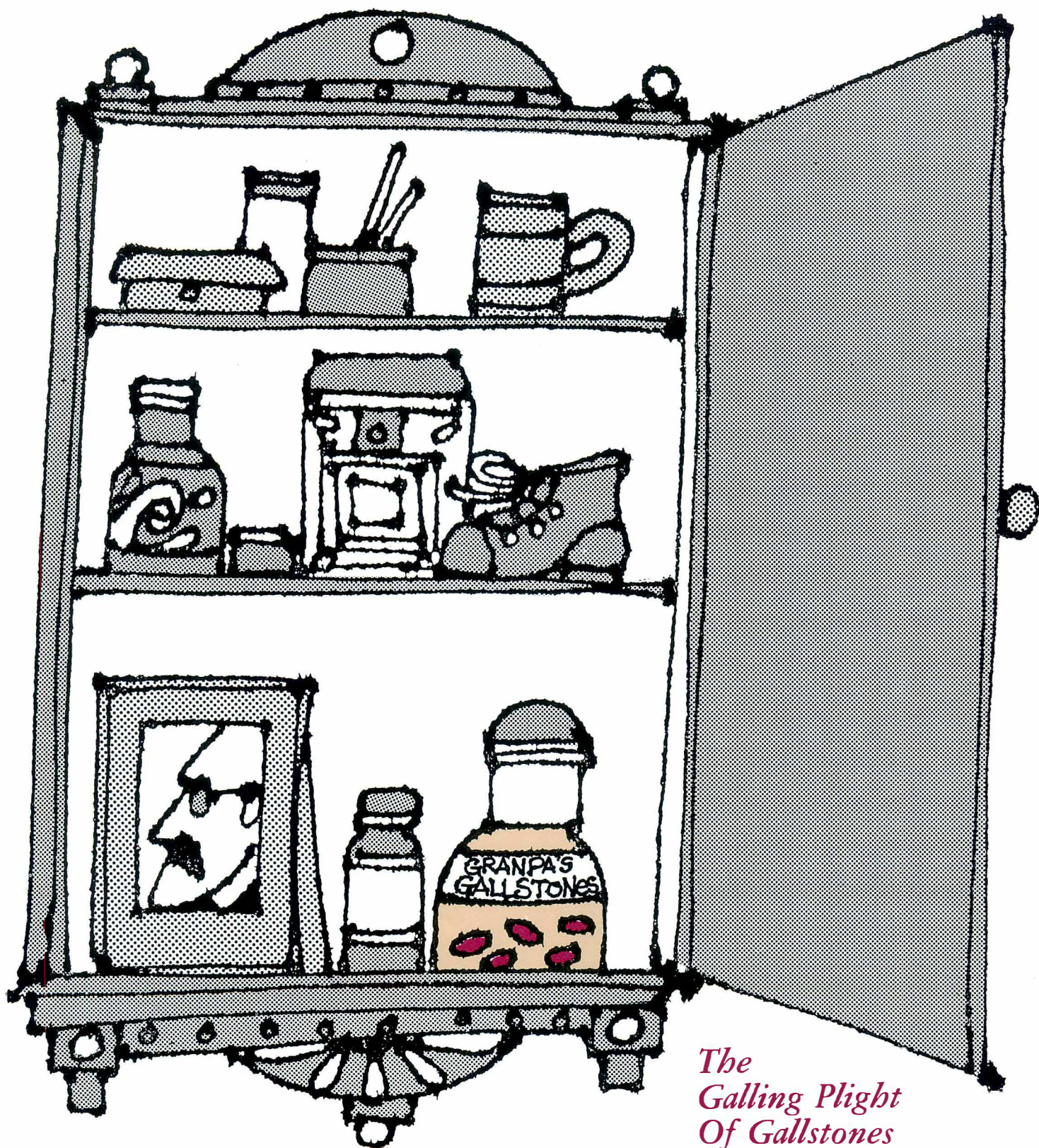
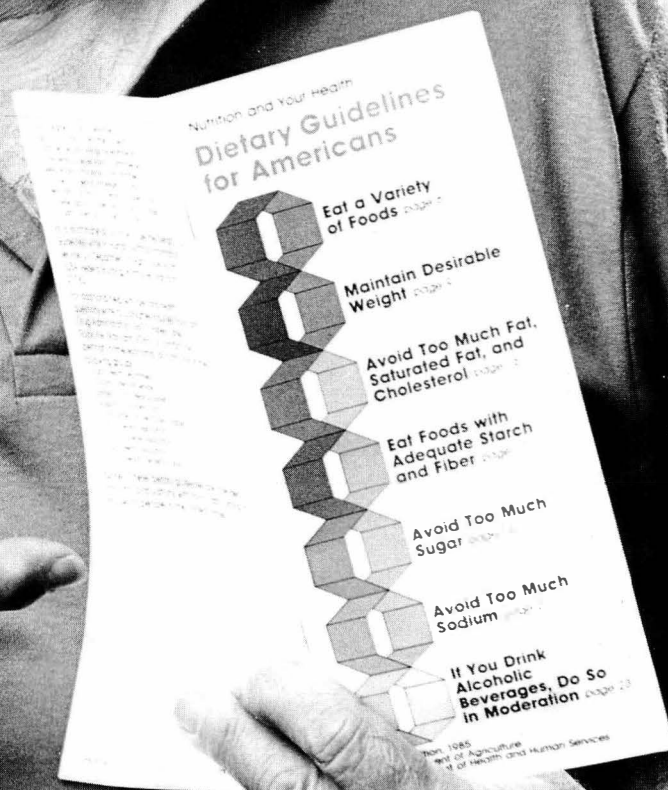


FDA
CONSUMER

November 1985



*The
Galling Plight
Of Gallstones*



The Gallling Plight of Gallstones

They come in a variety of shapes, colors and sizes. Some are the "silent" type; others make themselves known loud and clear. They're gallstones, and 25 million of us are carrying these potentially painful little nuggets around inside us, whether we know it or not.

Dietary Guidelines for Americans: No-Nonsense Advice for Healthy Eating

The federal government has issued new recommendations on how to eat for your health. A balanced, varied diet is the key, with more starch and fiber and less fat, sugar, sodium and alcohol.

Fever: What to Do—and What Not to Do—When the Heat Is On

Unless it is very high, a fever is not to be feared. In fact, it may even serve a useful purpose. But there are ways to make a feverish patient more comfortable till things cool off.

The Public Health Threat of Food-Borne Diarrheal Disease

The incidence of diarrheal disease, often caused by improper food handling, is far greater than previously thought, say two FDA scientists. Newly discovered pathogens are adding to the problem, and day-care centers are being especially hard hit.

Searching for Clues to Alzheimer's Disease

The degenerative brain disease known as Alzheimer's has been called the disease of the century. Its cause remains unknown and a cure has yet to be found. But certain of its symptoms can be treated.

Prenatal Care: The Key to Reducing Infant Deaths

More than 39,000 U.S. infants died last year, many because low birth weight cut their chances for survival right from the start. But the risk of low birth weight can be reduced if the mother-to-be follows good health practices during (and even before) pregnancy.

The Reasons Behind Blood Donor Screening

For some, the tedium of answering all those medical questions when they donate blood is more painful than the giving itself. But there are good reasons for this medical "third degree."

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Amid countless sources of advice—some good, some bad—on what to eat to be healthy, there's a new guide that cuts through the confusion with simple, straightforward and authoritative recommendations. It's the federal government's 1985 Dietary Guidelines for Americans. To learn more about what's good to eat, turn to page 10.

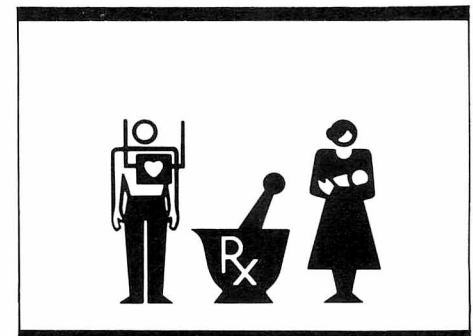
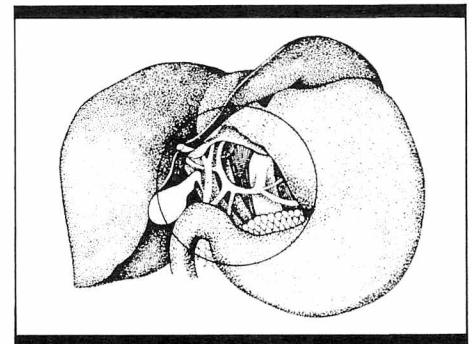
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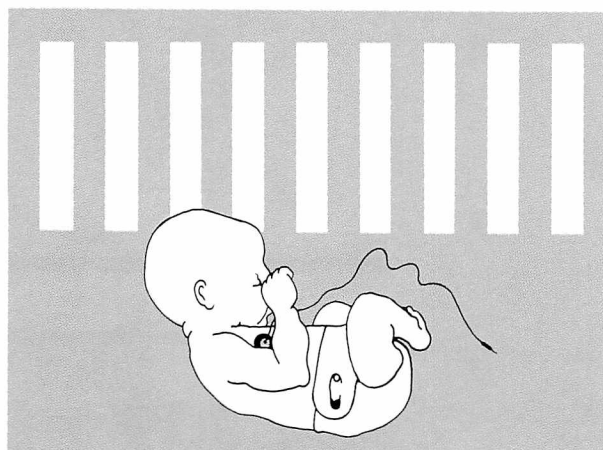
Cover Design: Michael David Brown



Warning on Apnea Monitors

Parents and health professionals should be alert to the possibility of electrical accidents with infant apnea monitors, used to detect breathing difficulties in newborns. Three unusual accidents involving such monitors, one of them fatal, have been reported to FDA.

In the fatal case, one end of the electric power cord was unplugged from the monitor while the other end was left plugged into the wall socket. At the same time, the electrode leads were disconnected from the monitor while the infant was still wearing the electrodes. An older sibling plugged the loose ends of the leads into the "live" electric cord, electrocuting the infant.



In one of the other cases, a young child plugged the loose ends of the electrode leads into a wall socket and in the other, a child plugged the leads into an electric cord. In both instances, the infant wearing the monitor suffered burns.

FDA is working with apnea monitor manufacturers to develop a permanent solution to this problem. In the meantime, parents and health professionals are advised to:

- Never allow the electrode leads to remain attached to the infant unless they are also attached to the patient cable or apnea monitor.
- Always unplug the electric plug from the wall socket, not from the apnea monitor.
- Take steps to prevent young children from inserting any object into electric power cords or wall sockets (for instance, cover unused electric outlets with safety covers).

For more information on sleep apnea, see "The Mystery of Crib Death" in the April 1983 *FDA Consumer*.

Free Fix for Unsafe Cordless Phones

Because of concerns about the possibility of hearing damage from certain models of cordless telephones, Uniden Corp. of America, AT&T, and ITT Telecom Products Corp. have agreed to modify certain of their phones without charge.

The phones in question have a loud ringer located in the earpiece. Unless the user remembers to switch off the ringer before placing the phone next to the ear, the next ring can be directly in the ear. The sound may be loud enough to damage hearing. The manufacturers will replace the ringer with one not as loud—no more than 125 decibels.

The affected AT&T models are the Nomad 200 and Nomad 400. Affected ITT models are PC-1800 and PC-1900. Owners are being notified directly by these companies about how to have the phones modified.

The Uniden units that will be modified by the manufacturer are:

Model No.	Eligible Units
EX-300, EX-900, EX-1500	All units
EX-1000, EX-1100, EX-7000	All units
EX-3000	Mfg. dates 6/82 thru 8/83, excluding serial nos. 33120001 to 33130000 with 8/83 mfg. dates
EX-3300	Serial nos. 33000001 to 330050000
EX-3500	Mfg. dates 1/83 thru 8/83
EX-4000	Mfg. dates 6/82 thru 8/83, excluding serial nos. 33067001 to 33089000 with 8/83 mfg. dates
EX-4500	Mfg. dates 1/83 thru 8/83
EX-5000	Mfg. dates 8/82 thru 6/83
EX-6000	Serial nos. 23000051 to 23009004, and 33000001 to 33011012
EX-7500	Serial nos. 33000001 to 33003000.

To apply to Uniden for a retrofit, write to Slope Ringer Retrofit Center, P.O. Box 50433, Indianapolis, Ind. 46250, giving your name, address, daytime telephone number, and your unit's model number, serial number, and date of manufacture.

FDA is continuing to work with other cordless phone manufacturers to develop similar modification programs for phones with earpiece ringers that may pose a hazard.

All of the major manufacturers have agreed to stop producing cordless phones with earpiece ringers. However, some phones of this design may still be on sale. A comprehensive list of cordless phones showing manufacturer, model number, and whether or not the ringer is located in the earpiece is available free from: Cordless Phone List (HFZ-265), FDA, Rockville, Md. 20857.

If you have a cordless phone that has the ringer in the earpiece, FDA suggests the following precautions:

- Never place the phone against your ear unless you have switched from the "standby" to the "talk" or "conversation" position, or have followed whatever other procedure the manufacturer recommends for preventing it from ringing in the ear.
- Be sure that other household members and visitors know how to use the phone safely.
- Keep the phone out of the reach of small children.
- Be particularly careful when using earpiece-ringer phones that have a paging feature, since some of these models can produce a loud signal in the ear when the paging feature is activated from the base unit.

Generic Valium

Three generic versions of the tranquilizer Valium, one of the nation's most widely used prescription drugs, were approved by FDA in September. The new versions will be manufactured by Myland Pharmaceuticals, Morgantown, W.Va.; Parke-Davis Division of Warner Lambert Co. of Morris Plains, N.J.; and Zenith Laboratories of Northvale, N.J. Valium has been marketed by its developer, Hoffmann-La Roche, since 1963.

The latest generic approvals mean that nine of the 10 top-selling drugs in the United States are available in alternative versions, generally at much lower prices.

Generic versions of seven prescription drugs, including four of the top 10 drugs, were approved since enactment of the Drug Price Competition and Patent Term Restoration Act in September 1984. The act simplified and speeded the approval of generic versions of already marketed drugs that are no longer protected by patents. (For more information on the new law and generic drugs, see "Generic Drugs: Cutting Cost, Not Corners" in the October 1985 *FDA Consumer*.)

In addition to Valium (known generically as diazepam),

generic versions of these drugs have recently been approved: Norpace (disopyramide phosphate), Darvocet-N (propoxyphene napsylate with acetaminophen), Reglan (metaclopramide), Inderal (propranolol hydrochloride), Motrin (ibuprofen), and Ativan (lorazepam).

The 10 top-selling prescription drugs are (brand name first, with generic following):

1. **Dyazide** (hydrochlorothiazide-triamterene)—a diuretic/anti-hypertension drug, for which there is a generic alternative but with differences in bioavailability and potency that a physician must adjust for.
2. **Inderal** (propranolol hydrochloride)—for hypertension, migraine headaches, and various heart problems, for which FDA in July and August approved generic versions by three firms.
3. **Lanoxin** (digoxin)—another heart drug, for which generics have been available for some time.
4. **Valium** (diazepam)—a sedative, tranquilizer and muscle relaxer, for which the three companies have just been given approval to make generic versions.
5. **Tylenol with codeine** (acetaminophen-codeine)—a painkiller for which there have been generic versions since the 1970s.
6. **Amoxil** (amoxicillin)—for bacterial infections, for which generic versions have been available, also since the 1970s.
7. **Tagamet** (cimetidine)—for ulcers and other gastrointestinal conditions, approved by FDA in 1983 and still under patent. As a result, there is no generic version available.
8. **Lasix** (furosemide)—a diuretic with uses including treatment of mild to moderate hypertension, for which a generic version was approved in 1983 on the basis of a literature search for public data on effectiveness and safety.
9. **Motrin** (ibuprofen)—a painkiller and arthritis medicine, for which generic versions were approved in July and August.
10. **Darvocet-N 100** (acetaminophen/propoxyphene napsylate)—a painkiller for which three generic versions were approved in June.

Sulfite Restrictions Proposed

FDA has proposed banning all use of sulfites on raw fruits and vegetables in supermarkets and restaurants, where the preservatives have been used extensively to keep salad bar fare looking fresh.

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The proposed regulation is based on an in-depth review of health hazards associated with sulfites, including reports of about 500 alleged adverse reactions and 13 deaths possibly associated with sulfite-treated foods, mostly those served in restaurants.

Early this year, a panel established by the Federation of American Societies for Experimental Biology to reexamine the safety of sulfiting agents concluded that for the majority of the population there is no hazard. But for the estimated 1 million people who are sulfite-sensitive, there are reasonable grounds to suspect a hazard of unpredictable severity. These people may suffer allergic reactions ranging from hives, nausea and diarrhea to shortness of breath and fatal shock after eating foods that contain sulfites.

The panel also concluded that additional labeling requirements alone would not ensure protection, particularly when sulfite-treated fresh fruits and vegetables are served in restaurants and sold in grocery stores. FDA concurred with the findings of the panel.

FDA regulations already require that labels on finished, packaged foods indicate if the product contains sulfites. Products so labeled include lemon juice, maraschino cherries, grape juice, some packaged fresh mushrooms, dried fruits and vegetables, and some canned soups.

Because FDA believes it must act quickly to diminish the likelihood of additional severe reactions to sulfites, only a 30-day period was allowed for comments on the proposed ban, published in the Aug. 14 *Federal Register*. For more about sulfites, see "Sulfites: Preservatives That Can Go Wrong" in the September 1983 *FDA Consumer*.

Warning on Experimental Baldness Drug

The anti-hypertension drug minoxidil should not be used to treat baldness except in controlled studies, FDA warns. The agency has asked the cooperation of medical professionals in not supplying patients with recombined versions of this drug and other drugs undergoing clinical trials for baldness before the developers' scientific testing and FDA's medical evaluation are completed.

Minoxidil in tablet form, marketed under the brand name Loniten by The Upjohn Co., was approved by FDA in 1979 as a prescription antihypertensive. Physician and patient labeling warned of potential adverse reactions, including increased heart rate, difficulty in breathing,

upper body pains, dizziness, fainting, nausea and vomiting. In 80 percent of users, hair growth occurs on some part of the body. As a result, Loniten is not the first choice for treating hypertension.

The hair-growth side effect prompted development of a topical solution of minoxidil (brand name Regaine), which is being used in clinical trials on male pattern baldness and alopecia areata (patchy baldness). Because



of minoxidil's known adverse reactions, the trials excluded anyone with hypertension, heart, kidney, liver or endocrine disease, as well as anyone more than 49 years old.

About 4,500 patients have been tested. During these controlled clinical trials, Upjohn has informed FDA that six patients being treated with Regaine have died. In addition, one death of a person using the drug but not enrolled in the company's study has been reported. After carefully reviewing reports for each of these patients, FDA and Upjohn have concluded that no cause and effect can be established.

During the years Regaine has been tested, ads have appeared nationally offering to sell topical minoxidil that has been recombined from Loniten tablets as a remedy for baldness or premature hair loss. In addition, there

have been reports that some private physicians, especially dermatologists, have been prescribing and either recompounding minoxidil or having pharmacists do so for their patients. FDA has asked Upjohn to change Loniten's labeling to specifically caution against recompounding for hair regeneration.

