FDA findings for all samples analyzed during the fiscal year ending Sept. 30, 1988, and discusses FDA's various pesticide monitoring activities.

FDA testing methods permit the agency to detect any one of 256 pesticides. Of that number, 118 actually were found last year—about the same as in 1987. In general, residues present at 0.01 parts per million or above can be measured. For some pesticides, levels in the parts per billion range can be measured.

To obtain copies of the report, *Residues in Food—1988*, contact Norma J. Yess, FDA, Division of Contaminants Chemistry, HFF-420, 200 C Street, S.W.,

Washington, D.C. 20204; telephone (202) 245-1152.

Two Nutrients Added to RDAs

The National Research Council's newly released Recommended Dietary Allowances (RDAs) adds RDAs for two nutrients—vitamin K (essential for maintaining normal blood clotting) and selenium (an essential trace element associated with development of the heart condition Keshan disease in young children and women of child-bearing age in China).

Other changes since the last edition, published in 1980, include an increased RDA for calcium for people between 19 and 25 (1,200 milligrams a day, up from 800) and a lowered RDA for iron for women of child-bearing age and adolescent males (15 mg/day, down from 18 mg).

Sodium requirements, expressed in the 1980 version as "estimated safe and adequate daily intake," are now listed as "minimum requirement for healthy persons." The 1989 minimum sodium requirement for adults 18 and older is 500 mg/day.

In some cases, new studies have helped define approximate amounts of nutrients needed and have provided the basis for some of the council's revised RDAs. As in the past, the RDAs are given for various age groups. The council emphasized that most people can meet the requirements by eating a varied, well-balanced diet.

FDA is reviewing these guidelines along with other information to evaluate whether to revise the U.S. Recommended Daily Allowances. (FDA developed the U.S. RDAs in 1973 to simplify the RDAs for use in labeling the nutrient content of foods.)

Nutrition Booklets Available

Americans who make small changes in what they eat can make a big difference in their overall health, according to information in a new public education effort by the U.S. Department of Agriculture's Human Nutrition Information Service.

The agency has produced four new booklets containing advice on how to shop for foods, fix quick meals, eat out, and enjoy snacks for a healthier diet. The booklets also contain information on planning menus, preparing foods, and making bag lunches and desserts.

Based on the *Dietary Guidelines for Americans*, developed by USDA and the Department of Health and Human Services, the booklets encourage people to eat a variety of foods that provide enough essential nutrients and calories to maintain a desirable weight, eat an adequate amount of starch and fiber, and avoid too much

fat, sugar, sodium, and alcohol. (See "Dietary Guidelines for Americans: No-Nonsense Advice for Healthy Eating" in the November 1985 *FDA Consumer*.)

USDA's Susan Welsh, Ph.D., says that most Americans would be surprised to find how big an effect little changes in eating can make. For example, many women can bring their fat intake within recommended levels simply by cutting their daily amount of salad dressing by one to two tablespoons.

The booklets are available from the Consumer Information Center, Department 70, Pueblo, Colo. 81009. To order, specify the item number(s) on your envelope and send a check or money order payable to the Superintendent of Documents.

- *Preparing Foods and Planning Menus Using the Dietary Guidelines*. Item No. 172-V. \$2.50.
- *Making Bag Lunches, Snacks and Desserts Using the Dietary Guidelines*. Item No. 173-V. \$2.50.
- *Shopping for Food and Making Meals in Minutes Using the Dietary Guidelines*. Item No. 174-V. \$3.
- *Eating Better When Eating Out Using the Dietary Guidelines*. Item No. 175-V. \$1.50.

Drug Approved for Psychiatric Disorder

FDA has approved the prescription drug clomipramine for the treatment of severe obsessive-compulsive disorder.

People with this disorder have recurrent ideas, thoughts, images, or impulses that they know are irrational but cannot control. They also engage in repetitive actions such as excessive hand-washing, which they also recognize as irrational.

Psychotherapy, behavior therapy, and various drugs have been used to treat obsessive-compulsive disorder without much success. Clomipramine is the first substantially effective drug treatment.

The drug's most serious side effect is seizure, which may occur in about 1.5 percent of treated patients each year. Other possible side effects include dry mouth, constipation, increased appetite, decreased sex drive, ejaculation failure, and impotence.

The drug is manufactured by Ciba-Geigy Pharmaceuticals of Summit, N.J., and will be marketed under the trade name Anafranil.

More Sentences in Animal Drug Scam

Jeffrey A. Engel, president and general manager of Custom Feed Blenders, Fort Dodge, Iowa, was sentenced Aug. 25, 1989, by a federal district judge in Nebraska to six months in prison and fined \$10,000 for illegally importing and selling unapproved animal drugs

(see "Snaring Smugglers of Animal Drugs" in the June 1989 *FDA Consumer*). Engel also must perform 1,500 hours of community service.

Five other defendants had pleaded guilty to a variety of felony and misdemeanor charges growing out of their participation in the scheme. Rex J. Blunk of Callender, Iowa, and Jon L. Engel, of Omaha, Neb., were fined \$5,000 each in federal District Court in Nebraska. Jon Engel, a brother of Jeffrey Engel, was ordered to perform 500 hours of community service.

In the U.S. District Court for the Northern District of Iowa at Sioux City, Howard Koedam, Larchwood, Iowa, was fined \$10,000 and sentenced to 60 days in jail, and Charles Leniger, Spencer, Iowa, was fined \$15,000 and sentenced to 60 days.

Another defendant in the case, Ardean Veldkamp of Edgerton, Minn., was fined \$25,000 in the U.S. District Court for the State of South Dakota.

Other defendants still await sentencing.

More than 30 tons of animal drugs, with a wholesale value of more than \$600,000, were seized in connection with the case after FDA investigated a growing number of complaints by legitimate veterinary drug sources about the availability of illegal bulk drugs throughout the United States. Investigators discovered the drugs originated in Europe and China and were smuggled into the United States by way of Canada.

Two businesses dealing in the smuggled veterinary medicines—International Manufacturing and Sales of

Omaha, and Zetapharm Corp., New York—were charged with misbranding and adulteration of animal drugs. International Manufacturing was fined \$40,000.

Americans Favor Government Regulation

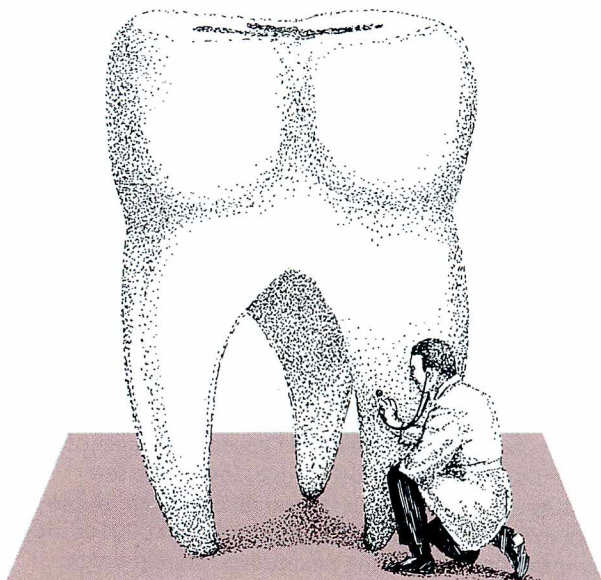
Americans are calling for more government regulations and stricter enforcement of the ones already on the books, according to a recent survey by the Roper Organization.

The environment tops the public's list of areas that need increased regulation. The government does not do enough to protect the quality of air and water, according to 75 percent of the people surveyed. Other areas requiring greater government control include airline safety (71 percent), chemical use and storage (67 percent, up 2 points from 1984), work environment (54 percent, up 6 points), and nuclear energy (53 percent, up 3 points).

Of particular interest to FDA, 48 percent of those surveyed think that the federal government should have a greater say in the ingredients that can be used in foods. This is up 8 points compared to a similar survey five years ago.

As for the effect of current regulations, 64 percent—an 8 point increase over 1984—say enforcement isn't strict enough. The Roper Organization says, "These findings strongly suggest that Americans will be increasingly receptive to greater government interventionism and activism in the years to come."

Consumer Forum



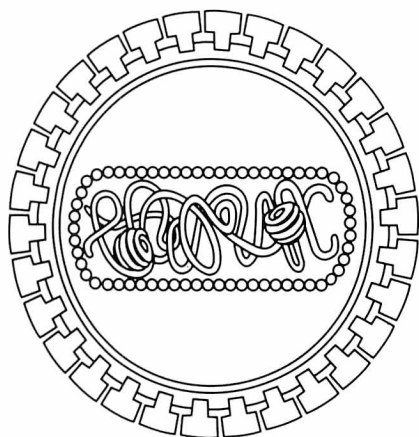
Sealing Teeth

The article "Sealing Out Decay" in the November issue [of *FDA Consumer*] raises the question of why so few sealants are being performed. . . .

Sealants are excellent *when indicated*. But like many other procedures it is possible to overuse and abuse a good thing. In my practice I've found that approximately 20% of my young patients will benefit from sealants. I agree with Dr. Ripa that all teeth do not require sealing.

It is not too much to expect dentists to use proper clinical judgement rather than the "better safe than sorry" attitude mentioned in your article or, even worse, economic motivation in choosing a treatment. Although the sealing of 4 to 8 teeth at from \$7 to \$26 may not seem to be an appreciable amount of money to Mr. Cohen, to many patients this would mean a true sacrifice, especially if the work was not necessary.

John E. Dodes, D.D.S.
Director, New York Chapter
National Council Against Health Fraud



“Compound Q”

FDA has completed investigating an unauthorized study involving people with AIDS treated with trichosanthin, a plant derivative commonly called “Compound Q.”

FDA began looking into this matter in June 1989 after the media reported that a large-scale unauthorized study of the drug was being conducted in California, New York, and Florida. Project Inform, a San Francisco-based AIDS activist group, was conducting this study of a trichosanthin-based preparation imported from China without FDA sanction or approval.

Trichosanthin is a plant protein that is being studied as a therapeutic agent against the AIDS virus. An FDA-sanctioned clinical study of GLQ-223, a refined form of trichosanthin, was started at San Francisco General Hospital in May 1989. This initial human study was designed to determine what dose levels of the drug can be tolerated by patients with AIDS, and has continued independent of the unauthorized trial.

After an initial assessment of the effects of the drug in the Project Inform study, FDA determined that the unsupervised use of trichosanthin was inherently dangerous, and consequently issued an import alert against the importation of trichosanthin.

The import alert, issued July 14, 1989, instructed FDA field offices to detain all incoming shipments of trichosanthin except those needed for the authorized San Francisco General Hospital study.

On Aug. 7, FDA’s Center for Drug Evaluation and Research wrote Project Inform to formally outline many serious concerns FDA had about the study’s safety and scientific reliability. The letter notified Project Inform that FDA determined that the trials were being conducted contrary to existing laws and regulations and should immediately be discontinued. The letter further stated that the agency was willing to meet with Project Inform to discuss how properly designed and conducted, FDA-sanctioned, community-based clinical trials of trichosanthin could be developed.

Project Inform responded by assuring FDA that administration of trichosanthin to patients in the unauthorized study had ended and that their researchers were interested in obtaining investigational new drug status from FDA to conduct future community-based studies of the drug. Accordingly, a meeting was held on Oct. 6 between FDA officials and representatives from Project Inform and other interested parties, including Genelabs Inc. of Redwood City, Calif., the sponsor of the San Francisco General Hospital study. At the meeting’s conclusion, Project Inform agreed to work with FDA in developing any future clinical studies of trichosanthin in order to ensure that the studies are scientifically sound and conducted in a manner designed to maximize patient safety.

In the meantime, FDA will continue to work closely with Genelabs Inc. and with other sponsors interested in pursuing clinical studies of trichosanthin through the agency’s investigational new drug process.

Screening Test Possible For AZT Resistance

The identification of mutations in the AIDS virus may lead to a screening test to determine which patients are resistant to treatment with the antiviral drug zidovudine, commonly called AZT.

In a study published in *Science*, researchers said they discovered common genetic changes in the AZT-resistant strains of the human immunodeficiency virus (HIV), which causes AIDS.

AZT is the only drug approved by FDA to fight HIV. While the drug is not a cure for AIDS, it prolongs life in many patients. A study done earlier this year, however, showed that in some patients the drug became less effective after six months of treatment. Another study found that after 15 to 18 months of AZT treatment, long-term survival declined substantially.

The researchers say that a screening test based on the genetic mutations in resistant strains could be developed, allowing AZT-resistant patients to switch more promptly to alternative treatments.

Perspective on Food

by Henry I. Miller, M.D., and Stephen J. Ackerman

The "new biotechnology" is in the news so much these days that it now goes by the handy nickname "biotech." In medicine, it has assumed heroic proportions, with *Science* magazine hailing it as the last great technical innovation of the 20th century—the progenitor of genetic probes, synthetic hormones, and other life-saving marvels.

In food production, however, it has not been so warmly welcomed:

- The European Economic Community has banned use of a genetically engineered hormone to increase milk production in dairy cows.

- American grocery chains have refused milk from such cattle.
- Activists fearing agricultural experimentation have sued to prevent field testing even of genetically engineered petunias.

What's going on with our food supply?

The short answer is "the new biotechnology," a scientific revolution less than 20 years old that's already changing the foods we eat.

The jargon of the "new biotech" may sound pretty ominous to the average con-

sumer. "Cloning," "genetic manipulation," "cell fusion," and "mutation" may seem more like fantasies out of "Star Trek" than the results of processes we want to contemplate at the supermarket. Nonetheless, these scientific processes are soon likely to be applied to more and more of our foods.

It's important to understand what food biotechnology is before forming our opinions about it. Although the jargon may sound unnatural, the science is the reverse. In fact, it can be viewed as a method of organizing nature to bring out



od Biotechnology

the best in nature. It's essentially a refinement of what we've known—and done—for a very long time.

"Biotech" Old and New

Biotechnology is the use of biological systems—living things—to create or modify products.

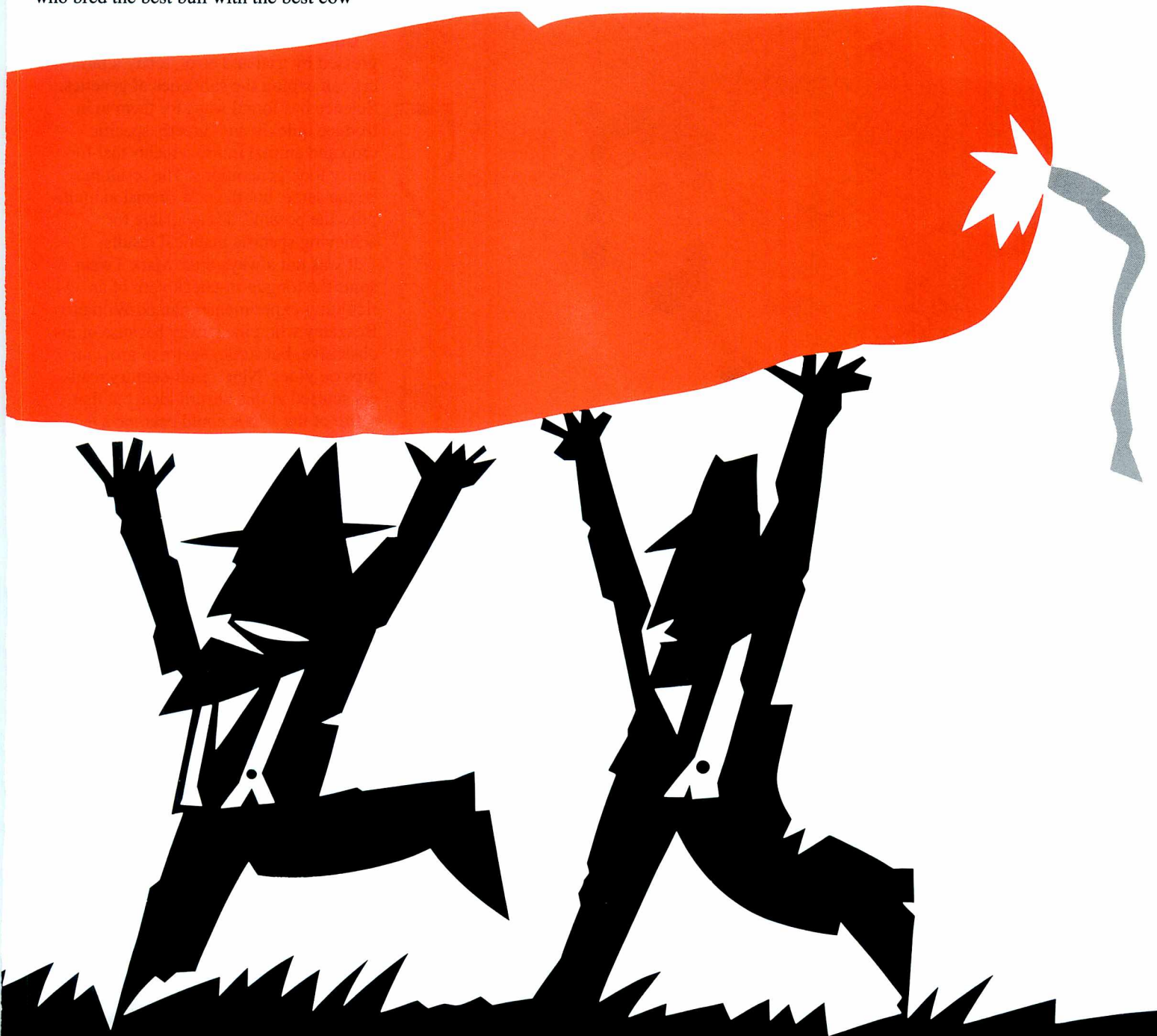
Traditional biotechnology is almost as old as agriculture itself. The first farmer who bred the best bull with the best cow

in the herd to improve the stock, rather than allowing the animals to breed randomly, was implementing biotechnology in a simple sense. The first baker who used yeast enzymes to make bread rise was likewise using a living thing to produce an improved product. Indeed, one anthropologist argues that a desire to raise grain for brewing beer—a classic

biotechnology product—was the impetus for the first systematic farming 10,000 years ago.

