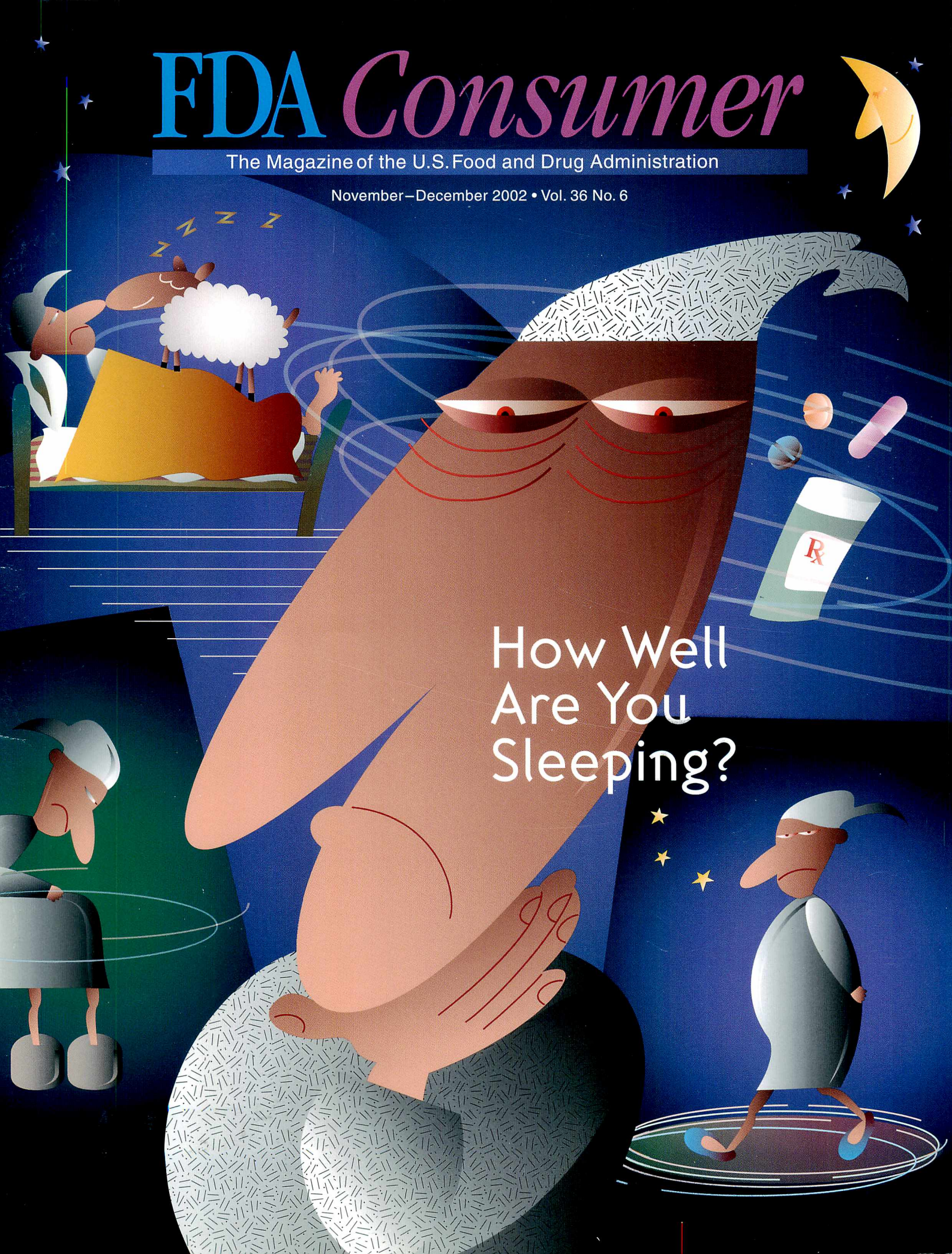


FDA *Consumer*

The Magazine of the U.S. Food and Drug Administration

November–December 2002 • Vol. 36 No. 6

How Well
Are You
Sleeping?





Tommy G. Thompson
Secretary of Health and Human Services

Lester Crawford, D.V.M., Ph.D.
Deputy Commissioner
Food and Drug Administration

Lawrence Bachorik, Ph.D.
Associate Commissioner for Public Affairs

Ray Formanek Jr. / Editor

Michael Ermarth / Art Director

Jan Elicker, Renée Gordon
Copy Editors

Linda Bren, Carol Lewis, Michelle Meadows
Staff Writers

Lisa Latimer / Production Assistant

Cover Illustration: Jack Lefkowitz

FDA on the Internet: www.fda.gov

FDA Consumer (ISSN 0362-1332) is published bimonthly by the Food and Drug Administration (HFI-40), 5600 Fishers Lane, Rockville, MD 20857, U.S. Public Health Service, Department of Health and Human Services.

Editorial Matters

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

Subscriptions

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

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

To continue to receive *FDA Consumer* without interruption, please return your renewal notice promptly. If your subscription has expired, send your mailing label with \$13.50 (\$16.88 foreign), using the form on the back cover, to Superintendent of Documents, Government Printing Office, Washington, DC 20402, and your service will be reinstated. Periodicals postage paid at Rockville, MD, and additional mailing offices. POSTMASTER: Send address changes to *FDA Consumer*, 5600 Fishers Lane, Room 15A-29, Rockville, MD 20857.

U.S. Department of Health And Human Services

FDA Consumer

The Magazine of the U.S. Food and Drug Administration

November–December 2002 • Vol. 36 No. 6

9 Oxygen Bars: Is a Breath of Fresh Air Worth It?

Dispensing oxygen without a prescription is against federal law, and oxygen bars may subject customers to unnecessary risk.

12 The 'Poison Squad' and the Advent of Food and Drug Regulation

One hundred years ago, government volunteers dined on carefully prepared foods laced with potentially poisonous preservatives in the interest of science.

Cover Story

16 How Well Are You Sleeping?

Can't keep your eyes open? Not getting enough quality sleep can have serious consequences. Here are tips for spotting and solving sleep problems.

24 Think It Through: A Guide to Managing the Benefits and Risks of Medicines

Medicines offer benefits, but there are risks, too. Here's how to make wise decisions about the drugs you take.

26 Sunning for Science The Effects of Common Substances on Sun-Exposed Skin

What happens to a person's skin when the chemicals in some moisturizing and beauty products are exposed to sunlight? The FDA wants to find out.

30 Plastics and the Microwave

From plastic wrap to popcorn bags, the FDA reviews substances used to make plastics for food use.

31 Public Affairs Specialists: On the FDA's Front Line

This year marks the 50th anniversary of this elite team of FDA professionals who deliver health messages to consumers.

Departments

2 Observations

2 Updates

6 Research Notebook

37 fda.gov

38 Investigators' Reports

40 The Last Word



◀ Inside Front Cover Photo:

Harvey W. Wiley, M.D., considered a zealot by some and a hero by others, served as head of the Department of Agriculture's Bureau of Chemistry (now the FDA) from 1883 until 1912. See page 12 for more on the start of food safety regulation.

OBSERVATIONS



True or False?

- *Sleep is a time when your body and brain shut down.*
- *If you regularly doze off unintentionally during the day, you may need more than just a good night's sleep.*
- *People need less sleep as they grow older.*

The answer to all of the above is False, according to the National Center on Sleep Disorders Research (NCSDR), part of the Department of Health and Human Services' National Institutes of Health.

Everyone feels sleepy at times. The amount of sleep needed each night varies from person to person. When allowed to sleep without restriction, the average time people sleep is just over eight hours. Some people need more, some less, according to the NCSDR.

About 40 million Americans experience sleep disorders, which include in-

somnia, sleep apnea, narcolepsy, and restless leg syndrome. Check out this issue's cover story, "How Well Are You Sleeping?" (page 16) for the latest on treating these disorders.

The early 1950s were a time when families huddled around the television to watch shows starring their favorite TV families—Ozzie and Harriet Nelson, Ricky and Lucy Ricardo, and Jim and Margaret Anderson. Hula-Hoops, transistor radios, Elvis, and drive-in movies were all the rage. Women, on TV at least, wore dresses, pearls and high heels around the house, and cooked dinner each night for their seemingly all-knowing husbands and well-behaved kids.

It also was a time of budding consumer awareness. An argument over whether soy flour was superior to wheat flour prompted the hiring 50 years ago of the FDA's first public affairs specialists. Today's PASS, like their predecessors, serve as key links between consumers and the agency whose mission it is to protect them. For more on the FDA's consumer education efforts, check out "Public Affairs Specialists: On the FDA's Front Line" beginning on page 31.

According to a 2000 report done by the United Nations, Americans spend

\$8 billion annually on cosmetics. Much of that is spent on lotions, creams, moisturizers and other products designed to help fight the effects of sunlight and aging on skin. Read about the FDA's efforts to determine if long-term sunlight exposure can affect the safety of chemicals registered for use in cosmetics and other products in our feature story titled "Sunning for Science: The Effects of Common Substances on Sun-Exposed Skin" (page 26).

Volunteers dubbed the "Poison Squad" played a key role in the development of food safety standards at the turn of the last century. Read about their leader, Harvey W. Wiley, M.D., considered by many to be the founding father of the FDA, and the special meals eaten by the volunteers in our article beginning on page 12.

And, just in time for holiday leftovers, we take a look at plastic wrap and its use in microwave ovens. We also ask FDA experts about one of the latest fads spreading across America—oxygen bars—and provide tips for making wise choices when it comes to medicines.

Happy Holidays from the staff of *FDA Consumer*.

Ray Formanek Jr.
Editor

UPDATES

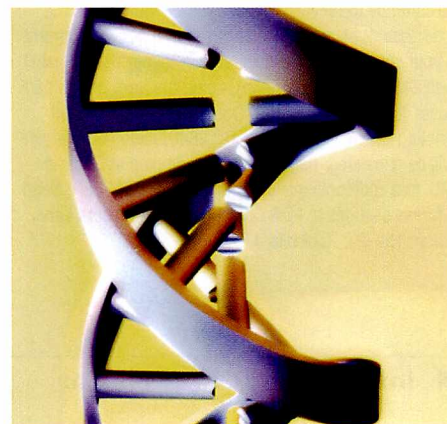
FDA Consolidates Review Process for New Pharmaceuticals

The FDA has announced its decision to consolidate responsibility for reviewing most new pharmaceutical products into the FDA's Center for Drug Evaluation and Research (CDER). Previously, this review had been performed in part by the FDA's Center for Biologics Evaluation and Research (CBER) and in part by CDER.

The change in review responsibilities will allow CBER to concentrate its scientific expertise in the crucial areas of

vaccines and blood safety—both top priority items critical to national defense and public health. In addition, CBER will be able to concentrate its expertise on such cutting-edge biological scientific areas as gene therapy, tissue transplantation, and new cellular therapies.

Companies should continue to work with CBER and CDER as they have in the past until the FDA issues further guidance. Deputy Commissioner Lester M. Crawford, D.V.M., Ph.D., expects to have an action plan and timeline for the consolidation in January.



PhotoDisc

CDC Helps in Battle Against West Nile Virus

The Centers for Disease Control and Prevention (CDC) awarded more than \$6.3 million in September to 25 states, three cities, and the District of Columbia to help combat West Nile virus. This brings the total CDC funding to states and cities for West Nile virus so far this year to approximately \$35 million.



New South Wales Health Dept.

In addition to funding, the federal government continues to provide technical and scientific support to states and communities in need of assistance. The CDC has deployed epidemiologists and clinicians to

Louisiana, Mississippi, Arkansas, and Chicago. "We are working closely with state and local health departments to bolster their efforts to protect residents from West Nile virus," says Health and Human Services Secretary Tommy G. Thompson.

Between January and early October 2002, more than 2800 human cases of West Nile virus had been reported in 35 states and the District of Columbia. Nationwide, at least 150 human deaths attributed to West Nile virus had been recorded during that period. The virus is spread by the bite of an infected mosquito, and can infect people, horses, many types of birds, and some other animals.

The CDC recommends that people take the following steps to help prevent

West Nile virus infection:

- Eliminate sources of standing water on their property—including potted outdoor plants that are watered regularly
- Use an insect repellent containing DEET
- Cover themselves with lightweight clothing as much as possible whenever they are outside.

Questions about West Nile virus can be directed to the CDC's toll-free public hotlines:

English: 1-888-246-2675

Spanish: 1-888-246-2857

Hearing-impaired (TTY):

1-866-874-2646

Or e-mail to cdcresponse@ashastd.org.

Contaminated Honey Imports

The U.S. Customs Service and the FDA are investigating shipments of honey from China that may be contaminated with low levels of chloramphenicol, a potentially harmful antibiotic and unapproved food additive.

The agencies announced in August that inspectors discovered contaminated honey during an investigation into a widespread scheme to evade payment of U.S. anti-dumping duties on bulk imports of Chinese honey.



PhotoDisc

Dumping of a product occurs when merchandise manufactured outside of the United States is sold in the United States at a price below the cost of production or below the price sold in the foreign home market. Foreign manufacturers or importers sometimes dump products on the U.S. market to gain

market share, because of political or social concerns, or to maximize profits and minimize losses in production.

In September 2000, several U.S. honey producers filed an unfair trade case alleging dumping of honey imports from China. In May 2001, the U.S. Commerce Department issued a notice that required customs to collect anti-dumping duties on imports of honey from certain Chinese companies.

The U.S. Customs attaché in Bangkok, Thailand, then received information that certain honey exports from China were allegedly being illegally transshipped through Thailand en route to the United States. The purpose of the alleged transshipment scheme was to circumvent payment of anti-dumping duties on Chinese honey imports in the United States.

As of September, the investigation had resulted in the detention of more than 50 containers of bulk Chinese honey at U.S. ports. Some of the bulk honey in these containers has tested positive for chloramphenicol, which is mostly used only to treat life-threatening infections in humans when other

alternatives are not available. Use of the antibiotic is limited because it is associated with a very rare, but potentially life-threatening, side effect called idiosyncratic aplastic anemia. For the very small number of people susceptible to this side effect, exposure to chloramphenicol could be serious.

To protect the public from unnecessary exposure to potentially harmful substances, food and animal products containing chloramphenicol are illegal in the United States. The U.S. Customs Service is stopping all suspect bulk honey imports to this country for the FDA to determine whether they contain chloramphenicol. Any shipments containing chloramphenicol will be detained.

At this time, the FDA is unaware of contaminated honey being on retail shelves, but continues to investigate this matter. No illnesses have been reported in association with the imported honey so far.

FDA Initiative Will Enhance Drug Good Manufacturing Practices

In another effort to ensure that medications will be of the highest quality, the FDA has announced a new initiative that will enhance the regulation of drug manufacturing and product quality.

The initiative is designed to improve public health promotion and protection by focusing on three major goals that will augment the agency's drug product quality assurance programs across the board.

More than 40 years ago, Congress directed the FDA to require that all drugs be produced according to a good manufacturing practice (GMP) program. The requirement was in response to significant concerns about below-standard drug manufacturing practices at the time, and it prompted the adoption of modern quality assurance and control principles for drug manufacturing.

The goals of the FDA's new initiative will focus on the GMP requirements and will cover human and veterinary drugs and human biological drug products, such as vaccines.

The first goal will be to focus on po-

tential risks to public health by providing additional regulatory attention and agency resources for those aspects of manufacturing that pose the greatest potential risk.

The second goal will be to help ensure that the FDA's essential work in establishing and enforcing drug product quality standards does not impede innovation and the introduction of new manufacturing technologies in the drug industry.

The third goal will be to make the FDA's approach to assuring production quality and safety among its regulatory centers and field operations more consistent and predictable.

The new initiative will be driven by the latest science and technology and will strengthen the public health protection achieved by the FDA's regulation of drug manufacturing, according to FDA Deputy Commissioner Lester M. Crawford, D.V.M., Ph.D.