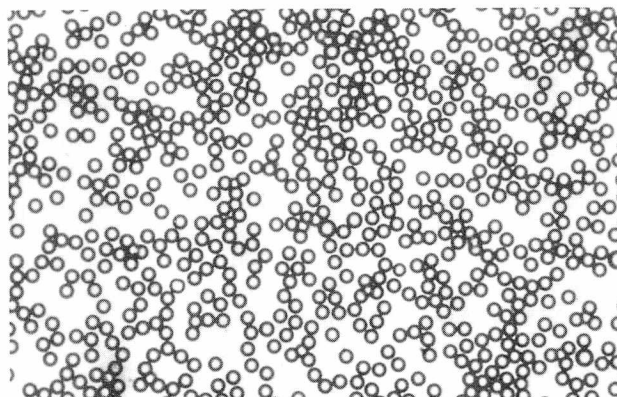
Loniten can cause salt and water retention, leading to heart failure in some cases. Because Regaine might enter the bloodstream through the scalp, FDA has asked Upjohn to study the extent of the drug's absorption and its effect on blood pressure in hypertensive males who had temporarily discontinued their regular anti-hypertensive medication.

Regaine is an experimental drug whose safety and effectiveness for growing hair have not been reviewed by FDA. Moreover, privately recompounded minoxidil is pharmacologically different from the formulation tested by Upjohn and may vary in strength and effect each time it is used. Commercialization of the recompounded drug may be illegal, FDA warns, and anyone prescribing or reformulating Loniten could be liable for harmful effects.

Space Beads

In the vial below are 30 million—more or less—polystyrene beads to be used by FDA's Laboratory for Cellular and Molecular Biology. They were made under

low-gravity conditions on a NASA shuttle flight, using a chemical process developed by Lehigh University that turns out perfectly round and uniform spheres 10 microns across. (See magnified photo.) Similar beads made on Earth can be lumpy, irregular, inexact, and otherwise unsuitable for precise scientific work. These are from the first batch released by the National Bureau of Standards, which certified their quality, and FDA is the first federal agency to acquire them. The FDA lab will use them—a few at a time—to align laser beams on an optical cell sorter used in colon cancer research. The vial holds about a year's supply.



The Galling Plight of Gallstones

by Evelyn Zamula

Proudly displayed in the curio cabinet in days gone by, in the place of honor beside the bronzed baby shoes, sat a keepsake of another kind—a small amber glass jar filled with gallstones. Surgeons used to send patients home with their gallstones. Some still do, but—thankfully—exhibiting them has gone out of style.

It is estimated that about 25 million Americans—about three quarters of them women—are carrying these potential trophies around in their gallbladders. About half of the people who have developed these stones don't know they have them. They trudge through life blissfully unaware because the stones aren't bothersome. The stone carriers may burp a little after eating or have mild indigestion now and then, but they can lay the blame on the hot dog they ate for lunch or the green pepper in the salad.

These "silent" gallstones are often discovered only when abdominal surgery or an X-ray exam is performed for some other medical problem. In many cases, the ultimate revelation comes after death. In one large autopsy study, gallstones were found in 16.8 percent of the women and 7.8 percent of the men over 20. It is estimated that 30 percent of all men and women over 60 have gallstones.

Sometimes, however, gallstones speak out loud and clear. They make their presence known every now and again with pain and indigestion, especially after their owners have eaten a large meal. They can also announce themselves dramatically in an acute attack that may involve a quick visit to the hospital emergency room at 2 in the morning and—quite possibly—a subsequent appearance in the operating room, where the stones *and* the gallbladder that contain them are removed.

The gallbladder, like the appendix, is a part of the body we can live without. Or so Dr. Carl Langenbuch of Berlin discovered in 1882, when he devised a way of removing the gallbladder of a patient who couldn't live *with* it any longer. (When the gallbladder is removed, bile needed for digestion flows directly from the liver into the small intestine.)

The gallbladder is a pear-shaped sac about 3.5 inches long that nestles under the right lobe of the liver, to which it is attached with loose connective tissue. Though not essential, it performs some useful functions. The gallbladder stores the bile that the liver manufactures continually at the rate of about two to three cups a day. When bile is needed for digestion, the gallbladder

contracts, discharging the bile into the small intestine through a series of ducts. There bile salts act like detergent to break up the fats we eat so that they—and fat-soluble vitamins A, D, E and K—can be absorbed by the small intestine.

The gallbladder also concentrates the liver bile, which is about 97 percent water. The other 3 percent consists of pigments (bilirubin, biliverdin) that give liver bile its pale yellow color, lecithin, bile acids (or bile salts), and cholesterol. What's left after the gallbladder finishes its concentrating is about four tablespoons of a thick yellow or brownish fluid with the consistency of motor oil.

The component of the bile that causes the trouble—and most gallstones—is the cholesterol. Though it has a bad reputation these days, cholesterol is needed by the body for certain essential functions. It's in the nerve tissue of the brain and spinal cord and it's an ingredient of some essential hormones. Cholesterol is produced by the liver, which uses some of it to make bile acids. What's left remains suspended in the bile.

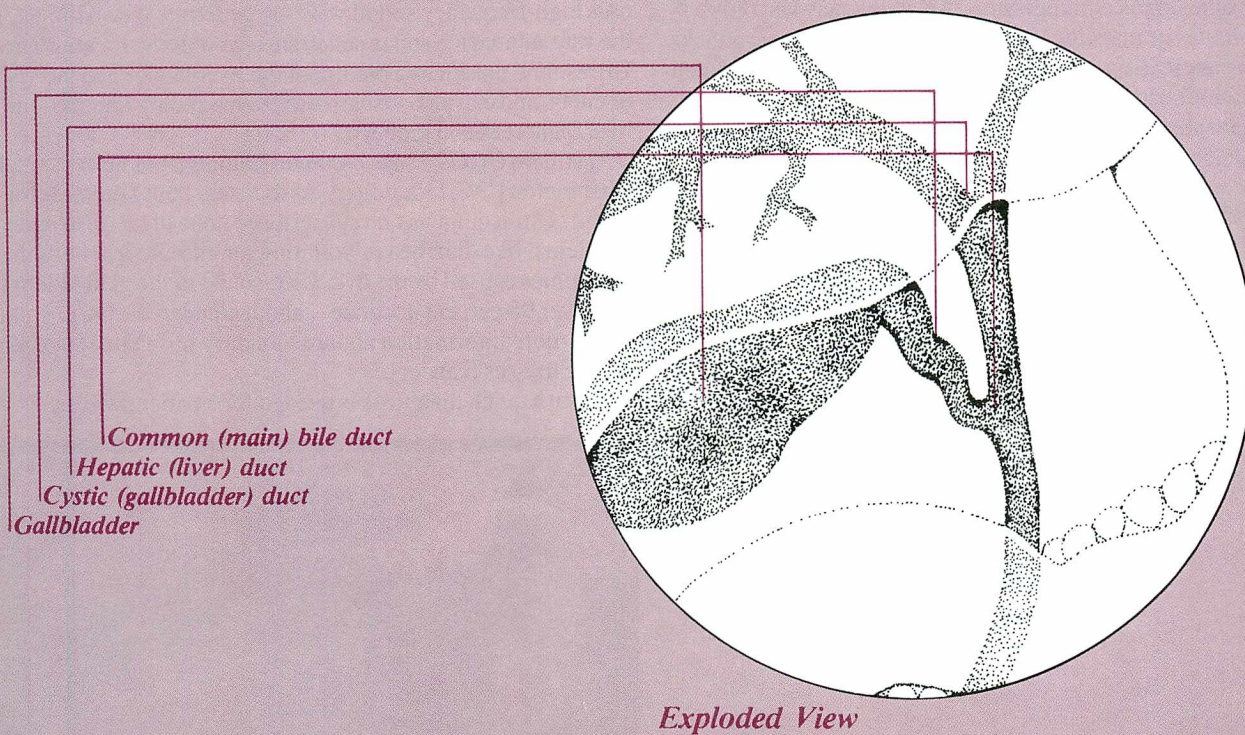
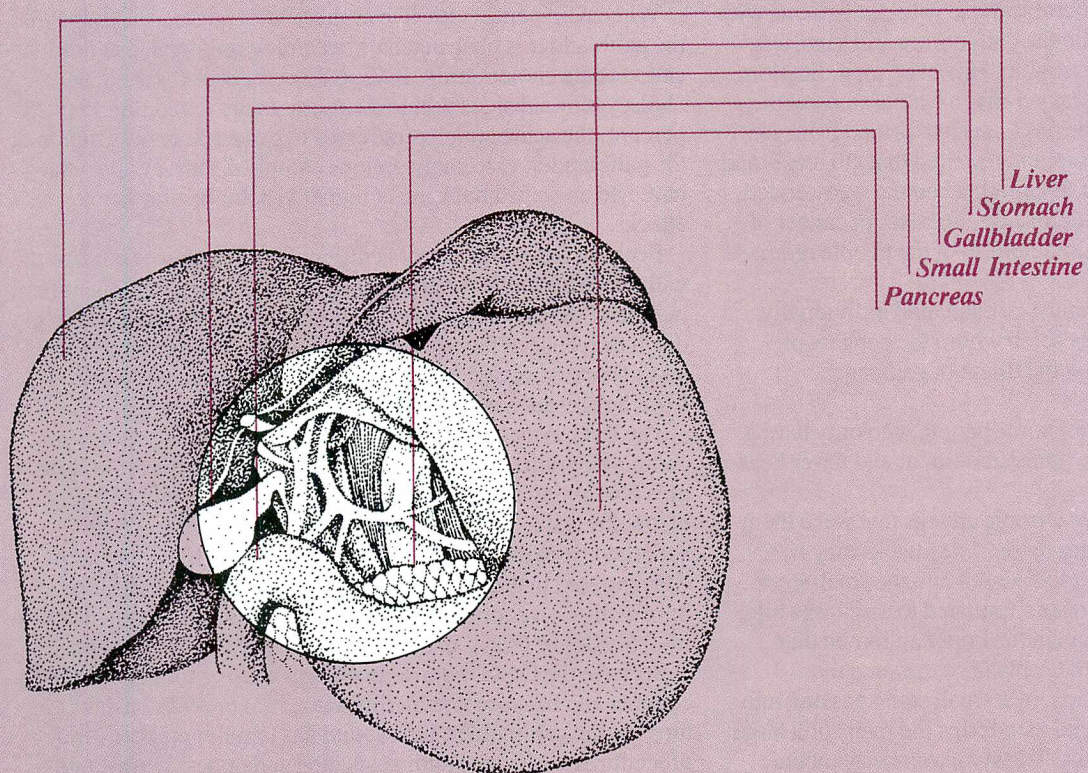
Normally, all the components of bile are nicely balanced. The problems begin, theorize some researchers, when the liver produces an oversupply of cholesterol or not enough of the bile acids that help emulsify the cholesterol. The bile then becomes loaded with cholesterol. When this supersaturated bile reaches the gallbladder, the cholesterol separates out as small crystals. The crystals stick together and pick up bilirubin pigment, small amounts of calcium, and bacteria and other cells floating around in the bile. Thus is born a cholesterol gallstone, the type most commonly found in American gallbladders.

Less common types are "mixed" gallstones (containing cholesterol, calcium bilirubinate, and calcium carbonate), pigment stones (composed of calcium bilirubinate and cholesterol), and calcium stones, made up almost entirely of calcium carbonate.

Gallstones grow into some interesting shapes. They may be so fine that they look like a layer of sludge in the gallbladder; or one stone can fill the whole sac. They may look like pearls, like quartz crystals, or even mulberries. Gallstones can be white from the cholesterol, black or brown from the pigments, or yellow or red.

(Continued on page 8)

The Gallbladder and Surrounding Organs



(Continued from page 6)

But no matter how many there are or what they look like, no one can predict with absolute certainty whether they will act up or not.

If gallstones are silent, doctors don't usually operate unless there is a good reason. Some doctors advise younger patients with gallstones to have them out while the patients are still vigorous—and before the gallstones cause trouble. However, an indication that surgery is not always necessary is given by one study at the University of Michigan. Routine physicals performed from 1956 to 1969 on university faculty members revealed that 110 males and 13 females had silent gallstones. By 1980, when the study ended, no one had died from gallbladder disease, no cases of cancer of the gallbladder had developed, and only 16 of the people required surgery.

Doctors stress that each case must be evaluated individually, especially for the elderly and obese, in whom the dangers of surgery must be balanced against the threat of gallstone complications.

Surgery is also questionable for some people who only have a bout or two of biliary pain in the upper abdomen, and never hear from their gallstones again.

Other unluckier sufferers have chronic attacks that wake them up at night, often after eating fatty foods. The attacks may be a dull ache that subsides after the food passes into the small intestine and the gallbladder is no longer stimulated to discharge bile; or they may be a sharp steady pain in the upper abdomen that radiates around to the right shoulder blade or between the shoulder blades—caused, perhaps, by a small stone passing into the common bile duct (the channel that drains the liver) or a large stone temporarily blocking a duct. The symptoms may include nausea and other signs of indigestion. An attack may last only about 20 minutes or may linger for several hours. Chronic attacks may lead to pancreatitis—inflammation of the pancreas—a potentially fatal complication.

Problems really begin when a stone roams out of the gallbladder and gets jammed in a duct. Gallstones most often get stuck in the cystic duct, the channel through which bile enters and leaves the gallbladder. Stones may also lodge in the common bile duct, and thereby block the pancreatic duct, which drains the pancreas.

Pain caused by a blocked duct is usually sudden and excruciating. It may be felt in the middle or right portions of the abdomen. It can spread throughout the abdomen or even to the back or chest. The pain may shift from side to side or settle in the right

shoulder. It is often so intense that the patient perspires heavily or vomits. The pain may go away after a few minutes or may go on for hours. Chills and fever may be present. If the stone has settled in the common bile duct, bile backs up into the liver, and the patient's skin and the whites of the eyes become yellow, or jaundiced: definitely time to see the doctor.

When pain persists for five or more hours, it may be a sign that the gallbladder is obstructed or becoming inflamed, a condition called acute cholecystitis. In 75 to 85 percent of cases, acute cholecystitis subsides within 72 hours. In the remaining 15 to 25 percent, the acute attack progresses to gangrene or perforation of the gallbladder, extremely serious complications. People who have had an acute attack are at higher risk for having future attacks.

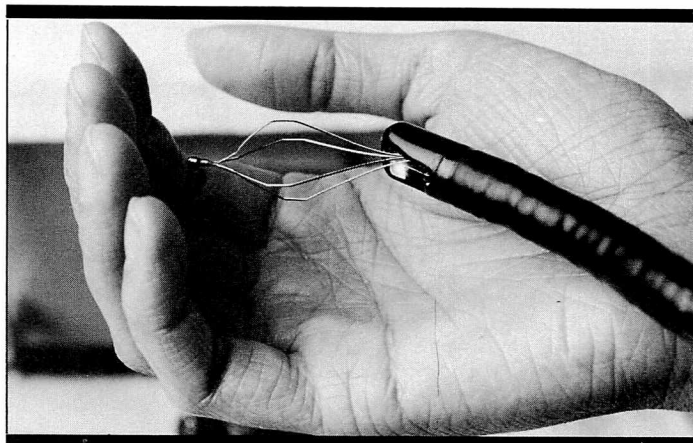
Because the symptoms of acute cholecystitis can be confused with those of a perforated peptic ulcer, acute appendicitis, inflammation of the pancreas, or even a heart attack, the only way to pin down the cause of the trouble is to undergo certain diagnostic tests. Doctors rely on multiple tests, since no one test will confirm the presence of gallstones 100 percent of the time.

The test most commonly used until recently has been the oral cholecystogram (OCG). In this procedure, the patient swallows pills containing an iodine-based contrast agent about 12 hours before the test is to be performed. After the "dye" has been absorbed from the intestine, excreted from the liver, and then concentrated in the gallbladder, X-rays are taken. (For more information on contrast dyes, see "Dyes Inject Contrast into X-rays' Shades of Gray" in the October 1985 *FDA Consumer*.)

Because the OCG requires overnight waiting for the dye to concentrate and because it sometimes does not provide a useful "picture" of the gallbladder, ultrasound has largely replaced X-ray procedures as a first test for suspected gallstones. Ultrasound uses high-frequency sound waves to penetrate the abdomen, just the way submarine sonar penetrates the water to locate objects. Ultrasound produces a picture of the gallbladder and the system of ducts, and can also visualize the surrounding organs—the liver, pancreas and kidneys.

"I still do OCGs," says Dr. Peter Dunner, a radiologist with Washington [D.C.] Radiology Associates, "but I prefer ultrasound. Ultrasound has no side effects, none of the gastrointestinal problems, like diarrhea or vomiting, or allergic reactions that are sometimes caused by the dye. Ultrasound of the gallbladder is now over 95 percent accurate—about equal to the OCG—plus it yields more information about secondary problems, such as pancreatic masses [cancer]."

When a quick diagnosis is needed for a patient who appears to



The wire basket pictured at right protrudes from the business end of a device called an endoscope, used to help snare and retrieve or crush gallstones in the common bile duct. The flexible endoscope also contains a small light to help guide the physician during the procedure.



This gallbladder is chock-full of gallstones of various shapes and sizes. The scale at the bottom is in centimeters. (About 2.5 cm = 1 inch.)

be having an acute attack of gallbladder pain, doctors can visualize the gallbladder and the ducts with nuclear medicine scans using radioactive compounds. The compounds are injected into a vein and travel through the circulatory system to the liver, the gallbladder, and the intestine. Their journey is tracked by a special device called a gamma camera, which detects the small amounts of radiation given off by the compounds. Fast and painless, this method is especially helpful in detecting an obstructed duct.

In most cases, the outcome of chronic or acute gallbladder disease is surgery to remove the stones and the gallbladder itself. By removing the gallbladder, the formation of future gallstones is prevented in the majority of patients. Of the 1 million people who each year discover they have gallstones, about 500,000 undergo surgery. It is the fifth most commonly performed surgical procedure in the United States, according to the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, and the mortality rate is less than 1 percent.

In the operation, the gallbladder is carefully dissected from the adjoining tissues and the cystic duct is cut and tied, forcing the bile produced by the liver to flow directly into the small intestine. Before the gallbladder is removed, the surgeon will inspect the common bile duct and remove any stones found there. If it is suspected that more are lurking in the duct, an X-ray will be taken on the spot or a medical device called a choledochoscope will be used to look inside the duct.

In the elderly or those in poor health, a gastroenterologist can sometimes remove stones from the common bile duct (not from the gallbladder) without surgery, using an endoscope. This device enables a physician to not only "see" the duct area but also to widen the opening, so that the stone can just slip through into the small intestine. Or a small basket can be attached to the end of the device to catch and withdraw or crush the stone. (The stone

fragments eventually leave the body via elimination.) For more information on endoscopy, see "A Physician's Spyglass for Looking Inward" in the December 1982-January 1983 *FDA Consumer*.

There is yet one more technique available for certain patients who are poor risks for surgery. Chenodeoxycholic acid (chenodiol) is a drug taken orally to dissolve gallstones by reducing the cholesterol content of the bile.

Chenodiol is most effective in people who have small, floating, cholesterol stones. It is not effective in dissolving pigment stones or stones with a high calcium content. The drug can have unpleasant side effects, including diarrhea, which occurs in 30 to 40 percent of patients, and other gastrointestinal symptoms. It may also cause liver damage. Unfortunately, the drug does not prevent stones from recurring. In clinical tests, gallstones recurred within five years in half of the patients. The quest for a better gallstone solvent goes on. Researchers are working with ursodeoxycholic acid and other drugs that have dissolved gallstones in animals and humans with some success.