The "old biotech" that produced these changes is obviously not a single process but a number of different methods. The one feature common to these traditional biotechnologies is use of natural processes to introduce changes in foods.

Continued on the next page



USDA horticulturist Olivia Broom examines cloned strawberries in growth chamber.



The “new biotechnology” is likewise a number of methods of using organisms to make or modify products. It differs from traditional methods by modifying the genetic material of organisms directly and precisely. It enables the transfer of genes between diverse organisms, allowing combinations unlikely to occur by conventional means.

Unlike their predecessors, who progressed by trial and error, today’s farmers can exploit the subtleties of genetics. Science has found ways for them to introduce quickly and directly specific crop and animal improvements that formerly took generations. The result may be the same, but the new precision multiplies the possibilities available for achieving specific practical results.

It was not always thus. Mark Twain spins the tongue-in-cheek yarn of an agricultural experimenter named William Beazeley who pined away because of his obsessive, but futile, desire to grow turnips on vines. Nineteenth-century readers scoffed at this absurd idea, but that satire of the 1860s could become a technical possibility in the 1990s if there were any point to achieving it. Fortunately, the new biotech projects in view have more practical goals than Beazeley’s.

New biotech springs from our ability to rearrange or recombine DNA, the basic genetic material of living things, a feat made possible in 1974, when American scientists first cloned (isolated and duplicated) a specific gene. From that beginning, the new biotechnology has developed as wide a range of applications as traditional methods. In food production, it is revolutionizing old processes like fermentation and cross-breeding. Both in the field and in the food-processing plant, it is joining in the age-old quest for a healthy, abundant and nutritious food supply.

Evolution or Revolution?

In the 1860s, Gregor Mendel, an Austrian priest (who, ironically, had flunked biology in his teacher’s examination),

In his Albany, Calif., greenhouse, USDA chemist Frank Green checks the development of genetically engineered wheat.



deduced the laws of heredity. Working with pea plants in his monastery garden, Mendel discovered he could predict the characteristics of plants bred from specific types of parents. From there it was just a short step to producing at will such characteristics as color, height, and pod position or appearance. Although published in the 1860s, his findings were ignored until researchers rediscovered and confirmed them in 1900.

Mendel's work ultimately made possible scientific farming based on genetics. By the 1930s, organ culture techniques made it possible to isolate plant embryos as a basis for breeding more successful hybrids. Corn production in the United States quickly doubled as a result. Through such methods, agricultural wheat was crossed with wild grasses in order to acquire such properties as greater yield, increased resistance to mildew and bacterial diseases, and tolerance for salt or adverse climate conditions.

Similar progress with many foodstuffs enabled China and India, threatened with famine in the mid-1970s, to invigorate their agriculture to the point that today they are net exporters of grain. Although much of this achievement came from ambitious applications of traditional biotechnology, the new biotech now sustains it, notably in work on rice and the other grains on which so many people worldwide subsist. Today, the new biotech strives to develop drought-tolerant crops that, in time, could alleviate the famines devastating Africa.

New biotech continues its quest for fruitful harvests only under protest. In one case in Maryland, opponents long delayed field testing of corn engineered to resist the European corn borer, a caterpillar that annually spoils \$400 million in American crops unless deterred by heavy treatments with pesticides. In Wisconsin, where farmers forfeit \$800,000 yearly in crops and pesticide expenses in their losing battle against brown spot disease in green beans, university researchers had to curb their hunt for a new-biotech alter-

native because of difficulties getting approval for field tests.

One current focus of research is a tomato genetically engineered not to go soft for far longer than ordinary products. Its developer claims that it looks the same, feels the same, and tastes the same as other tomatoes; its nutritional value is identical. The only difference researchers found—a difference achieved by isolating and counteracting a single gene that makes tomatoes rot rapidly—is that this tomato keeps longer. The reversal of that one gene in the 10,000 making up the plant is all that was needed to make this biotech tomato significant.

Waiting in the wings is another tomato plant altered to contain a bacterial protein toxic to plant-attacking insects but not to other living things. The primary safety issues with both of these “new” tomatoes are whether their introduction of single new properties might mask other unforeseen changes as well, and whether the products of these new genes are safe to eat.

The Context of Controversy

Traditional biotechnology also continues to develop even as the new biotech comes into play. A recent triumph is the “beefalo,” a hybrid animal whose meat combines the tenderness of domestic beef with the leanness of American buffalo. This development alarmed nobody and has won consumer acceptance.

Yet, when the traditional biotechnology of farmyard and field moves toward the “new biotech” of the laboratory, many people become alarmed at its very efficiency. As Margaret Mellon of the National Wildlife Federation put it, “I feel an affection for the natural world the way it is—the way 4 billion years of evolution have made it. I resist the notion of improving nature in the future, just as I lament the loss of nature as it was in the past.” Refinements that once would have taken generations may now be induced deliberately and rapidly—too rapidly for such observers.

Perhaps our imaginations have been colored by gimmick picture postcards of gigantic foodstuffs, whether gondola-sized potatoes or enormous bass asserted to be typical of particular resorts. Perhaps films showing humanity beleaguered by Frankenstein monsters or mutant insects dispose us to envision enor-

mities. More soberly, some critics make analogies to past introductions of novelties into our environment, such as kudzu plant, which became a troublesome weed, or the starlings whimsically imported into North America only to multiply and foul our cities. Others fear harm to consumers from new foodstuffs.

What is the individual to make of these fears? Is the new biotech following in the steps of the pioneer Mendel or the crackpot Beazeley? For example, bST (bovine somatotropin), a pituitary hormone produced in cattle, was recognized to increase milk production when injected into dairy cows as early as the 1930s. The recombinant technology of the 1980s allowed production of large amounts of pure bST, which could be used to increase milk yield and efficiency of production during part of the cow’s lactation period.

Because it is a protein, bST is digested and inactivated when eaten. Furthermore, bST is inactive in humans. People produce *human* somatotropin, but it is considerably different in structure from bST.

Since cows produce bST naturally, it is and has always been present in their milk. Treating the animals with the proposed levels of bST doesn’t increase the level of bST in milk above the levels occurring naturally. Nor does bST treatment alter the nutrient composition of milk. While FDA is still evaluating the animal and environmental safety of bST, the agency has determined that the milk from treated animals is safe for humans.

Recently, five U.S. supermarket chains publicized their refusal to buy dairy products from cows treated with bST. They curtailed purchases under pressure from a coalition of groups concerned with issues ranging from animal rights to an alleged current milk surplus and the survival of the small family farm. Uneasiness about the safety of consuming dairy products from “experimental animals” also apparently influenced the decision.

When it comes to farm crops, the U.S. National Academy of Sciences and its parent, the National Research Council (NRC), have not found any difference between the environmental safety of old and new biotech-derived plants. In 1989, NRC reported that “crops modified by molecular and cellular methods [i.e., the new biotechnology] pose risks no differ-

ent from those modified by classical genetic methods for similar traits.” It also noted that no adverse effects have developed from introductions of genetically modified organisms.

Moreover, some scientists argue that the precisely directed alterations of recombinant-DNA technology might in fact be far safer than the random shuffling of characteristics inevitable under more traditional techniques. As the NRC puts it, because “the new molecular methods are more specific, users of these methods will be more certain about the traits they introduce into plants” than those using traditional methods. Many projects now in the works to promote food safety (from displacing chemical pesticides or preservatives to improving food sanitation) are possible only through the new methods.

New Challenges for FDA

In insuring a safe, nutritious food supply, FDA can’t be complacent about the implications of the new biotechnology—or any technology. Old biotechnology occasionally posed regulatory puzzles, and FDA recognizes that the products of genetic technology give new twists to old regulatory questions.

Take the concept of food adulteration, for instance. The traditional idea of adulteration was that of impurities being added to a food—for instance, when milk might be exposed to *Salmonella* bacteria or in the case of fillers added to cereals. The new biotechnology, however, makes it possible to remove properties as well as to add them: the long-lasting tomato, for example. There are many exciting possibilities—like engineering cows or hens to eliminate the properties some people are allergic to in milk or eggs—but these undeniably raise questions about changes in quality.

The ultimate question may be how many properties can be changed in an organism before it becomes something else. A tomato improved in one specific way seems obviously to be still a tomato, but does it remain one if you alter it in 10 ways, or 20? When traditional methods crossed the tangerine with a grapefruit, the new genetic structure was clearly something else, now sold as a tangelo. The new biotech questions are far more subtle. FDA must grapple with concepts of this sort as it considers the



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many new biotech food applications now being developed.

Biotechnology on Your Table

Markedly different or even novel foods probably won't appear on the grocery shelves any time soon. In less spectacular form, however, the new biotechnology is already keeping its dinner date. For instance, Canadian salmon have been treated for most of this decade with a hormone that allows them to mature three times faster than normal, without changing the fish in any other way.

Most of the new biotech projects now in the works would do little to affect the taste or appearance of the food on the plate, although a few promise to improve the flavors and consistency of some vegetables or reduce the fat content of some meats. Most address foods in ways that can't readily be seen—by improving nutrition content, preventing spoilage, or even eliminating the need for chemical pesticides. Gene probes to detect rapidly

the source of food-borne illnesses have already proven their worth to health authorities. For example, a synthetic DNA probe recently was used to detect a shell-fish-related disease when other detection methods failed.

FDA recently surveyed more than 100 experts from government, business, and the universities to find out what sorts of developments in food biotechnology to expect in the near future. The survey made clear that the floodgates of innovation are opening. Nearly 800 different developments were reported as technically feasible, three-quarters of them potentially ready for commercial applications in a few years.

Prospects include meats with lower sodium and cholesterol content and longer shelf life, as well as weather-resistant crops with more abundant yield and nutritional content. Methods to better detect *Listeria* species or other food-borne germs are coming, to join the valuable gene probes already in use for de-

tecting *Salmonella* and other bacteria. Plants engineered to do without chemical pesticides are beginning to sprout. Potatoes might some day be raised to last without preservatives. To the consumer's eye and palate, these first fruits of the new biotechnology will seem only subtly different, but the benefits should be substantial.

"Biotech Burgers" won't be available at the drive-in any time soon. Apples the size of pumpkins aren't right around the corner. And don't hold your breath waiting for Beazeley's turnip vines. But there may soon be the option of buying low-fat, low-cholesterol steaks, long-lasting, nutritionally superior vegetables, and pesticide-free fruits abundant because of an extended growing season, all courtesy of the new biotechnology. ■

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EBDC'S *Becoming a Household Word*

by Marian Segal





“Say the secret ‘word’ and you’ll win a hundred dollars,”

Groucho Marx promised contestants on his 1950s television show “You Bet Your Life.” Wiggling his bushy eyebrows and puffing his cigar, Groucho explained that at the mention of a certain common household word, a toy duck would fall from the ceiling, signaling the win. The duck would not have appeared for a word like “ethylenbis-dithiocarbamates.” EBDCs, as they are called, may never be a household word, but more American consumers are becoming aware of these chemicals as attention focuses on their possible carcinogenicity (cancer-causing potential) in humans.

EBDCs have been used in the United States since the mid-1940s to control mold, mildew, and other fungal diseases in crops. This class of chemicals, which includes mancozeb, maneb and metiram, has been under review by the Environmental Protection Agency because animal studies show that ethylenethiourea (ETU), a breakdown product of the chemicals, causes cancer of the liver and thyroid in laboratory animals.

Last Dec. 4, EPA proposed to cancel the use of EBDCs on 45 of the 55 crops for which they are now registered. (EPA approves, or registers, pesticides for use on raw agricultural products and sets tolerance levels for residues of each pesticide. A tolerance is the maximum amount of residue permitted on a product.)

Although other fungicides have been developed since EBDCs came on the market, the older products have remained in wide use because they work against a broad spectrum of organisms and are relatively inexpensive. Some 12 million to 18 million pounds of the chemicals are used annually in the United States, and about 150 million pounds worldwide, particularly in areas where humid conditions are more conducive to the growth of fungus. The principal uses of EBDCs in this country have been on apples, potatoes, tomatoes, melons, cabbage, and spinach.

EBDCs are relatively unstable compounds. They degrade during production, storage, application, cooking, and heat processing. EPA has classified ethylenethiourea—a breakdown product of EBDC—as a probable human carcinogen, and scientists are concerned that the chemical can cause birth defects and possible damage to the thyroid gland as well, particularly in those who mix, load and apply the fungicide.

FDA Monitoring

The Food and Drug Administration monitors pesticide residue levels in domestic and imported foods and enforces tolerances on food shipped in interstate commerce (except for meat, poultry, and egg products, which are the responsibility of the U.S. Department of Agriculture). FDA has monitored for EBDCs and ETU for more than 10 years.

Between Oct. 1, 1987, and Sept. 6, 1989, FDA analyzed more than 100 different food commodities for EBDC or ETU residues. Ninety percent of the 2,156 samples tested had no detectable residues, and only 1 percent contained residues exceeding EPA tolerances.

“When FDA finds that a food shipment contains a residue that exceeds a tolerance or is otherwise illegal, we try to prevent that product from reaching the consumer,” explains Pat Lombardo, associate director of FDA’s division of contaminants chemistry. “The initial sampling is done at the wholesale level. If violative residues are found, we go back to the source—the grower or shipper—inform them of the problem, put a hold on the product if it’s still available, and collect and analyze follow-up samples. In that way, we can turn off the problem at the source.”

If necessary, the agency will initiate legal action, such as seizure or injunction, to prevent the product from reaching consumer channels. For imports, the food shipments may be refused entry into the country.

Domestic products that are not shipped out of state do not fall within FDA’s jurisdiction. In cases of violations not in-

volving interstate commerce, the agency alerts the state to the problem so that it can take appropriate action.

Additional data on ETU residues are now being gathered from FDA’s Total Diet Study, also referred to as the Market Basket Study, for which agency personnel purchase foods from local supermarkets and grocery stores throughout the country four or five times a year. Each of the market baskets comes from a different geographic region and is a composite of foods collected in three cities in that region. Different cities are selected each year. Each market basket contains 234 food items that have been chosen, based on nationwide dietary surveys, to represent the diet of eight different U.S. age-sex population groups. Agency personnel prepare the foods to be table-ready—from peeling bananas to making beef and vegetable stew. They then analyze the foods for pesticide residues.

Under an interagency agreement with FDA, USDA’s Gulfport, Miss., facility is also analyzing several commodities for ETU, primarily processed fruits and vegetables. In addition, USDA will determine ETU residue levels in 60 processed baby foods to enable scientists to better assess the exposure of children to the fungicide.

Regulatory History

EPA initiated a special review of EBDCs in 1977 to determine what action, if any, it needed to take to protect the public. The resulting “decision document,” issued in 1982, imposed protective clothing requirements for workers who apply the chemicals. The report concluded, however, that the scientific data then available were inadequate to evaluate the potential for EBDCs to cause cancer. EPA, therefore, postponed addressing this risk until the agency could acquire more complete information.

In 1984, following settlement of a suit brought against EPA by the Natural Resources Defense Council, the agency agreed to issue “data call-ins,” requiring EBDC manufacturers to submit exten-



sive product information for EPA to use in reassessing the risk of the chemicals. The manufacturers were directed to provide information relating to metabolism, skin absorption, ability to cause birth defects, residues and dietary exposure, ground water contamination, and long-term feeding and inhalation.

In 1987 EPA began a second special review, focusing on cancer risk from dietary exposure and risks of thyroid damage and birth defects for persons applying the pesticide.