New Treatment Approved for Chronic Hepatitis B

The FDA has approved Hepsera (adefovir dipivoxil) tablets for the treatment of chronic hepatitis B in adults.

Hepsera slows the progression of chronic hepatitis B by blocking an enzyme needed for the virus to reproduce within the body. It is approved to treat adults who have evidence of active replication of the hepatitis B virus and either elevations in the liver enzymes alanine aminotransferase (ALT) or aspartate aminotransferase (AST), or evidence of active disease.

Chronic hepatitis B is a serious disease caused by a virus that attacks the liver. The hepatitis B virus (HBV) can cause lifelong infection, cirrhosis (scarring) of the liver, liver cancer, liver failure, and death. According to the Centers for Disease Control and Prevention, more than 1 million Americans are chronically HBV infected.

The FDA based its approval of Hepsera on the results of two randomized, double-blind, placebo-controlled studies. At week 48 of the studies, 53 percent of patients receiving Hepsera in one study and 64 percent of patients in the other study showed significant improvement in the liver inflammation caused by HBV, compared to 25 percent and 35 percent, respectively, of patients receiving a placebo.

In addition, people receiving Hepsera had less scarring of the liver compared to the placebo groups. Moreover, Hepsera has been shown to be effective in treating people with clinical evidence of HBV that is resistant to another approved antiviral therapy called lamivudine.

Major side effects associated with the use of Hepsera include kidney toxicity and severe, acute worsening of hepatitis B after discontinuation of Hepsera. People who have discontinued other approved products for the treatment of chronic hepatitis B also have experienced severe, acute worsening of hepatitis. This adverse event occurred in up to 25 percent of clinical trial participants after discontinuation of Hepsera.

Kidney toxicity was reported in people who are at risk of or who have underlying kidney dysfunction. In addition, there is a theoretical concern

We're eager to hear what you like and what you don't like. We also want to know the subjects you'd like to see covered.

To contact *FDA Consumer*:

Letters to the Editor should be 300 words or less. If you would like your comments to be considered for publication, please include your name, address, and telephone number during business hours. The editor reserves the right to edit letters for space and appropriateness. E-mail your letters to FDAC-letters@oc.fda.gov or send to the address below.

Inquiries about the magazine: E-mail other questions to FDAC-queries@oc.fda.gov or write to the address below.

General FDA questions: E-mail webmail@oc.fda.gov.

Mailing address: Food and Drug Administration (HFI-40), 5600 Fishers Lane, Rockville, MD 20857

associated with Hepsera that resistance to HIV drugs could emerge in people with chronic hepatitis B with unrecognized or untreated HIV infection.

Gilead Sciences Inc. of Foster City, Calif., is the sponsor of the approved new drug application for Hepsera.

FDA and FSIS Issue Listeria Health Advisory

The FDA and the Food Safety Inspection Service (FSIS) are monitoring the food supply for possible increases in *Listeria monocytogenes* contamination, prompted by a recent increase in cases in the northeastern United States. Eating contaminated food products can cause miscarriages and stillbirths among pregnant women and can lead to serious and sometimes fatal infections (listeriosis) in newborns, frail or older people, and others with weakened immune systems. Healthy individuals may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain, and diarrhea.



PhotoDisc

The Centers for Disease Control and Prevention (CDC) announced on Oct. 4 that analysis had indicated the leading suspect food in this outbreak is sliced turkey deli meat. Federal, state, and local health officials were continuing to investigate to determine the origin of the product involved. The FDA and the FSIS are issuing this advisory as they continue to work closely with the CDC and the states. Because of the number of cases and serious illness

caused by *Listeria monocytogenes*, the agencies are providing the following information and advice to consumers.

People living in the affected region may reduce their risk of infection by not eating sliced turkey deli meats or by thoroughly heating them. In addition, people at risk for listeriosis and their family members or individuals preparing food for them should take the following precautions:

- Do not eat hot dogs and luncheon meats, unless they are reheated until steaming hot.
- Do not eat soft cheeses such as feta, brie and Camembert cheeses, blue-veined cheeses, and Mexican-style cheeses such as "queso blanco fresco."
- Do not eat refrigerated patés or meat spreads. Canned or shelf-stable patés and meat spreads may be eaten.
- Do not eat refrigerated smoked seafood, unless it is contained in a cooked dish, such as a casserole. Refrigerated smoked seafood, such as salmon, trout, whitefish, cod, tuna or mackerel, is most often labeled as "Nova-style," "lox," "kippered," "smoked," or "jerky." The fish is found in the refrigerated section or sold at deli counters of grocery stores and delicatessens. Canned or shelf-stable smoked seafood may be eaten.
- Do not drink raw (unpasteurized) milk or eat foods that contain unpasteurized milk.

Consumers experiencing the symptoms described above or concerned about exposure should contact their physicians immediately.

Recall of Gonorrhea Test Kits

Abbott Laboratories Inc., of Abbott Park, Ill., has begun a worldwide recall of 32 lots of laboratory kits used to diagnose gonorrhea. The test kits, which were distributed to hospitals and labs from Jan. 11, 2002, through June 24, 2002, have been shown to be unreliable because they may give false negative results.

Gonorrhea is a serious and highly contagious sexually transmitted disease. Untreated gonorrhea in

women can cause pelvic inflammatory disease that can lead to sterility. In pregnant women, infection can cause abortion, premature delivery, or infection in the baby. Untreated gonorrhea in men can cause an infection of the urethra that makes urination painful and difficult. In both sexes, infection can spread through the bloodstream and infect the joints, skin, bones, tendons and other parts of the body.

People who have had a negative gonorrhea test since Jan. 11 may wish to ask their physicians if they should be retested. Abbott notified labs about the recall and asked them to discontinue use of all test kits and to destroy any remaining product. Abbott also advised labs to contact health-care providers served by their facilities to determine if patients need to be retested. The company will reimburse expenses associated with repeat testing.

Abbott voluntarily recalled the gonorrhea test kits after learning through routine internal testing that certain lots did not meet specifications and could report positive results as negative.

The 16 lots that failed to meet specification when tested by Abbott are: 84073M400; 84075M400; 84142M300; 84146M300; 85487M200; 87007M400; 87103M400; 87243M100; 87377M200; 87899M200; 87905M200; 88097M300; 88105M300; 88107M300; 88439M200; and 88439M201. Patients who received a negative test result with test kits from these lots may need to be retested. About 750,000 test kits are affected.

Consumers or labs with questions can contact Abbott Laboratories at 1-800-527-1869. Physicians who have questions on this recall should contact Abbott at 1-866-233-0471.

GlucoWatch Approved for Children with Diabetes

The FDA recently approved a wrist-watch-like glucose monitoring device for use by children and adolescents with diabetes. The device, which was approved for adult use in March 2001, provides information that can be used to detect trends and track patterns in blood glucose levels.

The GlucoWatch G2 Biographer, manufactured by Cygnus Inc. of Redwood City, Calif., extracts fluid through the skin and then measures the glucose in the fluid. Once the device has been warmed up and calibrated through the use of a finger-stick blood glucose test, it is capable of providing up to six painless glucose measurements per hour for 13 hours.

Because results with GlucoWatch can differ significantly and these variations are unpredictable, individual GlucoWatch readings should never be used to make changes in insulin dose. Instead, GlucoWatch results should be interpreted with several sequential readings over time and then confirmed with a finger-stick test.

Diabetes is a chronic disease that affects the body's ability to produce or respond to insulin. This can cause wide

fluctuations in blood glucose levels, from extremely high to extremely low. More than 150,000 people under the age of 20 in the United States have diabetes, according to the Centers for Disease Control and Prevention.

FDA Expert Named First 'Americas Fellow'

The FDA's Andreas Keller, Ph.D., will serve as the United States' first "Americas Fellow" under a new exchange program announced by President Bush last year. This program sponsors exchanges of outstanding government officials from throughout the Western Hemisphere's democracies.

"HHS is proud to be among the first departments to take part in this important program to strengthen cooperation and understanding in the Americas," says Health and Human Services Secretary Tommy G. Thompson.

"We believe this program provides an excellent opportunity to advance the public health interest of all of the countries throughout our hemisphere," adds FDA Deputy Commissioner Lester M. Crawford, D.V.M., Ph.D.

Dr. Keller will use his expertise in microbiology to work with the Mexican government to improve agricultural

and manufacturing practices, as well as to assist with imported produce safety initiatives—programs designed to benefit food safety on both sides of the United States-Mexico border. He currently is a consumer safety officer in the FDA's Center for Food Safety and Applied Nutrition.

New Light Therapy for Acne

The FDA has approved a high-intensity light to help clear up a specific type of acne.

ClearLight, which works only on inflammatory acne and not severe or mild cases, theoretically kills the bacteria inside pimples. The blue light is a different wavelength than skin-damaging ultraviolet light, and is thought to cause no side effects.

According to studies done, if the acne does not appear to be better after two or three 15-minute sessions, there is only a 10 percent chance it will respond to the treatment at all.

Currently, other options for acne patients include topical ointments, antibiotics, and drugs such as Accutane.

ClearLight is made by Lumenis Inc. in Israel. ■

RESEARCH NOTEBOOK

Study: Improvements in Safe Food Handling by Consumers

Consumers continue to improve their food safety practices, according to the FDA and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS). The results of a nationwide telephone survey of 4,500 adults indicated that the dramatic improvement in food handling practices between 1993 and 1998 continued between 1998 and 2001.

Under the "clean, separate, cook and chill" safety messages stressed by the FDA and the FSIS since 1997, most consumers reported using improved food handling practices that reduce cross-

contamination after contact with raw fish, meat or chicken. The number of consumers eating pink hamburger, steak tartare (ground sirloin or tenderloin prepared uncooked), and raw eggs, however, stayed relatively the same.

But findings from another agriculture department study that measured changes in consumer knowledge and safe food handling practices show that, although consumers say they are more knowledgeable about food safety and have improved their practices, some are still using unsafe practices.

For example, while more people re-

portedly are purchasing food thermometers and their usage has doubled, the percentage of consumers who use food thermometers remains low, according to the study. The research included not only the survey data, but also observational studies of consumers preparing food as well as informal discussions with small groups of consumers.

The 2001 Food Safety Survey and related documents can be found at www.cfsan.fda.gov (click on National Food Safety Programs).

Mayo Clinic Study: Optimists Report Higher Quality of Life



PhotoDisc

A Mayo Clinic study indicates that optimists report a higher level of physical and mental functioning than their pessimist counterparts.

"How you perceive what goes on around you and how you interpret it may have an impact on your longevity, and it could affect the quality of your later years," says Toshihiko Maruta, M.D., of the Mayo Clinic Department of Psychiatry and Psychology in Rochester, Minn., and the principal author of the study.

Patients originally assessed in the

1960s with a personality test completed a follow-up self-assessment of their health status 30 years later. In the health survey, pessimists reported poorer physical and mental functioning. The results come two years after another Mayo Clinic study of the data found that optimists live longer than pessimists do.

Researchers looked at the health survey results reported by 447 patients during the 1990s. This group had originally completed the Minnesota Multiphasic Personality Inventory (MMPI) between 1962 and 1965. The MMPI is an assessment that helps researchers classify personality traits.

Using the MMPI scale of optimism and pessimism, Maruta and his colleagues classified 101 as optimistic, 272 as mixed, and 74 as pessimistic.

The researchers found that pessimists scored below optimists on quality-of-life assessments. Participants also scored lower than the national average on five of the eight scales that were measured: physical functioning, physical role limitations, bodily pain, general health perception, vitality, social functioning, emotional role limitations, and mental health.

"Our study provides documentation for beliefs commonly held by patients and health-care practitioners about the importance of optimistic and pessimistic attitudes," Maruta says. "However, questions remain about the practical significance of these findings for health-care practitioners."

The study appears in the August 2002 issue of Mayo Clinic Proceedings.

'Virtual Stomach' Reveals Pill's Path

Pennsylvania State University mechanical engineers, working with medical and pharmaceutical researchers, have developed the first computer-generated "virtual stomach" to follow the path of extended-release tablets that are designed to remain in the stomach for hours while slowly releasing medicine.

According to the researchers, many medications are prepared in extended-release form; however, the details of exactly how the pills break down and release medicine in the stomach are largely unknown. The new "virtual stomach" has shown that tablet motion and mixing are highly sensitive to the pill's location in the stomach and to the coordination between the stomach's contractions and the opening and closing of the valve leading to the intestines.

"We can simulate the tablet breaking down with our new approach, watch the slow release of medication happen in a computer movie, and analyze the process," says James G. Brasseur, Ph.D., Penn State professor of mechanical

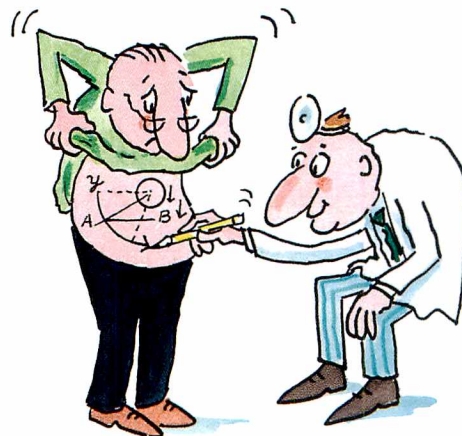
engineering and leader of the project. "Computer simulation allows us to 'control' the stomach and therefore provides more detail than you could get with human or even animal experiments."

In fact, Brasseur says, computer simulation may be the only way to observe the stomach's mechanical processes in such fine detail.

The researchers expect the new information provided by the virtual stomach to aid in the design and delivery of new extended-release tablet formulations, to shed light on diseases involving stomach motility, and to help explain basic gastric function.

The virtual stomach combines a sophisticated computer program with a realistic stomach geometry model derived from magnetic resonance imaging (MRI) movies of the human stomach. The resulting computer simulations are presented as colorful, cartoon-like movies of the human stomach showing pressures, the motion

of gastric fluid, and the path and breakdown of tablets. These computer simulations revealed that the stomach has three very different zones: one very gentle, one moderately stressful to tablets and conducive to mixing, and a third highly active zone where a tablet can break down rapidly and mixing is accelerated. The researchers also found that buoyancy affects longer-time mixing and drug release.



Artville

Federal Trade Commission Weighs In on Losing Weight

You've seen the ads in the back of magazines. Endorsements of miracle weight-loss plans, complete with before-and-after pictures and breathless testimonials from people who went from huge to petite in a few short weeks. A new report from the Federal Trade Commission (FTC) reveals how often those claims are just too good to be true.

Released by the FTC in September, "Report on Weight-Loss Advertising: An Analysis of Current Trends" concludes that false or misleading claims are widespread in ads for weight-loss products, and appear to have increased over the last decade.

Many marketers, the report states, use false claims, misleading consumer testimonials, and deceptive before-and-after photos to market their products. According to the report, nearly 40 percent of the ads in the study, including ads that appeared in mainstream, national publications, made at least one representation that is almost certainly false, and 55 percent of the ads made at least one representation that is very likely to be false. Often ads promised weight-loss results beyond what is possible. Nearly half of the ads claimed that the users could lose weight without dieting and exercise. In one ad, for example, the headline proclaimed: "LOSE UP TO TWO POUNDS DAILY WITHOUT DIET OR EXERCISE!" Other ads cited rapid, prolonged weight loss, such as claims that consumers can lose eight to 10 pounds per week over an extended period of time.

"We have known for some time now that there is a serious problem with weight-loss product advertising. This report demonstrates the extent of that problem," says FTC Chairman Timothy J. Muris.

The report, which examined 300 promotions that appeared in all major forms of media between February



PhotoDisc

2001 and May 2001, was prepared with the assistance of the Partnership for Healthy Weight Management (PHWM). The partnership is a coalition of representatives from science, academia, the health-care professions, government, and others whose mission is to promote sound guidance on achieving and maintaining a healthy weight.