The most recent advance (still in the experimental stage) in the treatment of gallstones involves inserting a catheter through the liver into the gallbladder. The catheter carries a form of ether that dissolves the stones in the gallbladder and bile duct in a matter of hours, depending on how large and how many there are—dozens, in some cases.

If gallstone sufferers who hope to avoid surgery can hang on long enough, there may be another solution to their problem. The makers of the Dornier Lithotripter, a device recently approved by the Food and Drug Administration for disintegrating kidney stones using shock waves, are now working on a machine to do the same for gallstones. If they succeed, there'd be no more gallstones to display in curio cabinets ever again. ■

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

Dietary Guidelines for Americans: No-Nonsense Advice for Healthy Eating

Advice on what Americans should or should not be eating to be healthy is as abundant—perhaps as overabundant—as the food supply in the United States. The public's dilemma was summed up in a recent speech by Sanford A. Miller, Ph.D., director of FDA's Center for Food Safety and Applied Nutrition, when he noted: "Consumers are bombarded constantly from many sources with an overload of information and misinformation about nutrition and health. Realistic, reliable guidance is critically needed to help the public sift and weigh this barrage of information, to make intelligent nutrition choices among the thousands of attractive foods in supermarkets, and to select food in the many places where it is consumed away from the home."

The latest "Dietary Guidelines for Americans," made public in September by the U.S. Department of Agriculture and the Department of Health and Human Services, are intended to provide healthy Americans with sensible, uncomplicated guidance on the kinds of foods they should be eating. Basically, their advice to Americans is: Concentrate on eating a balanced and varied diet that provides the nutrients essential to good health, increase consumption of starch and fiber, but reduce fat, sugar, sodium and alcohol. A nine-member committee of nutrition experts reviewed the latest scientific data before making its recommendations to the two federal departments. The committee stressed that current scientific evidence does not support more specific advice for the general public.

The 1985 guidelines differ little from those announced by USDA and HHS in February 1980. The advisory committee concluded that no recent nutrition research was persuasive enough to warrant any major changes. Not enough is known to describe an "ideal" diet for every individual because nutrition needs vary according to a person's sex, age, health, body size, and other factors. So the guidelines are aimed at those Americans who are in good health. They do not apply to people with diseases or conditions that affect nutritional needs.

A healthy, pregnant woman, for example, has special dietary needs. A person suffering from a chronic ailment—heart disease, cancer, high blood pressure, diabetes, and other conditions—may also have special diet requirements. Nutritional requirements also can be influenced by medications.

More than 40 different nutrients—in the form of vitamins, minerals, amino acids (from proteins), essential fatty acids (from fats and oils), and calories from carbohydrates, fats and proteins—are needed for good health. However, no one can be expected to keep track of all of them. Instead, most people generally can expect to satisfy their nutritional requirements by eating a variety of foods.

The guidelines do not suggest specific goals for such substances as fats and dietary fiber because of the need for more research. Instead, the guidelines state that "for the U.S. population as a whole, increasing starch and fiber in our diets and reducing calories (primarily from fats, sugars and alcohol) is sensible. These suggestions are especially appropriate for people who have other risk factors for chronic diseases, such as a family history of

obesity, premature heart disease, diabetes, high blood pressure, high blood cholesterol levels, or for those who use tobacco, particularly cigarette smokers."

Nutritionists are able to offer more specific advice about requirements for energy (calories), protein, and certain vitamins and minerals through the Recommended Dietary Allowances that are updated periodically by the Food and Nutrition Board of the National Academy of Sciences. Food product labels, in many instances, also provide consumers with valuable nutrition information, as well as a listing of ingredients used in foods.

Here are the seven guidelines and the rationale for each of them:

1. EAT A VARIETY OF FOODS

Most foods have more than one nutrient, but no single food provides all the essential nutrients. That is achieved by eating a balanced, varied diet that emphasizes the major food groups—fruits and vegetables; cereals and other foods made from grains; dairy products; and meats, fish, poultry, eggs, and dry beans and peas.

For example, dairy products such as milk are a source of protein, fats, sugar, vitamin A, riboflavin and other B vitamins, calcium, phosphorus, and other nutrients. But they provide little iron. Meat provides protein, several B vitamins, iron and zinc but little calcium. Vitamins A and C, folic acid, fiber, and various minerals are obtained from fruits and vegetables. Whole-grain and enriched breads, cereals, and other grain products provide B vitamins, iron, protein and fiber.

Although there are some exceptions, a varied diet based on these food groups will satisfy the nutrient requirements of most healthy individuals without the need for supplements. "There are no known advantages and some potential harm in consuming excessive amounts of any nutrient," the guidelines stress. "Large dose supplements of any nutrient should be avoided. You will rarely need to take vitamin or mineral supplements if you eat a variety of foods."

However, there are some exceptions. Iron supplements often are needed by women in their childbearing years. Pregnant and breast-feeding women have an increased need for certain nutrients, notably iron, folic acid, vitamin A, and calcium. Infants also have special nutritional needs. Breast-feeding is recommended for the first three to six months because infants absorb nutrients from breast milk better than cow's milk. Breast milk also contains substances that provide immunity to some diseases until the infant's body is able to produce these substances itself.

After three to six months, babies can start taking solid foods. Prolonged breast- or bottle-feeding without solid foods or iron supplements can result in iron deficiency, the guidelines point out. Flavoring baby foods with salt and sugar also is discouraged.

Elderly people also have to be extra careful about getting





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Dietary Guidelines for Americans

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enough of all the essential nutrients because many older people eat less. The guidelines stress meals based on the basic food groups and a reduction in the consumption of fats, oils, sugars, sweets, alcohol and other foods that are high in calories but low in other nutrients. Some elderly men and women who take certain medications that affect nutrient intake also may require supplements. Such supplements, however, should be taken only under the guidance of a physician.

2. MAINTAIN A DESIRABLE WEIGHT

Experts estimate that one-third or more of all adult Americans are overweight and that, at any given time, more than 20 million Americans are resorting to diets to shed excess weight. Obesity is a major health concern in the United States, for it increases the risk of such chronic diseases as high blood pressure, heart disease, stroke and diabetes.

Although many Americans keep searching for easy paths to losing weight, most such efforts are doomed to failure, in the view of most nutrition experts. Losing weight and not regaining it, the guidelines suggest, means eating foods high in nutritional value but with fewer calories, getting more exercise, and shedding weight at a sensible, gradual rate, a pound or two each week.

Quick weight-loss schemes are looked upon with disfavor. "Long-term success depends on new and better habits of eating and exercise," the guidelines stress. "That is why so-called 'crash' and 'fad' diets usually fail in the long run." (See "The Fad-Free Diet" in the July-August 1985 *FDA Consumer*.)

The guidelines warn that diets of less than 800 calories a day can be hazardous and should be followed only under medical supervision. Severely restricted, low-calorie diets make it extremely difficult to obtain the nutrients essential to maintaining good health, and they can have adverse effects. The guidelines warned: "Some people have developed kidney stones, disturbing psychological changes, and other complications while following such diets. A few people have died suddenly and without warning."

Frequent use of laxatives, induced vomiting, and other extreme measures should not be used to lose weight, according to the guidelines. Such actions can cause chemical imbalances that can lead to irregular heartbeats and even death.

The emphasis should be on keeping body weight at a reasonable level for one's sex, age and height. A table of "desirable body weight ranges" is included in the guidelines.

Severe weight loss—below what is recommended—also is discouraged. Some people have suffered nutrient deficiencies, infertility, hair loss, skin changes, cold intolerance, severe constipation, psychiatric disturbances, and other complications from excessive weight losses. A doctor should be seen about any sudden, unexplained loss of weight.

3. AVOID TOO MUCH FAT, SATURATED FAT, AND CHOLESTEROL

The American diet generally is high in fat and cholesterol compared to some countries, and Americans tend to have high blood cholesterol levels. High blood cholesterol is one of the risk factors for heart attack. Nutritionists lack enough research data to make specific recommendations about how much fat and cholesterol the general public should eat, but the guidelines urge a sensible reduction in total fat—especially saturated fat—and cholesterol.

Among the suggested ways of doing this is to trim excess fat off meats and to eat lean meat, fish, poultry, and dry beans and peas as protein sources; use low-fat dairy products; eat moderate amounts of eggs and organ meats; limit intake of foods high in saturated fat, such as butter, cream, heavily hydrogenated fats, shortenings, and foods with palm and coconut oils; and broil or bake, rather than fry, foods.

The effect of diet on blood cholesterol levels varies among individuals. Some people—for reasons not completely understood—can eat foods high in saturated fat and cholesterol and maintain reasonable blood cholesterol levels, while others on low-fat, low-cholesterol diets still end up with high cholesterol levels. Heredity is believed to play a role. Acknowledging the controversy over what recommendations would be appropriate for the general public, the guidelines state that it would be "sensible" for Americans to reduce their daily consumption of fat. This is especially appropriate, the guidelines say, for individuals who have other cardiovascular risk factors, such as smoking or family histories of premature heart disease, high blood pressure, and diabetes. The guidelines do not suggest complete avoidance of any foods, because many foods that contain fat and cholesterol also provide high-quality protein and many essential vitamins and minerals.

4. EAT FOODS WITH ADEQUATE STARCH AND FIBER

As in 1980, the guidelines favor a moderate increase in consumption of fiber-containing foods. The American diet generally is low in fiber, yet there is evidence that fiber can help reduce chronic constipation, diverticular disease, and some types of "irritable bowel." Fruits, whole-grain breads and cereals, vegetables, dry beans and peas, and nuts are good sources of starch and fiber. (See "Fiber: Something Healthy to Chew On" in the June 1985 *FDA Consumer*.)

Carbohydrates and fat are major sources of energy (calories). If Americans cut back on fat consumption, energy needs can still be met from carbohydrates, especially the complex carbohydrates. "Carbohydrates are especially helpful in weight reduction diets

because, ounce for ounce, they contain about half as many calories as fats do," the guidelines said.

Simple carbohydrates like sugar provide calories but little other nutritional benefit. In contrast, complex carbohydrates—such as starch in bread and other grain products, beans, peas, nuts, seeds, fruits and vegetables—contain other essential nutrients. Also, eating more foods with complex carbohydrates adds dietary fiber.

(Dietary fiber describes parts of plant foods that generally are not digestible by humans. Foods differ in the kinds of fiber they contain. Wheat bran has several kinds of fiber and has laxative properties but does not affect blood cholesterol levels. Other kinds of fiber have no laxative effects but seem to reduce blood cholesterol.)

Although in recent years there have been studies suggesting that the risk of colon cancer is greater among those with low-fiber diets, the guidelines state that more research is needed before definitive judgments can be made. "How dietary fiber relates to cancer is one of many fiber topics under study," the guidelines state.

5. AVOID TOO MUCH SUGAR

It is not necessary to avoid eating simple sugars. It would, in fact, be difficult, because sugars are naturally present in many foods and are added to many processed products, usually in the form of sucrose, glucose, maltose, dextrose, lactose, fructose, corn sweeteners, honey and syrups. The major health concern with excess sugar consumption is tooth decay, especially when sugars (and starches, as well) are consumed between meals. The guidelines discourage eating sweets between meals. The guidelines also restate the age-old advice about proper dental hygiene, brushing after meals, drinking fluoridated water, and using fluoridated toothpastes or mouth rinses.



6. AVOID TOO MUCH SODIUM

Sodium is essential to the human body, but most Americans consume far more than they need, especially from table salt (which is 40 percent sodium). An intake of 1,100 to 3,300 milligrams a day is generally recommended. Salt is not the only source, for a wide variety of sodium compounds is used in many processed foods and beverages. The principal concern with high sodium consumption is for people with hypertension (high blood pressure) and those who may be susceptible to it.

7. IF YOU DRINK ALCOHOLIC BEVERAGES, DO SO IN MODERATION

In urging moderate use of alcohol, the guidelines also support the national effort to discourage drinking and driving. From a nutritional standpoint, alcohol is high in calories but provides virtually no other nutritional benefit. The guidelines note that one or two standard-sized drinks daily appear to cause no harm in healthy adults.

Overweight people should be aware that alcohol adds calories. Heavy drinkers especially can suffer appetite loss, and this can lead to nutritional deficiencies and other health problems, such as cirrhosis of the liver and some types of cancer.

Pregnant women are advised by the National Institute of Alcohol Abuse and Alcoholism to refrain from drinking alcohol because excessive consumption may cause birth defects or other problems during pregnancy. The level of consumption at which risks to an unborn child occur has not been established, the guidelines declare.

For a single free copy of the "Dietary Guidelines for Americans," write to Consumer Information Center, Dept. 622N, Pueblo, Colo. 81009. For multiple copies, write to the Food and Drug Administration, HFI-40, 5600 Fishers Lane, Rockville, Md. 20857.

—Chris Lecos

Why Is Uncle Sam Telling Us What to Eat?

When the U.S. Department of Agriculture and the Department of Health and Human Services first published "Dietary Guidelines for Americans" five years ago, the recommendations elicited a good deal of criticism and controversy. Many groups and individuals from the health professions and the food industry questioned the scientific basis of the guidelines and even the federal government's authority to advise its citizens on what they should eat.

Now, with the publication of a revised set of guidelines by the two departments,

the head of food and nutrition activities in the Food and Drug Administration (a part of HHS) strongly defends the right of government and public health scientists to offer general nutrition advice to the American public.

Sanford A. Miller, Ph.D., director of FDA's Center for Food Safety and Applied Nutrition, declared at a food symposium earlier this year that: "It has always been a fundamental fact of American political and social philosophy that government does have a special role in assuring the

health and safety of its people." Sound nutritional advice is needed more than ever before, he said, because of the growing complexities of nutritional science, of the food industry, and of the food supply itself. "In today's world, with increasing separation of the consumer from the sources of production of food, with increasing application of contemporary technology that results in changing the shape and dimensions of the food supply, the consumer is no longer capable of making appropriate choices on the basis of

The Experts Behind the Guidelines

The Dietary Guidelines Advisory Committee was formed Feb. 23, 1983, by John R. Block, secretary of the U.S. Department of Agriculture. Serving as committee chairman was Dr. Bernard Schweigert, chairman of the Department of Food Science and Technology at the University of California, Davis. The other eight members included:

Dr. Henry Kamin, professor of biochemistry, Duke University, Durham, N.C.; Dr. David Kritchevsky, associate director of anatomy and biology, The Wistar Institute, Philadelphia; Dr. Robert E. Olson, professor of medicine and pharmacological sciences, State University of New York at Stony Brook; Dr. Lester Salans, professor of medicine, Mount Sinai Medical School, New York City; Dr. Robert Levy, professor of medicine, College of Physicians and Surgeons, Columbia University, New York City; Dr. Sanford A. Miller, director of the Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration; Dr. Judith S. Stern, professor of nutrition, University of California, Davis; and Dr. Frederick Stare, professor emeritus, School of Public Health, Harvard University, Boston.

traditional knowledge and experience," Miller said. "Equally important, contemporary science has moved so far into often [esoteric] regions that it is impossible for the average individual to stay abreast of the most recent information and to make appropriate choices based on this information."

The dietary guidelines are the result of an 18-month effort by an advisory body of nine scientists who reviewed, discussed and, at times, debated the general advice they would offer this year to Americans about the foods we eat.

The fact that no substantive changes were proposed this year is a reflection of the continuing sagacity and scientific durability of the guidelines, said Miller. Miller was one of three HHS representatives on the advisory committee. Three others represented USDA, and the remaining committee members were chosen from a list of names from the National Academy of Sciences.

Miller noted that the 1980 guidelines were issued at a time when debate was "almost explosive" among nutritionists on the appropriateness of government to offer even any general nutrition advice to the public. The guidelines also appeared at a time when increasing attention—by the public and the scientific community—was being focused on the relationship of diet to such diseases as cancer, heart disease, hypertension, obesity, osteoporosis, and other chronic conditions.

Research done in all these areas was carefully considered by the committee before recommendations were made, Miller noted. However, he stressed that

the nine scientists followed a policy of recommending changes only if they could be adequately supported by research and science. The advisory committee, he said, "did not feel that the state of knowledge was sufficient to go beyond the principles of moderation and general information about the relationship that is already in the guidelines."

The dietary guidelines proposed in 1980 were "as mild a set of proposals as has ever been drafted," yet they generated an outcry that in Miller's view was "unbelievable" and which only inflamed the controversy and muddled the real issues—namely, whether any important changes to the national diet should be recommended. "Fortunately," Miller said, "the good sense and professional integrity of the committee members did not allow irrelevant issues to interfere with their work. Open, often sharp debate occurred during committee meetings . . . on the principle issues, but not on personalities or innuendo. As a result, the [1985] report reflects this professional attitude."

By virtue of their training to question, probe, research, and even to disagree, scientists rarely—if ever—are able to flatly state their conclusions without qualification or reservation, Miller said. Some facts, he asserted, remain facts only until the next scientific paper is published. However, the ongoing debate that prevails in the scientific world can pose a dilemma for public health scientists.

"At some point in the collection of information concerning a public health problem, public health scientists must make what I like to call 'the leap of faith,' "

Miller said. "They must believe that the data are sufficiently convincing for them to take a public health action even though doubts may remain. If they delay in taking that action, they run the danger of imperiling the health of substantial numbers of people."

There are no acute nutritional problems in the United States today, Miller stresses. The available data suggest that the general health of Americans, as well as their quality of life, is on the upswing. The trend is downward for such major chronic diseases as cardiovascular disease and stroke. Cancer rates, relatively constant at present, would actually show a downward trend if lung cancer in women—which is on the rise—was not included in those totals.

Although improved medical care and technology have played a major role, it is generally believed that changing lifestyles also have contributed to the nation's improved health picture, Miller said. "Certainly among these lifestyle changes," he said, "has been a greater concern on the part of the American people for diet . . . The important point, I believe, is not that we need to consider the problem of diet and chronic disease because there is an epidemic of ill health in this country, but rather as an approach that could make substantial contributions to the further improvement of health . . ."

The need for reliable dietary guidance was apparent in 1980, Miller continued, and it is in even greater demand today because of the growing health-consciousness of Americans. For many people, he said, "nutrition has become a significant factor in making food choices. But there is substantial confusion about the nutritional value of foods in the marketplace and about the relationships between diet and disease." One "remarkable thing" about the guidelines, Miller continued, is that they provide Americans with "reasonable, appropriate guidance relative to several diseases that are prevalent in this country. The primary reason, of course, is the convergence of information from research that links diet with several disease conditions, including heart disease, cancer, hypertension and obesity. Thus, the principles of variety and moderation promoted in the guidelines represent a generally healthy pattern of eating which may contribute to disease prevention as well as health promotion." ■

FEVER

What to Do—and What Not to Do— When the Heat Is On

“Fever” can be a frightening word, particularly when it is part of the name of a disease, as in “yellow fever,” “typhoid fever,” “scarlet fever,” “childbed fever,” and so on. Literary descriptions of a heroine languishing with fevered brow or a hero dying of an unknown fever give the word an air of mystery, while “feverish activity” or similar phrases suggest frenzied excitement.

Unless it is very high, a fever is not to be feared. It is not a disease, simply a symptom, a warning sign that something is wrong with the body that needs investigation. A fever may even serve a useful purpose.

Fever usually occurs with a bacterial or viral infection or inflammation. Noninfectious conditions, such as thyroid and adrenal disease, dehydration in infants and the elderly, some skin conditions, stroke, cancer, and even some adverse drug reactions may also cause a fever.