In September 1989, the leading manufacturers of EBDCs—Rohm and Haas Corporation, E.I. du Pont de Nemours & Company, BASF Corporation, and Pennwalt Corporation—announced that they had asked EPA to amend the registrations for the chemicals to eliminate their use on all but 13 crops. Under the manufacturers' proposal, the fungicides would still be sold for use on almonds, asparagus, bananas, corn, cranberries, figs, grapes, onions, peanuts, potatoes, sugar beets, tomatoes, and wheat.

Linda Fisher, EPA assistant administrator for the Office of Pesticides and Toxic Substances, was quoted in the Oct. 30 *Food Chemical News* as saying that EPA has "enough concern about the dietary risks of the remaining EBDC uses to proceed with issuing a proposed regulatory action" despite the cutback in these uses. Fisher said EPA is examining "possible increased costs to farmers and consumers if EBDC fungicide registrations are cancelled, the availability of alternative pest control methods, and the possibility that the loss of the uses of EBDCs could result in incidents of human poisoning by produce infected with fungi." This would be in addition to evaluating the potential risk from eating treated foods or from handling or applying EBDC pesticides.

"Pesticide Reduction Pledge"

Four days after the EBDC manufacturers' announcement, several consumer and environmental groups held a press conference in Washington, D.C., to promote a food retailer "pesticide reduction pledge." At that conference, according to the Sept. 18 *Food Chemical News*, five small supermarket chains and one food

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distributor formally agreed with the Consumer Pesticide Project of the National Toxics Campaign Fund to reduce pesticide residues, including EBDCs, on produce sold in their stores. Their stated goal is to stop selling—by Jan. 1, 1995—any fruits or vegetables treated with probable cancer-causing pesticides, as defined by EPA.

EPA's Fisher expressed concern about the environmental/consumer coalition's program. "We are concerned that the coalition's campaign could cause confusion for consumers and unnecessary economic hardship for both consumers and American farmers," she said. Fisher noted that the present law requires EPA to balance the value to society with the risks that may be presented by pesticides, and that decisions must be based on "top quality science."

In early November, United Press International reported that some of Florida's largest produce growers had stopped using EBDCs, fearing the kind of "food safety scare that hit apple growers in February during the Alar controversy." The wire service reported growers' fears that vulnerable crops, such as lettuce, cucumbers and green peppers, would not survive Florida's warm, humid winter,

adding that, according to the Florida Fruit and Vegetable Association, there is no alternative fungicide for some crops, such as lettuce.

Risk Assessment

Then, on Dec. 4, based on review of the data available to the agency, EPA decided that the current use of EBDCs presented an unreasonable cancer risk. The theoretical lifetime total dietary cancer risk from the EBDCs used on the 13 crops was calculated to be two cancer cases per 100,000 population. However, according to EPA, this risk estimate does not take into account the rapid degradation of EBDCs, but is based on residue data close to harvest and assumes the highest allowable application rates.

Because these 13 crops are not always treated with EBDCs, because the maximum applications are not always used, and because residues may dissipate significantly before the food reaches the consumer, the agency maintains that if grocery store exposure estimates were used, the risks for most crops would be significantly lower. Therefore, EPA has required manufacturers to conduct a grocery store level study and furnish results in September 1990.

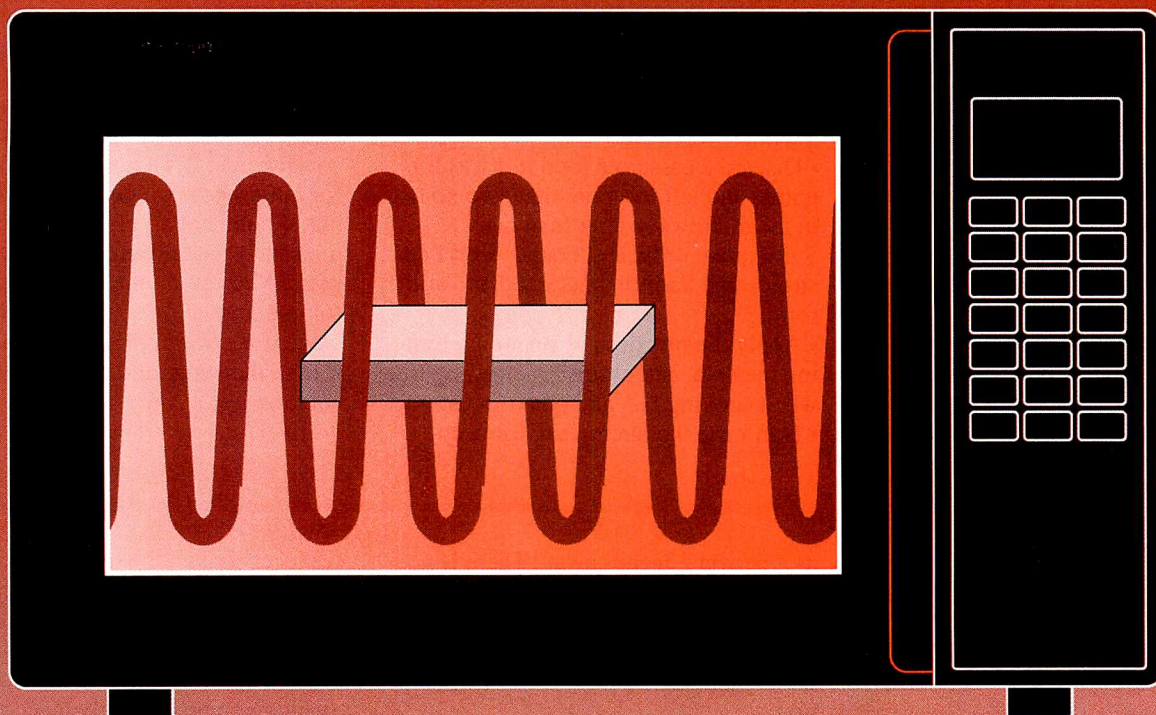
In the meantime, EPA has proposed to cancel use of all EBDCs on 45 crops. These include the 42 crops that the manufacturers had requested be deleted from the registrations, as well as three others—bananas, potatoes and tomatoes. The lifetime cancer risk of continuing use of the chemicals on the 10 remaining crops—almonds, asparagus, cranberries, figs, grapes, onions, peanuts, sugar beets, sweet corn, and wheat—is estimated at three in a million, and benefits from their use at \$13 million to \$26 million.

EPA maintains that EBDC residue levels on food are low and can be reduced further by washing and peeling fruits and vegetables. The chemicals remain on the surface of the produce; they don't penetrate. FDA also recommends peeling away outer leaves, skin or rinds and scrubbing certain vegetables such as potatoes and carrots. ■

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

Keeping Up with the Microwave Revolution

by Dixie Farley



Microwave oven cookery is on a roll—and the Food and Drug Administration is working to keep up.

Sales of microwave-packaged foods are expected to reach \$3 billion by 1992, up from \$900 million in 1987 and \$53 million in 1983. To capture this expanding market, industry has devised numerous packaging innovations. For instance, microwave-absorbing “heat susceptors” induce high temperatures to provide popcorn in a jiffy or brown and crisp pizza and other foods, and plastic “dual-ovenables” are prepared for use in either the conventional or microwave oven.

But the way FDA sees it, the revolutionary technologies producing these niceties were applied before the agency’s regulations were ready for them. Although both types of packaging may be manufactured with components that comply with various food additive re-

quirements, FDA has not evaluated the safety of all these materials at temperatures above 300 degrees Fahrenheit. Yet, heat susceptors sometimes exceed 500 F, and dual-oven plastic trays in conventional ovens are usually used at 350 F to 400 F.

FDA’s Center for Food Safety and Applied Nutrition (CFSAN) has no information to show a health risk. The center is concerned, however, that such high temperature use of these materials may cause packaging components such as adhesives, polymers, paper, and paperboard—known as indirect food additives—to migrate into food at excessive levels.

Indirect Additive Safety

Any new indirect additive used in making food-packaging materials must have FDA’s approval before marketing. The manufacturer must provide scientific

data proving that the additive is safe for its intended use. Test results, for instance, must show the nature and levels of the packaging materials, the components likely to migrate, and any potential hazards. The analytical procedures must reliably predict migration levels during the proposed uses. Approval takes the form of a regulation specifying the permitted conditions of safe use, such as temperature and type of food.

While these regulations describe permitted use conditions for packaging materials, they don’t limit uses to a specific manufacturer. As long as other firms use an approved additive according to regulations, further FDA approval is unnecessary.

The agency has been regulating indirect food additives since 1958, with the result that most of these regulations predate the technologies behind microwave heat-susceptor and dual-ovenable pack-

(Continued on page 19)

Microwaving Tips

More than a third of marketed raw chickens are contaminated with *Salmonella* bacteria, a common cause of food poisoning. Two types of worm, *Trichinella spiralis* in pork and *Anisakis* larvae in fish, can survive in undercooked food to cause illness. Thorough cooking of meat, poultry and fish is vital to prevent such food-borne illness.

The U.S. Department of Agriculture, which oversees the safety of meat and poultry, offers the following advice for safe cooking with the microwave oven:

- Arrange meat and poultry pieces uniformly in a covered dish so steam can help kill bacteria and promote uniform heating. Stir the food and turn the dish

several times. Observe standing time. Use a microwave temperature probe or check with a meat thermometer to ensure a safe temperature—160 degrees Fahrenheit for red meat, 180 F for poultry. Check in several spots.

- Cook stuffing separately from poultry.
- De-bone a roast. Turn it several times during cooking. Check its temperature for safety. Let the meat stand wrapped in foil at least 20 minutes for steam to complete the cooking.

Other sensible precautions when using the microwave are:

- Discard a casserole food if it was forgotten and left for more than two hours in the microwave after thawing. Subsequent ordinary cooking won't destroy some harmful bacteria that could form.
- Apply the practices of steaming, turning the dish, and observing standing time when cooking fish and other foods.
- Don't use the microwave for deep-

frying, canning, or heating baby bottles. These applications don't allow adequate temperature control for safe results.

- Stay with the oven when microwaving popcorn, for heat buildup can cause a fire. Time heating per instructions but lean toward the shorter time (some ovens can scorch popcorn in two minutes).
- Don't dry or disinfect clothing or other articles in the microwave because of the risk of fire.
- Use only microwave-safe utensils. Hot food melts some plastics, such as margarine tubs, causing migration of package constituents. It's a good idea to use glass for fatty foods, which get particularly hot, though not all glass and ceramics are microwave-safe. Here's a quick test for glass: Microwave the empty container for one minute. It's unsafe for the microwave if it's warm; it's OK for reheating if it's lukewarm; and it's OK for actual cooking if it's cool.

—D.F.

How Safe Is Your Oven?

Properly used, a microwave oven is extremely safe. Under authority of the Radiation Control for Health and Safety Act, FDA's Center for Devices and Radiological Health ensures that microwave ovens made after 1971 meet a radiation safety standard requiring:

- two independent interlock systems to stop microwave production the moment the latch is released or the door is opened
- a monitoring system to stop the oven if either or both of the interlocks fail.

The standard limits microwave leakage to 5 milliwatts per square centimeter (mW/cm²) at about 2 inches from the oven—a very low level of exposure. (Medical applications use up to 1,000 mW/cm² without apparent ill effects.) FDA tests have shown that *actual* microwave emission is under 2 mW/cm².

Moreover, exposure decreases dramatically with distance. Someone 20 inches from the oven would receive only about one one-hundredth of the radiation

as a person 2 inches away. There is no radiation residue after microwave production stops. The whirring noise some ovens make after the door is opened is the fan and has nothing to do with radiation.

To make sure the standard is met, FDA tests microwave ovens in manufacturing plants and its own laboratories. According to Joanne Barron, chief of CDRH's television acoustic and microwave products branch, recent tests by state health officials, FDA field inspectors, and laboratory analysts from the Winchester Engineering and Analytical Center in Massachusetts have very rarely detected an oven that emits leakage above the standard. She explains, "We get two to 20 complaints a year, but most turn out to be false alarms. When there is a real problem, it's usually due to abuse of the oven or improper servicing."

To be sure radiation levels from a microwave oven remain as low as possible, consumers can take these steps:

- Don't use an oven if an object is caught in the door or if the door doesn't close firmly or is otherwise damaged. If you have an older model oven with a soft mesh door gasket, check for deterioration, which would require servicing.
- If you suspect excessive microwave

leakage, contact the manufacturer, a reputable servicing firm, the local state health department, or the nearest FDA office. FDA has found the inexpensive home microwave-testing devices that are available to be generally inaccurate.

- Don't operate an empty oven if the instruction manual warns against this. In some ovens, the magnetron tube can be damaged by unabsorbed energy.
- If there are signs of rusting inside the oven, have the oven repaired.
- Clean the door and oven cavity—the outer edge, too—with water and mild detergent. Do not use abrasives such as scouring pads.
- Follow the manufacturer's instruction manual for recommended operating procedures and safety precautions.
- Be sure children who use the microwave can do so safely.

There previously was concern that electromagnetic emissions from a microwave oven could interfere with a heart pacemaker. Modern pacemakers are shielded against such interference, but some older models may still be adversely affected by proximity to a microwave oven. If in doubt, check with your doctor. ■

—D.F.



Above, high temperatures generated by the popcorn heat susceptor pad caused it to burn. At right, Timothy Begley of FDA's indirect additives laboratory uses a susceptor pad for browning pizza. In testing products such as these, Begley and colleagues found that packaging components had migrated into the food.

(Continued from page 17)

aging. Because FDA could not foresee the extreme heat produced by these innovations, it did not initially specify temperature for migration testing of many indirect additives. In September 1988, FDA issued new recommendations for migration testing protocols, including those for high heat applications.

A Possible Problem?

FDA's first hint that there might be a problem with heat susceptors came in the winter of 1987-1988 from some of its employees' personal experiences with the new packaging. During the cold weather, like many people, the staff of the CFSAN indirect additives laboratory enjoyed popcorn parties in their homes in front of the television set.

"We were talking at work about getting burn-through in popcorn bags we had used in our microwave ovens at home," says Henry Hollifield, Ph.D., director of the laboratory. "So, we brought several of these packages into the lab, popped the corn, and tested the temperatures. The heat-susceptor portion of the packages got as hot as 500 degrees F."

The food-contact surface of heat-susceptor packaging is usually a metalized

polyethylene terephthalate (PET) film laminated to paperboard with adhesive. This metalized film absorbs the microwave energy in the oven and, with most of the microwaves absorbed, the package becomes a little "frying pan" that actively participates in the cooking. (See "What Makes the Microwave Run?" page 20.)

Initial CFSAN studies indicated that the PET film is not a protective barrier between the food and the outer packaging and that the PET itself contributes migrants to the food. Three minutes of microwave heating with susceptors caused more than 70 percent of PET components, called oligomers, to migrate into the corn oil used in the studies to simulate food. Six minutes' heating caused 95 percent migration.

Because susceptors help cook the food, they're known as active packaging. Only a small percentage of microwave packages use susceptors. The vast majority use passive materials, which are transparent to microwaves; the waves pass through the materials to cook the food. These materials are heated solely from the cooking food, so they don't get much hotter than the food.

Still, even some passive packaging, such as dual-ovenables, will produce mi-

gration at high temperatures. When CFSAN laboratory personnel heated PET-containing dual-oven trays in a conventional oven at 350 F—following package instructions—they detected migration of the oligomer constituents at levels similar to those found with susceptors. Such migration is possible because foods must be cooked in conventional ovens for a longer time than in microwave ovens and because many conventional ovens heat higher than the temperature setting. (For example, an oven set at 350 F could in fact be heating at 400 F.)

Migration from the packages may turn out to be harmless. But CFSAN as yet doesn't have enough safety data to evaluate uses at these high temperatures.

CFSAN Goes to Industry

As a result of the indirect additives laboratory's initial findings, CFSAN held a public meeting on Sept. 22, 1988, in Washington, D.C., primarily to discuss the center's need for more information to evaluate the safety of heat-susceptor materials used at temperatures much higher than those set by existing regulations. CFSAN requested the following types of safety data on susceptors:

- chemical components used to make heat-susceptor packaging
- breakdown products formed in worst-case use conditions
- migration data from tests during likely

(Continued on page 21)

What Makes the Microwave Run?

Microwaves are a form of electrical and magnetic energy moving through space. They are useful in cooking because they're absorbed by foods but reflected by metal and because they pass through glass, paper, plastic, and similar materials.

Produced by a magnetron electron tube, microwaves bounce about inside the metal oven until absorbed by food. They cause food molecules such as water, a very efficient microwave absorber, to vibrate and thus produce heat to cook the food. That's why foods high in water content, such as fresh vegetables, can be cooked more quickly than other foods. Microwaved foods retain more vitamins and minerals than foods cooked other ways because microwaving takes less

time and doesn't require much additional water.