"There is no such thing as a miracle pill for weight loss," Surgeon General Richard Carmona says. "The surest and safest way to weight loss and healthier living is by combining healthful eating and exercising."

According to the report, a comparison of current ads to those that ran in 1992 suggests that there has been a dramatic increase in the number of weight-loss products and the amount of deceptive weight-loss advertising during the last decade. The report noted two major trends: 1) a shift away from

weight-loss products advertised as "low-calorie meal replacements" in 1992 to pills and other products that commonly claimed to work without dieting or exercise in 2001; and 2) that although ads from both 1992 and 2001 contain deceptive or false claims, the recent ads were much more likely to make specific misleading performance promises.

Since 1990, the FTC has filed 93 cases challenging false and misleading weight-loss claims involving over-the-counter drugs, dietary supplements, commercial weight-loss centers, weight-loss devices, and exercise equipment. Despite the unprecedented level of FTC enforcement over the last decade, misleading and deceptive ads continue to saturate the market.

According to health and nutrition experts, many of the weight-loss products and programs most heavily advertised are either unproven or unsafe, and they frustrate efforts to promote healthy weight-loss efforts by promising unrealistic results.

"As health professionals, we are concerned about the epidemic of obesity and are equally concerned about false and misleading claims in advertising of weight-loss products and services," says George L. Blackburn, M.D., Ph.D., chair in nutrition medicine at Harvard Medical School and a member of the PHWM. "The use of deceptive, false, or misleading claims in weight-loss advertising is rampant and potentially dangerous."

The weight-loss report, as well as resources for consumers, businesses and others, is available at www.ftc.gov/dietfit. For more on weight loss, see "Losing Weight: More Than Counting Calories," January–February 2002 *FDA Consumer*. ■



Corbis

Oxygen Bars:

Is a Breath of Fresh Air Worth It?

By Linda Bren

Peppermint, bayberry, cranberry, wintergreen. Breath mints? Scented candles? No—they're "flavors" of oxygen offered at your local oxygen bar. Since oxygen bars were introduced in the United States in the late 1990s, the trend has caught on, and customers are bellying up to bars around the country to sniff oxygen through a plastic hose (cannula) inserted into their nostrils. And many patrons opt for the "flavored" oxygen produced by pumping oxygen through an aroma en route to the nose.

The oxygen experience in a bar can last from a few minutes to about 20 minutes, depending on customers' preferences and the size of their wallets. The price of about a dollar a minute could leave you gasping for air, but frequent inhalers may get a discount.

Most oxygen bar proprietors are careful not to make medical claims for their product, and state that their oxygen is not a medical gas—it's made and of-

canister for your 20-minute supply is actually dispensing the prescription drug oxygen to you."

Although oxygen bars that dispense oxygen without a prescription violate FDA regulations, the agency applies regulatory discretion to permit the individual state boards of licensing to enforce the requirements pertaining to the dispensing of oxygen, says Szymanski. Many states choose to allow oxygen bars; others discourage the businesses

But there are no long-term, well-controlled scientific studies that support these claims for oxygen in healthy people. And people with healthy lungs don't need additional oxygen, says Mary Purucker, M.D., Ph.D., a pulmonary specialist in CDER. "We've evolved for millions of years in an atmosphere of about 21 percent oxygen."

The American Lung Association says that inhaling oxygen at oxygen bars is unlikely to have a beneficial physiologi-

Under the Federal Food, Drug, and Cosmetic Act, any type of oxygen used by people for breathing and administered by another person is a prescription drug

ferred strictly for recreational use. But under the Federal Food, Drug, and Cosmetic Act, any type of oxygen used by people for breathing and administered by another person is a prescription drug. "It doesn't matter what they label it," says Melvin Szymanski, a consumer safety officer in the Food and Drug Administration's Center for Drug Evaluation and Research (CDER). "At the other end of the hose is oxygen, and the individual that provides you with the nasal cannula and turns on the

by requiring strict compliance with the law. However, serious health claims made for oxygen, such as curing cancer or AIDS, or helping ease arthritis pain, would be investigated by the FDA, adds Szymanski.

Healthy or Just Hype?

Oxygen fans tout the benefits of oxygen as reducing stress, increasing energy and alertness, lessening the effects of hangovers, headaches, and sinus problems, and generally relaxing the body.

cal effect, but adds "there is no evidence that oxygen at the low flow levels used in bars can be dangerous to a normal person's health."

People with certain medical conditions are another matter. Some need supplemental oxygen, but should not go to oxygen bars, says Purucker. People with some types of heart disease, asthma, congestive heart failure, pulmonary hypertension, and chronic obstructive pulmonary diseases, such as emphysema, need to have their medical

Oxygen and Sports

We've all seen it on TV—a football player runs off the field after a play and dons an oxygen mask. "They don't need it," says Conrad Earnest, Ph.D., director of exercise physiology at the Cooper Institute in Dallas. "It's one of the biggest placebo effects going," he adds. "It's a combative activity, so yes, the players are going to be out of breath, but it's because of massive exertion—not because of lack of oxygen." The exception, says Earnest, might be athletes who play at higher elevations than they are used to, and don't have time to acclimate. "If the New York Giants go to play the Washington Redskins, the benefit of oxygen—if any—would

be so small it wouldn't be measurable. But if they go to play the Denver Broncos—going from sea level to a mile-high altitude—they may be helped by oxygen while recovering from a play."

And products with added oxygen, such as oxygenated water, sports drinks, and skin sprays don't impress Earnest, who refers to their suppliers as putting "sales before science." "If you drink oxygenated water, either the water passes through the gut and has no effect, or the acid in the stomach reacts with it and the only effect of the oxygen is that it will cause you to burp more," he says. ■

—L.B.

The Air Up There

Atmospheric pressure decreases as altitude increases, making it more difficult to breathe. But people living at high altitudes do adapt to their environment without using additional oxygen, says Mary Purucker, M.D., Ph.D., a Food and Drug Administration pulmonary specialist. "The blood becomes more efficient at transporting oxygen to tissues."

Healthy people traveling from lower to higher elevations don't usually need extra oxygen either, says Robert

Mazzeo, Ph.D., an exercise physiologist at the University of Colorado in Boulder. But if people who live at low elevations try to exercise at higher elevations, such as the mile-high city of Boulder, they should be aware that exercise will be more taxing. "Maximum capacity declines as altitude increases," says Mazzeo. "If you're used to running two miles a day, you can still run two miles, but not at the same speed." ■

—L.B.

oxygen regulated carefully to oxygenate their blood properly, says Purucker. "If they inhale too much oxygen, they can stop breathing."

People who have received bleomycin, a chemotherapy used to treat some types of cancer, are in danger if they are exposed to high levels of oxygen for too long, adds Purucker. "People think oxygen is good, but more is not necessarily better."

One of the FDA's biggest concerns about oxygen bars is the use of "flavored" oxygen, says Purucker. The

pathogens may lead to infection.

Other Oxygen Hazards

Although oxygen doesn't burn, it does fuel the combustion process. "Smoking anywhere near oxygen, even in the same room, can be extremely dangerous," says Duane Sylvia, a consumer safety officer in CDER. While some oxygen bars are located in health spas or other facilities that don't allow smoking, others are found in nightclubs or casinos where smoking is common. Another fire hazard is the

out of the air in the bar. Aviators breathing oxygen (ABO) is a medical-grade oxygen, not less than 99.0 percent pure, intended for commercial or private aircraft use. ABO should not be used for recreational inhalation or medical therapeutic treatment of humans or animals.

Many oxygen bars use a concentrator, which filters out the nitrogen and other gases in the air circulating in the room, and then delivers the concentrated oxygen, about 95 percent pure, through a hose at a continuous flow

Although breathing these low levels of oxygen may not hurt a healthy person, 'people have nothing to gain by frequenting oxygen bars, and subject themselves to unnecessary risk'

flavor is produced by bubbling oxygen through bottles containing aromatic solutions and then pumping the vaporized scent through the hose and into the nostrils. Some bars use oil-free, food-grade particles to produce the aroma, but others may use aroma oils. Inhaling oily substances can lead to a serious inflammation of the lungs, known as lipoid pneumonia. Even if an oil-free medium is used, the purity or sterility of the aerosol that is generated cannot be guaranteed. Susceptible customers run the risk of inhaling allergens or irritants that may cause them to wheeze. Inhalation of live contaminants such as bacteria or other

addition of substances, such as oils, in an oxygen-enriched environment.

Improper maintenance of oxygen equipment presents a potential danger. Some oxygen concentrators use clay filters, which can start growing pathogenic microorganisms that can cause infection if they are not changed regularly.

And oxygen cylinders can be very hazardous if they are stored on their sides or not kept in a well-ventilated area, says Sylvia.

Pumping Oxygen

Most oxygen bars use either "aviators breathing oxygen" or oxygen extracted

rate. But oxygen users inhale the surrounding air along with the oxygen pumped through the nose hose, which decreases the concentration. The concentration is further decreased when oxygen is pumped through an aroma. According to one oxygen bar supplier, the customer gets less than 50 percent pure oxygen.

Although breathing these low levels of oxygen may not hurt a healthy person, "people have nothing to gain by frequenting oxygen bars, and subject themselves to unnecessary risk," says Purucker. ■

The 'Poison Squad' and the Advent of Food and Drug Regulation

*"O, they may get over it but they'll never look the same,
That kind of bill of fare would drive most men insane.
Next week he'll give them mothballs, a la Newburgh or else plain;
O, they may get over it but they'll never look the same."*


Chorus from "Song of the Poison Squad"
Lew Dockstader's Minstrels, October 1903

By Carol Lewis

A century ago, 12 men sat down to a plate of food laced with poison and came back for more. Blessed by Congress, the dinner was the first in a series of meals containing steadily increasing doses of suspected toxic chemicals. What better animal to test toxicity in humans, than a human?

The infamous five-year human feeding experiment took place in the basement of the Agriculture Department's former Bureau of Chemistry, located on what is now Independence Ave., in Washington, D.C.

Complete with kitchen and dining room and backed by a government laboratory, the project was the brain-child of scientists from the Bureau of Chemistry (now the Food and Drug Administration). Chief chemist Harvey W. Wiley, M.D., considered by many to be the founding father of the FDA, spearheaded the effort to separate scientific facts on food safety from the recurrent food safety scares that had fast become the subject of growing public mistrust, inflammatory publications, and Congressional hearings. Wiley's earliest concerns stemmed from the widespread use of borax as a food preservative. And, in fact, fraud was so



NONE BUT THE
BRAVE
CAN EAT THE FARE

FDA History Office

The slogan of volunteers who participated in the "Poison Squad" experiments.

widespread that even products labeled "pure" were often counterfeits, such as purported "pure Vermont maple syrup" that was little more than colored and flavored Iowa corn syrup.

At the same time, however, manufacturers argued that certain preservatives, such as sulfur, were indispensable in processing products such as wines and raisins. Nevertheless, the public was becoming increasingly concerned about all kinds of toxic substances reportedly found in foods.

Although Wiley believed the burden of proving the safety of preservatives should fall on the manufacturers of such additives, still, he boldly asked Congress during Senate hearings on food adulteration in 1899 for money

to conduct such tests himself. Wiley hoped to learn "whether preservatives should ever be used or not, and if so, what preservatives and in what quantities." Ultimately, if Wiley could prove from his studies that food adulteration went beyond flagrant cheating to obvious harm, then both the public and Congress would likely support a national policy.

**'None But the Brave Can
Eat the Fare'**

Three years after Wiley's initial request, Congress enacted new controls over imported foods, including provisions for the inspection and rejection of adulterated shipments. Historians write that greater knowledge about the

safety of common preservatives, it was believed, would serve to strengthen enforcement of these new laws. Therefore, Congress included funding in the chemical division's 1902 budget appropriations to carry out the proposed "hygienic table trials."

Wiley and other scientists quickly assembled the first dozen young, able-bodied Department of Agriculture volunteers—dubbed the "Poison Squad" by newspapers—and fed them wholesome meals containing potentially harmful substances. The initial five preservatives studied were borax, salicylic acid, sulfuric acid, sodium benzoate, and formaldehyde. Dosages ranged from one-half gram daily to four grams by the end of the five-year study. Each



FDA History Office

Members of the "Poison Squad" dine at the "hygienic table" located in the former Bureau of Chemistry building in Washington, D.C. Experiments conducted there a century ago by Harvey W. Wiley, M.D., were designed to test the safety of food preservatives.

subsequent group of a dozen men tested one preservative, and in all of the five years, there was never a shortage of volunteers.

The squad pledged to eat all their meals at the "hygienic table." They agreed not to consume any outside foods or beverages, except water. Even that had to be measured and reported. Each participant recorded his weight, temperature and pulse rate before each meal, and what he ate. Every week, physicians from the Public Health and Marine Hospital Service examined the squad members. Any symptoms noted were reported.

From the men's point of view, perhaps the most annoying aspect of the study was submitting all their urine and feces to government chemists for daily analysis. Additionally, a portion of the study was devoted to determining whether any preservative was elimi-

nated through perspiration and respiration.

The men, of course, knew they were eating potential poisons. They didn't know, however, which foods contained the substances. At first borax was added to butter, to which the men developed a sudden distaste. Wiley then tried it in milk, meat, and coffee. Evidently, as the men determined which food contained the substances, they began eating less of it and eventually avoided that food altogether. Therefore, early on in the trials, Wiley decided he would no longer hide the preservatives and began putting them inside gelatin capsules instead. Previous tests showed that when taken in the middle of a meal, the capsules would quickly dissolve into digesting food, and in the case of borax, without discomfort. For the remainder of the five years, capsules were used for the study.

As daring as it was to submit to such testing in the first place, the men—who responded to Wiley's appeal to promote scientific knowledge while getting free meals—agreed to do so for at least six months. They also agreed to not hold the government responsible for any illness or injury that might result. The meals, which were prepared from high-quality ingredients by a certified Civil Service Commission chef, represented but a small reward for the hardships borne by the volunteers, including the possibility of long-term harm.

Bad Publicity for a Good Cause

Overnight, the Poison Squad became a national sensation. Wiley worried, however, that humorous banter about the squad would discredit the seriousness of his scientific project. But he also knew the importance of winning over the public—not only for the policy he

Ultimately, if Wiley could prove from his studies that food adulteration went beyond flagrant cheating to obvious harm, then both the public and Congress would likely support a national policy

was beginning to envision on chemicals in foods, but also for the progress of the pending federal food and drug law, then under debate in Congress.

After learning that reporters had taken to interviewing the Poison Squad's chef through a basement window, Wiley bowed to the inevitable interest and took reporters into his confidence. He reported to newspapers every detail of the experiment and its effects on the men, and also had the nerve to join the group for most of his own meals.

Wiley stopped the experiments only when the chemicals made several of the diners so sick that they couldn't function—nausea, vomiting, stomachaches, and the inability to perform work of any kind. By this time, though, stories of the men's indigestion had run rampant and were being followed by fascinated readers all over the United States. The table trials even made the minstrel shows. In the end, the publicity helped Wiley gain a Congressional hearing, as well as support for his contention that chemical preservatives had no place in food.

The Science Behind Food Additive Regulation

Wiley's findings on borax were not impressive. The results reported in 1904 showed that borax was one of the least toxic of the preservatives studied. More impressive, however, were the symptoms reported in the individual case histories as dosages of borax and other preservatives were increased: diminished appetite, feelings of fullness and discomfort in the stomach, dull and persistent headache, and in some instances, abdominal pain.

The amounts of preservatives eliminated in feces were found to be insignificant. The amount recovered from perspiration was not enough for a

quantitative determination by the methods used back then. The respiration study came back without significant results.