The cause of some fevers, particularly in children, are not so easily pinned down. These “fevers of unknown origin,” as they are called, are characterized by a rectal temperature of 101.3 degrees Fahrenheit or higher, measured on at least four occasions over a two-week period. They may often defy diagnosis for as long as a week. About half of these fevers in children are ultimately found to be caused by infections; 20 percent are caused by collagen inflammatory diseases, such as juvenile rheumatoid arthritis; and 10 percent are the result of cancer, primarily leukemia. The remainder are of miscellaneous or truly unknown origins.

That fever is associated with disease has been known and accepted for centuries. However, views on what should be done about it have not been as consistent. Ancient medical savants looked upon fever as something to be encouraged. It was considered the most important of the body’s natural defenses against increases of phlegm, one of the four “humors” of ancient physiology. (An overabundance of phlegm was associated with apathy and indolence.) The 17th century English physician Thomas Sydenham called fever “nature’s engine,” brought to the field to fight the enemy.

Medical attitudes toward fever changed in the 19th century when the French physiologist Claude Bernard reported that death in experimental animals quickly occurred when the body temperature rose to more than 107 degrees Fahrenheit. From then on, fever was deemed injurious to health and was treated vigorously with antipyretics—fever-reducing drugs—and “heroic measures” such as bleeding.

In modern medicine, the focus is on finding out what is causing the fever and treating that illness, rather than on treating the fever

itself. Of course, if the fever results in severe weakness, causes major symptoms such as convulsions or dehydration, or is affecting the central nervous system, the doctor will take steps to reduce it, whether or not the cause has been discovered.

There are some very good reasons for not treating a fever. For one, there is some evidence that a fever may play a role in stimulating the body’s natural defenses. The ups and downs of a fever also help in diagnosing an illness and following its course. And fever is often the only way to determine whether a particular treatment is working. If a patient is on an antibiotic, for instance, a persistent fever would indicate that the drug is probably not effective and that an alternative should be used.

A number of recent studies involving parents of young children have shown that the old fears about the dangers of fever still persist. Several researchers have dubbed this parental concern “fever phobia.”

In general, the studies revealed that parents worry a lot about fever and its possible harmful effects. They do not understand what constitutes a “high fever,” they fear that if the fever isn’t treated it will continue to rise to dangerous levels, and they believe that even moderately high temperatures could cause permanent harm, such as “brain damage.”

Many of the parents interviewed in these studies thought that temperatures as low as 100 degrees Fahrenheit were serious and said they would start giving their children medication as soon as the fever thermometer reached that point.

Some parents tend to check their children’s temperatures frequently—from five to eight times a day, sometimes even hourly. Quite a number of parents worry so much about fever that they wake the child to give additional medication to lower the temperature. Such aggressive treatment of childhood fevers isn’t always necessary, according to pediatricians.

Fever is one of the most common reasons parents bring their children to see a doctor. About 90 percent of these fevers are minor and self-limiting, caused by some common infectious agent such as an influenza virus. Truly high fevers—105 F or higher—are rare and may be the result of a serious infection or other condition that has upset the body’s temperature regulation.

Unless the fever is very high, the temperature of a feverish child who feels reasonably well otherwise (which is often the case) doesn’t have to be reduced, experts say.

There are exceptions, of course. Persistent fevers over 103 F and fevers in infants and very young children and in those who have a history of convulsions require prompt medical attention.

Even though professional health care isn’t needed for all

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The Body's Thermostat

Physiologically speaking, a fever is an abnormal rise of the body's temperature. The normal temperature in most people is 98.6 F (37 Celsius), 99.6 F if measured rectally. However, even a normal temperature varies a bit depending on the time of day. The temperature is often higher in the afternoon than in the morning, for instance.

What keeps the body's temperature at a normal level is the hypothalamus, a tiny area in the center of the brain that serves as the command center for the most critical of the body's functions, including food intake, endocrine levels, water balance, sexual rhythms, and the autonomic nervous system.

Body heat, produced primarily by muscular activity, is carried via the bloodstream to the skin, where it dissipates into the surrounding air. If the body is hot, as it might be after a vigorous game of tennis, for example, the hypothalamus will send a message to dilate (widen) the blood vessels, thus increasing the loss of heat. Sweating also promotes heat loss through evaporation.

If the temperature of the blood drops, the hypothalamus will order the blood vessels in the skin to constrict (narrow), decreasing heat loss. The hypothalamus also signals the adrenal glands to increase their production of the hormones that cause further constriction of the blood vessels and increase cellular metabolism and, therefore, heat production. The muscle activity involved in shivering also helps produce more heat.

In the case of fever, the hypothalamic thermostat is reset at a higher level by the action of "endogenous pyrogens," proteins released by the cells when they are stimulated by infection or other trauma.

There's evidence that the pyrogens do not act directly on the hypothalamus, but are involved in the manufacture of certain compounds called prostaglandins, which are released from the tissues when the body is under stress. Supporting this theory is the fact that aspirin, the best-known fever-reducing drug, interferes with the production of prostaglandins.

Fever usually comes on gradually, but it can start suddenly with a chill. During a fever, the temperature-regulating mechanism continues to function at the higher "thermostat setting." The body attempts to conserve heat by constricting the blood vessels (hence the pale, cold skin) and by producing heat through shivering. When the heat conservation measures have been successful and the temperature is above the new set point, the blood vessels dilate and the patient begins to sweat, a sign that the fever is coming down—or, as they said in many a melodrama, "the fever is broken." ■



On Taking Temperatures

What mother hasn't checked her child for fever by the time-honored method of the back of the hand on the forehead? It's more accurate, however, to use a thermometer.

Fever thermometers come in two styles—oral and rectal. You can tell them apart because the rectal thermometer is larger in diameter. Both contain mercury in a bulb at one end. When warmed, the mercury expands and rises up the narrow tube inside the shaft.

The degrees of temperature are marked on the shaft of the thermometer. Each little space between the numerals is equal to .2 degrees Fahrenheit. The normal temperature is marked with an arrow.

Temperatures should not be taken orally just after the patient has had a cold drink or brushed his or her teeth. Wait 15 or 30 minutes. Then follow these basic steps:

1. Wash your hands and rinse the thermometer in cool water.
2. Holding the thermometer by the top (not the bulb end), shake it with a quick snap of the wrist until the mercury goes to 96 F or lower.
3. Place the bulb end of the thermometer well under the patient's tongue with the instruction to keep the mouth closed without biting for at least three minutes. Young children and infirm elderly patients

should not be left alone with a fever thermometer in place.

4. Remove the thermometer and rotate it until the mercury level can be seen. A good light helps, but don't hold the thermometer close to a lamp. The heat could affect the reading.

When a patient cannot hold an oral thermometer in the mouth—as with an infant, for example—the temperature can be taken rectally.

To do so, follow steps 1 and 2, then:

3. Lubricate the thermometer with a lubricant such as vasoline.
4. Have the patient lie on one side and breathe through the mouth. Infants and small children may be on their sides, backs or tummies. Gently separate the patient's buttocks with your free hand and gently insert the thermometer almost half an inch (the length of the bulb) into the rectum. Leave it or hold it in place, especially in infants and toddlers, about four minutes.
5. Remove, wipe off the lubricant, and read it like an oral thermometer. Rectal temperatures are about one degree higher than oral readings.
6. After use, wash the thermometer in cool, soapy water. Never wash it in warm or hot water, and do not store it near heat.

A less reliable device for measuring body temperature is a strip of blackened plastic in which liquid crystals are embedded. When pressed against the forehead for 15 to 60 seconds, these "fever strips" register rises in skin temperature by markings such as letters (N for normal, F for fever) or numbers. They also may turn various colors—tan (warm), green (warmer), and blue (warmest).

One problem with fever strips is that normal, non-feverish forehead surface temperatures can vary two to eight degrees among individuals. In addition, the skin temperature can be affected by air temperature, artificial light, and even flushing of the face caused by an emotional state—factors that don't affect the internal body temperature.

Consumers using fever strips should read the product directions carefully and double-check with a clinical thermometer when a high reading is registered by the fever strip, or anytime a fever is suspected even though the strip registers normal. ■

Fever is one of the most common reasons parents bring their children to see a doctor.



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feverish children, tender, loving care is still in order. There are a number of measures parents can take to make the young patient more comfortable.

- Help the body maintain its own temperature regulation. Many well-meaning parents bundle up a sick child, thus preventing natural heat loss. The sick room should be kept at a moderate temperature and the bed coverings kept to a minimum.
- Sponging with lukewarm water can also make the patient more comfortable. This increases heat loss by evaporation. Iced water, alcohol in water, or cold water enemas should *not* be used. Cooling mattresses are frequently used in hospitals to help reduce fever.
- Be sure that the child gets plenty of fluids.
- If treatment with antipyretic drugs is recommended, among the most effective are aspirin and acetaminophen (known by several trade names, such as Tylenol, Datril, and Panadol, and also sold generically).

Both drugs work equally well in reducing fever, but each has other advantages of its own. Acetaminophen is available in liquid form—a plus if a small child is being treated—but it is not effective in reducing inflammation. Aspirin does fight inflammation, but it can have serious side effects, including gastrointestinal bleeding and interference with blood clotting if given for prolonged periods or in excessive amounts. Both drugs can be toxic if

taken in large amounts. Therefore, care should always be taken to keep the bottle out of the reach of the toddler or young child.

In addition, parents should be particularly aware that they should consult a physician before giving aspirin to children and teenagers with flu or chicken pox. Some studies have shown a possible association between such use of aspirin and the development of a rare but often fatal condition called Reye syndrome.

Symptoms of Reye syndrome include violent headache, persistent vomiting, lethargy, sleepiness, belligerence, disorientation and delirium. These symptoms are very serious and can develop quickly, sometimes within half a day after the child has apparently recovered from the original flu or chicken pox. Unless emergency medical treatment is initiated promptly in a hospital setting, Reye syndrome can cause brain damage and even death. (For more information on Reye syndrome, see “New Warnings on Reye-Aspirin Link” in the April 1985 *FDA Consumer*.)

In most cases, a fever is not serious, but still, it can be a sign that something is seriously wrong. That is why it is important to follow the general rule that if the temperature goes above 103 F in an older child or adult or the fever persists for more than three days (72 hours), or recurs, it's time to call the doctor. Fever in infants is potentially more serious and if it persists or recurs, the doctor should be contacted within 24 hours. ■

—Annabel Hecht

The Public Health Threat Of Food-Borne Diarrheal Disease

by Chris Lecos

Most people have had diarrhea at one time or another, but the tendency is to shrug it off as a discomforting nuisance that will last only a short time. Yet, according to a new study by two food safety scientists at the Food and Drug Administration, diarrheal disease is a major public health problem that is seriously underestimated and underreported. It afflicts millions of Americans each year, often as a direct result of the foods they eat.

It is brought on by numerous pathogens (disease-causing microorganisms such as bacteria and viruses)—many of them only recently discovered by scientists. Diarrheal disease is reaching alarming proportions among children in the nation's day-care centers, and it may be contributing to serious chronic illnesses among vulnerable segments of the population. Finally, the two scientists say, diarrheal disease is costing the nation billions of dollars annually in lost wages and medical bills.

Basing their calculations on various scientific studies and other health data, the FDA scientists—Douglas L. Archer and John E. Kvenberg—estimate that between 68.7 and 275 million cases of diarrhea occur in the United States each year. Diarrhea is a major symptom of food poisoning, and their study estimates that from 21 million to more than 81 million of all diarrhea cases are of food-borne origin—a conclusion that calls into question the food sanitation and hygienic practices followed in many homes, restaurants, and other feeding institutions. Of major concern, their study notes, is diarrhea among children in day-care centers, where, by one estimate, 3,740,000 children—out of 11,000,000 enrolled in 1980—are victims of the disease annually. Another 300,000 adult employees of the centers also are affected each year.

Archer and Kvenberg are on the staff of the division of microbiology in FDA's Center for Food Safety and Applied Nutrition. Archer, a microbiologist who specializes in immunology, is the division's deputy director. Kvenberg, an entomologist by training, is assistant to the director and deputy program manager for the center's biological hazards program. Their study is being published in the November 1985 issue of the *Journal of Food Protection*. The authors stress that the views expressed in the study are their own and not necessarily those of FDA.

The scientists said their estimate of 275 million cases was "consistent with an annual rate of 224 million clinically significant enteric (gastrointestinal) infections" cited in an August 1984 report of the Health Policy Task Force at Emory University in Atlanta. The task force staff included Emory faculty members and scientists from the U.S. Centers for Disease Control in Atlanta.

Yet Archer's and Kvenberg's estimates of food-borne diarrheal disease substantially exceed previous reports by other scientists who, like the two FDA men, closely monitor the public health and economic impact on food-borne and other diseases that result from infectious pathogens.

"It is generally accepted that the true incidence of foodborne

disease is underreported," Archer and Kvenberg said, "and that economic-loss estimates, which are directly dependent on incidence estimates, may also be underestimated." The scientists said their figures of total diarrheal and food-borne disease were based on projections made from data obtained from the National Center for Health Statistics, CDC and other sources.

"While the statement of the problem may be much lower than it really is, concern is growing over the number of pathogens [many of them newly discovered] that are causing the problem," Kvenberg said. "We're finding more and more causes of diarrhea associated with the food supply and with enteric pathogens, and we're finding that the population of people infected is much larger than we thought."

The different types of pathogens that can cause outbreaks of food poisoning number in the hundreds. Yet data on the incidence of food poisoning cases in this country, compiled and reported by CDC, are usually limited to only certain pathogens where laboratory identification of the pathogens can be made. This leaves uncounted many outbreaks caused by some of the recently identified food-contaminating microbes. Also, foods that may have caused an outbreak are not always available for analysis. Even when they are, identification is often missed because the wrong tests were performed or the laboratory was not equipped to apply the sophisticated analytical techniques needed to detect certain pathogens. Further, the transmission of food-borne diarrheal diseases from one person to another is not taken into full consideration, the FDA scientists said.

These and other factors result in an underreporting of food poisoning that Archer and Kvenberg took into account in formulating their estimates, which they believe more accurately reflect the true scope of the problem. "Our estimate of total and foodborne diarrheal disease is the strongest argument to date for increased surveillance and research," the two scientists declared.

Diarrheal disease can result from many physiological causes, but it is often transmitted through food and water or person-to-person contact. To a much smaller extent, the condition also can be transmitted from animals to humans. Person-to-person transmission of diarrhea-causing pathogens is often referred to by scientists as "fecal-oral" transmission because of an individual's ability to easily pick up pathogens from the feces and pass them to others by mishandling food or by coming into contact with other people or inanimate objects such as a table top or toy.

One of the basic principles of good sanitation, especially among food handlers, is to wash one's hands thoroughly after a bowel movement. Archer and Kvenberg cite studies showing that many causes of diarrhea in day-care centers could be traced to staff who change children's diapers and then handle food served to the children.

The scientists estimated that probably only one person out of every 25—at best—or one out of every 100—at worst—seeks medical attention for treatment of diarrhea. It is on the basis of

Diarrhea causes millions of deaths each year in poorer, undeveloped nations.

Diarrheal disease has become a major health concern in day-care centers, afflicting millions of children and hundreds of thousands of employees annually, according to studies.



Diarrheal disease is a major public health problem that is seriously underestimated and underreported, two FDA scientists say.

such ratios that the two men arrived at their estimate of total diarrheal cases.

Archer and Kvenberg also used a variety of studies for their estimates of food-borne diarrheal disease. Applying one study's ratio of 29.5 unreported cases of salmonellosis for every one actually reported, the number of cases of human salmonellosis in 1983 probably numbered about 1,147,000, based on 38,881 confirmed cases reported to CDC, they said.

Salmonellosis is considered a leading cause of food poisoning, but, they continued, there is growing evidence that a lesser known, and less publicized, pathogen—*Campylobacter jejuni*—is probably responsible for up to 2½ times more food poisoning outbreaks than *Salmonella*. If the basic data from various studies were extrapolated on a national basis, "it would mean that approximately 2,867,000 cases of campylobacteriosis occurred in the U.S. in 1983," they said. And if similar estimates were made for just *Salmonella*, *Campylobacter* and *Shigella* together, this would mean that more than 4.45 million cases of diarrhea resulted from those three pathogens alone, according to the study.

Archer and Kvenberg use such data as statistical steppingstones for arriving at their estimates. All known pathogens, they point out, are not considered in many estimates. Missing altogether is data from outbreaks attributable to such pathogens as *Escherichia coli*, *Cryptosporidium*, *Aeromonas hydrophila*, and a wide variety of enteroviruses (gastrointestinal viruses) that have been involved in diarrheal disease outbreaks and, in some cases, death.

Although a 29.5-to-1 underreporting ratio has been accepted by many scientists, there is a growing belief among some authorities that a 100-to-1 ratio is not unrealistic, they said. The 29.5-to-1 ratio results in the 24 million estimate; at 100-to-1, the estimate goes to 81.36 million cases of food-borne illnesses per year. "In the light of all the facts concerning variables and difficulties associated with estimating true incidence plus new epidemiologic data on virus transmission, this (larger) estimate does not seem unreasonable and in fact may still be conservative," the study authors said.

The potential public health impact of such large numbers, and the fact that so much needs to be learned, is only indicative, they said, of the greater effort that must be made to determine the incidence and causes of all diarrhea, and food-borne diarrheal disease in particular, in the country. Surveillance data on infectious diseases provide public health officials with a valuable and irreplaceable source of information on which to make priority public health decisions, and efforts must be intensified, not curtailed, their study contends.

The problem in the nation's day-care centers is a good example of the public health impact of diarrheal disease. The FDA scientists cited a study published in 1981 in which diarrhea in Houston, Texas, day-care centers was found to be occurring at a rate of 0.34 cases per person per year among the children and staff members at the centers. At that rate, Archer and Kvenberg projected, 34 percent—or 3,740,000—of the 11,000,000 U.S. day-care children were being stricken with diarrhea each year. Shigellosis, giardiasis and rotavirus were found to be the leading causes of diarrhea in day-care centers, the Houston study found.

A follow-up study found "the highest incidence rate in day-care centers where diapering by staff was combined with food preparation or service," Archer and Kvenberg noted.

Despite the widely held view of diarrhea as a "self-limiting, unpleasant nuisance," FDA's Archer contends that diarrheal disease can have long-term health consequences and can even be life-threatening for some segments of the population. In a study published in the April 1984 issue of the *Journal of Food Protection*, Archer said that although many people who suffer sporadic episodes of diarrhea do not develop long-term, debilitating diseases, there is some evidence that such episodes can contribute to such chronic conditions as autoimmune disorders (such as rheumatoid arthritis), cardiovascular disease, and allergies.

Diarrhea caused by various pathogens can damage the structure and function of the intestines and weaken the body's immune defense mechanisms. Such breakdowns in the immune system can, in some people, affect the body's ability to absorb essential

Diarrheal disease can result from many physiological causes, but it is often transmitted through food and water or person-to-person contact.

nutrients and lead to serious, long-term health problems and even life-threatening conditions, the two authors warned.

As Archer explained, the human gut contains a mucous barrier that protects the cells that absorb and transport nutrients to other parts of the body. There are also special antibodies to protect the body from harmful substances that have been ingested.

Diarrhea is an "explosive response" by the body, a means of purging the gastrointestinal tract of "unwanted, possibly harmful organisms or substances," he explained. "When a pathogen invades the body, it can strip away the mucous layer, leaving you with no barrier of defense. That makes it easier for organisms to penetrate the (absorptive) cells and destroy them, and any antibodies would be flushed out. Thus, in a sense, for a period of time, you are without the normal protection you would have against viruses and other invaders.