Though microwaves produce heat directly in the food, they really don't cook food from the inside out, says Joanne Barron, who heads the television acoustic and microwave products branch at FDA's Center for Devices and Radiological Health. "With thick foods like roasts," she says, "microwaves generally cook only about an inch of the outer layers. The heat is then slowly conducted inward, cooking along the way."

An area of a food where there is increased moisture will heat more quickly than other areas. So, when heating up a jelly roll, for instance, it's a good idea to let the food stand after cooking for a minute or two until the heat disperses

throughout. To promote uniform cooking, recipes for the microwave usually include directions such as "turn the food midway through cooking" and "cover and let stand after cooking."

As a rule, it's not good to use metal pans made for conventional ovens or aluminum foil because the reflected microwaves cause uneven cooking and could even damage the oven. However, some new metal cookware is specially configured for use in microwave ovens. Barron says these pans are safe, provided instructions for use are carefully followed.

Some oven models have a protector on the magnetron tube to allow use of a small amount of metal, such as meat skewers or strips of foil over chicken wings and legs. The instructions that come with each microwave oven tell what kinds of containers to use and how to test for suitability for use.

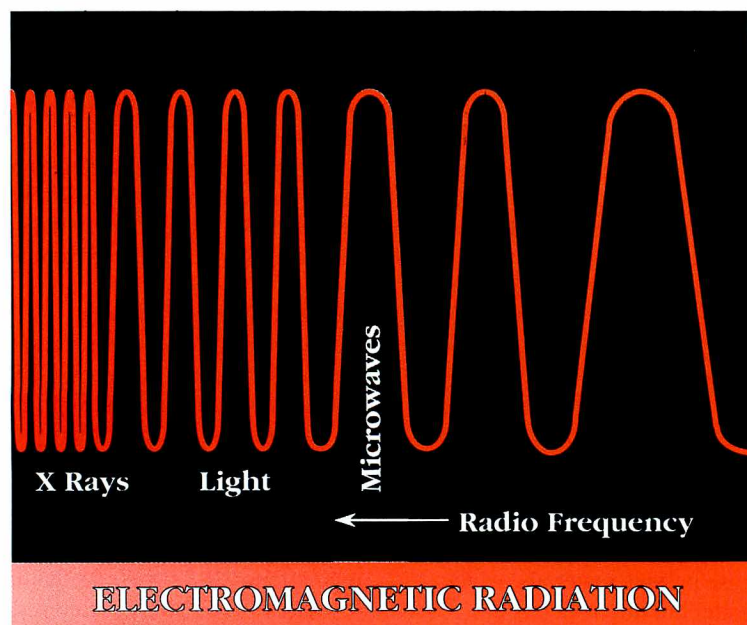
Microwave oven output, also given in an oven's packaging literature, can vary from 200 watts to around 750 watts—the bigger the oven, the greater the output tends to be. Ovens with fewer watts take longer to cook—sometimes as much as 30 percent more time. Some microwave-packaged foods are labeled with heating directions by wattage.

The Campbell Microwave Institute suggests the following test for gauging output:

- Fill a glass measuring cup with exactly 1 cup of tap water.
- Microwave, uncovered, on "high" until water begins to boil.

If boiling occurs in:	wattage is:
less than 3 minutes	600 to 700
3 to 4 minutes	500 to 600
more than 4 minutes	less than 500 watts

—D.F.



Microwaves are within the radio frequency band of electromagnetic radiation. They should not be confused with x-rays, which are more powerful.



Consumers visiting their favorite carry-out restaurants may soon be given their food in Nuke-It, a new self-venting, disposable rewarming unit that recently went on the market. Also new: ovens like this one with a choke system built into the door to prevent leakage, eliminating the need for the older soft mesh gaskets, which can deteriorate.

(Continued from page 19)

maximum time and temperature conditions

- toxicological data for migrant substances
- information about use conditions such as heating times, temperatures, and types of food to be used in the packages.

In response, the Society of the Plastics Industry and the National Food Processors Association jointly sponsored a committee to obtain the information and to work with the American Society for

Testing and Materials to develop standardized tests for susceptor packaging.

On Sept. 8, 1989, CFSAN published a notice in the *Federal Register* specifying the data industry is required to provide and the deadlines for these submissions. CFSAN will use the information to make decisions about amending indirect food additive regulations.

And the Heat Goes On

The story continues to unfold.

Members of the food-packaging industry had claimed CFSAN's use of corn oil

simulant rather than food in the laboratory tests did not represent actual use conditions. So, during the spring and summer of 1989, CFSAN chemists developed analytical methods to measure the extent of migration of heat-susceptor packaging components into food. They tested different kinds of susceptors and looked at pizza, popcorn, waffles, and breaded products such as fish sticks. In a meeting with the industry's ad hoc committee on Sept. 25, CFSAN released findings about one sample—french fried potatoes: 5 to 7 parts per million (ppm) of PET oligomers and 15 ppm of diethylene glycol dibenzoate (an adhesive component) had migrated from the film to the food. Though that was only one example, it showed that susceptors used under high heat conditions can cause migration and demonstrated that CFSAN now has test methods to show this actually occurs in food.

While current reports to CFSAN show no health hazard due to substances migrating from heat-susceptor and dual-ovenable packaging, the center will continue working with industry to obtain more conclusive safety information. CFSAN also has contracted with an outside firm to examine migration of packaging components into food. ■

Dixie Farley is a staff writer for FDA Consumer.

For More Information

Questions about microwave ovens or food packaging can be directed to the nearest FDA office listed in the telephone book. Questions about cooking poultry and meat in a microwave oven should be directed to USDA by calling its food safety hot line, 1-800-535-4555 (202-447-3333 in the Washington, D.C., area), 10 a.m. to 4 p.m. weekdays or by writing to The Meat and Poultry Hotline, USDA-FSIS, Room 1165-S, Washington, D.C. 20250.

Pursuing 20/20 at 40+

by Margie Patlak

Although few of them care to admit to it, baby boomers are getting older. Seventy-six million post-war infants are heading into their 40s, where they will encounter not only gray hair and wrinkles, but also another sign of aging—blurred vision when doing close work, such as reading.

This particular vision impairment goes by the name presbyopia. Most people first notice signs of presbyopia when they are in their 40s, and virtually everyone older than 50 has the condition. It gets its start, however, at about age 10 when the eyeball stops growing. Because the eye's lens still continues to churn out new cells after this age, its cells become so crowded together that the lens gradually loses its flexibility. Consequently, the eye's muscles cannot bend or focus the lens for the sharp, clear vision needed for near objects. A person who is farsighted may experience the symptoms of presbyopia earlier than average, whereas nearsightedness can sometimes delay the condition by a few years.

The most common sign of presbyopia is blurred vision at a normal reading distance, with a tendency to hold reading materials further away in order to see them better. Eye fatigue and headaches commonly result from doing close work. Sometimes a person with the beginnings of presbyopia finds that he or she can read without blurriness in the morning, but has hampered close vision by the end of the day. This "now you see it, now you don't" phenomenon occurs because eye muscles are fatigued from trying to focus the eye lens throughout the day for close vision, so that by evening the muscles don't have the strength to focus the eye sufficiently for near sight.

Conditions other than presbyopia, such as farsightedness and cataracts, can also

cause blurred vision close up, however. Only a thorough eye exam by an optometrist or ophthalmologist testing the eye's ability to change focus can determine which eye condition is causing the problem.

Research has not yet provided us with any clues to preventing presbyopia. But the wide range of bifocal, trifocal, reading, and progressive addition eyeglasses, as well as specialized contact lenses now available, can provide crisp near vision to people who lack it. All of these are regulated by the Food and Drug Administration.

Reading Glasses

First used in the late 13th century by middle-aged scholars, reading glasses improve near vision only. Since they tend to blur objects in the distance, reading glasses can be worn only for close work.

Dr. Richard E. Lippman, O.D., director of FDA's division of ophthalmic devices, describes the experience of using reading glasses. If you're working at a desk, he says, "and someone comes into the room, you're going to have to take your reading glasses off in order to see him clearly." A person with nearsightedness or other vision problems must alternate using reading glasses for close work with other eyeglasses or contact lenses for distance vision.

Reading glasses may be inconvenient when shopping or doing anything requiring good vision at more than one seeing distance. Reading glasses in a half-frame can sometimes relieve that inconvenience for people who have no vision problems besides presbyopia. These eyeglasses are particularly useful when doing office work, cooking, or pursuing such hobbies as playing cards or knitting.

The continual putting on and taking off of reading glasses calls for sturdy frames. A typical pair of prescription reading glasses costs anywhere from \$20 to \$200, depending on the type of frame purchased and where it is bought.

Although nonprescription reading glasses are available for less than \$15 a pair, these mass-produced eyeglasses may not accurately correct vision. While the correction of both lenses often is the same in these glasses, almost everyone needs a different lens prescription for each eye. These commercial reading glasses also can cause headaches, tired eyes, and other symptoms of eyestrain because the wearer's line of sight may not coincide with the optical center of the lenses.

Bifocals

Many older adults wear bifocals or trifocals because they need different lens prescriptions to see clearly at different distances, and find it inconvenient to continually switch between reading glasses and their regular glasses. Some people who have presbyopia but who also have normal distance vision may also wear bifocals with a nonprescription (technically called "plano") segment on top to avoid the inconvenience of taking off reading glasses to see something far off.

Generally, an upper portion of a bifocal lens is used for seeing far distances and the lower portion for seeing near. To read, a person looks down through the lower portion.

Bifocals come in a variety of types to meet specific vision needs. A person who works at a large desk, for example, and needs to see things near over a wide range often opts for bifocals in which the entire bottom half of the lens can be used



Optician lines up bifocal correction in lenses with lines on "prescription aligner" to make sure lenses are positioned properly.



for near vision. A casual reader, however, can get by with a near vision segment that is a small circle or half-sphere at the bottom of the lens. Electricians, in contrast, who work close overhead when connecting wires, may need bifocals that have the prescription for near vision in the upper portion of the lens.

Bifocals are about \$25 to \$50 more expensive than reading glasses, and most people take more time adjusting to them since they must learn how to use eye and head movements in order to take best advantage of the lenses. For example, it's best to gaze downward with the eyes when reading, and tilt the head down when walking down a flight of stairs.

According to Lippman, some wearers adjust to bifocals after wearing them for just a few minutes, but other people never feel comfortable with them. He feels success with bifocals depends on motivation and need. "If a patient feels that bifocals make him look old and consequently is opposed to wearing them, for example, he'll have a hard time adjusting," he says. A person who must see both near and far objects, however, will often adjust rapidly to bifocals, he adds, because they relieve the inconvenience of continually switching from one set of glasses to another.

Trifocals

Generally, presbyopia worsens with age. People older than 50 often find that though they can see well close up with the bottom part of their bifocals and can see objects clearly in the distance with the top part, there's a range of vision between 16 and 24 inches that becomes blurry. Clear vision at that range may be critical when using a computer, for example, or playing cards.

If bifocals don't meet all vision needs, trifocals may be the answer. These

glasses have a bottom portion of the lens for near viewing, a top portion for far viewing, and a middle section with power in between the other two segments so that the wearer can see things clearly at a mid-distance range. Because three different prescriptions are crammed into one lens, however, the field of vision for each distance is limited. This makes it more difficult to adjust to trifocals than bifocals. They are also more expensive than conventional bifocals.

Progressive Addition Lenses

Bifocals and trifocals wearers who are bothered by the telltale lines on these glasses may want to consider getting what are known as progressive addition lenses. These eyeglasses give a gradual invisible change in lens power from the top of the lens to the bottom. To get clear vision from far to near distance, you move your eyes up or down.

Progressive addition lenses cost about \$25 to \$50 more than bifocals, and adjustment to them is more difficult. The main problem these lenses pose is distortion in the peripheral areas of the lenses. If wearers have to look through the edges of their lenses in order to see someone beside them, for example, the person may appear blurred. The amount of blurring experienced can be limited, however, by turning the head rather than the eyes to look at something not directly in front.

The distortion on the periphery of progressive addition lenses may also be spatially disorienting. "People who use these glasses for the first time may feel they are moving up or down hill when in fact they are on level ground," says Lippman. The distortion on the sides may increase the more complex the prescription is for other vision problems besides presbyopia, such as astigmatism or

nearsightedness. Lippman recommends that only properly motivated people who understand the limitations of these lenses consider using them as an alternative to conventional bifocals or trifocals.

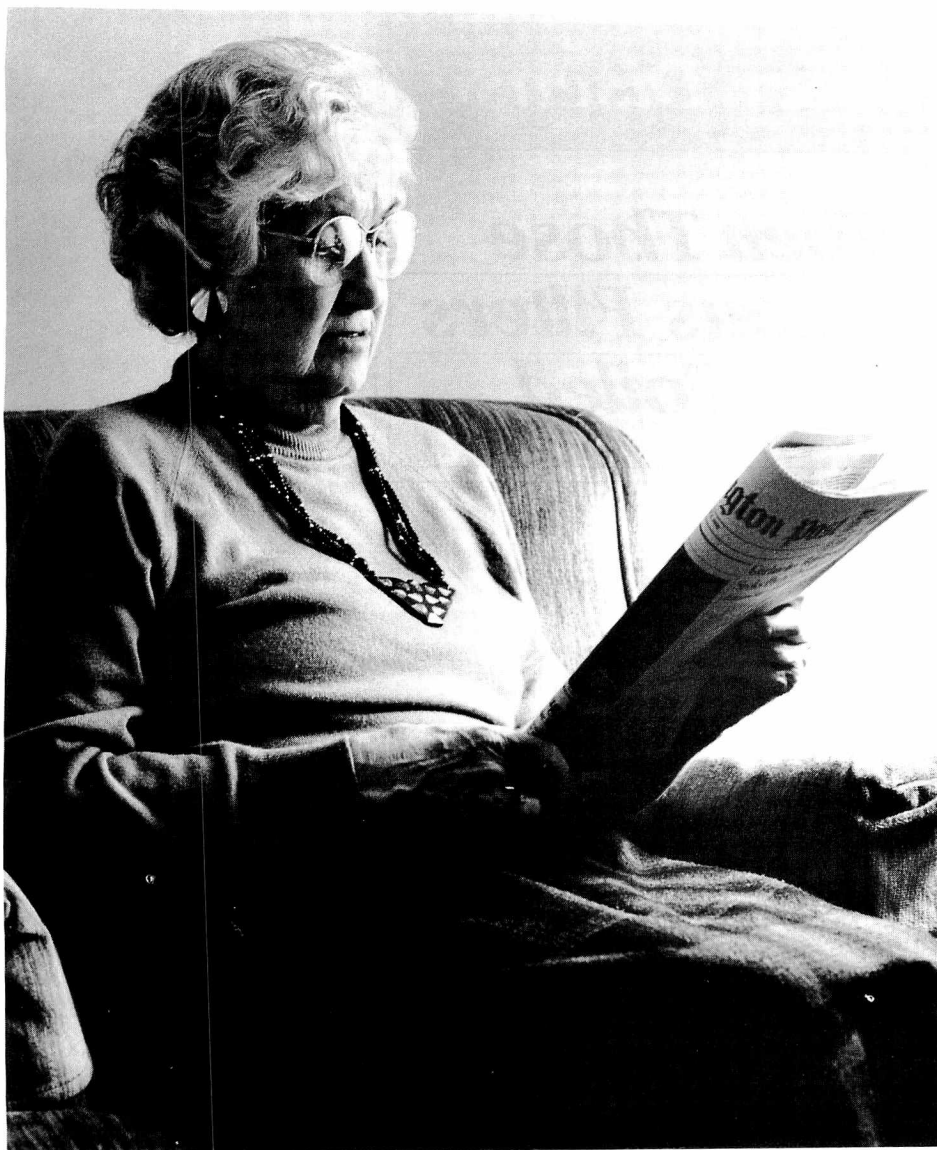
Contact Lenses

Those who prefer contact lenses to glasses may not have to give them up when presbyopia strikes. Many people find they can continue to wear their regular contacts for distance vision and put on reading glasses for close work. Because the prescription for these glasses is determined, in part, by the prescription for the contact lenses, the reading glasses alone cannot provide good close vision.

Hard, gas-permeable, and soft contact lenses are all available with bifocal corrections. Bifocal contacts come in a variety of designs. Working with an eye-care professional, consumers can decide which option will work best for them based on individual vision needs, eye shape, and other factors.

It is harder to adjust to multifocal contact lenses than to multifocal eyeglasses. Fewer than one 1 of 3 people using bifocal contacts, for example, is able to adjust to them, whereas most people can adjust to bifocal eyeglasses. Because of this difficulty, most practitioners usually recommend bifocal contacts only to people who have successfully worn contacts in the past.