For the sake of the food industry, which wielded a powerful influence over lawmakers, Wiley eventually admitted that very small amounts of preservatives might be harmless, and might even protect consumers from more serious dangers of food spoilage. But he argued that the accumulation of such additives was a danger to public health since he couldn't determine, much less control, quantities of a given substance that a person might ingest over time. Wiley was convinced that any kind of regulation would have to treat all preservatives alike—ruling out discrimination between food chemicals according to their risks and benefits.

Wiley didn't win all of his fights, and not many federal court cases were aimed directly at the chemicals fed to the Poison Squad. But four of the preservatives tasted by the Squad are long gone from the food additive market—borax, salicylic acid, formaldehyde, and copper sulfate. In the end, the Poison Squad, and all that they ate, helped pave the way for federal regulation of foods and drugs in the United States—the Pure Food and Drug Act of 1906, also called the "Wiley Act" and later its successor, the 1938 Federal Food, Drug, and Cosmetic Act.

Although Wiley's dining experiment was quite politicized, highly controversial, and remains scientifically contentious today, his efforts led to the scientific regulation of food additives, with rational limitations. The result? Preservatives found safe could be legally added to foods, but not to cover up the use of ingredients unfit for human consumption.

As scientists learn more about the action of certain chemicals in our



FDA History Office

William R. Carter, hired in 1902 as the chef for the Poison Squad experiments, later earned a degree in pharmaceutical chemistry and worked for 43 years in FDA laboratories.

bodies, the FDA can use this information to re-evaluate further uses of preservatives.

Although no formal long-term follow-up was done on members of the Poison Squad, anecdotal reports indicate that none were harmed. According to William O. Robinson of Falls Church, Va., the human guinea pigs suffered no permanent illness or injury. Robinson, a member of the Poison Squad, was 94 years old when he died in 1979. ■

Suzanne White Junod, Ph.D., FDA historian, contributed to this story.

How Well Are You Sleeping?



By Michelle Meadows

IT'S A HORRIBLE FEELING TO BE CAPTAIN OF THE ship when the ship goes down. That's how Antonina Radzikowski, 55, says she felt after falling asleep while driving down a Maryland highway one afternoon in 1994.

Radzikowski and her husband, Phillip, were heading home after dropping their teen-age son off at a gifted and talented summer program. Roughly 60 miles away from home on I-70 near Hagerstown, Md., the car Radzikowski was driving smashed into the guardrail, flew over it, and fell 30 feet before landing on railroad tracks on the opposite side of the highway. Radzikowski's husband died and she was left with severe brain injuries that shortened her attention span and led to her retirement from teaching.



Black Star/Dennis Brack

Dr. Jeffrey Hausfeld, M.D., adjusts a Continuous Positive Airway Pressure (CPAP) device for Antonina Radzikowski of Silver Spring, Md. The CPAP device treats obstructive sleep apnea by delivering continuous air pressure through the nasal passages to keep the upper airway open.

"I sometimes felt drowsy before, but I never knew why until after the accident," Radzikowski says. A sleep study revealed that she suffers from obstructive sleep apnea, a condition in which her breathing stops for about 10 seconds to as long as a minute while she's sleeping. Her effort to breathe wakes her up, and this stop-and-start cycle of waking to breathe can repeat hundreds of times a night. A person with sleep apnea isn't aware of the frequent awakenings, but is likely to feel overwhelming sleepiness during the day.

There are many reasons for sleep deprivation. Each year, there are about 40 million people in the United States

who suffer from sleeping disorders. An additional 20 million have occasional sleeping problems.

People who work nights, for example, probably never completely adapt because our bodies want to be awake during the day and asleep at night. We are governed by the circadian rhythm, an internal clock that regulates sleep and wake cycles. Sleep deprivation can also result when people choose to skimp on sleep in favor of work, parties or late-night television.

Whatever the reason for sleep loss, research has shown that it takes a toll on us both mentally and physically. While we sleep, our bodies secrete hor-

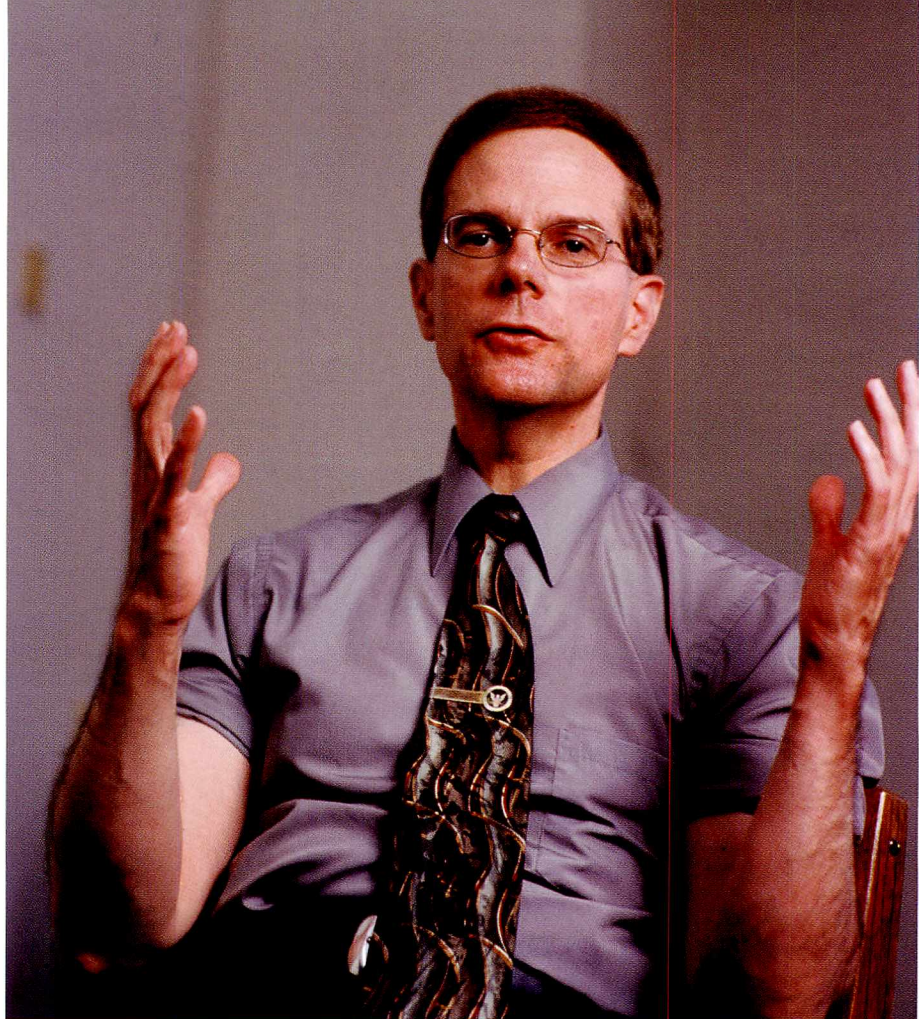
mones that affect our mood, energy, memory, and concentration. Testing has shown that with a driving simulator or a hand-eye coordination task, sleep-deprived people may perform just as badly as intoxicated people.

Sleep deprivation and fatigue have long been issues for professions that have traditionally held long work hours. Pilots have federal regulations that limit their work hours to eight hours of flying time within a 24-hour period. Truck drivers can't drive more than 10 hours without a mandatory eight-hour break. Physician advocacy groups are pushing for the passage of a bill introduced in 2001 (the Patient

and Physician Safety Protection Act) that would set limits nationwide on the number of hours worked by medical residents.

According to the American Medical Student Association, residents sometimes work 100-120 hours a week in 24- and 36-hour shifts. Some have reported making mistakes with medication, falling asleep while driving home, and experiencing health problems, such as depression. The bill would limit residents to 80 hours per week with at least 10 hours off between shifts, among other provisions.

Recent research suggests that if sleep deprivation is long-term—whether because of lifestyle choices or sleep disorders—it may increase the severity of age-related chronic disorders such as diabetes and high blood pressure. In a study published in the Oct. 23, 1999, issue of *The Lancet*, Eve Van Cauter, Ph.D., professor of medicine at the University of Chicago, led researchers who restricted 11 young men to four hours of sleep for six nights, and then recorded their bodily functions. The researchers then allowed the same young men to spend 12 hours in bed per night for six nights, and compared their bodily functions to those recorded earlier. The researchers found negative



Black Star/Dennis Brack

Mike Shockey of Stafford, Va., who has struggled with insomnia for 30 years, says there have been times when he's slept only 15-20 hours during a week.

sleep was unrestricted.

"There's a need to look at sleep on the same level of importance as diet and exercise," says Carl Hunt, M.D., director of the National Center on Sleep Disorders Research, part of the

and waking up too early. Insomnia is more common in females, people with a history of depression, and in people older than 60.

Temporary insomnia can be caused by noise or a stressful event like the loss

There's a need to look at sleep on the same level of importance as diet and exercise

effects on metabolic and endocrine functions when the men were sleep-deprived similar to those seen in older people as a result of normal aging.

In another study, published in the Sept. 25, 2002, issue of *The Journal of the American Medical Association*, Van Cauter and colleagues found a marked decrease in the response to flu vaccination in young, healthy people who were immunized after four days of sleep restriction, compared with those whose

National Heart, Lung, and Blood Institute. "All three are equally important for good health."

Here's a look at some common sleep problems and what you can do about them.

Can't Fall Asleep-Can't Stay Asleep

Most people experience short-term insomnia at some time. Insomnia includes having trouble falling asleep, having trouble getting back to sleep,

of a job or a death in the family. A National Sleep Foundation poll of 993 adults over 18 found that close to half of the respondents reported symptoms of insomnia as they tried to sleep in the nights immediately following the terrorist attacks on September 11, 2001.

Certain medications could keep you awake, particularly those that treat colds and allergies, heart disease, high blood pressure, and pain. And some of us practice bad habits that sabotage our

sleep. This includes drinking alcohol and eating too close to bedtime, says James Walsh, Ph.D., president of the National Sleep Foundation and executive director of the Sleep Medicine and Research Center in Chesterfield, Mo.

"Alcohol works as a sedative, but it's also metabolized quickly—within two to three hours for moderate doses," Walsh says. "So you'll have a rebound effect. You may sleep soundly for the first couple of hours but then toss and turn later." And large meals in the two hours before bedtime could cause indigestion (see "Tips for Better Sleep," page 21).

Short-term insomnia lasts only a few days and is usually not a cause for con-

cern. For example, with jet lag, your internal body clock will readjust itself within several days. It's wise to read labels carefully and check with your doctor before using over-the-counter (OTC) sleep medicines for short-term insomnia. These drugs use sedating antihistamines to make you drowsy. Examples include Nytol (diphenhydramine) and Unisom Nighttime (doxylamine).

People with breathing problems, glaucoma, or chronic bronchitis, pregnant or nursing women, and people who have difficulty urinating due to an enlarged prostate should not use these medicines. People with sleep apnea shouldn't take sleep-promoting medi-

cine because it could suppress their respiratory drive, making it harder to wake up when they experience an episode of interrupted breathing.

Insomnia is considered chronic when it lasts most nights for a few weeks or more. This longer-term condition deserves professional attention, says Tom Roth, Ph.D., head of the Sleep Disorders and Research Center at Henry Ford Hospital in Detroit. If you're unsure about whether you have chronic insomnia, Roth suggests looking at it like a headache. "If it goes on day after day and nothing you do makes it go away, then you should see a doctor," he says. "Ask yourself: Do you know the cause?"

Kids and Sleep

When they're infants, it's middle-of-the-night feedings. When they're toddlers and school-age, it's awakening to give medicine or soothe them after a nightmare. It's no surprise that, according to the latest poll from the National Sleep Foundation (NSF), more people without kids in the house rated their sleep as "excellent" or "very good," compared to those with children.

Some sleep interruptions come with the territory. But experts say the best thing people can do for themselves and their children is to develop a regular sleep routine and bedtime for youngsters so that they get used to falling asleep on their own. Experts say school-age children generally need 9-12 hours of sleep each night.

According to the American Academy of Child and Adolescent Psychiatry, many childhood sleep problems are related to irregular sleep habits or anxiety about bedtime. Young children view bedtime as a time of separation, which is why they pull out a number of stalling tactics such as repeated requests for water and trips to the bathroom.

Here are some sleep tips for children from NSF:

- Establish positive sleep habits with your child at an early age. Have a set sleep schedule for bedtime and waking. Keep the same schedule for weekdays and weekends. Know how much sleep is appropriate for your child's age.

- Establish a 20-30 minute nightly "calm-down" bedtime routine that can include taking a bath, putting on pajamas, reading, and other relaxing activities. TV viewing at bedtime, especially having a television set in the child's bedroom, may interfere with falling asleep.

Other childhood sleep problems include talking during sleep and bedwetting. Many children get over sleep problems as they grow. But if you have concerns, talk with your child's doctor.

If you think your child may have a sleep problem, ask yourself these five questions (remember them by the acronym "BEARS"):

- **Bedtime:** Does my child have problems going to bed or falling asleep?
- **Excessive daytime sleepiness:** Does my child seem sleepy or overtired during the day? Is he or she difficult to get up in the morning?
- **Awakenings:** Does my child awaken frequently during the night or have trouble getting back to sleep?
- **Regularity and duration of sleep:** What time does my child go to bed and get up on weekdays? Weekends? How much sleep does he or she get? Need?
- **Snoring:** Does my child snore loudly? Does he or she seem to have breathing problems at night? ■

—M.M.

Sometimes insomnia is caused by an underlying illness that needs treatment, such as a thyroid disorder, anxiety, depression, arthritis, or asthma. Georgi Moyer, 60, of Gaithersburg, Md., has had problems with insomnia for 38 years because of restless leg syndrome, a condition that causes tingling and crawling sensations in the legs. "It feels like ants crawling around inside your legs," says Moyer. "The only thing that helps is moving your legs. So I end up pacing the floor or kicking my husband in bed."

Moyer, who is a nurse, chooses to work nights because her problem is at

its worst from about 8 p.m. until 3 or 4 in the morning. There are no drugs approved by the FDA for restless leg syndrome. Moyer says she has found some relief with drugs that treat symptoms of anxiety.

For others, the cause of insomnia may be a combination of factors and hard to pinpoint. Mike Shockey, Ph.D., 52, of Stafford, Va., has had a severe case of insomnia for 30 years. There have been times when he's slept only 15-20 hours during a week. A sleep test indicated that he hasn't been reaching the deepest—and most restorative—stages of sleep for years (see "The Stages

of Sleep," page 22).

As a result, Shockey has felt both the mental fog and a physical slowdown from sleep deprivation. "Sometimes, my legs have felt like stone," says Shockey, who is a college professor and novelist. "I've had to hold onto the podium to stay up. Or I might drive somewhere and sit in my car for awhile because it's a huge effort to get across the parking lot." He says he's often jealous of his wife. "She falls asleep soon after she hits the pillow and I look over and think—it sure must be nice."

About 85 percent of people who have insomnia can be helped with a combination of behavioral therapy and medicine, says Marc Raphaelson, M.D., a neurologist with the Greater Washington Sleep Disorders Center in Rockville, Md.

Prescription hypnotic drugs act in areas of the brain to help promote sleep. There have been advances with the development of more short-acting drugs to decrease drowsy spillover effects in the morning. Sonata (zaleplon), for example, is a drug designed to help you fall asleep faster, but not for keeping you asleep. Ambien (zolpidem) is an example of a drug indicated for both getting to sleep and staying asleep.

Insomnia has traditionally been viewed as a symptom of an underlying medical or psychiatric illness, and drugs to treat insomnia are approved for short-term use only, until the primary condition can be treated.

Hypnotic drugs are potentially addictive. Generally, their use is limited to 10 days or less, and the longest that they are approved for use is about 30 days, says Paul Andreason, M.D., a drug reviewer in the FDA's Division of Neuropharmacological Drug Products. "Drug sponsors have not done longer-term studies that evaluate the drugs' effectiveness for longer periods," he says.