"Conditions like colitis, where the cells may have been invaded by pathogens like *Shigella*, can produce damage that extends into the area where the normal immune system resides. As long as that bug is there, the normal defense mechanisms attack it, but at the same time, they are killing good cells. That is called inflammatory bowel disease, and when that occurs it can become a chronic inflammatory condition where you are malabsorbing and the normal immunological defenses are thrown out of whack."

Those most susceptible to long-term effects from bouts with diarrhea, Archer said, are people already afflicted with other health problems—the elderly (because the immune system weakens with age), children and infants (whose immune systems are not fully developed), and people who are malnourished.

Diarrhea is a leading cause of death—in the millions each year—in poorer, undeveloped nations where disease, famine, starvation and malnutrition are common. But even in advanced countries like the United States, diarrhea is a matter of concern. Archer explained that "diarrheas caused by bacteria, viruses, protozoa and parasites all may cause malabsorption. When the absorptive cells . . . are damaged, they can't transport nutrients." In addition, there can be loss of fluids and this can result in loss of all types of essential nutrients. "So now you have double stress," Archer said. "You can't bring in nutrients and you also are losing nutrients. The seemingly insignificant loss of even a single nutrient may have severe consequences on host defense mechanisms and may contribute to a vicious cycle of diarrhea-malnutrition-infection.

"The important factor is that any loss of nutritional status may greatly increase morbidity [illness] from other causes and generally erodes the overall health of the population," Archer said.

"Although it can happen to adults, children seem particularly susceptible to nutritional stress caused by diarrhea. In infants, the immune system develops slowly. When an infant is first born, its ability to produce special antibodies is limited, so the breast-fed child gets this immunity from the mother. In six months the infant catches up. In old age, the immune system starts to tire and wear out. Also, infants and elderly people don't have as much hydrochloric acid in the stomach, and this also weakens their defenses."

Despite growing evidence that seems to demonstrate a link between diarrheal disease and more serious chronic conditions, Archer and Kvenberg readily acknowledge that far more research is needed. They also point out that scientists are faced with the problem of just trying to keep up with a constantly growing list of new pathogens as well as finding ways of detecting them in the laboratory.

"It's a matter of all these newly recognized pathogens seemingly hitting us at once," Archer continued. "It's only been in the last five years or so that we've seen the list coming in so fast that we are having difficulties keeping up with developing detection methods. Each food presents a different set of chemical problems that we must resolve before we can develop valid and effective methods for each pathogen."

FDA's concern over pathogens in the food supply is reflected in its present pathogen surveillance program that was started in 1983. The program, through samples from a variety of food products, concentrates on laboratory isolation and identification of the 12 microorganisms with the greatest potential to produce food-borne illness.

The 12 are: *Aeromonas hydrophila*, *Bacillus cereus*, *Campylobacter jejuni*, *Clostridium perfringens*, *Escherichia coli*, *Listeria monocytogenes*, *Vibrio cholera*, *Vibrio parahaemolyticus*, *Vibrio vulnificus*, *Yersinia enterocolitica*, *Salmonella*, and *Staphylococcus*.

Archer and Kvenberg acknowledge that their estimates of overall diarrheal disease and food-borne illnesses may be challenged. But, they noted, the incidence certainly is serious and large enough to warrant more intensive surveillance and research.

An intensified effort, they suggest, also would produce economic benefits. "Diarrheal disease from food-borne sources is generally preventable," they pointed out. "Any money spent on research, surveillance and public education would be only a small fraction of the cost otherwise borne by the economy when disease occurs."

Chris Lecos is a member of FDA's public affairs staff.

Searching for Clues To Alzheimer's Disease



by Annabel Hecht

The occasion was a public hearing before the Maryland Governor's Task Force on Alzheimer's Disease and Related Disorders. A middle-aged woman rose to ask a question. When she prefaced her remarks with "As a future Alzheimer's patient . . ." heads turned. Asked how she could predict such a diagnosis, she replied that she was already having some loss of memory. While watching television, she couldn't remember what had come before the commercial breaks.

The woman's concept of Alzheimer's disease is not surprising. Although this degenerative disease of the brain was first described nearly 80 years ago, it is still not fully understood, even by scientists, and there are many popularly held misconceptions about it, one of which is the belief that any memory loss is a sure sign that Alzheimer's will follow. It's gotten to the point where middle-aged people and even youngsters joke about their "Alzheimer's acting up" when they forget a name or that fact that's just on the tip of the tongue.

Forgetfulness is not reserved for the elderly. In fact, it can occur at any age. However, when memory loss becomes severe and other cognitive functions—reasoning, concentration and judgment—fail, it is a sign that the patient is suffering from some form of dementia, a classification that includes Alzheimer's disease.

Alzheimer's disease was named for Alois Alzheimer, a German physician credited with the first description of the disorder. In 1906, he told a medical group of a 51-year-old patient whose problems began with memory loss and disorientation, progressed to depression and hallucinations, and eventually resulted in severe dementia and death.

When he examined the dead patient's brain, Alzheimer found severe atrophy (shrinkage) and an unusual clumping and distortion of fibers in the nerve cells of the cerebral cortex, or outer layer of the brain.

Because the progression of symptoms occurred in a middle-aged patient, it was long thought that Alzheimer's was a disease that developed before age 65. Thus it was known as presenile dementia. Dementia that developed after 65, called senile dementia, was attributed to "hardening of the arteries" and was believed to be a normal part of growing old.

As brain research continued, it was learned that the lesions

Alzheimer found in his patient were also found in older patients with senile dementia. Blood vessel changes commonly related to age were found in only a small percentage of cases. The term "senile dementia of the Alzheimer's type" then came into use to refer to the late-onset form of the disease. Today, it is generally agreed that Alzheimer's is Alzheimer's, no matter at what age the illness starts.

The onset of Alzheimer's disease is gradual, usually starting with memory loss, particularly for recent events. What is striking is that the loss is complete, even including the circumstances surrounding the forgotten event. Eventually, the memory loss is so profound that the Alzheimer's victim can't remember the previous sentence in a conversation, can't identify once-familiar persons or objects and, in the end, can't remember the names of family members.

Other early behavioral changes include an inability to concentrate, anxiety, irritability, agitation, withdrawal and petulance. Later, the patient may have trouble with figures and understanding what is being read, and may become disoriented as to time and place.

Some Alzheimer's patients wander about and lose their way; others have temper tantrums and obsessional behavior, like washing and rewashing dishes. Depression and delusions are not uncommon. Often the victims accuse their spouses of being imposters or carry on conversations with imaginary people. Some forget how to dress themselves or become less neat in appearance.

Apathy, disorientation, and loss of bladder and bowel control mark the late stages of the disease. In extreme cases, Alzheimer's victims are totally incapable of caring for themselves. Death generally comes in three to 10 years after onset of the disease, usually from pneumonia or some other infection that afflicts bedridden patients.

Despite this array of symptoms, Alzheimer's disease is difficult to diagnose in its early stages. There are no specific laboratory tests for this disorder and many other conditions have similar symptoms. A thorough physical examination, medical history (with particular attention to the drugs the patient has been taking), and standard laboratory tests are essential to rule out other, reversible conditions. An electroencephalogram (EEG) and computerized tomography (CT) brain scan may supplement the clinical evaluation.

(Continued)



Today is a beautiful day.

The dog run down the street

I love my husband
and all my children

Illustration courtesy of Dr. Robert Katzman, Albert Einstein College of Medicine

Sentences written by a patient with Alzheimer's disease early after the disease was diagnosed (top) and later as it progressed: silent evidence of mental deterioration.

Assessment of the patient's mental status, using simple questionnaires, and information about behavioral changes provided by family members also aid in establishing the diagnosis.

Unfortunately, a diagnosis of Alzheimer's can really only be confirmed after death. An autopsy will show the brain lesions Alzheimer described eight decades ago. They are neurofibrillary tangles—twisted nerve fibers inside nerve cells—and neuritic plaques—degenerating bits of nerve cells surrounding a core of fibrous material called amyloid.

In addition to the tangles and plaques, there also is a loss of nerve cells in regions of the brain essential for memory and thought processes, and in certain more primitive regions at the base of the brain.

No one yet knows the cause of these neurological changes but a number of theories are being explored. One suggests that Alzheimer's is a genetic disease. Studies have shown that while the general population over age 65 runs a 2 percent or 3 percent chance of developing Alzheimer's disease, the likelihood increases to about 7 percent or 8 percent if a parent or brother or sister is afflicted.

Another theory is that some kind of infectious agent, such as a virus, may be the cause of Alzheimer's disease. This supposition is based on evidence that two rare kinds of dementia in humans—Creutzfeldt-Jakob disease and kuru—as well as scrapie, which is a neurological disorder of sheep, can be transmitted to animals by injecting diseased brain tissue into their brains. Neuritic plaques with amyloid, similar to those found in Alzheimer's patients, have been observed in the brains of victims of these diseases.

Recent research suggests that the agents causing these diseases may not be viruses at all, but an unconventional kind of agent dubbed a prion. Prions, which are protein particles, were first isolated from the brains of sheep afflicted with scrapie.

Another theory—that Alzheimer's disease is somehow caused by aluminum—has stirred up a tempest in a cooking pot. Many consumers have worried, unnecessarily, about using aluminum cookware.

The aluminum intoxication hypothesis got its start when some scientists found brain changes similar to those of Alzheimer's disease in animals that had been injected with aluminum. Other researchers found an excess accumulation of aluminum within the neurofibrillary tangles in the brains of Alzheimer's patients.

In addition, aluminum has also been implicated in "dialysis

dementia," a frequent side effect of long-term kidney dialysis. However, the brain changes in dialysis patients are not the same as those in Alzheimer's patients.

According to FDA officials, no direct causative effect between aluminum and Alzheimer's disease has been shown to date. (See "Cookware as a Source of Additives" in the March 1982 *FDA Consumer*.)

The most promising theory concerns the cholinergic system of the brain, particularly the neurotransmitter acetylcholine, which is involved in both memory and learning. (Neurotransmitters are chemicals secreted by nerve cells to enable signals to move from one cell to another.)

Many researchers have found a severe loss—as much as 90 percent—of choline acetyltransferase (CAT) in the brains of Alzheimer's patients. CAT is an enzyme that plays a key role in the production of acetylcholine. This loss in Alzheimer's patients is far greater than any associated with normal aging.

Research on animals has shown that destruction of an area of the forebrain called the nucleus basalis results in a dramatic loss of acetylcholine in the cerebral cortex. This seems to indicate that the production and regulation of acetylcholine originates in the nucleus basalis, and thus Alzheimer's disease may result from a slow dying off of the cells in this area of the brain.

Many drugs have been studied in an effort to develop a useful treatment for Alzheimer's disease, including lecithin and piracetam, naloxone, corticotrophin and vasopressin. However, the sad reality for today's Alzheimer's patient is that nothing can be done to stop the progressive, merciless course of the disease.

But just because the disease can't be cured doesn't mean that its victims should be ignored. Certain symptoms, such as depression and delusions, *can* be treated, slowing the decline of some patients. Concomitant ills, such as heart problems or Parkinson's disease, can also be alleviated. When such "excess disabilities" are lifted, the patient is better able to function and the family is better able to cope.

On the psychological front, the skills that still remain should be preserved. Even years after the disease has been diagnosed, some patients are able to function in important ways—for example, cooking (under supervision), playing an instrument, or singing.

Alzheimer's disease has been called *the* disease of this century. Although the term "Alzheimer's" was hardly used as recently as a decade ago, this devastating illness is now recognized as the most

The sad reality for today's Alzheimer's patient is that nothing can be done to stop the progressive, merciless course of the disease.

severe form of intellectual impairment in the elderly. Because of the seriousness of its impact on both victim and family, Secretary of Health and Human Services Margaret Heckler in 1983 established the Departmental Task Force on Alzheimer's Disease to coordinate research on Alzheimer's, share information, identify promising avenues of research, and translate that research into policy and programs to help patients.

In the House of Representatives, a bill titled the "Comprehensive Alzheimer's Assistance, Research, and Education Act of 1985" has been introduced to provide for improved care and assistance for Alzheimer's victims and their families, create a national educational effort, and expand research.

In addition, Congress has sponsored a resolution designating November 1985 "National Alzheimer's Disease Month," to focus

on the serious and insidious nature of this disease and promote recognition that mental deterioration is not an inevitable consequence of aging.

Providing family support, public information and education is the mission of the Alzheimer's Disease and Related Disorders Association, Inc. Headquartered in Chicago, the association represents seven independent organizations concerned with research, care and treatment of Alzheimer's and related disorders. Information on the association's programs, publications, or referrals to local affiliates can be obtained by writing to the association, 360 North Michigan Ave., Chicago, Ill. 60601. The telephone is (312) 853-3060. ■

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

The Many Faces of Dementia

Despite its name, dementia is not synonymous with insanity; it is not a psychiatric disorder but rather an abnormal loss of the use of parts of the brain associated with intellectual skills.

Many people fear that dementia (and therefore Alzheimer's disease) is an inevitable part of aging. This is not so. Only about 5 percent of the U.S. population 65 and over is severely affected by dementia, and another 10 percent may be mildly to moderately impaired. Nevertheless, this represents from 2.5 to 3 million people and the numbers will grow as the population ages.

Some of these individuals, perhaps 20 to 25 percent of them, have dementia that is reversible. Their condition may be secondary to another, possibly treatable, disorder such as a brain tumor, abnormal thyroid function, or abnormalities in the spinal fluid system (hydrocephalus).

Or they may have a "pseudodementia"—a condition whose symptoms mimic those of true dementia. One of the most common pseudodementias in the aged is drug intoxication. The elderly, as a group, take more medication than younger people. Often victims of one or more chronic diseases, they may take as many as 14 to 18 different prescription drugs in the course of a year.

This, along with age-related changes in the way their bodies handle drug metabolism, makes the elderly more vulnerable to side effects and interactions between different drugs that can lead to confusion and disorientation (see "Medicine and the Elderly" in the September 1983 *FDA Consumer*). Diuretics, digitalis, oral anti-diabetic drugs, painkillers, anti-inflammatory agents, sedatives, and anti-psychotic drugs have all been implicated in such adverse drug reactions.

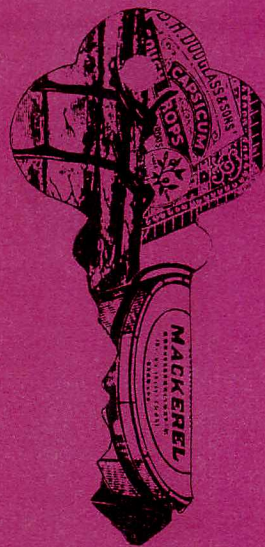
Another common cause of usually treatable dementia-like symptoms is depression. Depressed individuals are often passive and unresponsive and may appear confused, slow and forgetful. Chronic alcoholism can also impair mental faculties, particularly memory for recent events.

For the remaining 75 to 80 percent of those elderly who suffer from dementia, the condition is irreversible—it cannot be cured. A small number of these victims have multi-infarct dementia. In these cases, obstruction of the blood flow to the brain has caused a series of minor strokes resulting in death of brain tissue. (At one time, this condition was called, somewhat inaccurately, "hardening of the arteries of the brain.") The rest have Alzheimer's disease. ■

Prenatal Care: The Key To Reducing Infant Deaths

by Dixie Farley

In September's FDA Consumer, staff writer Dixie Farley reported on how technology-filled intensive-care units are helping low-birth-weight and other high-risk infants win their battles for survival. In the following article, Farley examines how low birth weight and its countless life-threatening complications can be prevented. Because a baby's health is affected by the mother's health even before conception, the article stresses the need for mothers-to-be to adopt a healthy lifestyle before they become pregnant and then to seek prompt and thorough medical care when they find they are expecting.



The U.S. infant mortality rate is too high, and one of the main reasons is that birth weights are too low.

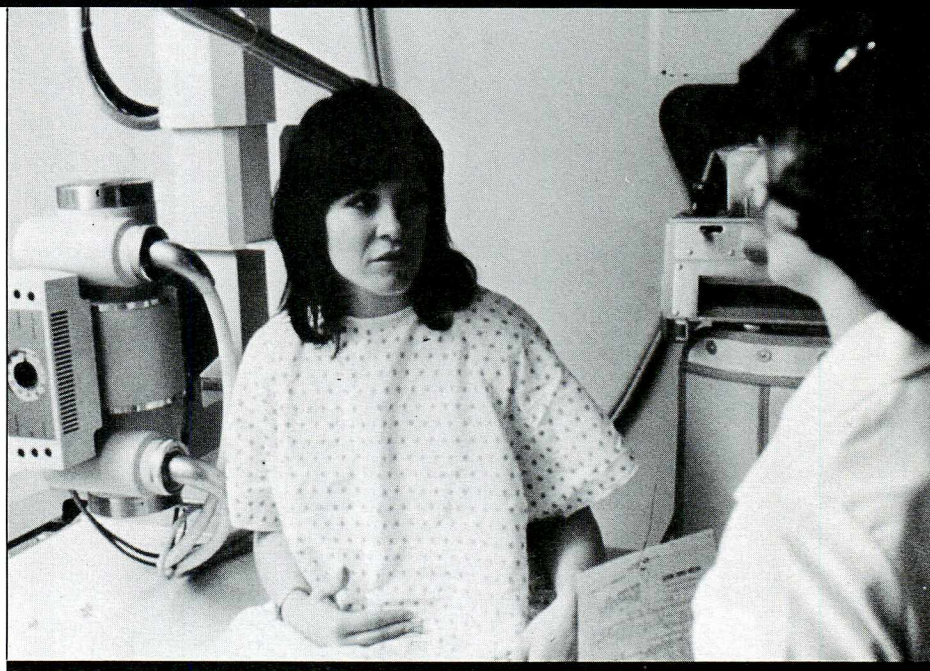
Or, as the National Academy of Sciences' Institute of Medicine put it in its 1985 report *Preventing Low Birthweight*: "Low birth-weight is a major determinant of infant mortality in the United States."

What's more, the institute says low birth weight can be reduced or prevented by proper pre-pregnancy and prenatal care. (Low birth weight is defined as 5½ pounds or less.)

The infant mortality rate for 1984 is estimated at 10.6 per 1,000 live births. For 1983, it was 10.9 per 1,000 births. Those are improvements over 1978, when it was 13.8 per 1,000. But the 1983 and 1984 ratios still add up to more than 39,000 infant deaths each year.

Citing the 1978 figure in his 1980 report to the nation, the U.S. Surgeon General established a national public health policy of reducing the rate to no more than nine per 1,000 by 1990.

The Institute of Medicine says that recent declines in the mortality rate are attributed mainly to highly specialized newborn intensive-care units and the consequent survival of larger low-birth-weight babies. (See the September 1985 *FDA Consumer*, "When Newborns Need Intensive Care.") But roughly half of the very-low-birth-weight babies, who weigh about 3¼ pounds or less, do not survive. And although health risks decrease rapidly as birth weight increases (4- and 5-pound babies generally are expected to thrive), low-birth-weight babies are 40 times more likely than normal-birth-weight babies to die within the first 28 days of life, five times more likely to die later in the first year, and



three times more likely to develop neurological problems, such as cerebral palsy and seizure disorders.