Multifocal contacts can be double or triple the price of multifocal eyeglasses. A much less costly contact lens alternative is to fit one eye with a contact lens for near vision and, if needed, the other eye with a lens for distance vision. Contacts worn in this way are referred to as "monovision" lenses. They cost about the same as regular contacts and are easier to replace or change. However, contacts worn in this manner may hamper



Adjustment Tips

To get the best results with your bifocal or trifocal eyeglasses, let your eye doctor know all the various tasks you do both on and off the job that require clear vision. This information will help in the correct placement of the various lens prescriptions. Improperly placed lens segments can make seeing difficult and cause accidents, particularly when walking, using stairs, or driving.

The American Optometric Association offers these suggestions to new bifocal and trifocal wearers:

- Don't look at your feet when walking.
- Hold reading material closer to your body and lower your eyes, not your head, so that you are reading out of the lowest part of the lens.
- Fold the newspaper in half or quarters and move it, rather than your head, to read comfortably.
- Wear the lenses continuously for the first week or two, until you are accustomed to them, even though you may not need them for all tasks.
- Make sure that eyeglass frames are always adjusted for your face so that the lenses are properly positioned.■

depth perception and peripheral vision. "I wouldn't want to fly a plane with them," Lippman says. Monovision contact lenses work more successfully in people whose normal vision lacks fusion—that is, their eyes do not work together properly.

The greater difference there is between the prescriptions for far and near vision, the harder it is to adjust to this manner of wearing contact lenses. "In people with early stages of presbyopia, the difference is not that great, but as you get older, monovision contacts are less of an option," Lippman says.

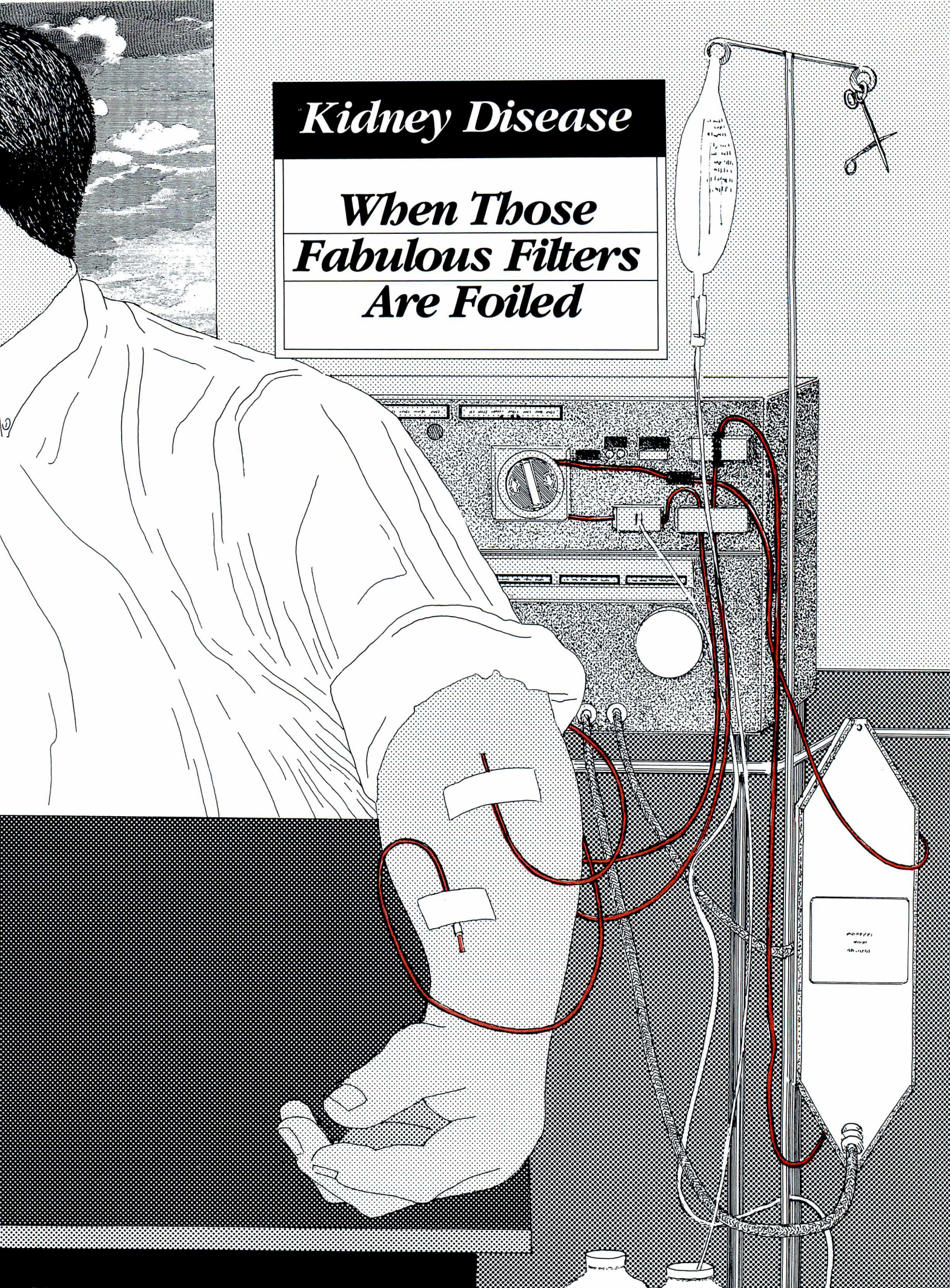
New on the market are "diffractive" contact lenses. The surface of these lenses has invisible ridges molded into concentric circles. The space between the circles gets smaller as the distance increases from the center of the lens, which is used for distance vision. The ridges bend light in such a way that the wearer is able to see things both close and far alternatively. Consequently, a person using diffractive contacts doesn't have a narrowed area on the lens in which to look to see far or near, as with bifocal lenses. Wearers must learn to adjust to diffractive contacts, however, and since they are relatively new, it's too early to tell how successful these contact lenses will be. They are more expensive than bifocal contacts.

Whether opting for reading glasses, multifocal lenses, or contacts, wearers usually need new ones every 12 to 18 months to correct for worsening presbyopia. "It doesn't pay to get old," says Lippman. "My advice is to stay young."■

Margie Patlak is a free-lance writer in Portland, Ore.

Kidney Disease

When Those Fabulous Filters Are Foiled



by Ken Flieger

What is man . . . but a minutely set, ingenious machine for turning, with infinite artfulness, the red wine of Shiraz into urine?

—Isak Dinesen

Seven Gothic Tales

Most of us think of ourselves as more than just ingenious machines. But Isak Dinesen was certainly right about the artfulness with which the human body, day in and day out, reduces everything eaten or drunk—red wine or milk, a lamb chop or a bowl of rice—into the nutrients that sustain life. Plus a couple of quarts of urine.

Behind the lower ribs on either side of the spine are a pair of organs whose major life-sustaining function is both mundane and elegant—simple in principle, yet so complex it has yet to be fully explained by science. Through elaborate processes of extraction and reabsorption, these two fist-sized, bean-shaped organs—the kidneys—cleanse circulating impurities and excess fluid from the blood and change them into urine.

If the kidneys falter or fail, we lose an internal pollution control system without which virtually every other bodily process becomes awash in potentially toxic wastes. And that's not all. Besides purifying blood, the kidneys synthesize hormones and vitamins that control growth and help control blood pressure, regulate the production of red blood cells, and maintain the right balance of minerals and chemicals in the body.

"The Body's Master Chemists"

Every 24 hours kidneys process some 200 quarts of fluid brought to them by the circulating blood. In a typical day, about 1 percent of that fluid—two quarts—is excreted as urine. The other 198 quarts—cleansed, restored to the proper acid-alkaline balance, and adjusted to contain the mix of minerals and chemicals the body needs to function normally—are returned to the bloodstream.

The workers in this remarkable process are about 1 million nephrons (from the Greek for kidney). Each nephron consists of a filtering unit—a glomer-

ulus—attached to a tubule. Blood entering the glomerulus is filtered to get rid of wastes produced by cellular activity in the body. The filtered fluid travels along the tubule, where chemicals and water are either added or removed depending on the body's current needs. Finally the excess fluid and waste materials, in the form of urine, pass from the kidney and move through tubes called ureters to the bladder. Urine is held there for one to eight hours and is then excreted.

The urine of a normal healthy person is sterile; in an emergency it can safely be used to clean a wound. The color normally ranges from pale to dark yellow depending on what and how much a person has had to eat and drink, the amount of recent vigorous exercise, the use of medications, and other factors.

The odor of normal urine is faintly pungent, but again, diet and medicines can change the odor without indicating that anything is wrong. (Detailed discussions of how the kidneys work are found in "The Kidneys: Complex Cleansing Units" in the December 1981-January 1982 *FDA Consumer* and "Urinalysis: Looking into the Void" in the October 1989 *FDA Consumer*.)

When Things Go Wrong

Diseases of the kidneys and urinary tract are among the most common major illnesses affecting Americans. The National Institute of Diabetes and Digestive and Kidney Diseases, one of the National Institutes of Health in Bethesda, Md., estimates that between 20 million and 25 million Americans have kidney, urinary tract, or related diseases. Some 260,000 people die each year from these illnesses. More than 140,000 Americans were being treated in 1988 for kidney failure, or what is termed "end-stage renal disease." The number of such patients is rising at a rate of 10 percent annually.

Although the exact cause of much kidney disease remains a mystery, it's clear that other conditions can increase the risk of kidney problems. For example, about 50 percent of people with Type 1 (juvenile onset) diabetes and 10 percent of those with Type 2 (adult onset) diabetes will develop kidney disease leading to permanent kidney failure. Because diabetes damages small blood vessels throughout the body, vessels in the kidneys of a person with diabetes are less able to filter the blood. That leads to

fluid retention (edema) and the accumulation of toxic wastes, typical manifestations of advancing kidney disease.

High blood pressure can be both a cause and a result of diseased kidneys. In uncontrolled hypertension, blood vessels in the kidneys become thickened and rigid, reducing the flow of blood and impairing filtering efficiency. A vicious circle is set in motion: The kidneys, damaged by high blood pressure, are less able to remove water and salt. Edema develops, putting an added burden on the heart and causing a decline in blood flow. The result is a further loss of kidney function and eventual kidney failure.

Types of Disease

Kidney diseases generally fall into one of three categories—hereditary, congenital or acquired. Hereditary conditions usually produce symptoms from teenage years to adulthood. The most common is polycystic kidney disease (PKD), in which, for reasons unknown, destructive cysts form in both kidneys and sometimes in the liver, pancreas, colon, blood vessels, and heart valves. Over a long period—usually a number of years—the growth of cysts impairs kidney function. Most people with PKD lead normal lives until they have lost 90 percent or more of kidney function, usually after age 40. Some PKD patients never experience renal failure or don't develop it until they are much older.

Congenital kidney disease is present at birth and usually involves a malformation of the genitourinary tract, typically an obstruction that makes the patient susceptible to urinary infection and destruction of kidney tissue. Eventually the destruction can progress to chronic kidney failure.

Acquired kidney diseases are numerous and are often lumped together under the generic term nephritis, meaning inflammation of the kidney. The most common form of acquired kidney disease is glomerulonephritis, in which the glomerulus is the chief site of injury.

Glomerulonephritis can be either acute or chronic. The acute form develops a couple of weeks after a streptococcal infection, usually a sore throat or skin infection, and is most often seen in children and young adults. The symptoms—loss of energy, pallor, puffiness around eyes and ankles, and ultimately blood in the urine—persist for several weeks.



When kidney dialysis is life-saving, it can put a smile on your face.

(Photo courtesy of the National Kidney Foundation, Inc.)

Most people with acute glomerulonephritis recover fully, though complete recovery may take a year. In 2 to 3 percent of cases, however, complications—including heart or kidney failure, high blood pressure, and convulsions—are fatal.

Unlike the acute form, chronic glomerulonephritis involves progressive kidney failure and is the most frequent cause of end-stage renal disease. In the early stages, the only sign that the patient is ill may be abnormal findings in a urinalysis—typically red and white blood cells and protein in the urine. If the kidneys are beginning to lose function, the patient may have high blood pressure.

As the disease progresses, hypertension becomes persistent and difficult to treat. With severe loss of kidney function, patients experience diminished appetite, nausea and vomiting, extreme fatigue, difficulty sleeping, itching and dry skin, and muscle cramps.

Yet another kind of glomerulonephritis, rapidly progressive glomerulonephritis, is marked by accelerated kidney failure. It appears suddenly, is characterized by a decrease in urine output, and is irreversible.

Disease Product

Strictly speaking, kidney stones are not a disease but the product of a disease. Nevertheless, the more than 800,000 Americans treated for this ailment each year know that kidney stones can cause excruciating pain before they pass out of the body by themselves or are cut out on the operating table. Stones can be caused by hereditary factors, diet, occupation, metabolic disturbances, the amount of water a person consumes, and even climate. The fact is, scientists are not entirely sure why some people develop kidney stones while—mercifully—most don't. Nor do they understand why black people have far fewer stones than do whites or why three males are affected for every female.

Most kidney stones are hard masses of salt and mineral crystals deposited on the inner surface of the kidney. (Similar stones that form in the bladder or pass from the kidney to the bladder via the ureter are properly called "bladder stones.") A stone that breaks loose from the kidney and passes through the ureter to the bladder and then through the urethra outside the body may go entirely unnoticed. About 90 percent of stones do that. But sometimes they lodge somewhere en route through the urinary tract and continue to grow. This leads to tissue damage, internal bleeding, and the exquisite pain that is the hallmark of a stuck stone.

Prevention and Treatment

Since many forms and individual cases of kidney disease are of unknown cause, it's hard to identify preventive measures. On the basis of experience, though, scientists think that increasing urine output by drinking fairly large amounts of liquids each day can lessen the risk of kidney stones. A better understanding of metabolic factors that seem to be involved in stone formation together with careful use of drugs to regulate body chemistry may soon make recurrent kidney stones a preventable condition.

The prospects for preventing the various forms of nephritis, whose causes are even less well understood, are not as bright. Keeping hypertension under control, however, can have a bearing on the risk of developing nephritis. Moreover, adequate control of blood pressure is crucial in the care of patients with kidney disease at every stage of their illness.

People with diminished kidney function benefit from avoiding a diet high in sodium and protein as well as careful control of minerals such as potassium, calcium and phosphorus. However, the value of diet in preventing kidney disease is uncertain. Diet isn't likely to lower the risk of developing inherited kidney disease, and it can't help a baby born with a congenital malformation that will lead to kidney problems.

Treatment of kidney disease depends on several factors, among them the exact diagnosis, the stage of the disease, other illnesses that may be present, and the age and general condition of the patient. In some cases treatment may consist of little more than rest and dietary restrictions. In others, notably end-stage renal disease, the patient may benefit from such medical marvels as an artificial kidney (dialysis) or a kidney transplant, techniques that improve the quality of, and prolong, life for many thousands of kidney disease patients.

Kidney Stones. Stones that aren't causing any trouble, so-called "silent" stones, usually don't require treatment. Acute attacks, however, may demand hospitalization because the pain is so severe. In most cases, the stone is small, and the patient needs medication to control pain and instruction on how to recover the stone for examination when it passes.

If a stone gets lodged in the ureter, physicians may try to remove it in a basket-like device passed into the ureter through a cystoscope, a hollow tubular instrument that can be passed through

the urethra to allow visualization of the bladder.

If a stone gets stuck in the bladder itself, it can be crushed by a tiny instrument inserted via the cystoscope. The fragments are either washed out or allowed to pass in the urine. For stones lodged inside the kidney, physicians can insert a needle through the skin of a patient under local anesthesia to create a passage directly to the stone. Instruments are then passed through this passage either to remove or break up the stone. Stones that are formed primarily of uric acid can sometimes be dissolved by the use of drugs. But if neither medicines nor specialized instruments can be counted on to work, surgery may be the only option.

Several years ago, FDA approved a device that uses high-intensity pressure waves traveling through water to disintegrate some kinds of kidney stones and enable them to pass out of the body on their own. Known as extracorporeal shock wave lithotripsy, the procedure may involve lowering a patient under local or general anesthesia into a tank of water in which a powerful electric or other source generates a shock wave that, with the aid of x-ray or sonographic imaging, is directed precisely at the stone to be shattered. Multiple shock bursts are "fired" at the stone, reducing it to fragments. Lithotripsy takes about an hour, and the patient is usually out of the hospital in two days—some are treated as outpatients—and can resume normal activities. (Patients who have surgery for kidney stones are generally hospitalized for several days and need up to five weeks to recuperate.)

Another lithotripsy technique that uses a laser instead of shock waves was approved by FDA in 1986. The laser, passed through a tube to the location of the stone, reduces the stone to particles the size of grains of sand that are then excreted. Laser lithotripsy is especially useful in treating stones in the lower ureter.