Raphaelson says there is a gap in approved treatments because some people with this chronic condition may need long-term treatment. About 20 percent of people with chronic insom-



Black Star/Dennis Brack

Richard Bernstein of Baltimore takes Provigil (modafinil), a drug approved by the FDA to improve wakefulness in people with narcolepsy. People with narcolepsy are excessively sleepy even after a full night's sleep.

nia have a primary form of it, which means it's not associated with another medical condition.

"Most people I've seen are frightened of the medications for fear of addiction," Raphaelson says. "But there is little indication that people with insomnia abuse these medications."

As with any prescription medication, it's important to not increase doses or stop taking hypnotic drugs without consulting a doctor. No drugs that promote sleep should be taken with alcohol. And because of the sedating effects, caution must be used when getting out of bed, driving, or operating other machinery.

Sleepy During the Day

Feeling tired every now and then during the day is normal. But it's not normal for sleepiness to interfere with your routine activities. For example, you shouldn't be dozing off while reading the newspaper, during business meetings, or while sitting at a red light. Slowed thinking, trouble paying attention, heavy eyelids, and feeling irritable are other warning signs.

If you're feeling sleepy frequently during the day, you might simply need to make more time to sleep. "Every year, a couple of people will come see me and say that they go to bed late and wake up early, and ask if I could give them a pill to help them feel more refreshed," Raphaelson says. "I tell them to sleep."

Experts say that most adults need at least eight hours of sleep every night to be well rested, but this varies from person to person. The bottom line is that you should sleep for the number of hours it takes for you to feel rested, refreshed, and fully alert the next day. If you've had a good sleep, you shouldn't feel drowsy during the day.

Naps can be good, but the American Academy of Sleep Medicine recommends napping before 3 p.m. and for no longer than an hour so that it doesn't interfere with falling asleep at night.

If you are sleeping an adequate amount and you still feel drowsy going about your day-to-day routine, or if adjusting your sleeping habits hasn't helped, then you should talk with your health-care provider.

Overwhelming daytime sleepiness could be due to a number of sleep disorders. For example, people with narcolepsy experience excessive sleepiness even after a full night's sleep. "Some people may be able to sleep, but the sleep quality is no good," Raphaelson says. "If you look at the brain as a rechargeable flashlight, some people don't hold the charge very well." They

Tips for Better Sleep

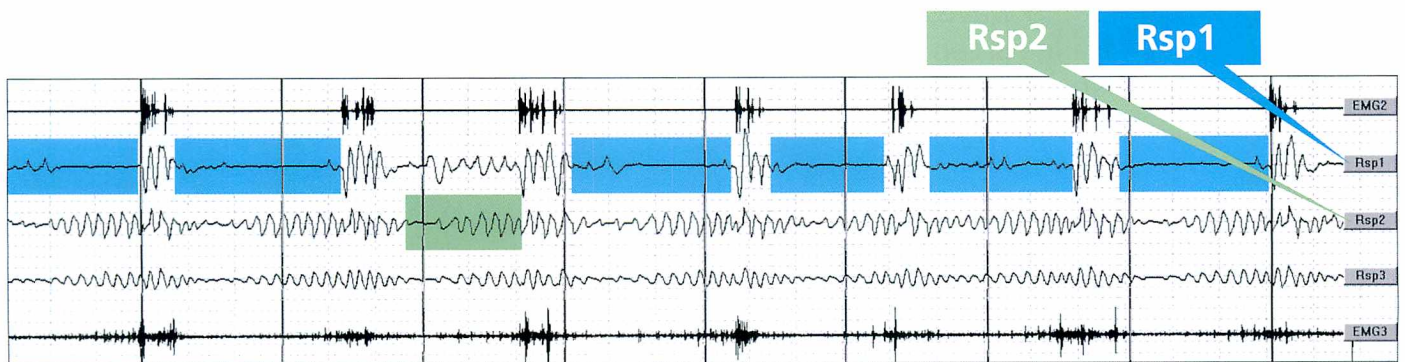
- Keep a regular sleep-wake cycle. Try to go to bed and wake up at the same time every day.
- Avoid caffeine, alcohol, and nicotine in the four to six hours before bedtime.
- Don't exercise within two hours of bedtime. Exercising five or six hours before bedtime may help you sleep more soundly.
- Don't eat large meals within two hours of bedtime.
- Don't nap later than 3 p.m.
- Sleep in a dark, quiet room with a comfortable temperature.
- If you can't fall asleep within 20 minutes, do a quiet activity somewhere else and return to bed when you're sleepy.
- Wind down in the 30 minutes before bedtime with a relaxing pre-sleep ritual such as a warm bath, soft music, or reading. ■

—M.M.

Sources: American Academy of Sleep Medicine; James Walsh, Ph.D., National Sleep Foundation

may have sleep attacks, sometimes at very inappropriate times such as while eating or talking. But not all cases present this way.

Richard Bernstein, 46, of Baltimore, says he can remember always falling asleep very easily, wanting to take naps, and having a hard time getting up. "When I was a child, my mother used to say that waking me up was like moving mountains." Even after sleeping all



Marc Raphaelson, M.D., The Greater Washington Sleep Disorders Center, Rockville, Md.

A five-minute sample of data gathered during sleep by special recording devices attached to a person with severe sleep apnea. The line labeled Rsp1 shows the combined nasal and oral airflow. The flat areas of the line represent six discrete apneas—temporary stops in breathing. The line labeled Rsp2 records chest movement. A single hypoapnea is shown—a reduction of breathing of 50 percent or more.

night, he'd wake up too tired to get out of bed, which often meant missing school or work. "I've lost jobs over this," says Bernstein, who works as an airline customer service representative.

Bernstein was diagnosed with narco-

or call me lazy and say that I was sleeping my life away." He says he's found some improvement since taking Provigil (modafinil) for the past two years. The drug is approved by the FDA to improve wakefulness in people with

hydroxybutyrate, also known as GHB) to treat this condition.

Snoring

Snoring is noisy breathing during sleep that occurs when relaxed struc-

If you've had a good sleep, you shouldn't feel drowsy during the day

lepsy after taking a multiple sleep latency test, which measured how quickly he fell asleep. Most people take between 10 and 20 minutes to fall asleep. People who do it in less than five minutes may have a serious sleep disorder.

"There's definitely a stigma to it," Bernstein says. "People used to tease me

narcolepsy. Potential side effects include headaches and nausea.

Some people with narcolepsy experience episodes of cataplexy, a condition characterized by weak or paralyzed muscles such as buckling knees. In July 2002, the FDA approved Xyrem (sodium oxybate or gamma

tures in the throat vibrate and make noise. Most snoring is harmless, though it can be a nuisance that interferes with the sleep of others. Some snoring can be stopped with lifestyle changes, particularly losing weight, cutting down on smoking and alcohol, and changing sleeping positions. This generally

The Stages of Sleep

Stage 1:

Light sleep. We drift in and out and can be awakened easily. Our eyes move slowly and muscle activity slows.

Stage 2:

Our eye movements stop and our brain waves become slower with occasional bursts of rapid waves called sleep spindles.

Stage 3:

Deep sleep. Extremely slow brain waves called delta waves appear, interspersed with smaller, faster waves.

Stage 4:

Deep sleep. The brain produces mostly delta waves. There are no eye movements and no muscle activity.

Stage 5:

REM sleep. Breathing becomes more rapid, irregular, and shallow. Eyes jerk rapidly, limb muscles become temporarily paralyzed. Dreams almost always happen in this stage, but may occur in other sleep stages as well.

Source: National Institutes of Health

It takes about two hours to go through all five stages of sleep, and then they repeat. Rapid eye movement (REM) sleep usually occurs about 90 minutes after we fall asleep. Adults spend half of their sleep time in stage 2, 20 percent of the time in REM sleep, and 30 percent in the other stages. Infants start out spending about half of their sleep time in REM.

means keeping snorers off their backs and on their sides as a way to keep the airway more open during sleep. There are over-the-counter nasal strips that are placed over the nose to widen the space in the nose and make breathing easier. Read labels carefully because these strips are only intended to treat snoring. The labels point out certain symptoms that require a doctor's care.

The trick is figuring out the cause of snoring. It could be related to allergies or structural abnormalities such as nasal polyps or enlarged adenoids, which are lymphoid tissue behind the nose.

If your snoring is loud and frequent and you also have excessive daytime sleepiness, you could have sleep apnea. People with sleep apnea tend to also be overweight, and it's more common among men than women.

When a person with sleep apnea tries to breathe in air, it creates suction that collapses the windpipe and blocks the flow of air. Blood oxygen levels fall and the brain awakens the person, who then snorts or gasps for air and then resumes snoring. This cycle is typically repeated

challenge because unlike adults, kids push through daytime sleepiness and keep going. "Sometimes you might see the child struggling to get air or moving around a lot in bed," Hausfeld says. "Rather than being noticeably tired, kids with sleep apnea may do poorly in school."

Doctors use an all-night sleep study to make a definitive diagnosis of sleep apnea. During the test, sensors are attached to the head, face, chest, abdomen, and legs. The sensors transmit data on how many times the person being tested wakes up, as well as changes in breathing and in blood oxygen levels.

Medications generally aren't effective for sleep apnea. There are about 20 FDA-approved devices available by prescription for snoring and obstructive sleep apnea, says Susan Runner, D.D.S.,

For More Information

National Center on Sleep Disorders Research
National Heart, Lung, and Blood Institute
Two Rockledge Centre, Suite 10038
6701 Rockledge Drive, MSC 7920
Bethesda, MD 20892-7920
301-435-0199
www.nhlbi.nih.gov/about/ncsdr/

National Sleep Foundation
1522 K St. N.W., Suite 500
Washington, DC 20005
www.sleepfoundation.org

American Academy of Sleep Medicine
One Westbrook Corporate Center, Suite 920
Westchester, IL 60154
www.aasmnet.org

Surgery also is an option to treat snoring and sleep apnea. This may include removal of the tonsils or adenoids. To treat snoring, a laser-assisted procedure called uvulopalatoplasty is used to enlarge the airway by reshaping the palate and the uvula, making them less likely to vibrate. For sleep apnea, a laser

Each year, there are about 40 million people in the United States who suffer from sleeping disorders

many times during the night. It results in frequent awakenings that prevent people from reaching the deepest stages of sleep, which leaves them sleepy during the day.

"In this case, snoring is not just noisy, but could be a silent killer," says Jeffrey Hausfeld, M.D., the author of a book titled *Don't Snore Anymore* and an associate professor of surgery in the department of otolaryngology at George Washington University School of Medicine and Health Sciences in Washington, D.C. "Sleep apnea has been linked to heart disease, high blood pressure, and stroke," says Hausfeld, whose father suffered from sleep apnea and died of a stroke at age 66.

Hausfeld says that recognizing the signs of sleep apnea in children is a

branch chief for dental devices in the FDA's Center for Devices and Radiological Health. "These work for some," she says. "The devices pull the tongue or jaw forward to open the airway." There are no similar over-the-counter devices approved by the FDA. Potential side effects include damage to the teeth and jaw joint.

The most common treatment for sleep apnea is continuous positive airway pressure (CPAP) with a device that pushes air through the airway at sufficient pressure to keep the airway open while sleeping. Radzikowski says using CPAP makes her feel rested during the day. It involves wearing a mask over the nose while sleeping. A blower attached to the mask pushes air through her nasal passages.

procedure called uvulopalatopharyngoplasty is used to remove excessive tissue at the back of the throat.

If you're troubled by sleep problems, ask your health-care provider about how your problem should be evaluated and which treatments may be appropriate for you. Experts say it's important to know that you don't have to suffer through sleep problems. Radzikowski says she had never heard of sleep apnea before the car accident that killed her husband.

"I was overweight and I knew I snored loudly. But snoring was like a big joke in our family," she says. "I didn't really take it seriously, and I wish I did." ■

Think It Through:

A Guide to Managing the Benefits and Risks of Medicines



PhotoDisc

FOR MANY PEOPLE, taking medication is a regular part of the daily routine, and these medicines are relied upon to treat disease and improve health. Although medicines can make you feel better and help you get well, it's important to know that all medicines, both prescription and over-the-counter, have risks as well as benefits.

The benefits of medicines are the helpful effects you get when you use them, such as lowering blood pressure, curing infection, or relieving pain. The risks of medicines are the chances that something unwanted or unexpected could happen to you when you use them. Risks could be less serious things, such as an upset stomach, or more serious things, such as liver damage.

Here are some tips from the Food and Drug Administration and some of its public health partners to help you weigh the risks and benefits when you make decisions about the medicines you use.

Managing Risk

When a medicine's benefits outweigh its known risks, the FDA considers it safe enough to approve. But before using any medicine—as with many things that you do every day—you should think through the benefits and the risks in order to make the best choice for you.

There are several types of risks from medicine use:

- The possibility of a harmful interaction between the medicine and a food, beverage, dietary supplement (including vitamins and herbals), or another medicine. Combinations of any of

these products could increase the chance that there may be interactions.

- The chance that the medicine may not work as expected.
- The possibility that the medicine may cause additional problems.

For example, every time you get into a car, there are risks. You could have an accident, causing costly damage to your car, or injury to yourself or a loved one. But there are also benefits to riding in a car: you can travel farther and faster than walking, bring home more groceries from the store, and travel in cold or wet weather in greater comfort.

To obtain the benefits of riding in a

car, you think through the risks. You consider the condition of your car and the road, for instance, before deciding to make that trip to the store.

The same is true before using any medicine. Every choice to take a medicine involves thinking through the helpful effects as well as the possible unwanted effects.

Here are some specific ways to lower the risks and obtain the full benefits of medicines:

Talk With Your Doctor, Pharmacist, or Other Health-Care Professionals

- Keep an up-to-date, written list of all of the medicines (prescription and over-the-counter) and dietary supplements, including vitamins and herbals, that you use—even those you only use occasionally.
- Share this list with all of your health-care professionals.
- Tell them about any allergies or sensitivities that you may have.
- Tell them about anything that could affect your ability to take medicines, such as difficulty swallowing or remembering to take them.
- Tell them if you are or might become pregnant, or if you are nursing a baby.
- Always ask your health-care professional questions about any concerns or thoughts that you may have.

Know Your Medicines—Prescription and Over-the-Counter

- The brand and generic names

- What they look like
- How to store them properly
- When, how, and how long to use them
- How and under what conditions you should stop using them
- What to do if you miss a dose
- What they are supposed to do and when to expect results
- Side effects and interactions
- Whether you need any tests or monitoring
- Always ask for written information to take with you.

Read the Label and Follow Directions

- Make sure you understand the directions; ask if you have questions or concerns.
- Always double-check that you have the right medicine.
- Keep medicines in their original labeled containers, whenever possible.
- Never combine different medicines in the same bottle.
- Read and follow the directions on the label and the directions from your doctor, pharmacist, or other health-care professional. If you stop the medicine or want to use the medicine differently than directed, consult with your health-care professional.

Avoid Interactions

- Ask if there are interactions with any other medicines or dietary supplements (including vitamins or herbal supplements), beverages, or foods.

- Use the same pharmacy for all of your medicine needs, whenever possible.
- Before starting any new medicine or dietary supplement (including vitamins or herbal supplements), ask again if there are possible interactions with what you are currently using.