The woman who has a low-birth-weight baby is more likely to be black, poor, a smoker, under 17 or over 34, unmarried and under-educated. She may be addicted to alcohol or drugs. She probably practices poor nutrition. However, some women *not* in those population segments also have low-birth-weight babies, and other factors can be involved. In fact, the Institute of Medicine has identified 41 potential risk factors associated with low birth weight, from high blood pressure to exposure to toxic substances.

An overwhelming risk factor that is not yet well understood is race. Black women are about twice as likely as white women to have low-birth-weight babies. Some reasons that may partially explain this are known. For instance, proportionately more black than white mothers are teenagers, are slow to seek prenatal care, and have a low income and an education of less than 12 years—all factors associated with low birth weight. Yet these factors do not fully explain the birth-weight gap between blacks and whites.

The U.S. Assistant Secretary for Health reported in 1984 that even when several factors are controlled simultaneously, the gap remains. "The fact," he said, "that mature, married, college-educated black women who received prenatal care are still twice as likely as their white counterparts to deliver a low-birth-weight infant indicates that the black-white disparity is not a simple phenomenon." Researchers continue to study the problem.

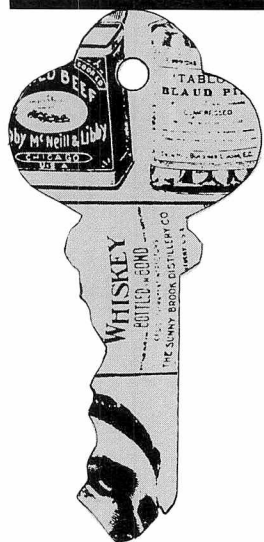
An adverse outcome in a previous pregnancy—such as premature birth, malnutrition, multiple spontaneous abortions, stillbirth—may increase a woman's chance of having a low-birth-weight baby in a later pregnancy. Complications arising *during* pregnancy that can add to the risk of low birth weight include infections, uterine bleeding, sustained high blood pressure, and detachment of the placenta.

To give her baby the best chance for a normal birth weight, it's essential that a pregnant woman seek early and frequent prenatal care from a physician. In 1971, a study with a prematurity prevention program funded by the French government was implemented

at Haguenau, France. Reported in *Pediatrics* in August 1985, the program demonstrated declines from 1971 to 1982 in low-birth-weight rates from 4.6 to 3.8 percent and in preterm-birth rates from 5.4 to 3.7 percent. In urging more vigorous efforts and greater government commitment in the United States to maternal and infant preventive health care, the Institute of Medicine pointed out that, for each dollar spent on prenatal care, there could be a savings of \$3.38 on neonatal intensive care because of healthier babies.

Many private and public organizations are working to improve maternal and infant health. One such group is the Healthy Mothers, Healthy Babies coalition, which was founded by the U.S. Department of Health and Human Services' Public Health Service, the U.S. Department of Agriculture, the March of Dimes Birth Defects Foundation, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American Nurses' Association, and the National PTA. The coalition now comprises more than 75 national groups in more than 40 states. As part of this program, the Food and Drug Administration and other agencies offer print and broadcast public education materials. (For an example, see the poster reproduced on the inside back cover of the June 1985 *FDA Consumer*.) Functioning primarily through health departments, states are active in projects that range from loaning infant car seats, to promoting legislation, to offering speakers and conducting workshops. The national coalition, located in Washington, D.C., offers a directory of educational materials, a program to help states with their public education efforts, a handbook to help communities start chapters, and other materials. A recurring theme of both local and national educational programs is how women can avoid the preventable risk factors linked to poor infant health and infant mortality, such as smoking, alcohol consumption, and drug abuse.

"Smoking," the Surgeon General has said, "slows fetal growth, doubles the chance of low birthweight and increases the risk of stillbirth." Unfortunately, an estimated 20 to 30 percent of the pregnant women in the United States smoke. And even after the



Women who are pregnant or who are considering pregnancy should seek medical care from a physician. It's especially important to get care early in pregnancy.

baby is born, there are risks from the mother's smoking. The National Institute of Child Health and Human Development has found that nicotine is secreted into breast milk and that large doses of it can inhibit milk production. Also, maternal smoking has been associated with sudden infant death syndrome—the sudden, unexpected and unexplained death of an apparently healthy infant.

For the most part, what the mother ingests, her baby does too. If it's nutritious food, the baby should benefit. If it's alcohol or another drug, the baby can suffer. In fact, between 1,800 and 3,600 babies are born each year in the United States with fetal alcohol syndrome, a pattern of birth defects caused directly by the mother's drinking alcohol while she was pregnant. Babies with this syndrome are inappropriately small. Birth defects can include small brains, mental retardation, narrow eyes, short and upturned noses, and poor physical coordination. Another 36,000 newborns each year may be affected by a range of less severe alcohol-related effects. Among babies born to problem drinkers, as many as 29 per 1,000 have fetal alcohol syndrome. Because this condition is incurable and because scientists don't know for certain how much alcohol is "safe," the Surgeon General has advised women not to drink alcoholic beverages during pregnancy or when considering pregnancy.

Some medicines may harm the fetus. As soon as a woman suspects she may be pregnant, she should discuss with her physician any over-the-counter preparations (aspirin and cough syrups, for instance) or prescription drugs she may be taking. She should tell any physician or dentist who prescribes drugs for her that she is pregnant. Of course, regardless of whether a woman is pregnant, she should avoid illegal drugs, but this is especially true during pregnancy. The baby of a pregnant heroin user, for instance, can be born addicted and have withdrawal symptoms after birth. Even vitamins shouldn't be self-prescribed, says the March of Dimes, because some can accumulate and harm an unborn baby.

There is no doubt that proper nutrition for the mother is good

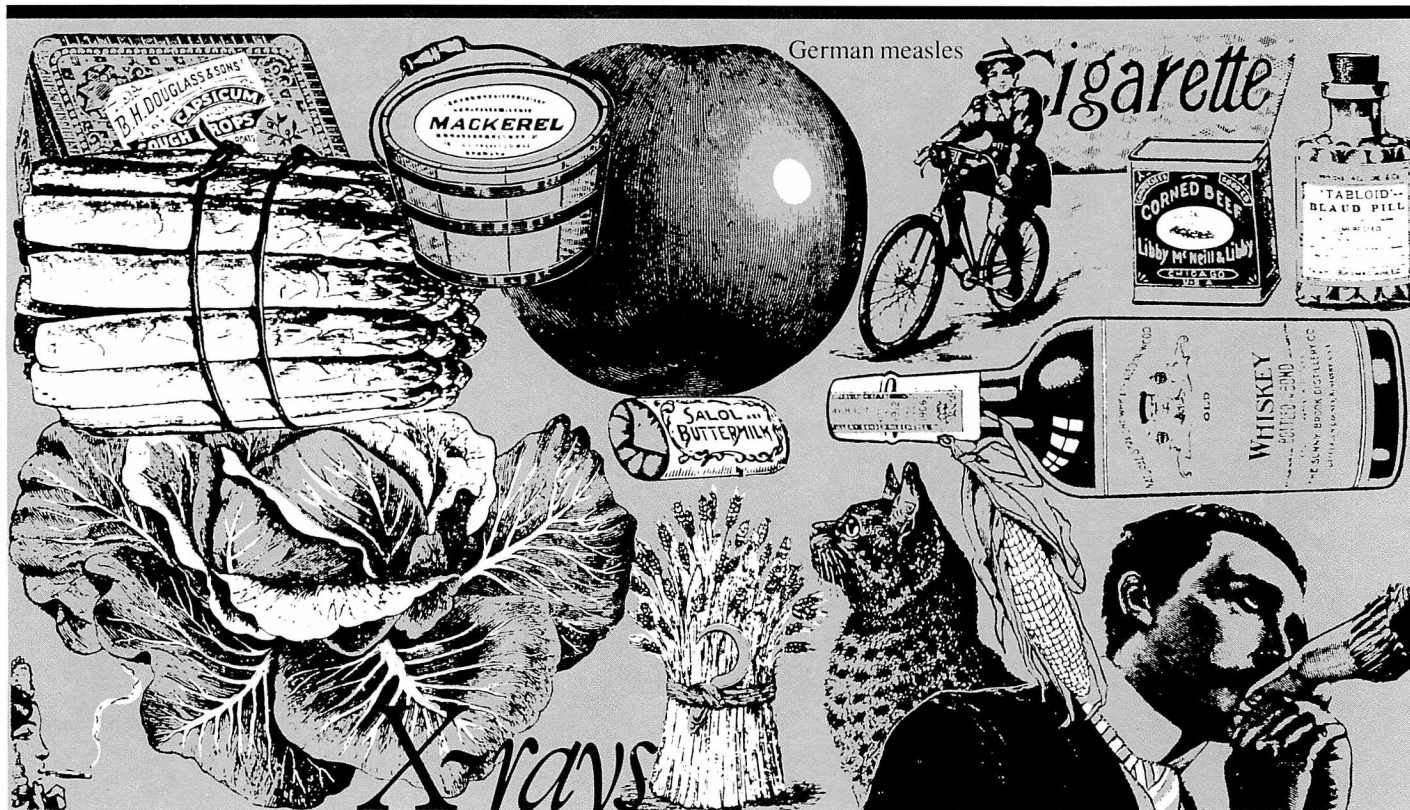
for the baby's health. The effect of maternal nutrition on low birth weight is difficult to assess, however, because of the complicated relationship between poor nutrition and other risk factors and between a woman's usual weight and her weight gain during pregnancy. In a 1984 study, Selma Taffel and Kenneth Keppel of the National Center for Health Statistics concluded that, even when many factors were controlled, including pre-pregnant weight, "Mothers who gained less than 21 pounds were still 2.3 times as likely to bear a low weight infant as mothers who gained at least 21 pounds."

According to the American College of Obstetricians and Gynecologists, 22 to 27 pounds is an acceptable weight gain during pregnancy. And even if a woman is overweight before pregnancy, weight gain should not be rigidly restricted, as that could potentially harm fetal growth and development. (For more information about nutrition during pregnancy, see the March 1984 *FDA Consumer*, "All About Eating for Two.")

For poor women who are malnourished, supplemental food programs during and between pregnancies may help improve infant birth weight. One such program is the Special Supplemental Food Program for Women, Infants and Children (WIC), which also provides nutritional counseling. Because WIC prenatal participants must document that they are pregnant, the likelihood of an initial prenatal medical visit is increased. The program's tie to prenatal care is further enhanced because WIC sites often are located at health centers with prenatal clinics.

It's essential that health risks be identified as early as possible. Women considering pregnancy should seek medical advice about any existing health problems. Certain risk factors—such as diabetes mellitus, high blood pressure, and infectious diseases—warrant treatment before conception. A woman who is malnourished may be counseled by her physician to eat the right types of food to improve her nutritional status. Also, because German measles (rubella) can cause birth defects, women who didn't get immunized during childhood should do so before becoming pregnant.

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Proper, frequent medical care is important throughout the entire pregnancy. If a woman is diagnosed as being at risk for early labor, she may need more frequent checks by her physician to prevent premature birth. Some investigators are studying the possibility of monitoring pregnant women for early labor with a device that has a sensor located in an abdominal belt. Should the investigations prove successful, FDA could allow the device to be available for general use.

The risk factors associated with low birth weight and, thus, infant mortality point out the need for the woman who is or might be pregnant to adopt a healthy lifestyle, continue good health care during pregnancy, seek early and frequent prenatal care, and follow all treatments her physician prescribes.

From the March of Dimes Birth Defects Foundation, here are general guidelines for having a healthy pregnancy:

- **Infectious Diseases.** Before conception, get vaccinated against German measles. During pregnancy, don't eat undercooked meat and don't empty the cat's litter box. Undercooked meat and cat feces may contain an organism that can cause toxoplasmosis, a disease that can cause birth defects. Tell your physician if you or your sexual partner have had genital herpes, chlamydia, gonorrhea, or other sexually transmitted diseases; and report any occurrence or recurrence of these diseases.
- **Smoking.** Don't smoke. If you won't quit, at least cut down; the negative effects of smoking on the fetus are linked directly to the number of cigarettes smoked.
- **Drugs and Alcohol.** If you are pregnant or think you might be, tell any doctor or dentist who prescribes drugs for you. Check with your physician before taking *any* medicines. Don't take illegal drugs. Don't drink alcoholic beverages during pregnancy.
- **X-Rays.** If you are pregnant or think you might be, tell any doctor or dentist who prescribes X-rays for you. Abdominal, pelvic, lower back, and hip X-rays are of greatest concern because they expose the fetus to the direct X-ray beam. (FDA's Center for Devices and Radiological Health, which regulates X-ray equip-

ment, advises that, while no X-ray examination is completely risk-free, exams of the chest, head, teeth, hands or feet that are medically necessary are "safe enough," provided a lead apron properly protects the abdomen. The center points out that it's a good idea to take care of any needed dental work before becoming pregnant.)

- **Physical Activity.** Unless your physician says otherwise, moderate exercise is healthy during pregnancy, but you shouldn't overexert. Walking is especially good for digestion and circulation. If you've been physically active, consult your physician about what sports are safe to continue. Also, rest is essential. Get eight hours of sleep at night, and rest during the day.

- **Sex.** Unless your physician says otherwise, sexual intercourse during a normal pregnancy is safe if no bleeding or uterine contractions occur afterwards.

- **Diet.** Don't try to lose weight, even if you were overweight before becoming pregnant. Drink several glasses of water each day. Eat four servings daily from each of the major food groups: dairy products, grains, meats and fish (proteins), and fruits and vegetables.

- **Warning Signals.** If any of the warning signals listed below should appear, tell your physician immediately. (The health threats the signals may indicate are in parentheses.)

Sudden increase in vaginal discharge or sudden gush of water from the vagina (ruptured membranes).

Vaginal bleeding (a separating or malpositioned placenta).

Chills, fever, or painful or burning urination (infection).

Rashes or lesions (sexually transmitted disease).

Severe or continuing nausea and vomiting, fainting spells, loss of consciousness, continuing or severe headache, blurred vision, spots before the eyes, or swelling of the face, hands, feet or ankles (high blood pressure).

Pelvic pressure, low dull backache, painless contractions, or sudden abdominal pain or cramping (premature labor). ■

Dixie Farley is a member of FDA's public affairs staff.

The Reasons Behind Blood Donor Screening

by Roger W. Miller



Detection of a virus known to cause AIDS—acquired immunodeficiency syndrome—is but the latest effort to protect the nation's supplies of donated blood. Screening blood donors for the antibody to the virus, known as HTLV-III, was recommended earlier this year by the U.S. Public Health Service and adopted almost immediately by nearly all of the nation's 3,200 blood and plasma donating centers.

A similar action was taken in 1972 when blood centers were required to screen their donors for hepatitis B virus. Such screenings are designed to protect the eventual recipients of the blood that is to be donated. Other parts of the screening process protect the donor as well as the recipient. Guidelines for the screening process are set by the Food and Drug Administration and elaborated on in standards established by the American Association of Blood Banks (AABB).

Here's a rundown of what potential donors face when they go to give blood and why the information is needed:

Blood type—There are eight major types of blood: A, B, O, AB, and their associated Rh type, either positive or negative. If the types are improperly mixed, adverse reactions such as shock, kidney failure and even death can result.

Age—Blood donors must usually be between 17 and 65. However, persons 66 and older may be accepted at the discretion of a blood bank physician, and persons under 17 may be taken if the proper

consent is provided. Donations may be dangerous for persons above or below those ages.

Date of last donation—Eight weeks is required between donations in order for the body to build up the blood's supply of red cells again.

Weight—Anyone over 110 pounds can give the full amount. Donors who weigh less than 110 pounds may be accepted for proportionately less, as such an individual has proportionately less blood and can't spare a pint so easily.

Temperature—Not to exceed 37.5 degrees Celsius or 99.5 degrees Fahrenheit. Higher temperatures can indicate an infection or some other health problem.

Pulse—A range of 50 to 100 beats per minute is acceptable; however, the AABB's standard for blood banks says a lower rate may be accepted from "an athlete with high exercise tolerance." Again, rates below or beyond the accepted ranges could indicate a health problem for the potential donor.

Blood pressure—The systolic pressure may be between 90 and 180, while the diastolic (lower) reading may be between 50 and 100. Thus, the ranges are 90/50 to 180/100.

Hemoglobin concentration—This is obtained by testing a sample of blood, usually taken from a fingertip. Hemoglobin is the oxygen-carrying red part of red cells. Anemia is associated with a low

hemoglobin level. The normal hemoglobin count for men is around 16 grams per deciliter of blood (expressed as 16 g/dl) and 14 g/dl for women. The AABB minimum is 13.5 g/dl for men and 12.5 g/dl for women.

In addition to the information discussed above, most potential donors are asked a series of medical history questions. Typical are the questions on the American Red Cross donor registration form. They follow—along with the reasoning behind each question:

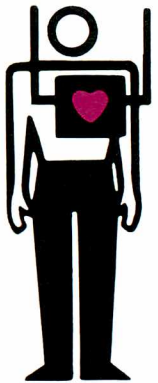
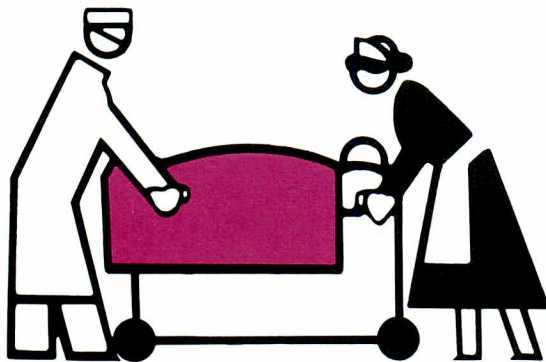
Have you ever had yellow jaundice, liver disease, hepatitis, or a positive test for hepatitis? Some forms of hepatitis are transmitted in blood. A donor may be an asymptomatic (without symptoms) carrier of the disease.

Have you ever taken self-injected drugs? Hepatitis is known to occur more frequently among intravenous drug abusers because they often share needles and other equipment.

Have you in the past six months received blood transfusions, blood injections or tattoos? Hepatitis can be transmitted by these procedures.

In the past six months, have you been exposed to anyone with yellow jaundice, hepatitis, or on a kidney machine? Obviously, the question is once again aimed at detecting hepatitis, some 200,000 cases of which occur annually following blood transfusions. However, some hepatitis is transmitted other than through blood, and

Donors with cardiovascular problems may be increasing their risk for a heart attack or stroke by donating blood.



this question seeks to screen out those who may have picked up the disease in another way. For example, hepatitis is commonly found among patients using kidney machines.

Have you ever had malaria? Malaria can be transmitted by blood, even after the disease is no longer active in an individual.

Have you in the past three years been outside the United States? Another malaria-related question. Potential donors who have been taking preventive medications against the disease are deferred from donating blood for three years in order to ascertain that they are disease-free.

Have you ever had any serious illness? Some diseases pose a potential danger for the blood donor or the recipient. A positive answer will lead to more detailed questioning of the potential donor.

Have you in the past six months been hospitalized? Also designed to learn about

any serious illnesses.

Are you feeling well today? A question aimed at learning about any current disease in the donor.

Have you in the past six months taken any medication? Another question probing for signs of disease.