Nephritis. Treatment for the various kinds of nephritis aims chiefly at controlling kidney damage and dealing with the consequences of progressive kidney failure. It can and often does involve a combination of dietary restrictions, drugs, and, when the patient develops end-stage renal disease, dialysis and transplantation of a donor kidney.

The kind and degree of dietary restriction depends on the stage of a patient's

disease. In general, patients are advised to limit protein intake and be sure that a certain portion of it is "high quality" protein found in foods such as eggs, meat, fish, poultry, milk, and cheese. Because of its role in high blood pressure, sodium is sharply limited in the diets of most kidney disease patients. Calcium intake is also limited, requiring the patient to limit consumption of milk and milk products. Patients on dialysis may have to restrict potassium and water, but that's not usually necessary in the early stages of kidney disease.

Several kinds of medication can help manage the symptoms of kidney disease, though no specific drug is known to be effective against the fundamental cause of nephritis. Steroidal anti-inflammatory agents, diuretics, and antihypertensive drugs are useful in retarding kidney damage and lowering blood pressure.

But eventually the disease will progress to a point at which the kidneys can no longer cleanse the blood adequately. At that stage, life-saving measures are needed.

Role of Dialysis

Dialysis is a procedure that artificially replaces some of the kidney's normal function, enough at least to allow most patients whose kidneys have failed to live relatively normal lives. There are two types—hemodialysis and peritoneal dialysis. In hemodialysis, the patient's bloodstream is diverted to an external machine that continuously filters the blood, corrects its chemistry, and returns it to the body.

Usually, hemodialysis patients are treated about three times a week. The procedure can be carried out in a hospital, a dialysis center, or at home. Home dialysis can be more convenient for the patient, but it requires that the patient or care-giver be thoroughly familiar with the dialysis procedure and equipment and the critical importance of measures to prevent contamination of the blood supply. At home or in a health-care facility, each dialysis treatment lasts about five hours.

In continuous ambulatory peritoneal dialysis the patient's blood is not shunted outside the body. Instead, a catheter placed in the patient's abdomen allows the abdominal space to be slowly filled with a solution—the dialysate—used to clean and re-balance the chemistry of blood flowing through vessels in the abdomen. After about four or five hours,

the dialysate is allowed to drain through the catheter and a fresh supply is introduced. The procedure is repeated several times a day while the patient goes about normal activities.

Cycling peritoneal dialysis is basically identical. It, however, requires an external machine and is usually done for about an hour and a half at night while the patient sleeps. Intermittent peritoneal dialysis is a hospital procedure that takes 10 to 12 hours. The oldest form of dialysis, it is often used in emergencies or as the first dialysis procedure following total kidney failure.

Help for Patients with Failed Kidneys

Patients suffering from chronic kidney failure frequently have severe anemia because the kidneys cannot produce enough erythropoietin, a hormone that stimulates red blood cell production. As a result, they need frequent transfusions, which raises the risk of infection from contaminated blood and eventually causes a dangerous build-up of iron. In June 1988, FDA approved Epogen, genetically engineered erythropoietin that can be administered to patients to boost their red cell production, thereby sharply lowering the need for transfusion.

With present incomplete knowledge of the cause and cure of kidney disease, transplantation offers an alternative to repeated dialysis for patients who have end-stage kidney failure. Some 7,000 Americans a year receive a kidney transplant, but about 60 percent of them need long-term treatment to prevent their own immune systems from attempting to reject the transplanted kidney. The anti-rejection drug Sandimmune (cyclosporine) is widely used in these cases, as are steroids such as prednisone. In June 1988, FDA approved a new agent to reverse acute kidney transplant rejection, Orthoclone OKT3 (muromonab-CD3). The drug blocks the action of T-cells, the white blood cells that are responsible for the body's rejection of foreign tissue.

The treatment of kidney failure is one of the most successful and beneficial applications of modern medical science. Although there is still a long road ahead to effective prevention or cure, current medical developments give those with a diagnosis of kidney disease strong reasons to be optimistic about treatment. ■

Ken Flieger is a free-lance writer in Washington, D.C.



When Teens Take Over The Shopping Cart

by Dale Blumenthal

Now that her mother works an evening job in addition to her full-time day job, 18-year old Di'Onna Parker is the brains behind the family grocery shopping. Di'Onna makes more meals at home for herself than her mother does. So, when they go together once a month to shop for their three-person family, "my mother asks me what we need, and I tell her," Di'Onna says.

They buy most of their groceries on that monthly shopping trip. But Di'Onna, who usually prepares dinner for herself, and for her mother and brother "for when they get home," also makes occasional extra trips to the store when they run out of an item.

She shops strictly for price, comparing brand names with store name products. The amount of cholesterol, fat and sodium doesn't concern her, she says. But when she hears about a food safety problem, she stays away from that product. For instance, Di'Onna says, she stopped buying mushrooms for a long time after her mother told her about a problem with canned mushrooms contaminated with the bacteria that causes botulism poisoning.

Jer Gallay, 16, is a teenager who eats more meals at home than does his single father. Although his father does the bulk of the shopping, Jer makes frequent runs to the grocery store. When he buys food for himself, Jer says, he looks for taste and convenience. Bagels and cream cheese and anything that can be put in the microwave are favorite items. Unlike Di'Onna, when Jer shops for the family, he looks for low-fat, low-cholesterol foods. His father has high cholesterol, and Jer reads labels to select foods good for his father's health.

Teenage Shoppers

Teenagers these days are still crowding rock clubs and filling movie theaters. But they are also frequenting supermar-

kets. According to a 1986 Rand Poll, 93 percent of female teenagers grocery shop for their families and frequently prepare meals.

Information from Teenage Research Unlimited supports the finding that teenagers (both boys and girls) are doing more food shopping. The Lake Forest, Ill., research firm studies teenage trends. A recent Teenage Research Unlimited survey revealed that 9 out of 10 teenagers shopped for themselves or their families in 1988, spending \$47.7 billion on groceries and household products. Survey results showed that teenagers spend just under 1 1/2 hours a week shopping for the family—about 1 hour for males and 1 3/4 hours for females.

Peter Zollo, president of Teenage Research Unlimited, explains that with more single working parent families and families in which both parents work, "teenagers have been forced to accept more responsibility in the home—and that includes grocery shopping." In fact, the Teenage Research Unlimited study showed that in 70 percent of homes where both (or single) parents work, teenagers do much of the grocery shopping.

Bewildering Choices

The supermarket—with more than 25,000 items—can be a bewildering place to shop. Nutritionists are concerned that teenagers make healthy food choices. Food manufacturers want to present products that will appeal to this new market. Both industry and health professionals are interested in what teenagers look for when they shop.

Di'Onna says she looks for price. Jer looks for convenience and low-fat products. Michael Shaw, a 16-year-old from a suburban family in which both parents work, chooses favorite brand-name products that he can use to concoct weekend gourmet surprises for his family.

These teenagers come from different backgrounds, and they have varying grocery concerns. Looking at an even wider cross-section of American teenagers, the fifth annual "Teen and Food Nutrition Study," conducted by *Forecast* magazine, reveals common choices of the teenage shopper.

Forecast magazine distributed questionnaires to 3,000 home economics students. Of the nearly 1,000 teenagers who responded, 45.2 percent said they considered price the most important factor in their food selections. Taste was a close second at 44 percent, and brand name was third at 12.4 percent. Many of the students selected more than one of the listed choices (which also included nutritional value, ease of preparation, calorie content, and packaging), so the total percentage of responses added up to 140 percent. (In some cases, students found it difficult to pick a single most important factor.)

Half the students said they sometimes use a shopping list, and another 30 percent said they always go to the grocery store armed with a list. Of these 80 percent, 45.4 percent said they were the ones in charge of making the list. An almost equal amount (46.6 percent) said someone else in the family developed the shopping list.

However, many of these teenagers claimed they make their own decisions about what brands to buy. Nearly 70 percent said they often chose a national brand they had used and liked in their home economics class. Eighty-seven percent said they had at least some influence on selection of brands for the family shopping.

Fast and easy-to-prepare food was a top item on the lists. Seventy-seven percent said they used a microwave daily, and nearly that many students said they used the microwave to cook at least part of the meal.



Like the teenagers in this article, Robin Russell of Potomac, Md., does the family food shopping.

Reading the Labels

Among the array of different brands, colorful packages, and signs pointing to frozen foods that are fun and easy to make is another consideration begging for teenagers' attention: good nutrition. Giant Foods, a supermarket chain in the Washington, D.C., area, now distributes bright orange and green leaflets addressing nutrition concerns for teenagers. "The Choice Is Yours When Eating on the Run," reads one flyer—which lists a number of healthy food choices. For instance, it recommends selecting cheese pizza over nachos because "both have calcium but nachos can have twice the fat and sodium."

According to a recent Gallup Poll, teenagers talk a healthy diet, but act differently. For example, the poll of 375 teenagers found that teens said they selected a diet they thought was good for them. But, potato or corn chips, cookies, candies, ice cream, and other sweets led the list of preferred snack foods. Only 10 percent named fruit as their favorite snack food.

The "Teen and Food Nutrition Study" provided more evidence that teenagers do not, in fact, select healthy snacks. Po-

tato chips were the favorite with almost three-fourths of respondents, ice cream was second, and candy third.

Half the teenage shoppers said they never read labels. Of those who do, calorie content was by far the most sought information.

Special Cases

The link between diet and health does seem to impress teenagers when nutrition affects their special needs. Now that Michael Shaw plays basketball in the winter and is on the golf team in the spring, he says he has been making healthier between-meal snack selections. When his 18-year-old sister Leslie was a star high school gymnast, she strictly followed a high-carbohydrate diet recommended by her coach.

Dieting to lose weight is by far the most common concern of teenagers. Forty-three percent of the teenagers in the "Teen and Food Nutrition Study" said they had tried to lose weight in the last year. More than half (55 percent) of these teenagers attempted to lose weight by cutting out desserts and sweets. Increasing physical activity was second and skipping meals third.

It's well accepted that anorexia and bulimia are problems that often begin in adolescence. (See "The Gender Gap at the Dinner Table," in the June 1984 *FDA Consumer*.) A Giant Foods leaflet recog-

nizes the prevalence of dieting and the potential for teenagers to develop eating disorders and suggests low-calorie but nutritious meals that teenagers can pick up at the grocery store: salad bar selections, self-serve frozen yogurt, and soup or chili from the soup bar. Chili, for example, says the Giant flyer, provides iron from beef and beans, and coleslaw provides vitamin C and is low in calories. In its information directed to teenagers, Giant says, "What may surprise the dieter is that the body actually responds to crash dieting as it would to starvation." The body lowers its metabolic rate, the pamphlet explains, thus burning fewer calories.

Findings from a recent, small study conducted by the National Dairy Council suggest that nutrition education in schools may encourage teenagers to improve their eating habits. However, as Teenage Research Unlimited's Peter Zollo acknowledges, the effect of large-scale nutrition education campaigns on teenagers has yet to be explored by market researchers.

Teenagers like Jer and Di'Onna seem to be most influenced by information they pick up from their families. Nutrition can become a family concern. Ellyn Satter, a family therapist and dietitian with the Family Therapy Center in Madison, Wis., points out that parents plan the menus for their young children and set an eating style for the family.

Driver's License and Grocery Cart

Teenagers most likely to be checking out the supermarket are from upper and lower income families in cities and lower income families in small towns, found Teenage Research Unlimited. That's where the greatest percentage of working mothers are. Traditional male/female roles also are changing. Although 94 percent of teenage females surveyed were shoppers, 90 percent of the males were also doing the food shopping. Of 35 percent of teens shopping one or more times a week, reports a recent issue of *Food Processing* magazine, the boys are shopping 8 percent more than the girls.

Most of these teenagers are 16 or older (the age when, in most states, teenagers can obtain their driver's license). Perhaps the trend of the future will be for 16-year-olds first to obtain their driver's license, next the family car, and then a grocery shopping cart. ■

Dale Blumenthal is a staff writer for 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.

■ FDA has revised action levels for amounts of residue of the pesticide **heptachlor** permissible in foods and animal feeds (FR Dec. 4).

■ FDA is soliciting comments on its "Second Draft Proposed Standard for the **Infant Apnea Monitor**—October 1989." Send requests for single copies of the document to the Operations Staff (HFZ-84), FDA, 5600 Fishers Lane, Rockville, Md. 20857. Submit written comments on the draft standard to the Dockets Management Branch (HFA-305), Room 4-62, FDA (address above) (FR Dec. 6).

■ A draft "Guideline for the Human Food Safety Evaluation of **Bound Residues Derived from Carcinogenic New Animal Drugs**" has been issued by FDA. For single copies, write the Division of Chemistry (HFV-140), Center for Veterinary Medicine, FDA, 5600 Fishers Lane, Rockville, Md. 20857 (FR Dec. 6).

■ A memorandum of understanding between the Ministry of Agriculture of the Republic of Chile and FDA affirms mutual cooperation in establishing and implementing emergency procedures to ensure that **fresh fruit exported from Chile** to the United States is safe and in accordance with the Federal Food, Drug, and Cosmetic Act (FR Dec. 7).

■ **Absorbable surgical gut sutures** have been reclassified by FDA from Class III (requiring pre-market approval) to Class II (must meet established performance standards) medical devices (FR Dec. 11).

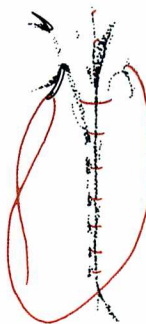
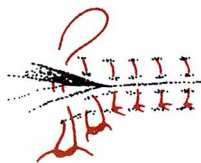
■ "**Frozen Dessert Processing Guidelines**," for use by industry, FDA, and state regulatory personnel to improve the safety and quality of frozen desserts, are now available. For single copies of the guidelines, write to FDA, Docket No. 89D-0470, Center for Food Safety and Applied Nutrition, Division of Cooperative Programs (HFF-340), 200 C Street, SW, Washington, D.C. 20204. Include two self-addressed adhesive labels with your request (FR Dec. 11).



■ The Federation of American Societies for Experimental Biology and FDA are preparing a report on the role of nutritional support in the **care of AIDS patients**. The organization will be asking for comments on the draft, which will be available by April 2. For single copies, write the Life Sciences Research Office, FASEB, Docket No. 89N-0482, 9650 Rockville Pike, Rockville, Md. 20814. Submit comments by June 1 to the same address (FR Dec. 11).

■ The NutraSweet Co. has filed a petition with FDA proposing that the food additive regulations be amended to provide for the safe use of **aspartame** as a sweetener in soft candy. For further information, contact Carl Gianetta, Center for Food Safety and Applied Nutrition (HFF-334), FDA, 200 C Street, SW, Washington, D.C. 20204; phone (202) 426-5487.

■ EPA has issued a final rule amending disposal and storage regulations for **polychlorinated biphenyls (PCBs)**. A tracking system, an approval program for commercial storers, and record-keeping requirements for PCB waste are covered in the provisions of the rule (FR Dec. 21).