Monitor Your Medicines' Effects—and the Effects of Other Products That You Use

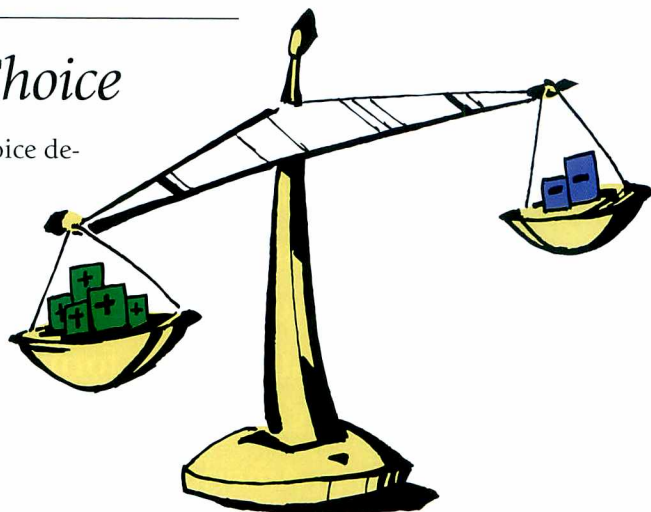
- Ask if there is anything you can do to minimize side effects, such as eating before you take a medicine to reduce stomach upset.
- Pay attention to how you are feeling; note any changes. Write down the changes so that you can remember to tell your doctor, pharmacist, or other health-care professional.
- Know what to do if you experience side effects and when to notify your doctor.
- Know when you should notice an improvement and when to report back. ■

The preceding was adapted from a publication of the Partnership for Safe Medication Use, a group of professional associations and societies, trade associations and government agencies dedicated to educating and empowering health consumers. For more on the partnership's members, go to www.fda.gov/cder/consumerinfo/think.htm.

Weighing the Risks, Making the Choice

The benefit-risk decision is sometimes difficult to make. The best choice depends on your particular situation.

You must decide what risks you can and will accept in order to get the benefits you want. For example, if facing a life-threatening illness, you might choose to accept more risk in the hope of getting the benefits of a cure or living a longer life. On the other hand, if you are facing a minor illness, you might decide that you want to take very little risk. In many situations, the expert advice of your doctor, pharmacist, or other health-care professionals can help you make the decision. ■





Sunning for Science

*The Effects of Common Substances
on Sun-Exposed Skin*



By Carol Lewis

A BEAUTY-CONSCIOUS PUBLIC clamors for cosmetics formulated to give a more youthful look. Yet some ignore the warnings of premature aging and worse to pursue a love affair with the sun. Others prefer the needle-and-ink approach when it comes to skin enhancement. The once-taboo practice of tattooing in its various forms has moved out of seedy parlors frequented by bikers and sailors and onto the backs, shoulders, ankles, and arms of mainstream America.

These obsessions with appearance have one thing in common: skin—the largest organ of the human body.

Sensitive enough to feel a gentle breeze, yet tough enough to resist all kinds of environmental assaults, skin creates the first line of defense against possible invasion by bacteria and other germs. Skin also secretes lubricating fluids that serve as a barrier to toxic substances.

Skin can be a virtual open book to a person's state of health. Very red skin, for example, may mean high blood pressure, while sagging, leathery skin is the hallmark of a long-time smoker or sun-worshipper.

exposure to the sun is skin cancer, a delayed effect that usually doesn't show up for many years.

Health and Human Services Secretary Tommy G. Thompson strongly warns young people to take simple preventive steps now to help avoid skin cancer later. "Even a few serious sunburns," he says, "can increase a person's risk for skin cancer." (See "Reducing the Risk for Skin Cancer," page 29.)

Sunburn is associated with the shorter wavelengths of UVR, known as ultraviolet B (UVB). The longer wavelengths, known as ultraviolet A (UVA), however, can penetrate the skin and

serious form, is increasing by 3 percent annually. In fact, statistics indicate that 1 out of 7 people in the United States will develop some form of skin cancer during their lifetimes.

Many dermatologists believe that there may be a link between childhood sunburns and melanoma later in life. Linda L. Lutz, M.D., assistant professor of dermatology at the University of Maryland in Baltimore, says, "Most of the sun damage we receive is before age 20. It's the cumulative effect of sun exposure that causes problems."

While the link between sun exposure and skin cancer has been established, FDA scientists are looking into the

FDA scientists are looking into the effects of the thousands of chemicals that go into commonly used cosmetics

Experts already know that exposure to ultraviolet radiation (UVR), either from sunlight or by artificial sources, contributes to the risk of developing skin cancer. Now, because of the public's increasing exposure to UVR through outdoor activities and more frequent use of artificial sources, the Food and Drug Administration's National Center for Toxicological Research (NCTR) in Jefferson, Ark., is studying whether the combination of sun and the ingredients found in cosmetics or the chemicals used in tattoo inks can be linked to toxic effects or cancer.

The Skin You're In

Sunlight reduces the skin's elasticity, leading to premature aging in the form of early wrinkles. Since sun damage may not be immediately visible, many people don't realize the dangers of tanning. In fact, any tan is a sign of adaptation of the skin to potentially damaging UVR. Tanning occurs when the skin produces additional coloring (pigment) to protect itself against sunburn. The most serious consequence of over-

damage connective tissue at deeper levels, even if the skin's surface feels cool. It is important to limit exposure to both UVA and UVB.

Sunlamps used for tanning produce UVR. FDA policies require sunlamp product manufacturers to develop an exposure schedule and establish a maximum recommended exposure time based on the UVR emission characteristics of their products. The agency also warns that, while some tanning operators may claim that UVA sunlamps are safer than both the sun and UVB lamps, this has not been definitely shown. In fact, exposure to UVR from sunlamps adds to the total amount of UVR people get from the sun during their lifetimes, potentially increasing their risk of cancer.

Physicians and scientists are especially concerned that cases of skin cancer—the most common type of cancer in the United States, according to the National Cancer Institute—will continue to increase as people now in their teens and twenties reach middle age. The incidence of skin cancer is increasing each year, and melanoma, the most

effects of the thousands of chemicals that go into commonly used cosmetics and what effects, if any, the chemicals may have on the skin when combined with sunlight.

Testing the Safety of Chemicals

Today, more than 80,000 chemicals are registered for use in the United States in everyday items such as foods, drugs, and personal care products, according to the Department of Health and Human Services' National Toxicology Program (NTP). An estimated 2,000 new ones are introduced each year. The effects of many of these chemicals on health are unknown. For scientists in general and regulatory agencies in particular, the tasks of researching and regulating these chemicals are daunting. Since the FDA is responsible for protecting the public health in regard to chemicals included in foods, drugs, and cosmetics, research at NCTR contributes to the FDA's ability to regulate and ensure the safe use of products containing these ingredients. NCTR studies investigate the toxicity of these chemicals, contributing to

a database used by the FDA to make regulatory decisions.

The NTP is based at the National Institute of Environmental Health Sciences (NIEHS), one of the National Institutes of Health. It was established in 1978 to set priorities and coordinate the testing of chemicals that the public may be exposed to. Advised by several government agencies, the NTP manages information on potentially hazardous chemicals added to a variety of industrial and consumer products, as well as those occurring in food naturally or as unintentional contaminants.

The FDA and the NIEHS established an interagency agreement in 1992 to cooperate on toxicological studies. The agencies recognized the need for toxicological testing on chemicals in the presence of sunlight (phototoxicology). The result, in 1998, was the construction of a new laboratory, designated as the NTP's Center for Phototoxicology (NCP).

Paul C. Howard, Ph.D., director of the laboratory, says that one of the program's objectives is to provide

reliable short-term testing of carefully selected compounds that are in wide use and that may affect public health. "We not only test the outcome of the combined use of a product and light on an animal," Howard says, "we additionally try to determine the mechanism by which the chemical affects the animal."

The NCP tests not only cosmetic chemicals but also other potentially light-sensitive (photoactive) drugs and substances to assess if they can become toxic or increase cancer risks in combination with UVR. For example, foods such as celery and herbal remedies such as St. John's wort both contain chemicals that react to sunlight.

"This unique facility evaluates the toxicity of compounds for which the FDA has regulatory responsibility, but which have not been tested by current standards," says NCTR Director Daniel A. Casciano, Ph.D.

The NTP invites and encourages government and private organizations and the general public to nominate chemi-

cals and other substances for study. Member agencies that are the primary sources for nominations include the FDA, the NIEHS, and the National Institute for Occupational Safety and Health.

Each nomination goes through a selection process. Substances selected are generally of greatest concern for public or occupational health based on the extent of human exposure or suspected toxicity. Once a chemical is recommended for testing, the recommendation is published in the *Federal Register* for public comment. Following the approval of a nomination, studies are designed and implemented as time and resources permit.

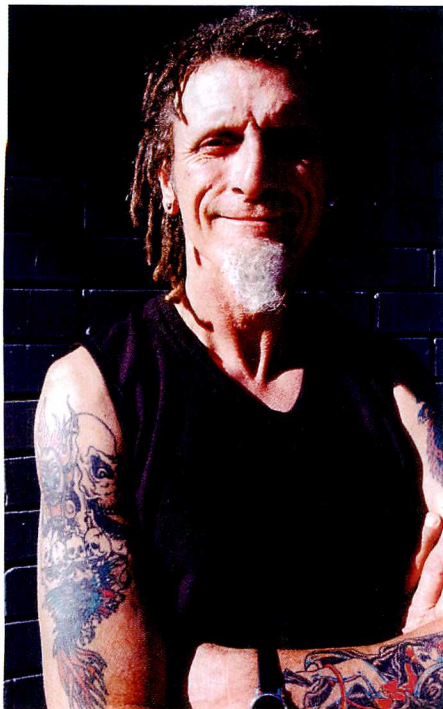
Ongoing Research

Research is now being done for the FDA on alpha- and beta-hydroxy acids—two components common in a large number of skin-care creams and lotions used in the United States. Many of these lotions are marketed as aids to correct sun-damaged skin. The studies



FDA/Michael Ermarth

A number of items such as these skin-care products contain ingredients that are candidates for the FDA's cancer and toxicity testing program.



The popularity of elaborate body tattooing is prompting the FDA to take a closer look at safety issues related to sun-exposed tattoos and the risk for skin cancer development.

are being conducted to determine if there is a relationship between the appearance of sunlight-induced skin cancer and the continuous use of these topically applied acids. The FDA's Center for Food Safety and Applied Nutrition, which generally regulates cosmetics after they are on the market, nominated the alpha-hydroxy acids in 1998 because they are used by millions of people (mostly women) and have never been tested.

The FDA has particular concerns that, unlike traditional cosmetics, these acids might peel away layers of the skin to the point where sunlight can damage DNA in cells at the skin's deepest levels and promote skin cancer. And so, says Howard, "vanity may have a price." The question, he says, is "whether the use of these acids causes a change in skin cancer rates, and if so, whether glycolic acid (an alpha-hydroxy) and salicylic acid (the most widely used beta-hydroxy acid) work differently."

To begin answering this question, the spectrum of sunlight to which humans are normally exposed had to be simu-

lated in the laboratory using 6,500-watt, xenon-arc lamps. With this equipment, Howard says, "We can mimic sunlight from anywhere on the planet." In addition, the laboratory is equipped to generate any combination of fluorescent radiation, such as UVA and UVB lamps and tanning lamps. This means that the NCP can experimentally reproduce nearly any source of light to which humans are exposed.

In the ongoing experiment involving alpha-hydroxy acids, test creams are applied to the backs of specially bred hairless mice. The mice are then placed two meters from the light source, and they receive a dose of light that is less than 10 percent of the amount required to elicit a sunburn. The intensity of the light at two meters is equivalent to about 25 percent of the intensity of noon summer sunlight. "NCP is capable of determining the impact of this light on the toxicity or carcinogenicity of chemicals," says Howard.

The research involved in these studies is long-term, and, as a result, none of the studies has progressed to the point at which their results can guide public health decisions. For example, it can take up to a year to set up the study protocol and conduct preliminary toxicity studies, another year to conduct the study, a half year to complete pathological tissue analyses, and another six months to complete audits and finalize reports. A one-year study, therefore, actually can take between three and four years to complete.

Other studies at NCTR that are part of the interagency agreement with NTP have been completed and are at the "cusp" of influencing public health decisions, according to Howard. Studies conducted on fumonisin (a fungus present on corn worldwide), for example, were used by the FDA and the World Health Organization to determine acceptable levels of the toxin in products intended for human and animal consumption.

"The Center for Phototoxicology," Howard adds, "is just a small part of a larger effort at NCTR and the NTP."

Aloe vera (marketed as a cosmetic ingredient among other skin-care uses), retinyl palmitate (used to correct

unwanted skin lesions), and tattoo pigments are currently being studied simultaneously. Ongoing research may include dozens of chemicals at one time.

Future Scientific Studies

Many other compounds, including sunblock chemicals, tanning enhancers, skin colorants, and tattoo inks are candidates for future NCP studies to determine whether UVR or simulated solar light induce toxicity and cancer in laboratory animals.

With regard to tattoos, Howard says considerable change has taken place in the use and social acceptance of tattooing since the 1990s. "It used to be 'Go Marines,'" says Howard. "Now it's a Picasso." Wider use is making these kinds of chemicals likely candidates for NTP studies.

In short, "We are conducting studies that will address the public health impact of many cosmetics and chemicals in the presence of sunlight," adds Howard, "and are providing the FDA and NTP with an additional resource to bring to bear on a chemical of questionable or unknown safety." ■

Reducing the Risk for Skin Cancer

- ✓ Wear clothes, hats and sunglasses to protect the skin.
- ✓ Use a sunscreen effective against UVA and UVB radiation and with a sun protection factor of 15 or more.
- ✓ Limit exposure to the sun during the peak hours between 10 a.m. and 4 p.m.
- ✓ Seek shade, especially from the midday sun.

For more information, visit the Centers for Disease Control and Prevention's Web site at www.cdc.gov/chooseyourcover/.

Source: Centers for Disease Control and Prevention

Plastics *and* the Microwave



The Glad Products Company

By Michelle Meadows

Stories about the dangers of chemicals leaching from plastic into microwaved food have circulated on the Internet for years. As a result, the Food and Drug Administration continues to receive inquiries from concerned consumers.

Consumers can be confident as they heat holiday meals or leftovers in the microwave that the FDA carefully reviews the substances used to make plastics designed for food use. These include microwave-safe plastic coverings that keep food from splattering and microwave-safe containers that hold frozen dinners. Even microwavable popcorn bags, which look like paper, actually contain a metalized plastic film that allows them to reach high temperatures so the corn can fully pop.

Under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, new substances used to make plastics for food use are classified as "food contact substances." They must be found safe for their intended use before they can be marketed.

"It's true that substances used to make plastics can leach into food," says Edward Machuga, Ph.D., a consumer safety officer in the FDA's Center for Food Safety and Applied Nutrition. "But as part of the approval process, the FDA considers the amount of a substance expected to migrate into food

and the toxicological concerns about the particular chemical." The agency has assessed migration levels of substances added to regulated plastics and has found the levels to be well within the margin of safety based on information available to the agency. The FDA will revisit its safety evaluation if new scientific information raises concerns.

One chemical called diethylhexyl adipate (DEHA) has received a lot of media attention. DEHA is a plasticizer, a substance added to some plastics to make them flexible. DEHA exposure may occur when eating certain foods wrapped in plastics, especially fatty foods such as meat and cheese. But the levels are very low. The levels of the plasticizer that might be consumed as a result of plastic film use are well below the levels showing no toxic effect in animal studies.

Other claims have asserted that plastics contain dioxins, a group of contaminants labeled as a "likely human carcinogen" by the Environmental Protection Agency. "The FDA has seen no evidence that plastic containers or films contain dioxins and knows of no reason why they would," Machuga says.

Machuga says that consumers should be sure to use any plastics for their intended purpose and in accordance with directions. If you don't find instructions for microwave use, you should use a

different plate or container that you know is microwave-safe. Such containers are made to withstand high temperatures.

For example, carryout containers from restaurants and margarine tubs should not be used in the microwave, according to the American Plastics Council. Inappropriate containers may melt or warp, which can increase the likelihood of spills and burns. Also, discard containers that hold prepared microwavable meals after you use them because they are meant for one-time use.