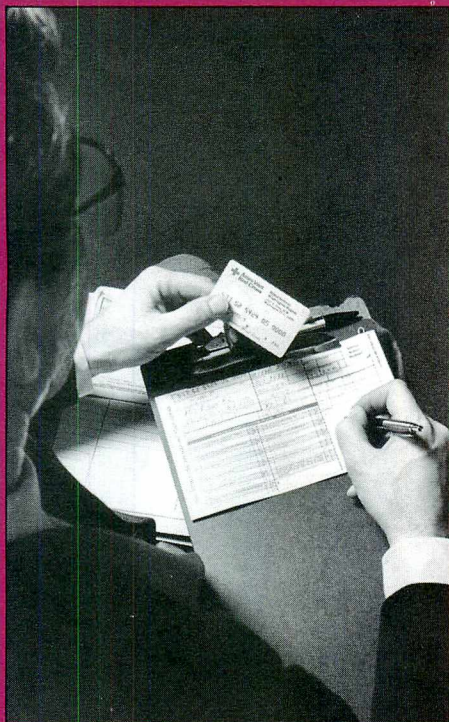
Have you ever been deferred as a blood donor or had problems donating? A general question to determine if some problem existed in the past that might still prohibit an individual from donating blood.

Have you ever had heart disease, chest pain, or shortness of breath? Potential donors with such symptoms may have cardiovascular problems and may be increasing their risk for a heart attack or stroke by donating blood.

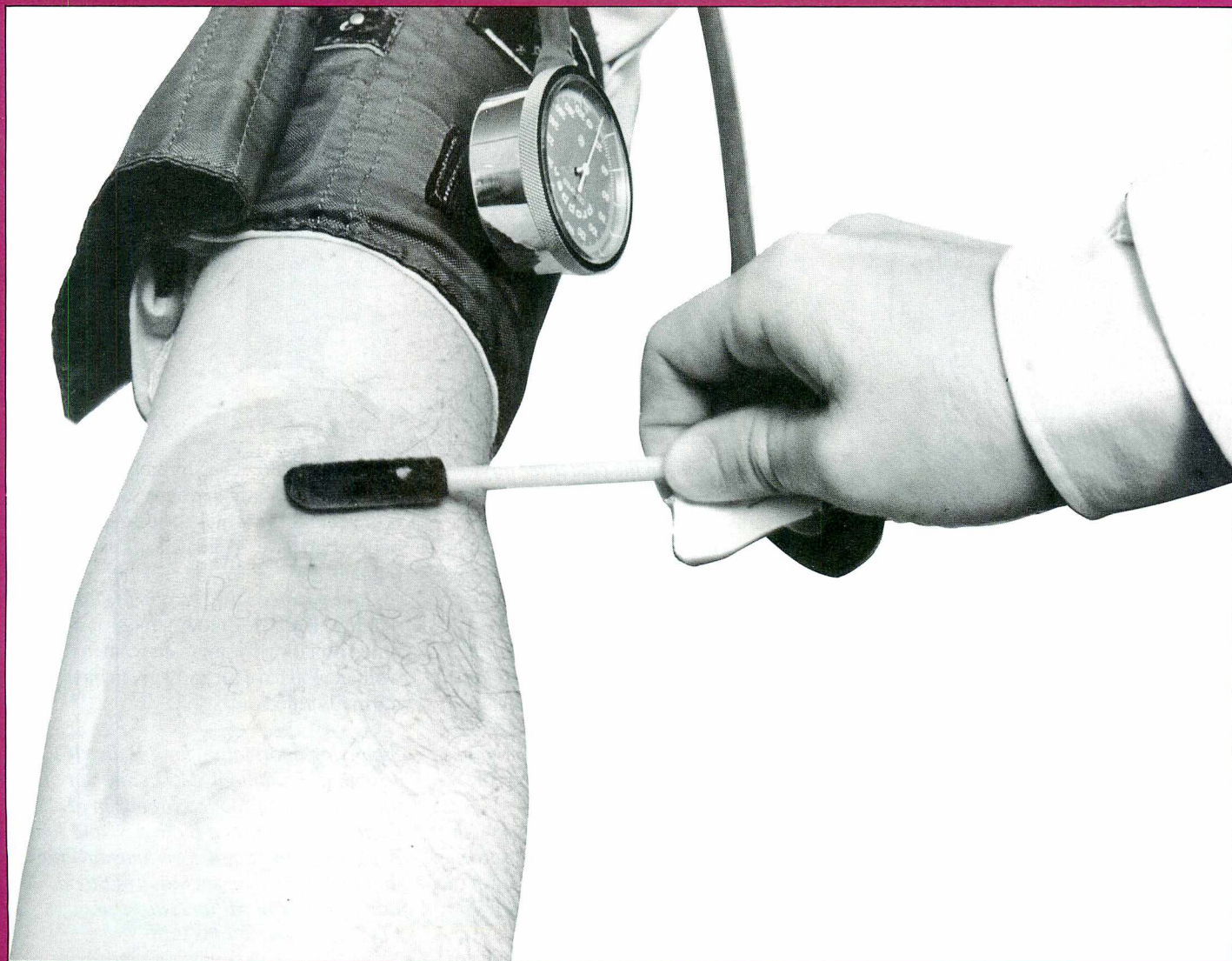
Have you ever had convulsions, seizures, or fainting spells? Like the previous question, this one is asked to protect the potential donor.



(Continued on page 34)



Blood donors get asked a lot of questions, all for good reasons. The questions are aimed at learning about the potential donor's past medical history and current health, information that indicates the suitability of the donor and his or her blood. The donor prospect pictured at left is speeding along the process by answering the stock questions on the donor form. Below, the donor's arm is swabbed with an antiseptic before insertion of the needle into the vein where the blood will be drawn.



AIDS Risk Category Broadened

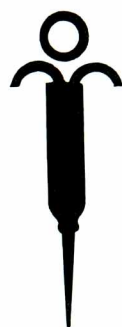
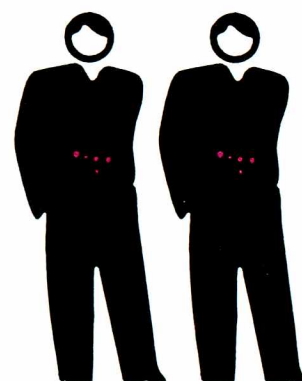
Any man who has had sex with another man since 1977 should not donate blood because of a risk of transmitting AIDS, according to FDA. This new definition of high-risk groups for AIDS (acquired immunodeficiency syndrome) includes even those individuals who have had only a single homosexual experience and may not regard themselves as homosexual or bisexual.

Under earlier recommendations to prevent the spread of the AIDS virus, individuals in high-risk groups—homosexuals and intravenous drug abusers—were asked not to donate blood. Since March 1985, blood and plasma collection centers have used a new screening test to detect antibodies to the HTLV-III virus that causes AIDS. The low prevalence of con-

firmed positive reactions to the screening tests suggests that voluntary deferral has been highly effective.

In a Sept. 1, 1985, memorandum to all registered blood establishments, FDA said the change in risk group definitions was prompted by the discovery that the majority of interviewed individuals who had positive test results were homosexual or bisexual males who nonetheless felt that they were not in a risk group.

In addition, the memorandum noted that the availability of a test that has allowed the evaluation of stored blood samples has provided a more accurate determination of the time at which AIDS began spreading in the U.S. homosexual population—1977, rather than the previous date of 1979. ■



(Continued from page 32)

Have you ever had a blood disease or cancer? This is for the benefit of both the donor and the recipient. Although the evidence isn't firm, there's reason to be concerned about the possible transmission of cancer by blood.

Have you in the past year had any vaccinations or immunizations? For a period after immunization, the immunizing agent may circulate in any individual and cause disease in anyone receiving the blood. The AABB suggests acceptable time limits for the various vaccinations.

Do you have any acute respiratory disease or trouble breathing now? This is intended to detect an infectious disease that may be a danger for the donor, the recipient or both.

Have you had, in the past three days, any dental work? Dental work may lead to bacteremia (bacteria in the blood). These bacteria, which come from the mouth and enter the bloodstream via opened vessels in the gums, could be transmitted by transfusion and cause disease in the recipient.

Have you had night sweats, unexplained fever or weight loss, lumps in the neck, armpits or groin, discolored areas of the skin or mouth, persistent cough, or persistent diarrhea? These are symptoms of AIDS.

Have you been exposed to anyone with AIDS? Another question aimed at screening out anyone who may be a carrier of the AIDS virus.

Have you been to Haiti or Zaire? A final AIDS-related question. The incidence of

the disease has been extremely high among some Haitian groups, while Zaire is the country in which the disease is believed to have originated among humans.

Have you been pregnant in the last six months? Because of low hemoglobin, blood donation by pregnant women or women who have recently given birth is normally ruled out. ■

Supplying information for this article were Joseph C. Fratantoni, M.D., director of the blood bank products branch in FDA's Center for Drugs and Biologics, and Joan A. Maher, director of governmental affairs for the American Association of Blood Banks. Roger W. Miller is director of FDA's communications staff.

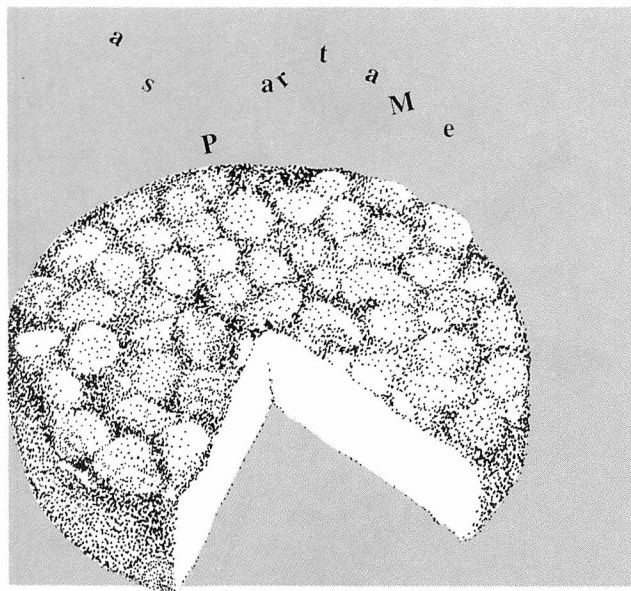
The Notebook

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

■ The sixth edition of FDA's **Approved Drug Products With Therapeutic Equivalence Evaluations** is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. The list includes currently marketed drug products approved by FDA, information on patents, New Drug Application numbers, and approval dates.

■ To decrease the chance of adulterated meat getting into human food channels, the U.S. Department of Agriculture is intensifying procedures for detecting **sulfonamides and antibiotics** in calves of up to 3 weeks in age or 150 pounds in weight (FR Aug. 9).

■ Foodways National, Inc., has asked FDA for permission to use **aspartame** in frozen cheesecake, fruit, and fruit



toppings. Pfizer Inc. has asked permission to use aspartame in frozen desserts (FR Aug. 23).

■ The Public Health Service's Office of Health Technology Assessment is seeking information on the safety and clinical effectiveness of fully automated ambulatory **blood pressure monitoring** (FR Aug. 2).

■ The United States Pharmacopeial Convention has issued the 1986 edition of **USAN and the USP dictionary of Drug Names**. The new dictionary lists not only U.S. adopted names (USAN), but also international non-proprietary names for drugs not currently recognized in the United States, plus miscellaneous other names.

■ The Centers for Disease Control in Atlanta is funding a study to evaluate the extent and magnitude of elevated levels of **polychlorinated biphenyls (PCBs)** in the blood of persons living around three waste disposal sites in Bloomington, Ind. (FR Aug. 26).

■ The comment period on a Treasury Department proposal to disclose on the labels the presence of **sulfites** in alcoholic beverages has been extended to Dec. 23. Send written comments to Chief, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 385, Washington, D.C. 20044-0385 (FR Aug. 23).

■ Revised guidelines for the uniform **labeling of blood** and blood components are available from FDA's Dockets Management Branch (HFA-305), 5600 Fishers Lane, Rockville, Md. 20857 (FR Aug. 30).

■ Two agencies cooperated with the National Advertising Division of the Council of Better Business Bureaus in July to resolve challenges to their **advertising of health and beauty products**. Grey Advertising, Inc., substantiated claims that Massengill Vinegar and Water Disposable Douche is "extra cleansing," and Leber Katz Partners agreed to clarify a statement that Pantene Shampoo ingredients can "nourish" the hair.

■ Revised FDA **laser performance standards** widen the wavelength range that defines laser radiation, establish a new "Class IIIa" laser product, and add new reporting and record-keeping requirements. The new rules relax some safety requirements, including those for safety interlocks, viewing optics, and remote control connectors (FR Aug. 20).

■ Joseph Weider and Weider Health and Fitness, Inc., a Woodland Hills, Calif., manufacturer of **nutrient supplements**, will have to make refunds to purchasers of "Anabolic Mega-Pak" or "Dynamic Life Essence" under a proposed Federal Trade Commission consent agreement. If the refunds total less than \$400,000, the corporation will have to donate the difference for research on the relationship of nutrition to muscle development. The corporation will also be prohibited from making any more unsubstantiated claims that its products promote muscular development, produce human growth hormone, or are unique (FR Aug. 21).

■ **MARKET BASKET:** A uniform size for whole, half and quarter styles of **peaches** is one of the requirements in new FDA standards for canned peaches (FR Aug. 27).

FDA has granted temporary permits to Rogers Walla Walla, Inc., Walla Walla, Wash., and Continental Can Co., Stamford, Conn., to market-test **canned spinach** containing added zinc chloride; and to Great Lakes Cheese Co., Newburg, Ohio, to market-test **grated cheese** containing powdered cellulose as an anti-caking agent (FR Aug. 30).



Dr. Jack—the 'Black Plaque' Quack

by Carol Ballentine

"It's 11 past 9," says the radio announcer, "and for those of you who have just joined our show and may not know some of the background of Dr. Jack Kulp, who is a regular guest on this show, Dr. Kulp practices out of Buffalo, N.Y. He is a chiropractor . . . and he's a nutritional expert. He specializes in holistic health. Is that a good way of putting it, Jack?"

Unequivocally no, said the Food and Drug Administration and the U.S. Postal Service, who brought Kulp before a magistrate on a charge of misbranding a drug under the Food, Drug, and Cosmetic Act.

Jacob William Kulp advertised himself as an expert nutritionist and espoused his nutritional theories in lectures and on the radio. He was a regular guest for four years on a talk show hosted by Canadian broadcaster John Michael on a radio station in Niagara Falls, Ontario, that was heard throughout western New York and southern Ontario.

Kulp practiced his "nutritional therapy" in his office in Cheektowaga, N.Y., near Buffalo. He charged patients \$25 to take a "Nutrient Deficiency Test" and then sold them nutritional supplements he said they needed, to the tune of \$100 or more. He also designed a treatment for one patient that he said would get rid of her "black intestinal plaque." Unfortunately for Kulp, that patient turned out to be U.S. Postal Service employee Esther Kocieniewski.

The Postal Service had been asked to check out Kulp's credentials by a local registered dietitian. Accordingly, Kocieniewski and postal inspector R.B. Harding attended one of Kulp's lectures. Handouts at the lecture included Kulp's resumé, brochures on chiropractic care and nutrition, and a brochure on the Nutrient Deficiency Test.

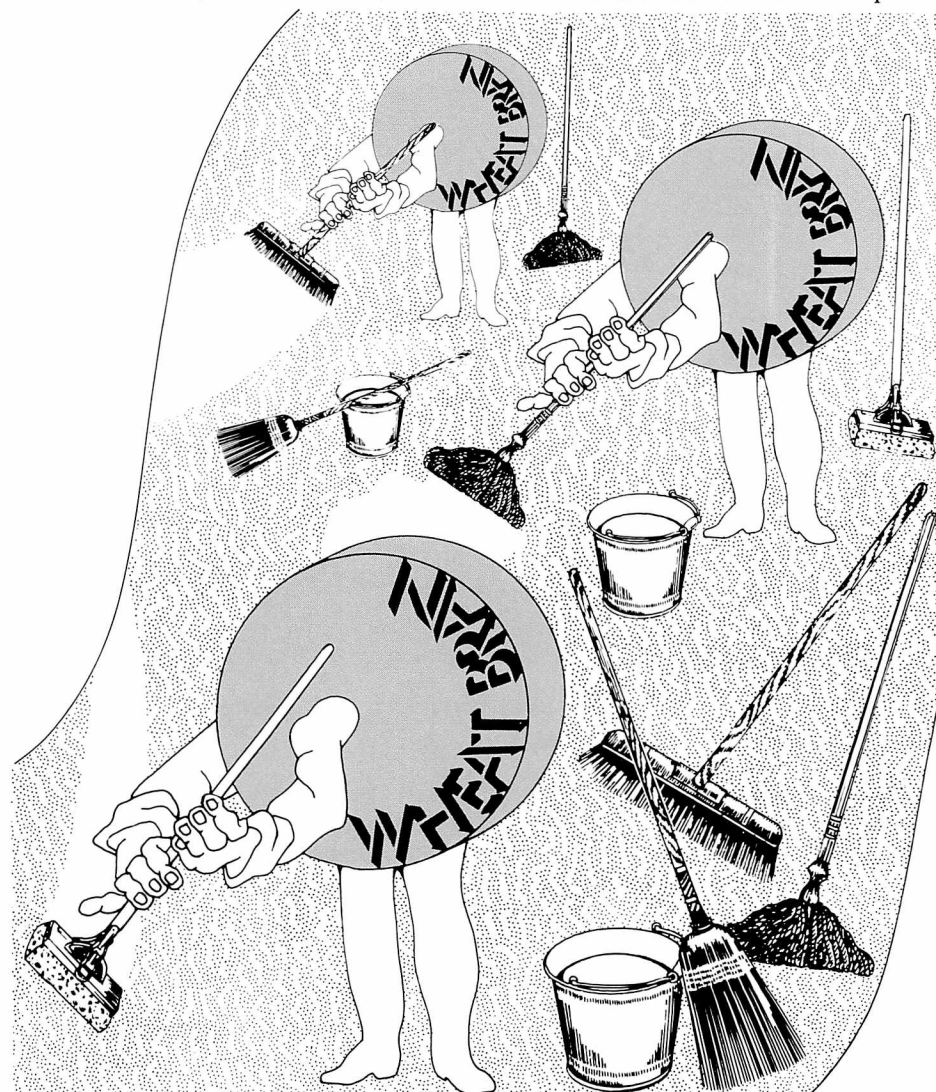
The first thing that proved fraudulent was the resumé. Kulp said he had received his degree from Donsbach University in California and had done postgraduate study at and been certified by two colleges and the Kyoto Pain Institute in Japan. Investigation by the FBI found that the pain institute apparently didn't exist and

the two colleges in Japan had never heard of Kulp. Donsbach University does exist but it is not accredited and offers "mail-order" degrees.

As part of the investigation, Kocieniewski arranged to take the Nutrient Deficiency Test, which was done through the mail. She then received a four-page computerized report of her nutrient status, which said that she needed extra amounts of zinc and extracts of pituitary, thyroid and pancreas. When she called Kulp's office, she was told that she could buy the necessary supplements from his secretary, which she did for \$30.

The Postal Service sought out some true nutrition experts. One was Dr. Victor Herbert, chief of the Hematology and Nutrition Laboratory with Bronx Veteran's Administration Center. The other was Dr. Victor Frattali, deputy director of the division of nutrition in FDA's Bureau of Foods (now the Center for Food Safety and Applied Nutrition). Both agreed, in affidavits, that the Nutrient Deficiency Test was essentially worthless for diagnosing nutrient, digestive or glandular deficiencies.

Kocieniewski met with Kulp, who sold her another \$102.50 worth of food sup-



plements and suggested she take the Nutrient Deficiency Test again. She did and met with Kulp to discuss the results. Her conversation with Kulp was electronically monitored and recorded by postal inspectors outside the building.