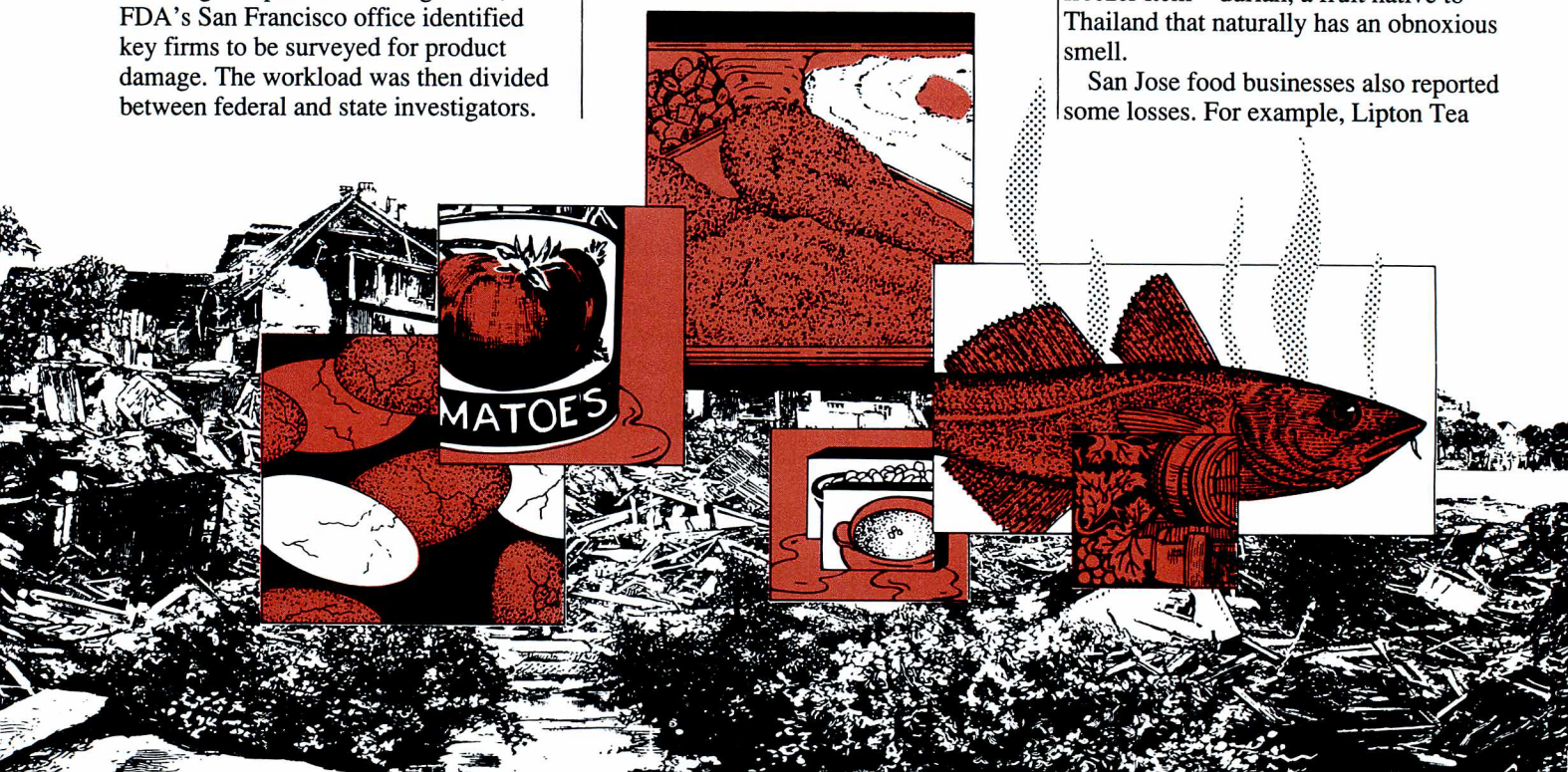


by Paula Kurtzweil

FDA began its work to identify contaminated products the day after the quake. Working with California's food and drug and public health agencies, FDA's San Francisco office identified key firms to be surveyed for product damage. The workload was then divided between federal and state investigators.

According to Merlyn Wurscher, a consumer safety officer with FDA's Salinas resident post, company officials esti-

San Jose food businesses also reported some losses. For example, Lipton Tea



Co. lost more than 800 pounds of imported bulk tea, worth an estimated \$1,000, and 50 pounds of dehydrated split peas that were being held in a public storage facility.

Overall, damage in the San Jose area was minimal. FDA's Kam estimated that, despite their proximity to the epicenter, almost 95 percent of firms lo-

cated in the San Jose area survived the earthquake intact.

Citing media reports, the investigators said the type of soil and the topography of the land were considered major factors in determining how well a building fared during the quake. Those on sandy, moist ground were more likely to sustain damage than those built on more solid

ground, they said.

"The damage varied terrifically, regardless of the epicenter," Scholl noted. "Businesses we surveyed either reported they had a catastrophe or they hadn't noticed the earthquake."

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

Faulty Catheter Prompts New Requirements

A "balloon-on-a-wire" device may sound like something frivolous. In fact, it's a new type of life-saving catheter for treating blocked heart arteries. A recent recall of a hazardous model pointed up the unique danger these instruments pose and led FDA to tighten its pre-marketing requirements for all balloon-on-a-wire catheters.

The new balloon-tipped catheter is as thin as paper-clip wire, making it narrow enough to traverse and open clogged coronary arteries, which are very small. FDA learned, however, that in certain models the inflated balloon can wrap around the wire shaft, cutting off the heart's blood supply and preventing removal of the device. In other models, the tip of the catheter can become lodged in the artery, break off, and remain in the heart. In the past, manufacturers could market a balloon-on-a-wire catheter after submitting to FDA a supplement to a previously approved application for a standard balloon catheter. But now, because the agency is aware of the unusual problems associated with these small-diameter catheters, a complete pre-market approval (PMA) application is required.

FDA's more stringent application of PMA rules occurred after C.R. Bard, Inc., of Billerica, Mass., changed its original balloon-on-a-wire catheter, which had been a supplement to the firm's 1980 PMA for its USCI Gruntzig catheter, the first balloon heart catheter ever approved. Bard described some, but not all, of the changes in supplements to the PMA. Apparently minor changes had created a new catheter with new problems, as FDA later discovered.

The Gruntzig and balloon-on-a-wire catheters are variations of a PTCA (percutaneous transluminal coronary

angioplasty) catheter—a long, flexible tubular instrument with a balloon at the tip. PTCA catheters are used to treat atherosclerotic disease, in which plaque buildup in the coronary arteries restricts blood flow to the heart. The cardiologist threads the catheter into an artery in the patient's leg, through the blood vessels, to the blocked coronary artery. The balloon is then inflated at the point of blockage to press the obstructing material against the artery wall, opening the artery for resumed blood flow.

On July 15, 1987, Bard submitted a PMA supplement requesting approval to market the USCI Probe I, an ultra-thin PTCA catheter.

"Because of its small size, the Probe I could enter arteries too narrow for a standard PTCA catheter, which is about the

size of a cooked spaghetti noodle," says Lynne Reamer, who oversees the review of heart catheters for FDA's Center for Devices and Radiological Health.

Any PTCA catheter can cause complications such as injury to the coronary artery, blood loss, a drop in blood pressure, or heart attack, which may lead to emergency bypass surgery or even death. "Some of these complications were seen in human studies with the Probe I," says Reamer, "but not to a greater degree than with other such catheters."

In clinical trials, Bard found the Probe I could fail if a cardiologist twisted the catheter too far in one direction while trying to navigate the curving heart arteries. The firm therefore relabeled the catheter to limit rotation.

CDRH approved the Probe I in No-



vember 1987 and a supplement adding two balloon sizes to the Probe I in March 1988. The following November, Bard submitted a supplement for approval of its USCI Probe II catheter, claiming it was the same as the Probe I except for an added inner tube to allow increased catheter rotation. No mention was made about balloon wrapping with the Probe I.

Meanwhile, Reamer learned that two deaths from the Probe I had been reported to CDRH—one due to balloon rupture, the other to a balloon leak. But these problems were not uncommon with balloon catheters, and the Probe II was approved in January 1989.

CDRH later received documents from other PTCA catheter firms indicating Bard was marketing another catheter, the Probe C. Bard had written its customers March 17, saying it received 33 complaints about Probe II tips breaking and describing in a diagram the differences between the Probe II and a Probe C. Reamer said that, after examining CDRH records and finding nothing about a Probe C, she alerted CDRH's office of compliance and surveillance that Bard might be selling an unapproved catheter.

On April 25, CDRH held the first of many meetings with Bard. CDRH repeatedly stressed that, in issues of patient safety, firms cannot arbitrarily redesign a device and market it without FDA approval. Data gathered at these meetings and at plant visits by investigators from FDA's Boston district office showed that Bard had withheld important facts from FDA, such as that balloon deflation problems with the Probe I were the reason for changing the catheter.

At FDA's recommendation, Bard voluntarily recalled all Probe IIs because the tip failure was excessive for PTCA catheters. Because the Probe C had never been approved by FDA, Bard voluntarily recalled this catheter. The Probe I is the only Bard balloon-on-a-wire catheter still on the market.

Handcrafted Pottery Recalled

Even fine handcrafted pottery can be dangerous to your health, as investigators from FDA's Cincinnati district office recently discovered.

In April 1988, during a routine inspection of Turtlecreek Pottery, a small Ohio

pottery company that employs artisans to create pottery modeled after early American designs, FDA found that some of the pieces intended for food use leached lead at a rate of 11.6 parts per million, more than twice as much as the 5 ppm allowed under FDA's standards. The company did not keep records of "firing" times and temperature. These are two important factors in rendering lead glazes acid-resistant, which prevents or limits lead from leaching from the pottery into food. The company also failed to run quality control tests to determine if the ceramic pieces had been fired properly and were within the tolerance for leachable lead.

The line with excessive lead levels included mugs, punch bowls, plates and platters, porringers, trenchers, pie birds, and demitasse cups. The company sold its wares through mail order, wholesalers, and retail shops.

Turtlecreek agreed to recall all its pottery—2,765 pieces—produced in 1988 and the early part of 1989. The company placed notices in *Early American Life* magazine and *Antique Review* to notify customers of the pottery's high lead content and the recall. Turtlecreek also issued a press release on the recall through the wire services, United Press International, and Associated Press.

Turtlecreek no longer makes pottery intended for food use and has decided to craft only reproductions of museum pieces.

Serum Shipped Out For Not Shaping Up

FDA's Newark district office investigator Jacques Maravic looked on last October while 7,500 1/2-ounce bottles of Clarin's Double-Serum Multi-Regenerant Anti-Aging Total Skin Supplement and 94,000 accompanying pieces of literature in English and Spanish were loaded into a 40-foot-long container. The goods, valued at nearly \$100,000, were on their way to being shipped back to the French manufacturer from whence they had come. In any language, it spelled fraud.

A brochure called "Reference Guide for a Youthful Face, a Firm Bust, a Toned Body" touted the product as the "only formula in existence which suc-



cessfully combines the 18 highly concentrated 'anti-aging' ingredients needed to effectively combat the appearance of the aging process of the skin."

As FDA wrote in a May 1, 1987, regulatory letter to the distributor, Clarins, Inc. of New York, the claims suggest that "the articles are intended to affect the structure and function of the human body, and that the products are adequate and effective for such uses as preventing the effects of the aging process, rebuilding the epidermis, refining the shape of the face, stimulating cell renewal and other claims." According to FDA, these claims classify the product as a drug.

Clarins never obtained FDA approval of Double-Serum as a safe and effective anti-aging agent. (Nor has anyone else.) The agency informed the firm that sale of the product with unsubstantiated drug claims was illegal under the Food, Drug, and Cosmetic Act and warned the firm to correct the violation. On June 30, Clarins' marketing manager wrote to FDA's New York district office, stating that the labeling changes would be complete by Aug. 15, 1988. But they weren't.

Inspecting the firm's Oakland, N.J., warehouse in October 1988, Newark district investigators found that Double-Serum labels continued to include drug claims. In addition, the brochures were found at department store counters in Washington, D.C., and New York City in December 1988 and March 1989. During a follow-up inspection in May, investigators found 1,560 units of Double-Serum at the Oakland warehouse with 87,000 pieces of literature making false claims for the product. On July 20, at FDA's request, the materials were seized, and in September, Clarins entered into a consent decree, agreeing to export the materials back to the supplier, Clarins, S.A., in Paris, France.

—This small sample of reports from the field was prepared by Dixie Farley, Judy Folkenberg, and Marian Segal.



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

Food/Poisonous and Deleterious Substances

PRODUCT: Pistachio nuts in 15-oz. cans, at San Francisco, N. Dist. Calif.; Civil No. 86-1156 SC.

CHARGED 3-12-86: While held for sale, the article contained the added poisonous or deleterious substance aflatoxin—402(a)(1).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 64846; S. No. 86-497-201 et al.; S.J. No. 1)

Food/Contaminants, Spoilage, Insanitary Handling

PRODUCTS: Conch meat fillets, at San Juan, Dist. Puerto Rico; Civil No. 87-1352.

CHARGED 10-6-87: While held for sale, the article contained decomposed conch meat—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65267; S. No. 87-512-403; S.J. No. 2)

PRODUCT: Fernbrake, dried, and other Oriental-style food stocks, at Dallas, N. Dist. Texas; Civil No. 3-87-2481-R.

CHARGED 10-20-87: While held by D.Y. Imports, Dallas, Texas, the articles had been held under insanitary conditions—402(a)(4).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 65284; S. No. 87-455-175 et al.; S.J. No. 3)

PRODUCT: Lily flowers, dried, crystallized ginger, preserved plums, mung beans, dehydrated cole, and other Oriental food stocks, at San Francisco, N. Dist. Calif.; Civil No. C 88 277 TEH. **CHARGED** 7-14-88: While held by Lop Keung Trading Co., San Francisco, Calif., all of the articles had been held under insanitary conditions—402(a)(4); and the named articles contained rodent filth—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65508; S. No. 88-540-265 et al.; S.J. No. 4)

PRODUCT: Rice, Pari Brand, at San Jose, N. Dist. Calif.; Civil No. 87-20236-WAI.

CHARGED 4-14-87: When shipped by Sachdeva & Sons Rice Mills, Amritsar, India, the article contained insect filth—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65145; S. No. 87-449-840; S.J. No. 5)

PRODUCT: Rice, Pari Brand, at Walnut Creek, N. Dist. Calif.; Civil No. 87-1885-TEH.

CHARGED 4-22-87: When shipped by Sachdeva & Sons Rice Mills, Amritsar, India, the article contained insect filth—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65144; S. No. 87-496-699 et al.; S.J. No. 6)

Food/Economic and Labeling Violations

PRODUCT: “Cod” fillets, at Gloucester, Dist. Mass.; Civil No. 87-0470-K.

CHARGED 2-23-87: While held for sale, the article labeled “Georges Bank . . . Skinless Cod . . . Mantia Fisheries Corp., . . . Gloucester, Mass.” had had pollock substituted for cod in the article—402(b)(2); the article’s labeling was false and misleading in representing that the only fish in the article was cod—403(a)(1); pollock was offered for sale under the name of another food (i.e., cod)—403(b); and the article’s label lacked the name and place of business of the manufacturer, packer or distributor, since the listed producer was no longer in business—403(e)(1).

DISPOSITION: Consent—authorized release to Dawnkist Seafoods, Inc., Gloucester, Mass., for bringing into compliance.

(F.D.C. No. 65126; S. No. 87-531-165 et al.; S.J. No. 7)

Drugs/Human Use

PRODUCT: “Naproxen” tablets, in bulk and in retail vials, at Santa Clara, N. Dist. Calif.; Civil No. C 87-3028JPB.

CHARGED 6-15-87: The articles (which did not contain naproxen, but which contained a combination of acetaminophen and aspirin) were counterfeit drugs, since they, their containers, and their labeling, without authorization, bore the trademark, trade name (*Naprosyn*), imprint (*Syntex* and 273), or likeness thereof of a drug manufacturer other than the person or persons who in fact manufactured, processed, packed, or distributed the article—201(g)(2).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65177; S. No. 87-450-372; S.J. No. 8)

Drugs/Veterinary

PRODUCT: Caco-Iron-Copper Solution for injection, other new animal drugs, drugs lacking veterinary prescription legends, drug components, and in-process products, at El Monte & Arcadia, C. Dist. Calif.; Civil No. 88-5036-SVW(Tx).

CHARGED 8-17-88: While held by Anthony Products Co., t/a Anpro Pharmaceutical, Arcadia & El Monte, Calif., specified articles were new animal drugs without effective approved New Animal Drug Applications—505(a); and the labeling of specified articles lacked adequate directions for use—502(f)(1).

DISPOSITION: Certain drug components (dexamethasone, prednisolone and prednisone) were claimed by the possessor-processor, and a consent decree of condemnation authorized release of those articles to the claimant for salvaging. A default decree of condemnation ordered the other articles destroyed. (F.D.C. No. 65488; S. No. 88-444-768 et al.; S.J. No. 9)

PRODUCT: HP Vehicle emulsion for use in intrauterine infusion, at Hamilton, N. Dist. N.Y.; Civil No. 88-CV-877.

CHARGED 8-17-88: While held by West Agro, t/a Hamilton Pharmacal Co., Hamilton, N.Y., who had manufactured the article using interstate mineral oil, the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to the article’s intended use—501(a)(5); and the article’s labeling was false and misleading because it suggested that the article was suitable for use as a vehicle in intrauterine infusion for various conditions, including metritis and pyometra—502(a).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 65478; S. No. 88-471-611; S.J. No. 10)

Medical Devices

PRODUCT: Condoms, at Charlotte, W. Dist. N.C.; Civil No. C-88-0343-P.

CHARGED 7-29-88: The quality of articles, which were labeled “Ultra Shape [or “Evening Magic”]... Distributed Exclusively by Barnett’s, Inc., Charlotte, N.C.,” fell below the article’s purported quality, since the articles contained holes—501(c).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65517; S. No. 88-566-101 et al.; S.J. No. 11)

PRODUCT: Depilatron hair removal devices, at Minneapolis, Dist. Minn.; Civil Nos. 4-78 Civ. 309 and (upon removal) 78 Civ. 4917 (LBS).