Microwave-safe plastic wrap should be placed loosely over food so that steam can escape, and should not directly touch your food. "Some plastic wraps have labels indicating that there should be a one-inch or greater space between the plastic and the food during microwave heating," Machuga says.

Always read directions, but generally, microwave-safe plastic wraps, wax paper, cooking bags, parchment paper, and white microwave-safe paper towels are safe to use. Covering food helps protect against contamination, keeps moisture in, and allows food to cook evenly. Never use plastic storage bags, grocery bags, newspapers, or aluminum foil in the microwave. ■

Public Affairs Specialists:

On the FDA's Front Line



FDA History Office

The FDA's first full-time consumer consultants from around the country met in Washington, D.C., in 1964. Agency policymakers learned about consumer attitudes from the consultants, who, in turn, learned about FDA activities and health messages that they could carry back to consumers.

By Linda Bren

NERVOUS, YET EAGER TO make her appearance, Cynthia Leggett awaited her turn in front of the television cameras. Had she known she would soon be sharing the stage with a 500-pound lion, she might have been a little less eager.

It was 1974 and Leggett, an FDA public affairs specialist, was about to give a live interview on WSB-TV in Atlanta. She knew her colleagues would be watching as she spoke about the FDA's role in regulating cosmetic products.

Once on the stage, Leggett began to confidently answer her interviewer's questions. But soon she said something that neither she nor anyone else in the audience was prepared for: "There's a lion in the back of the studio."

Shortly after Leggett's announcement, the lion walked in front of the

camera and slowly laid down just a few feet from her. Leggett remained calm. The interviewer, however, jumped up on his chair and screamed. The show went to a commercial break while the lion, part of a Ringling Bros. and Barnum & Bailey circus promotion, was retrieved by his apologetic trainer.

"I've got to finish this interview," said Leggett. "I've got a message to get out." The interviewer allowed Leggett to proceed, and she finished her talk on cosmetic safety without further interruption.

Not every day is filled with drama for the FDA's public affairs specialists (PASs) located throughout the United States and in Puerto Rico. But, like Leggett, these health educators are dedicated to delivering the FDA's messages to the public—messages to help them make informed and responsible health decisions.

This year marks the 50th anniversary of this elite team of more than 40 professionals. Today's PASs, like their predecessors, serve as key links between consumers and the agency whose mission it is to protect them. Their job is to tell consumers—as well as industry, academia, the health community, and the local media—about FDA-regulated products and related health issues.

"PASs have to take highly technical, scientific material, figure out what it means, and then explain it to the outside world," says Leggett, now a PAS at the FDA's headquarters in Rockville, Md.

Last year, FDA PASs reached more than 1 million people through 2,300 outreach and educational programs and 450 workshops, conferences, and meetings. All told, the team responded to over 10,000 inquiries in 2001.

Along with educating consumers, the PASs take the pulse of the public, reporting consumer concerns to agency management. Through this feedback, future FDA programs and messages can be better targeted and agency decisions can be responsive to shifting public health needs.

Breaking New Ground

On Nov. 9, 1952, FDA Commissioner Charles Crawford announced the appointment of the first 16 part-time public affairs specialists, then called

first task was to circulate 400 questionnaires at meetings of different organizations to determine consumer preferences in the canning and labeling of tuna. These preferences, along with accounts of food poisoning, misleading labels, deceptive packaging, and other product complaints, were reported back to FDA headquarters. Some of the consultants were brought to Washington, D.C., to testify on consumer needs at food standards hearings.

Based on the FDA philosophy that informed consumers need less

devices, biologics, and veterinary products.

Before the creation of the Environmental Protection Agency and the Consumer Product Safety Commission in the 1970s, the early consumer consultants had to be well-versed in other areas, such as water and air, baby cribs, flammable products, and even toys, says Lois Meyer of Buffalo, N.Y. Meyer was one of the FDA's first full-time consultants hired when, in 1964, the FDA recognized the tremendous impact made by the part-time consultants and

*Today's public affairs specialists, like their predecessors,
serve as key links between consumers and the agency
whose mission it is to protect them*

"consumer consultants." Ironically, a controversy over white bread was a catalyst for hiring these consultants, says Suzanne White Junod, Ph.D., an FDA historian. Following World War II, the FDA held open hearings to establish standards for white bread. A vocal coalition of consumers and academics alike criticized the FDA's proposal that white bread should be made with wheat flour, arguing that soy flour was more nutritious and should be America's standard bread ingredient.

"FDA officials came to realize that the agency needed a means both of keeping abreast of the newest consumer concerns and of explaining the agency's position to consumers directly," says Junod. The consumer consultants became that means. These 16 pioneers, all women, were highly regarded as home economists, dieticians, or nutritionists. Some held high positions in the educational field; others were homemakers who were active in civic affairs and had wide responsibilities in women's organizations.

Paid \$20 per day, the consumer consultants worked part time up to four days per month. They were expected to forge relationships with key consumer and community groups to determine public attitudes and concerns. Their

protection by the government, a two-way communication soon evolved. In addition to reporting consumer views, the consultants educated the public on FDA-regulated products.

Lorena Meyers of Kansas City, Mo., one of the original 16 part-time consultants, frequently gave speeches on seized and fraudulent products to community organizations. "I was given a few seized products for show-and-tell," says Meyers. One such product was a foam rubber mask that was worn after dipping in buttermilk, cucumber juice, or rainwater, supposedly to make wrinkles vanish.

The consumer consultants enjoyed a reputation in their communities for providing good, solid facts. "The job was exciting and I loved it," says Meyers, adding that a consumer approached her after one of her speeches and said, "I didn't know anybody in the government knew as much as you did!"

Spreading Public Health Messages

Public affairs specialists must continually adapt to the ever-changing world of food and health and must stay current on the many kinds of products regulated by the FDA. Today, these include foods, drugs, cosmetics, radiation-emitting products, medical

began a full-time program.

In the 1960s, the FDA tried a new approach to consumer protection with its toy safety program. It trained and "deputized" consumers, who then went to retail stores to make sure that dangerous toys on the FDA's Banned Toy List had been removed from shelves. The program, which was supervised by the consumer consultants, had mixed results, and was eventually discontinued.

Although today's public affairs specialists don't deputize consumers, they do train and rely on them to help spread the FDA's public health messages. Many of these training programs are supported by grants from the FDA's Center for Food Safety and Applied Nutrition, the FDA's Office of Women's Health, and other organizations.

Lynne Isaacs in Orlando, Fla., teaches senior citizens to educate other seniors about nutrition, food safety, and health fraud. Armed with their new knowledge, handouts, videos, and a food safety teaching kit (food thermometers, chopping mats, cleaning products, and other kitchen aids), the seniors go out to educate others at senior centers, county fairs, libraries, Meals-on-Wheels programs, and other sites.

Isaacs' elder education program,

conducted in partnership with the University of Florida Extension Service, was pilot tested in Brevard County, Fla., where nearly one-third of the population is over 55. "The kitchen food safety teaching kits were ultimately distributed to all 67 county extension offices statewide and used by agents and volunteers in hundreds of training programs, reaching millions of consumers," says Isaacs.

Programs like this have been put into practice by the PASs over time, and are one of their most successful means of getting information to the public, says Meyer.

Cultural Considerations

As consumer audiences broadened over the years, outreach efforts changed to keep pace. Target audiences in the 1950s consisted of older people, schoolteachers, and union workers. During the 1960s, they expanded to include youth, low-income families, and Hispanics. By the end of the decade, 20 full-time and 10 part-time consumer consultants had participated in over 400 FDA-sponsored conferences for these audiences.

In the 1970s, consumer consultants got a new name—"consumer affairs officers"—and continued to broaden their outreach efforts. They were given cultural sensitivity training and, for the first time, targeted other minority groups in their outreach programs.

Today's public affairs specialists continue to focus much of their outreach on minority or under-served populations. PAS Laurel Eu of Los Angeles often works with Asians and Pacific Islanders, including Native Hawaiians and people from Japan, China, the Philippines, Vietnam, Samoa, Tonga, and the Marshall Islands.

Community leaders are very concerned about the increasing rates of diabetes, obesity, and cancer in these groups, says Eu. "Many health professionals are not familiar with these individuals and their culture. That is why it is so important to partner with community organizations that work closely with these groups. Teaching people how to read the food label, how to use medicines safely, and becoming aware of diabetes and diabetes management

can have a big impact on these communities."

Eu relies on certified translation services, when available, and field tests materials to ensure that these consumers get accurate and culturally appropriate health education materials. "In some cases, it takes many words in the Asian or Pacific Islander language to say one word in English," says Eu. "There may be no native equivalent for certain words like 'cholesterol.'"

Evelyn DeNike, the PAS in Detroit, trains bilingual Arab women to teach other women in the Dearborn, Mich., area, home to the largest Arab community outside of the Middle East. "In their culture, a woman doesn't go to a doctor without her husband or brother," says DeNike. "There is a certain trust factor involved, so it's important to have another Arab woman speaking to them in their native tongue."

Training in food safety is particularly important for this community, says DeNike. "The processed foods here are

very different from native Arab foods. They need information about the proper preparation and storage of food."

Hispanics in New York City are benefiting from the work of PAS Dilcia Granville. After discovering a high incidence of emergency room visits for children with foodborne illness in Manhattan, Granville partnered with a local nonprofit organization, the Dominican Women's Development Center, to train childcare providers in food safety. After being trained, the providers then taught others throughout the community.

"They were highly motivated," says Granville, adding that the women showed up faithfully for Friday night training sessions for eight weeks. An unexpected but gratifying result of the program was the involvement of apartment building superintendents. "I gave every woman a thermometer so she could take the temperature of her refrigerator and report back to me," says Granville. "Several refrigerators were



Black Star/Tom Johnson

FDA Public Affairs Specialist Laurel Eu provides health information to Luz Mamawal at a Filipino American Cultural Festival in San Pedro, Calif. Many of the FDA's outreach programs target underserved groups such as Pacific Islanders.



Black Star/Santa Fabio

FDA Public Affairs Specialist Evelyn DeNike discusses the proper use of a food thermometer with Maryam Asoufy of Dearborn, Mich. DeNike often teaches food safety practices to Arab women in the Detroit area.

not working at all and the food was spoiling quickly." After Granville explained the problem to the superintendents, they fixed or replaced the faulty units.

Making a Difference

Reaching out to the public sometimes means staying in the office to field phone calls and answer letters and e-mail. PASs often deal with the anger, frustration, and even despair of individual consumers. But they know they make a difference. Sometimes people call to tell them so.

When he became a PAS 22 years ago, Don Aird of St. Louis got his first consumer call from a young woman who was having problems with her medication for manic depression. "Her doctor had given her a prescription and sent her home," says Aird. "The physician should have been helping her adjust the dosage for her lithium, something that could take several weeks." Relying on his training as a microbiologist and a discussion with a physician in his office, Aird was able to provide further information to the woman, who then sought the opinion of a second physician. Two months later, she

called Aird to thank him "for giving me back my life."

In addition to being educators, PASs must be networkers, recruiters, trainers, and salespeople. "We invented networking and partnerships before they became popular out of a sheer sense of survival," says Isaacs, who has been a PAS for 25 years. Like other PASs, Isaacs maximizes her public outreach by developing "train the trainer" programs, participating in media events, and partnering with grassroots organizations to get information to a larger audience.

One important audience is people with HIV/AIDS. In 1989, the FDA initiated an AIDS Health Fraud Task Force Network to monitor and counter the promotion of suspected fraudulent AIDS products, such as "energized" water and "ozone therapy." The task forces, established in 21 states, Puerto Rico, and the U.S. Virgin Islands, have built coalitions to educate consumers through telephone hot lines, newsletters, public service announcements, exhibits, and videos.

"It involves a lot of time and work, but it's well worth it," says Isaacs, who remembers speaking at conferences

where she required a guard to protect her from angry AIDS activists. Now, as a member of Florida's AIDS Health Fraud Task Force, Isaacs collaborates with the activists, the medical community, and other government organizations to develop educational materials used nationally on good nutrition, food safety, AIDS health fraud, and HIV infection. "It's one of the most rewarding groups that has ultimately reached millions of people," she says.

Long Hours, But Never Dull

To reach their many constituents, PASs often work long hours and travel many miles. Alan Bennett, a PAS for 11 years in Portland, Ore., covered three events and more than 1,700 miles in a three-day period in May 2002. On a Thursday, he attended a food safety conference in Idaho. The following day, he spoke at a meeting in Montana on bioterrorism. Saturday evening found him in Oregon playing a bacterium in Portland's famous Starlight parade. Bennett marched the entire two-mile parade route in a green, cumbersome FDA "Fight BAC" costume, much to the delight of the children in the audience. "I was covered in sweat, but I made it without lagging too far behind the other microbes," he says.

PASs Virlie Walker and Devin Koontz of Denver scramble to cover their 404,000-square-mile territory that includes four states (Utah, Colorado, Wyoming, and New Mexico) and 9 million customers. "There's never a dull moment," says Walker, a PAS veteran of 16 years. "You pray for dull moments."

Far from dull was Walker's "once-in-a-lifetime experience" as a PAS: working at the 2002 Winter Olympic Games in Salt Lake City.

"It was a long, cold and busy month," says Walker, who worked seven days a week during the games. For a year and a half prior to the Olympics, Walker traveled to Salt Lake City monthly to prepare for her role as a public information officer representing the U.S. Department of Health and Human Services (HHS) and the FDA. During the games, she responded to health-related requests from the public and worked

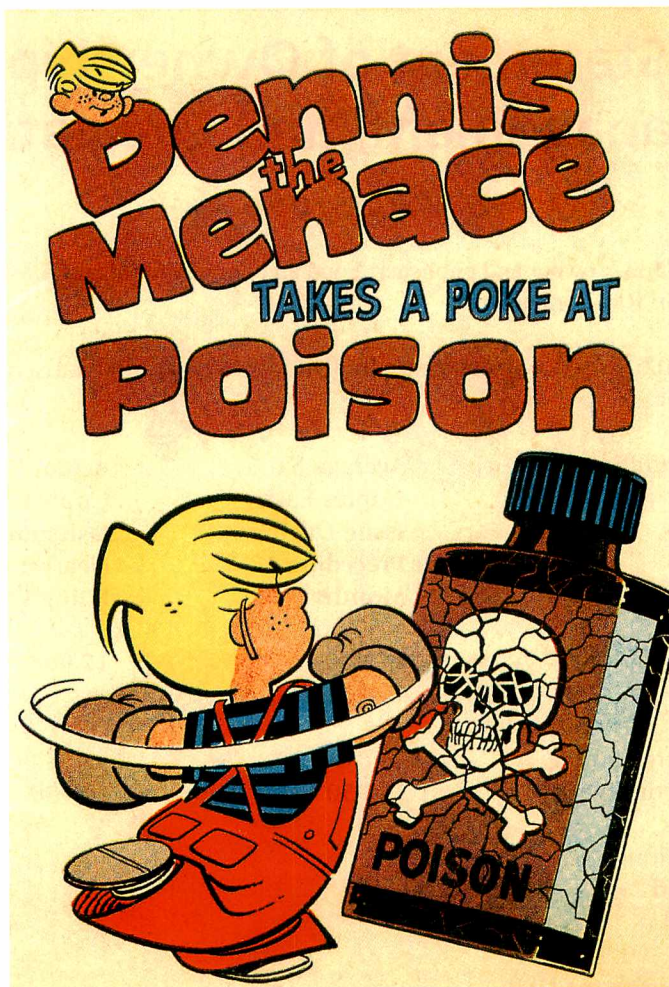
with the media to tell the story of the HHS Emergency Response Teams. These five-person teams of medical volunteers from 17 states were poised for action in the event of a disaster or other incident that could pose a threat to the several thousand athletes and 70,000 visitors per day.

"Every day we had four conference calls and at the end of the day we filed a situation report," says Walker. Military personnel armed with M-16's were stationed every few feet, she adds. "It was the safest place in America."

Changing Times

Fifty years ago, consumer consultants fielded questions—mostly from women—about food, nutrition, and drugs. They are still the main areas of concern today, says Leggett. "Not much goes away—we just add to it. The information and products become more technical, more complicated, and there are more gray areas."

Although the majority of callers today still are women, men increasingly are contacting PASs. "The minute FDA approved Viagra, I had more men call me in the one week that followed than in the 38 years I've worked here," says PAS Darlene Bailey of Chicago. "One man asked, 'If I take two Viagra pills instead of the one daily as recommended, will I have double the action?'" says Bailey, who recommended to the caller that he follow the instructions on the label.



FDA History Office

FDA health educators in the 1950s used the cartoon character of Dennis the Menace to caution parents and children about poisonous household products and medicines.

"Probably the greatest change that happened in the way the job was done is in communications," says Mary-Margaret Richardson, who retired in 2000 after nearly 30 years as a PAS. Before the Internet and other sophisticated technology, it took a few days to get information out to the public. "Now, you can't hide," says Richardson. "The information needs to be immediate."

Bailey learned the importance of immediate information in 1982, when seven people died from poisoning after swallowing Tylenol that had been tampered with. "Because it involved so many agencies and FDA was the lead agency, we had to keep everyone informed by the minute and we were on the phones constantly (there were no computers at the time) with headquarters, the laboratory, media, state and local health departments, and other authorities," says Bailey. "We had meetings in our offices approximately four to five times a day and we really worked as a team to make sure everybody was speaking with one voice."

The Internet has been both a blessing and a curse in their jobs, according to today's PASs. "It makes more information accessible to the public, but with the facts they also get the frauds and the urban legends," says Bennett, who has had to assure people that bananas don't contain

flesh-eating bacteria, a rumor widely circulated on the Internet. With the advent of the Internet, Bennett was worried at first that the public wouldn't need him anymore. "Now they need me as a guide to find the right information on the Web," he says. "But that's what we're all about—getting good information to the public." ■

How to Contact a Public Affairs Specialist

Consumers seeking information about the FDA and the products it regulates can find a public affairs specialist in their area by looking up the phone number in the telephone directory of the nearest large city. Look for the Food and Drug Administration under the

Department of Health and Human Services in the blue U.S. Government section to find the nearest FDA district office. Or check the FDA's Web site at www.fda.gov/ora/fed_state/dfsr_activities/fdapas.html. ■

Statement of Ownership, Management, and Circulation

(Required by 39 U.S.C. 3685)

FDA Consumer, ISSN 0362-1332; owner and publisher: Food and Drug Administration (HFI-40), 5600 Fishers Lane, Rockville, MD 20857; Editor: Ray Formanek Jr.

Date of filing: October 2002, issued 6 times annually (bimonthly); annual subscription price \$13.50 (\$16.88 foreign).

Extent and Nature of Circulation:	Average No. Copies Each Issue During Preceding 12 Months	Actual No. Copies of Single Issue Published Nearest to Filing Date
A. Total number of copies (net press run)	17,968	17,968
B. Paid and/or requested circulation		
1. Paid/requested outside-county mail subscriptions	14,950	14,950
2. Paid in-county subscriptions	-	-
3. Sales through dealers and carriers, street vendors, and counter sales (not mailed)	-	-
4. Other classes mailed through the USPS	-	-
C. Total paid and/or requested circulation (sum of B1, B2, B3 and B4)	14,950	14,950
D. Free distribution by mail (samples, complimentary, and other free)	2,061	2,061
E. Free distribution outside the mail (carriers or other means)	625	625
F. Total free distribution (sum of D and E)	2,686	2,686
G. Total distribution (sum of C and F)	17,636	17,636
H. Copies not distributed	332	332
I. Total (sum of G and H)	17,968	17,968
Percent paid and/or requested circulation (C / G x 100)	84.8%	84.8%

I certify that the statements made by me above are correct and complete.

Ray Formanek Jr., Editor

By John Henkel

New Sites Feature Bioterrorism Act, Industry Information

New counterterrorism legislation requires the FDA to implement actions that include greater oversight of imported foods and drugs. A new Web site (www.fda.gov/oc/bioterrorism/bioact.html) has the complete text of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 as well as background on how the FDA plans to implement the law, signed by President Bush in June. In addition, the site features links to various dockets so anyone interested can comment on proposed regulations related to the bioterrorism law.

Also new to the FDA's Web site is a portal page that makes it easy for FDA-regulated companies to find information needed to comply with agency regulations. At www.fda.gov/oc/industry, the page offers direct links to guidance documents, inspection references, import information, warning letters, and other topics useful for regulated industries. Companies can use the page to contact the FDA with questions, or to submit comments electronically about proposed FDA regulations.

Making Wise Choices About Taking Medicines

Prescription and over-the-counter medicines can do wonders to treat disorders such as high blood pressure and serious infections. But all drugs carry risks along with their benefits. To help consumers make informed decisions about using medicines, the FDA's Center for Drug Evaluation and Research has compiled several helpful publications on a new Web site called *Consumer Education: What You Should Know About Buying and Using Drug Products*. Among the site's offerings:

- questions and answers about generic drugs
- how to be a savvy consumer when buying medicines online
- how to know when an over-the-counter drug is right for you
- what you should know about drug interactions.

Several of the materials are offered in Spanish, and the site also has links to useful information from other agencies about using drug products wisely.

For more, go to www.fda.gov/cder/consumerinfo/DPAdefault.htm.

Help for Those Choosing a Nursing Home

It's not the most pleasant of tasks, but placing a loved one in a nursing home is an obligation many of us will face. It's a critical decision that requires considerable homework. But there's help at *Nursing Home Compare*, a Web site that offers detailed information about the performance of every nursing home certified by Medicare and Medicaid. For example, the site, at www.medicare.gov/Nhcompare/home.asp, lists:

- the number of beds in each facility and type of ownership
- information about each home's residents, such as what percent have urinary incontinence, pressure sores, and other maladies
- deficiencies found during the most recent state survey and from complaint investigations into each facility
- background on the staff, including the average number of hours worked by nurses per resident per day.

The site also has information about Medicare eligibility, claims and appeals.

How to Deal With the Hazards of Lead

Lead is a highly toxic metal that was used for many years in paints and other household products, especially in houses built before 1978. Lead has been linked to a range of adverse health effects, from behavioral problems to learning disabilities, and even seizures and death. At greatest risk are children under age 6.

To help explain lead contamination, the Environmental Protection Agency has created a Web site at www.epa.gov/lead that tells how to determine if your home has lead and what to do if it is found. Typically, household environmental lead contamination is found in deteriorating lead-based paints, and in lead-contaminated dust and soil. The EPA site suggests some simple steps to help protect your family from these hazards.

For those who want to delve deeper into the science of environmental lead, the site includes a number of technical reports, including ones that examine the extent of lead hazards, lead removal, and the link between blood lead concentrations and environmental lead exposure. ■

John Henkel is a member of the FDA's Website Management Staff.



Dairy Owners Charged With Milking Customers

By Michelle Meadows

Robert and Arlen Bechtel, former owners of Bechtel Dairies Inc. of Royersford, Pa., thought they had devised a way to boost profits by increasing the poundage of the milk they sold. But their scam soured when they were caught adding skim milk powder and water to fluid milk from the cow. They packaged, labeled and sold it as fresh whole milk to consumers, including school lunch programs, without revealing that the milk was made with powder and water.

According to documents filed in the U.S. District Court for the Eastern District of Pennsylvania, the defendants bought 1,781,500 pounds of skim milk powder from vendors in Michigan, North Carolina, and Minnesota from January 1993 to December 1997. They traveled to these places, paid cash, and arranged to have the powder shipped to Bechtel Dairies. The Bechtels then directed employees to mix the out-of-state powder with water, producing about 19,596,500 pounds of reconstituted skim milk.

Since at least 1996, the Bechtels and Patricia Hughes, the dairy's controller, not only schemed to defraud purchasers of milk by adding powdered milk and water to it, but also under-filled milk containers, sold milk in mislabeled containers, repackaged old milk that was about to expire along with new milk and falsified freshness dates.

Besides schools, customers who received the milk included Veterans

Affairs hospitals, the Department of Defense, and retail stores. More than half of the company's milk business was believed to be from schools participating in the National School Lunch Program. This program gives children at the poverty level a free or reduced-price lunch, and milk provided as part of the program must be fluid milk from the cow.

Investigators charged that Bechtel Dairies routinely added water so that it made up two-thirds the amount of milk in milk containers. But the defendants labeled the containers as milk without listing water or skim milk powder as ingredients. Also, the Bechtels routinely illegally packaged skim milk in whole milk containers.

These actions violated the Federal Food, Drug, and Cosmetic Act because they introduced misbranded and adulterated food into interstate commerce. Food cannot be misbranded with false or misleading labels, and food cannot be adulterated by leaving out essential ingredients, substituting ingredients or adding a substance to increase the food's weight. The FDA's Office of Criminal Investigations' metro Washington field office and the United States Department of Agriculture (USDA) Office of Inspector General jointly worked on the investigation.

The Bechtels and Hughes also were charged with submitting false reports to the Milk Market Administrator (MMA) regarding milk sales and milk powder usage. The MMA, a service of

the USDA, regulates milk prices and activities of milk handlers and dairy farm cooperatives.

In an earlier case, Bechtel Dairies paid the USDA \$550,000 in administrative penalties for submitting false statements about its milk powder usage. The penalties were levied after the company had indicated the use of 1.7 million pounds of milk powder from 1985 to 1989, when the actual amount was 17 million pounds.

In the most recent case, investigators searched Bechtel Dairies in February 1998 and found two sets of books. One contained the monthly total milk sales matching false reports the defendants submitted to the MMA. The second contained actual milk sales, which were substantially greater. Based on these two sets of records, the defendants routinely understated sales by \$70,000 per month, according to court papers. Investigators also found a record of actual amounts of milk powder usage, which was much greater than reported.

The Bechtels and Hughes pleaded guilty to conspiring to misbrand milk products with intent to defraud. The Bechtels were fined \$5,000 each, and Patricia Hughes was fined \$250. Each of the defendants also received three years probation. Bechtel Dairies went out of business and was sold to another dairy in Pennsylvania in 1998. ■

The FDA's Public Affairs Specialists: Making a Difference

By Mary-Margaret Richardson



My question was simply about directions for a newly purchased product. I dialed the customer service number, and was immediately met with an automated menu of choices, none of which offered the promise of actually answering my question. Since I selected none of the options, my call was terminated.

A day or so later I needed to confirm an airline reservation. Again dialing the toll-free num-

ber I got what I thought was a person. Wrong. A robot with a human voice was asking me questions. I didn't provide the responses the robot wanted. In a burst of annoyance I sputtered "HELP." Instantly a human being responded! She answered my questions but, more importantly, provided me with the password. "Just say 'agent,'" she said. "You may have to say it a couple of times but it will get you to a person."

Needing information from the FDA, I dialed the local office seeking the public affairs specialist. You guessed it—I got a menu of options! I selected the option for PAS. The phone mail gave me instructions on leaving a message. I tried saying "PAS" several times to the automated attendant. That was not the password here. I left a message and a PAS called me back later.

What could I possibly want to know that the Internet could not answer? Pages and pages of information are available. Click. It's done. Or what did I want to know that I couldn't learn from the national news sources that provide us with the latest information 24/7? Actually I wanted to know what the FDA was doing in my local community. That takes a real person.

I remembered the "good old days" when I was a "consumer affairs officer," the title they gave us before public affairs specialist. There was no Internet, no home page, no cell phones. News interviews were done on film the day BEFORE an interview was going to air; no instant satellite feeds.

Before I retired three years ago, I said in an interview that technology was one of the greatest tools that the public affairs specialist had. Today, I'm wondering if technology could replace the public affairs specialists? Has technology made them obsolete?

The FDA's public affairs program has always been about the public's right to know. The challenge of the PAS is to tell the public about the FDA and to tell the FDA about the public. Consumer consultants, the first FDA public affairs specialists, began that long history of person-to-person contact. They worked diligently capturing public opinion, reporting it to the FDA, and providing valuable information for the FDA's public education programs. Their successes were rewarded, and challenges increased.

Later, the charge became to assess the needs in their communities and to devise FDA educational programs to meet those needs. Many programs ran only on ingenuity and creativity. Budgets were small to none.

In the early days of public affairs programming, I believe we were somewhat naïve. We assured people that they were safe because the FDA was there. Toward the end of my FDA career, I knew that this couldn't be the message anymore. Life is more complex and uncertain. Advances in both science and technology increase the challenge and the risk of the message. We now know that no one government agency, industry or person can provide total safety. But we can continue to provide credible information to assist persons in making their own decisions.

The various crises of the past were as serious in the public's mind as are those facing us today. But they pale in the light of shifting priorities, which have changed dramatically since 9/11. Tampering was the issue; now it is terrorism. Food additives, product recalls, unsafe products, microwave oven radiation and X-rays were the issues. Food safety meant basic sanitation rather than bioterrorism, genetically altered foods, *E. coli*, and other issues.

The trust Americans place in the FDA to provide credible information is in large part, I think, reflected through the work of the public affairs specialists, who are often recognized widely in local communities. Citizens believed that there was a voice of calm and reassurance in the face of crisis situations. The PAS, then and now, has the obligation of being the truth-speaker. That voice is as necessary today as it ever was.

Public affairs specialists made obsolete by technology? I certainly hope not. Give me a public affairs specialist over a robot any time! ■

Mary-Margaret Richardson retired from the FDA after nearly 30 years as a public affairs specialist.

Keep the Holidays Happy!

Clean Up

- Thoroughly wash your hands with soap and water for a full 20 seconds *before* and *after* handling raw products.
- Use plastic or other non-porous cutting boards. Cutting boards should be run through the dishwasher—or washed with soap and hot water—after each use.

Combat Cross-Contamination

- Store raw meat, poultry, and seafood on a plate or tray, so raw juices don't drip onto other foods.
- Use one cutting board for raw meat products and another one for salads and other ready-to-eat foods, or wash cutting boards in between each use.
- Never place cooked food on a plate that previously held raw meat, poultry, or seafood *unless* the plate has been washed.
- Don't spread bacteria with dirty sponges, dishcloths, or towels. Bacteria often thrive in the moist areas of these items where bits of food may also exist. Use paper towels or freshly-cleaned sponges or cloths and soap and hot water to clean food preparation surfaces.

Cook Safely

- For meat, poultry, and other dishes, use a food thermometer to make sure foods are cooked to a safe internal temperature.
- Cook eggs until the yolks and whites are firm or reach 160 F on a food thermometer. Don't use recipes in which eggs remain raw or only partially cooked. Cook egg dishes until they reach 160 F.
- Cook fish until it's opaque and flakes easily with a fork.
- When microwaving, make sure there are no cold spots in food (where bacteria can survive). For best results, cover, stir, and rotate food for even cooking. If there's no turntable, rotate the dish by hand once or twice during cooking.
- When reheating sauces, soups, and gravies, bring them to a boil. Heat other leftovers thoroughly to 165 F.

Chill Thoroughly

- Make sure the refrigerator temperature is 40 F or below and zero F or below in the freezer. Occasionally verify these temperatures using an appliance thermometer.
- Refrigerate or freeze perishables, prepared foods, and leftovers within 2 hours.
- Never defrost or marinate food at room temperature. Use the refrigerator. You can also thaw foods in airtight packaging in cold water (change the water every 30 minutes, so the food continues to thaw). Or thaw in the microwave if you'll be cooking the food immediately.
- Divide large amounts of leftovers into shallow containers for quick cooling in the refrigerator.
- Don't over-stuff the refrigerator. Cold air must circulate to keep food safe.