CHARGED 7-26-78 and amended 12-1-78 and 1-10-79: The articles were labeled “Depilatron Epilator Model . . . Universal Technology, Inc. [or “Depilatron, Inc.”] Woodbridge, Conn., and were accompanied by a brochure reading “Depilatron What You Should Know About the Depilatron Method of Hair Removal” and by a leaflet reading “Harvey Glass, M.D. . . . December 29, 1975 . . . I have studied the Depilatron method of hair removal from both a theoretical and practical point of view”; the accompanying labeling contained the following false and misleading claims: (a) the device was adequate and effective for electronically removing unwanted hair permanently; (b) the device used radio frequency for its operation; (c) the device directed radio frequency to the hair root; (d) the device’s operation was similar to electrolysis in a number of specified respects; and (e) the device was a permanent, safe and painless method for removing unwanted hair—502(a).

DISPOSITION: The article was claimed by Depilatron, Inc., Linwood, N.J., who denied the charges and asserted several affirmative defenses, including collateral/equitable estoppel due to a State of California action, and the alleged unconstitutionality of 21 U.S.C. 334(a)(2).

Meanwhile, pursuant to stipulation, the action was removed to the Southern District of New York.

The government filed an amended complaint for forfeiture and subsequently a second amended complaint. The claimant moved to dismiss the action.

After a hearing, the court denied the claimant’s motion to dismiss. The court rendered an opinion in which the court sustained the government’s argument that 21 U.S.C. 334(a)(2) was a valid exercise of Congress’ power under the Commerce Clause, and found that Congress had a sufficient basis for concluding that the regulation of the intrastate sale and distribution of medical devices was necessary for the proper regulation of interstate commerce.

As to the claimant’s argument of collateral estoppel, the court noted that, on their face, the claimant’s allegations that federal agencies were in communication with, and gave some assistance to, California authorities did not rise to the contention that the federal government controlled the California litigation. The claimant was also requesting an opportunity for further discovery to determine whether government participation in the California action rose to the level found in *State of Montana v. United States*, 440 U.S. 147. The government had submitted affidavits that made it clear that the involvement of the federal government in the California proceeding was of a very limited nature and involved no element of federal control or direction. Accordingly, the court concluded that additional discovery was not warranted and that the government was not precluded from bringing this action by the doctrine of collateral estoppel.

The government served written interrogatories on the claimant and a request for documents. The government subsequently filed a notice of motion for a stay amending the order entered with the court’s opinion denying dismissal. The claimant moved for certification pursuant to 28 U.S.C. 1292. The court denied both the claimant’s motion for certification and the government’s motion

for a stay. The claimant served on the government several sets of written interrogatories and requests for documents.

The claimant's attorney moved to withdraw as counsel, and the motion was granted. Subsequently, the claimant's attorney was reinstated and the parties began extensive settlement negotiations. The claimant submitted a protocol for clinical testing, and the government recommended changes in the proposed protocol. The court ordered the action transferred to the suspense docket and, after an additional delay, the court ordered the action statiscally closed.

Ultimately, settlement negotiations were abandoned; and, after a number of years, the action was dismissed with prejudice, pursuant to stipulation of the parties. (F.D.C. No. 61815; S. No. 78-130-072 et al.; S.J. No. 12)

PRODUCT: Examination gloves, latex, at Orange, C. Dist. Calif.; Civil No. 88-05045 CBM (Bx).

CHARGED 8-18-88: The quality of the article, which was being distributed by Dentastar International, Orange, Calif., to health professionals for medical use, fell below the article's purported quality, since the article contained holes—501(c); the article's labeling was misleading because the labeling failed to reveal that the gloves were grade "B" and not for medical use—502(a); and the article's label lacked the name and place of business of the manufacturer, packer or distributor—502(b).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65522; S. No. 88-446-851 et al.; S.J. No. 13)

CRIMINAL ACTIONS

DEFENDANTS: Chitty & Co., and H. Marshall Thompson, vice president, **Dennis B. Thompson,** treasurer, and **Lawrence R. Ludwig,** warehouse manager, Jacksonville, M. Dist. Fla.; Criminal No. 87-166(S)-Cr-J-HES.

CHARGED 10-22-87 by grand jury: While held for sale after interstate shipment, flour was held under insanitary conditions in a building accessible to rodents and was contaminated with rodent filth—402(a)(3), 402(a)(4); and, when shipped to Charleston, S.C., rice had been held under insanitary conditions—402(a)(4). **DISPOSITION:** The defendants filed a number of motions and sought extensive discovery. Subsequently, the parties entered into a plea agreement in which the parties agreed to plead guilty to two misdemeanor offenses. Guilty plea by corporation—\$20,000 fine. Guilty plea by vice president—\$5,000 fine and imprisonment for 179 days. Guilty plea by treasurer—\$5,000 fine, imprisonment for one year (suspended) and probation for two years with standard conditions and one special condition. Guilty plea by warehouse manager—imposition of sentence suspended and probation for two years with standard terms and the special condition of 120 hours of community service. (F.D.C. No. 64769; S. No. 86-356-824 et al.; S.J. No. 14)

DEFENDANTS: NCWNM Co., Inc., and Willy Ng, president, Dist. Columbia; Criminal No. 88-0350M-01(CR).

CHARGED 6-2-88: While food starch (count 1), chow mein noodles (count 2), and egg roll covers (count 3) were held for sale, those foods were held under insanitary conditions in a building accessible to and infested with rodents and were contaminated by

rodent filth (counts 1, 2 & 3) and animal filth (counts 2 & 3)—402(a)(3), 402(a)(4); and, when shipped to Silver Spring, Md., chow mein noodles (count 4) had been held under insanitary conditions and had been contaminated with rodent and insect filth—402(a)(3), 402(a)(4).

DISPOSITION: The parties entered into a plea agreement. The individual pleaded guilty to count 4 and was placed on probation for two years, was fined \$500, and was ordered to pay a special assessment of \$25. The corporation pleaded guilty, was fined \$1,000, and was ordered to pay a similar assessment. (F.D.C. No. 65016; S. No. 87-440-897; S.J. No. 15)

INJUNCTION ACTIONS

DEFENDANT: Robert R. Blease, D.V.M., t/a Vet Med Co., Stewartsville/New Village, Dist. N.J.; Civil Nos. 81-2383 & 87-2076.

CHARGED 7-27-81 in the initial complaint for injunction: That the defendant, at his Stewartsville facility, compounded and/or manufactured, and distributed to veal farmers in Pennsylvania, New York, Indiana, Virginia, and other states a number of veterinary drugs, such as "CDC Plus" (chloramphenicol, oxytetracycline, dexamethasone), "CDC Follow-Up" (chloramphenicol, oxytetracycline), "SKS Plus" (penicillin G procaine, dihydrostreptomycin sulfate, tylosin, dexamethasone), and "SKS Follow-Up" (penicillin G procaine, dihydrostreptomycin sulfate, tylosin); that such drugs were new animal drugs lacking an effective approved New Animal Drug Application for their uses or intended uses—501(a)(5); that the defendant was not licensed to practice veterinary medicine in any of the above-named states; that he often distributed such drugs in such states without establishing a *bona fide* veterinarian-client relationship; that he also instructed farmers in methods of injecting drugs in veal calves so as to escape detection by U.S. Department of Agriculture inspectors when the calves were slaughtered; that veal containing such undetected drug residues might be harmful to the consumer, and that the new animal drugs causing such residues were in violation of the law because there was no approved New Animal Drug Application with respect to such intended use—501(a)(5); and that the defendant was aware that FDA considered his actions to be in violation of the law.

DISPOSITION of Initial Complaint: A consent decree of permanent injunction enjoined the complained-of violations with respect to "CDC Plus," "CDC Follow-Up," "SKS Plus," "SKS Follow-Up," and any similar new animal drugs. The decree also enjoined the administration, prescription, recommending, or suggesting of unapproved uses of drugs in food-producing animals in such a way as to cause the occurrence of illegal residues of drugs or their byproducts.

CHARGED 5-27-87 in a second complaint for injunction: That the defendant, at his Stewartsville and New Village facilities, compounded and/or manufactured, and distributed to veal farmers outside of New Jersey a number of veterinary drugs, such as "A&S with furazolidone" (chlortetracycline, or tetracycline, sulfamethazine, and furazolidone), "A&S with neomycin" (chlortetracycline or tetracycline, sulfamethazine, and neomycin), and "ALS 500" (lincomycin, spectinomycin, and amino acids); that he also distributed to veal farmers outside of New Jersey veterinary

drugs such as chloramphenicol capsules and oral solutions, phenylbutazone tablets, dexamethasone injection, gentamicin sulfate injection, amoxicillin trihydrate injection, and sulfamethoxazole/trimethoprim tablets; that such drugs (except amoxicillin trihydrate) are new animal drugs, and no approval of a New Animal Drug Application was in effect with respect to the uses or intended uses of such drugs—501(a)(5); that the labeling of such drugs (except for the sulfamethoxazole/trimethoprim tablets) lacked adequate directions for use and the drugs were not exempt because the drugs were prescription veterinary drugs and the defendant was dispensing such drugs outside the course of his professional practice and veterinarian-client-patient relationship—502(f)(1); that FDA had advised the defendant that he had not established a record of compliance with the earlier injunction, and had sent him a copy of the criteria of the American Veterinary Medical Association for a valid veterinarian-client-patient relationship, but he continued to violate the law.

DISPOSITION of the Second Action: The government moved for a preliminary injunction. The defendant argued as follows: first, that the drugs were not “new animal drugs” because they were not manufactured and sold at large; second, that the Federal Food, Drug, and Cosmetic Act was not intended to regulate licensed veterinarians practicing their profession; third, that he did not run a mail-order house, as alleged, but, rather, that he maintained a professional client-patient relationship with all the farmers; and, finally, that all drugs used by veal calves must be considered adulterated by FDA since none had been labeled as FDA-approved for use in veal calves. The court found that the drugs were new drugs, that the defendant generally did not visit the farmers, but he distributed drugs based on telephone discussions and did not examine the animals; that he was a long distance from the veal farmers and was unable to provide “readily available . . . follow-up” treatment; and that, accordingly, the farmers, public and animals were not protected against potential harm from improper use or sale of such new animal drugs.” The court also found that the defendant’s arguments that the 10th Amendment and the FDC Act prohibited FDA from regulating a licensed veterinarian’s practice were arguments lacking in merit. The court concluded that great deference should be given to FDA in interpreting the FDC Act, that a potential danger to public health existed, that the court had the power to enjoin present and future violations of the FDC Act solely on the basis that such violations had been established, and that the government’s motion for a preliminary injunction was granted.

The government moved for summary judgment as to a permanent injunction. The defendant renewed a number of his earlier arguments and also asserted that no veterinarian had ever succeeded in processing a New Animal Drug Application. The court found for the government and ordered the issuance of a permanent injunction.

When the government submitted a form of order for the permanent injunction, the defendant objected, by way of moving to have the court reconsider its opinion and to issue a declaratory judgment that 21 U.S.C. 360b(a) did not apply to veterinarians. However, since the defendant failed to provide any new evidence or arguments that militated in favor of reopening the matter, the court denied the defendant’s motion and entered an order of

permanent injunction.

APPEAL: The defendant appealed the grant of summary judgment to the government. After considering the contentions raised by the defendant, the Court of Appeals affirmed the District Court’s judgment, essentially for the reasons given in the District Court’s opinion. The defendant petitioned the Court of Appeals for a rehearing, noting that the Court of Appeals’ order assumed that the law applied by the District Court was correct and that the Court of Appeals had not given a formal written opinion. The defendant claimed that for FDA to hold veterinarians to the same pre-clearance authority established for commercial drug companies and manufacturers was a burdensome requirement, impossible to meet, not the intent of Congress, and unconstitutional. He also asserted that the court had recently been hearing cases dealing with extra label use and interpreting the law differently. The petition for rehearing was denied by the Court of Appeals. (Inj. No. 912; S.J. No. 16)

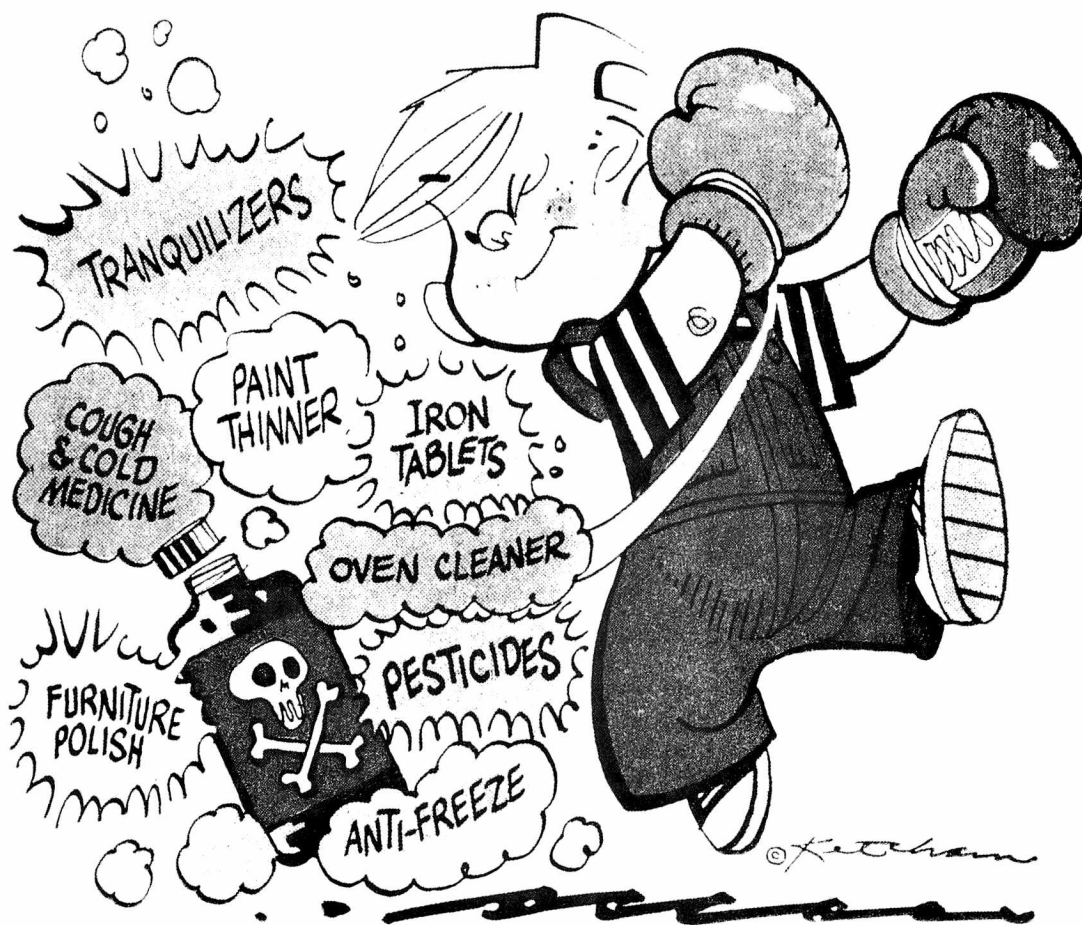
DEFENDANTS: **Humco Laboratory, Inc.,** and **William Pearson Walsh**, president, and **Larry Gene Copeland**, general manager, Texarkana, E. Dist. Texas; Civil No. TX-88-117-CA.

CHARGED 6-30-88 in a complaint for injunction: That the defendants manufactured, processed, packed, labeled, stored, distributed in interstate commerce, and held after interstate shipment of one or more components various drugs (including ipecac syrup U.S.P., iodides tincture, and isopropyl alcohol); that the circumstances used by the defendants in the manufacture, processing, packing, and holding of their drugs failed to conform with current good manufacturing practice; that the defendants had mislabeled iodides tincture as ipecac syrup and had mislabeled eucalyptus oil as ipecac syrup; that FDA inspection of the defendants’ plant revealed serious deviations from current good manufacturing practice; and that the defendants were aware that they had distributed misbranded products and had failed to adhere to current good manufacturing practice and, most particularly, practices designed to ensure adequate and proper labeling and packaging—501(a)(2)(B), 502(a).

DISPOSITION: A consent decree of permanent injunction enjoined the complained-of violations and enjoined interstate drug operations (except for drugs previously tested and released by the Texas Department of Health) unless and until a number of specified conditions had been met, including the establishment of manufacturing controls in conformity with current good manufacturing practice regulations and the certification by an expert that specified requirements had been met. Under the terms of the consent decree, so long as the Lumpkin Drug Co. did not assume any of the duties of Humco Laboratory, Inc., the injunction did not apply to the defendant firm’s president in his capacity as chairman of the board of Walsh-Lumpkin Drug Co. In addition, the defendant’s in-process and finished (labeled) stocks of orally administered and prescription drugs were to be tested for identity, their batch records reviewed, and all incorrectly labeled drugs were to be brought into compliance or destroyed. Subsequently, FDA inspection found the firm’s operations to be in compliance. (Inj. No. 1197; S. No. 88-455-158 et al.; S.J. No. 17)

Dennis the Menace

TAKES A POKE AT POISON



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