Kulp told her that her nutrient deficiencies were caused by malabsorption of nutrients from her intestinal tract due to buildup of "black intestinal plaque." He explained that she needed to "wash the inside of the body" with fiber and sold her \$40 worth of wheat bran tablets to do the job.

According to Dr. Herbert's affidavit, this is nonsense, and there is no such thing as "black intestinal plaque."

This was enough for the Postal Service, which obtained a search warrant and seized a variety of materials from Kulp's office, including the computer software and the computer used in the Nutrient Deficiency Test. The Postal Service asked FDA's Buffalo district office to assist in the case. A chemist with the Buffalo laboratory ran the Nutrient Deficiency Test repeatedly, with different hypothetical data, and found that every single printout contained the statement, "It appears you have several nutrient deficiencies . . ." along with a list of vitamins and minerals. The suggested amount of each supplement was always the same whenever it appeared on the list.

The district office then made transcripts of Kulp's radio broadcasts on the Canadian talk show. On the show, Kulp promoted the Nutrient Deficiency Test and offered nutritional advice that was mostly nonsense and frequently dangerous. He suggested, for instance, the use of megavitamins and coffee enemas to treat cancer. When one caller said that the doctors at one cancer clinic didn't go along with a lot of vitamins, Kulp responded, "Oh they don't go along with any vitamins, dear, and of course if we don't go along with self-help, then everybody doesn't go to the cancer clinic if we help ourself [sic], and then what kind of jobs have we got left for those people? They'd be in the unemployment lines. . . . The American Cancer Society is one of the most redundant organizations in the world, the way they've blown your millions of dollars in so-called research."

Faced with the prospect of a felony indictment for mail fraud, Kulp entered into a plea agreement with the U.S. attorney's office. Kulp pleaded guilty to a misdemeanor violation of the Food, Drug, and Cosmetic Act, specifically for selling wheat bran tablets lacking adequate direc-

A Master of Misinformation

"Dr." Kulp was a master of misinformation. The following excerpts from a radio broadcast in May 1982 are typical of the sort of nutritional nonsense he spouted.

Kulp: *Beer, if it's natural carbonated beer, you'd probably tolerate it much better rather than one that has been charged with, you know, the gases they use. The hydrogen gases. Because that forms and, ah, and grabs up a free chlorine radical which forms hydrochloric acid in your system.*

. . . We're seeing the diseases because of chlorination in our water, the arteriosclerosis, the stroking, the heart attacks, ah, the cardiovascular disease, and I told you around about 1910 there was no such thing, ah, as cardiovascular disease. . . . Around 1890 is when they started to chlorinate the water and we talked about the fact that it takes maybe 20 to 30 years before the onset of that disease where it affects these arterioles and it starts to plaque them up. . . . You know they've always pinned cholesterol as the poor culprit which it is not. Cholesterol is the last thing to come on the scene. You can eat three, five, six, eight eggs a day, I don't think it's ever gonna bother ya. I just think we're pointing the finger at the wrong thing! I think it's sugar, as we told you. But the chlorine is the baby that really triggers it all. . . .

Listener: *I always thought milk was good for you.*

Kulp: *Hah! Hah! You know who tells you that? The milk people, only the dairy associations! You never heard a cow say that.*

The cow feeds it, its young ones. A cow has milk, O.K.? and it has five teats, and it feeds its calves. Now my mother only ever had two, but I know when I was an age, her

milk dried up, her breasts dried up, when I was at an age where I could be moved into solid foods. Now if I was to drink milk and milk was good for me, then my mother's breasts would have had milk all their life in them. So that I could have had milk. . . .

Listener: *When you're pregnant, they say you're supposed to drink a quart of milk a day.*

Kulp: *Well they say a lot of things. You don't get enough calcium from milk, first of all, because most people cannot manage the calcium that's in milk, they can't break it down, it solidifies out and the next thing we know we start seeing people with a lot of kidney stones and gallbladder problems. . . .*

I said you take the tuna from the ocean and you take it from its ecological state and put it into the processing of the plant, and it now has 40,000 times the amount of lead than when it left the ocean. And if continued, if we continue to eat these types of foods . . . the average person consuming this food would be in a market to be able to be classified as fully disabled because of lead poisoning and put on a pension! . . . And how much lead poisoning is there out there? Well this is why we do the Nutrient Deficiency Test that we talked about.

Listener: *Now what about natural foods like, ah, we buy an ice cream with no preservatives in it.*

Kulp: *Good, good, because ice cream has formaldehyde in it, it has lacquer thinners in it, it has, my God, if I told you some of the constituents, gum tars, you wouldn't believe what's in ice cream! . . . And my God, why is cancer at such epidemic proportions in the North American continent today? Because of all the chemistries! You're not living better through chemistry, angel, don't let anybody kid ya.*

tions for use as a drug in removing "black intestinal plaque." Of course, no such directions could be written without scientific evidence that "black intestinal plaque" exists and can be removed by wheat bran tablets.

While awaiting sentencing, Kulp went back on the air promoting bee pollen and royal jelly (a substance produced by bees) for sexual impotence, and seawater for psoriasis. He also claimed that a product called Banfi could cure baldness and that he had the product for sale and was using it in clinical tests. (No treatments for baldness have been approved by FDA.)

In addition, Kulp claimed on the radio that he had been "set up" by the government because he was "anti-establishment," and that he had been "railroaded" into pleading guilty. He said that government agents had terrorized his family with drawn pistols at the time his office was searched.

Buffalo district staff concluded that Kulp would continue to violate the FDC Act unless restrained legally. The U.S. attorney concurred and sought special terms of probation.

On Dec. 19, 1983, in the U.S. District Court for the Western District of New

York, Kulp was placed on probation for six months. Under the terms of his probation, Kulp was prohibited from posing as a nutritionist or as an expert in nutrition, or from giving nutritional advice through broadcast media, unless and until he obtained a graduate degree in nutrition from an accredited college or university.

He was also prohibited from promoting or offering for sale any food or drug product for any therapeutic uses except those appearing on the labeling of the product.

In addition, the magistrate lectured Kulp for saying on the radio that his family had been terrorized by government officials. Kulp was forced to admit in court

that those statements were false.

Canadian officials have barred Kulp from entering the country.

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

Tracking Aldicarb

What's a summer picnic without the joy of burying your face in a fat slice of fiery red watermelon or having a contest to see how far you can spit the seeds? 1985 almost became a year in which such pleasures were but a memory for some Americans when watermelons on the West Coast were found to be contaminated with the pesticide Aldicarb, a chemical that had no business in watermelons at all. Countless melons had to be destroyed.

To make certain that this problem had not spread, FDA ordered a nationwide check of watermelons. Each of the agency's 21 districts around the country obtained samples of melons that were analyzed in six district laboratories equipped to detect the presence of the chemical.

FDA's Kansas City laboratory is one of the six with this capability. The watermelon assignment was issued July 10 and the Kansas City office arranged with FDA's Chicago, Cincinnati and St. Louis offices to collect melon samples. By the

following weekend, 30 samples had arrived and by Monday the analyses were completed. All were negative, with the exception of one collected by the Cincinnati staff that showed trace levels of Aldicarb.

Cincinnati investigators went back to the produce dealer from whom the melons had been obtained and discovered that it would not be easy to track down their original source. The melons had been bought from a trucker who had gotten them from the Cordele, Ga., Farmer's Market. The purchase was made on a cash, rather than credit, basis and the dealer had no shipping records. In fact, since this was the first time the Cincinnati dealer had ever done business with this particular trucker, he wasn't even sure of the man's full name.

Fortunately, shortly after the FDA investigators' visit, the trucker's wife called the produce dealer to offer him another load of melons. He told her about the Aldicarb problem. The trucker's wife then called the Farmer's Market where her

husband had purchased a truckload of the popular summer fruit.

Farmer's Market personnel immediately contacted the Atlanta, Ga., health department, which in turn contacted FDA's Atlanta office. With the help of the Farmer's Market people, FDA investigators determined that the trucker lived in London, Ky., and drove for the Mason-Dixon Trucking Co. Market personnel were asked to be on the lookout for a Mason-Dixon driver.

When the driver arrived that same day, he agreed to wait until FDA investigators could come from FDA's Tifton, Ga., office, about a 30-minute-drive away. As luck would have it, he still had the weight tickets from the earlier run that identified the farm from which the suspect melons had come.

FDA and state officials visited the suspect farm locations and collected watermelon and soil samples representing fields on six farm sites. Aldicarb residue was confirmed the next day in melons from one of the six sites. This farmer had used



Aldicarb the previous year on a peanut crop. The remaining watermelon crop was voluntarily destroyed that afternoon by plowing the melons under. No injuries were reported from consumption of the Georgia melons.

Putting the Vet Back in Vet Rx

A Massachusetts-based firm that for years has sold veterinary drugs directly to farmers and dairymen without the supervision of a veterinarian has been told to stop the practice.

The firm is Independent Buyers Association, Inc., of Millbury, a distributor of veterinary products that operates nationwide through franchised dealers. Its line includes 17 prescription drugs that—by law—may be dispensed only by order of a licensed veterinarian. However, IBA dealers were selling these to customers, who would sign a form that said they were buying the drugs on the order of a veterinarian.

Federal District Judge Thomas D. Lambros, hearing the case in Cleveland, ruled last May that this was an attempt by IBA to get around the law. The forms did not originate with a veterinarian and therefore did not meet the requirement that there must be "direct communication" between a veterinarian and the drug dispenser.

Such controls are needed to prevent indiscriminate use of these drugs by persons who may not realize the risks to animal and man that can go with these medications.

The IBA case began back in 1978 when FDA first sought a court injunction to prevent drug sales by IBA dealers in Ohio. A year later, FDA sought a similar injunction against IBA itself in Massachusetts.

The Massachusetts case was combined with the one in Ohio, where a federal court in 1980 ruled against FDA, saying that the agency had—by regulation—created a new category of veterinary drugs not intended in the law.

This ruling was reversed the following year by the federal appeals court in Cincinnati, and the validity of the veterinary prescription drug regulation was upheld. The litigation continued, however, with IBA claiming its form met the requirements of the law. IBA also argued that FDA's regulatory framework for veterinary drugs was unconstitutional and that the agency had continued investigating the firm after an earlier court order prohibited it from doing so.

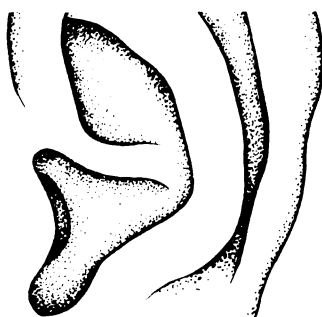
In his decision last May, Judge Lambros

rejected the IBA arguments and issued the long-sought injunction. It prohibits IBA from selling veterinary drugs directly to users without a veterinarian's intervention. He also denied an IBA motion for a stay or reconsideration of his order.

The case is now on appeal by IBA.

Failure to Listen

Sonotone International, Inc., a firm that makes hearing aids in Ossining, N.Y., turned apparently deaf ears to FDA's advice about its manufacturing practices. The poor reception of FDA's message resulted in a court-ordered seizure of the firm's products.



During an inspection of the firm, FDA found several violations of Good Manufacturing Practice (GMP) regulations. Complaint handling and records were inadequate. Procedures for accepting or rejecting components were inadequate. And there were no written procedures for checking the quality assurance program or for establishing acceptance criteria for finished devices. The result? FDA issued a Notice of Adverse Findings.

But Sonotone must have completely tuned out FDA, because subsequent inspections showed that the firm was still deviating from the law. FDA therefore sent a letter pointing out the GMP deviations to the firm's management and warning that, unless the firm acted immediately to correct the situation, the agency would take court action. In response, the firm—for the most part—either denied, misunderstood or disagreed with the alleged deviations or promised to make corrections that were inadequate.

A follow-up inspection revealed that the firm failed to make the required GMP corrections listed in the letter. FDA also found the Sonotone hearing aids to be misbranded in that labeling claims implied the devices had been tested in accordance with a standard that is generally used by the industry. In truth, however, evidence showed that such testing had not been per-

formed. Further FDA visits to the firm indicated that, although certain GMP deviations had been corrected, others persisted. FDA ultimately found that Sonotone failed to meet eight GMP regulations.

The agency filed a complaint with the U.S. attorney's office for the Southern District of New York, asking that Sonotone's hearing aids be seized and condemned. The court agreed with FDA and, last April, an FDA investigator accompanied a U.S. marshal to the firm, where 49 hearing aids with accompanying literature were seized. Retail value of the seizure was about \$20,000.

Sonotone has filed a claim and answer to the complaint denying the allegations that the hearing aids are adulterated or misbranded. The case is still pending.

Elusive Reserpine

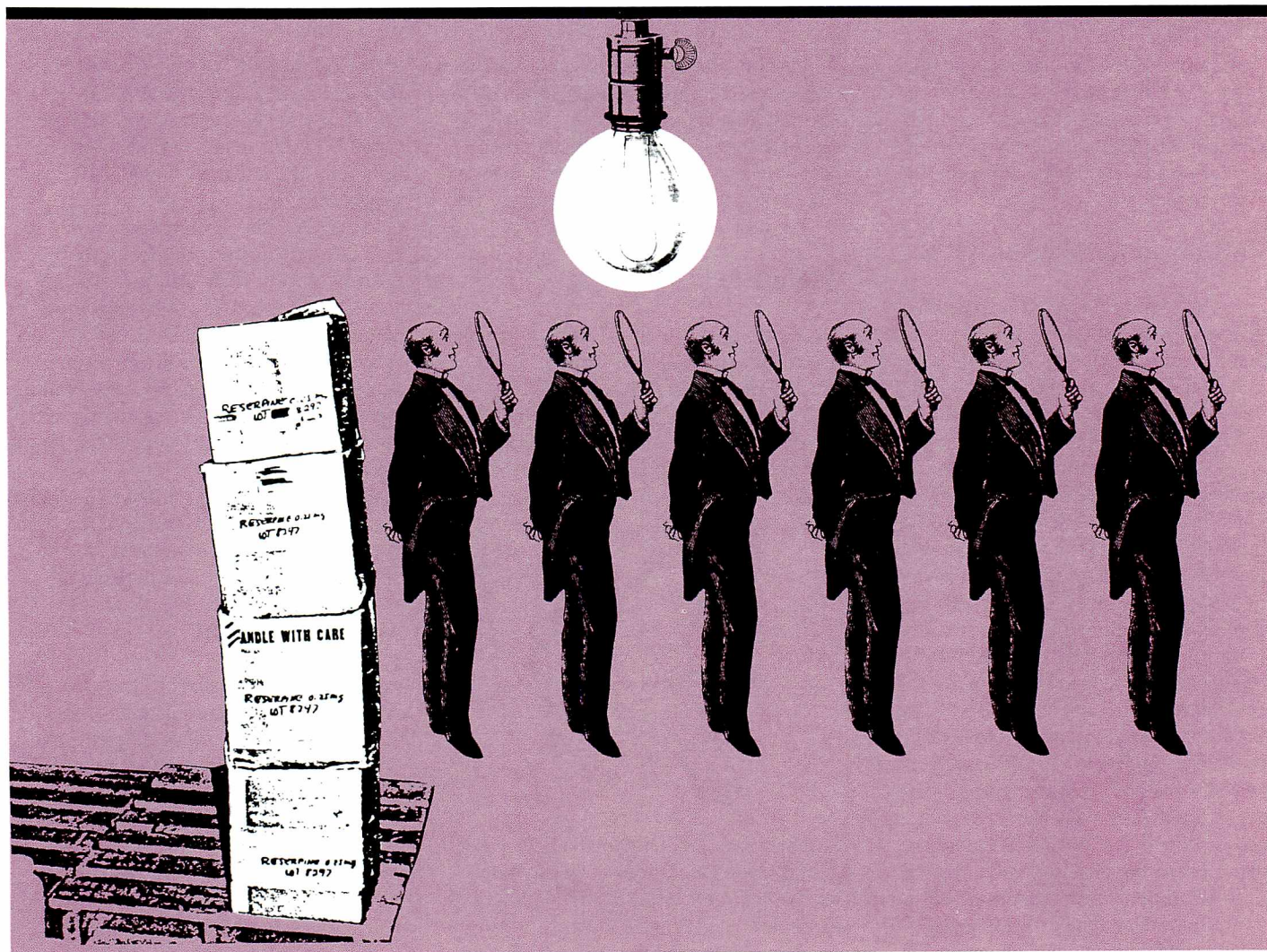
For Marshall Pharmacal Corp., lot 8297 of bulk reserpine alkaloid tablets (25-milligram size) became an albatross that eventually led to a fine for the company and a jail term for the firm's president.

In 1979, investigator Larry Johnson from FDA's Newark district office made a routine inspection of the South Hackensack, N.J., manufacturer of generic human drugs. He collected samples of various drugs, including one from lot 8297 of reserpine alkaloid, a prescription drug used to treat hypertension. FDA laboratory analysis showed that the reserpine failed U.S. Pharmacopeia requirements for content uniformity—that is, the active ingredient was not evenly distributed, so some of the tablets might be superpotent and others subpotent.

A second FDA investigator, Frank Mark, returned to the firm and discussed the results of the lab tests with the firm's president, Gustave A. Godinez. Godinez argued about the results and said he would continue to prepare lot 8297 for sale.

The district requested that the lot be seized, but before the necessary legal work was finished, Godinez's attorney called to say that the lot had been destroyed. Investigator Mark returned to the firm to confirm that this was true. He walked through the premises with Godinez and found no reserpine tablets. Godinez also gave Mark a letter stating that lot 8297 of reserpine tablets had been destroyed. The government therefore stopped its request for seizure.

(Continued on next page)



(Continued from previous page)

Three years passed. FDA sent out a request to hospital pharmacies across the nation asking them to participate in a drug stability testing program. The pharmacists were asked to submit samples of their oldest drug products in three categories: prednisone, pilocarpine ophthalmic solution, and reserpine. A sample of reserpine submitted by a pharmacist in Thiells, N.Y., failed the U.S.P. content uniformity test. The sample was from a 1,000-tablet bottle distributed by Glenlawn Labs, Stamford, Ct., and manufactured by Marshall Pharmacal Corp. The lot number was 8297.

The company in Stamford destroyed the lot while an FDA investigator watched. And two Newark investigators went to Marshall Pharmacal to find out what was going on. Godinez checked his records and said that he had a note about FDA sampling lot 8297 but he did not remember being told anything further about it or the results of the lab analysis. He said that if he had destroyed the lot he would remember it.

Godinez and his lawyer then met with

the staff of the Newark district office. Their story had changed somewhat. They explained that Godinez had intended to destroy lot 8297 in 1979 and had sent the four boxes containing the tablets to the shipping/receiving area of the plant, where refuse was placed until it was hauled away each Friday. Godinez said investigator Mark must have overlooked the boxes and that sometime later "someone" must have moved them into the area where finished products were stored. Two years later, he said, Glenlawn Labs requested some reserpine and that lot was shipped out. He said he did not mean to violate the law and that it was an innocent mistake.

FDA didn't buy the story. For one thing, this account was refuted by investigator Mark, who stated that there was no area of the Marshall Pharmacal premises he had not searched and that he had checked the shipping/receiving area. It was also refuted by the president of Glenlawn Labs, who signed an affidavit stating that Godinez had called *him* with an offer to sell the reserpine.

Newark district staff requested criminal proceedings against Marshall Pharmacal and Godinez, charging them with intent to defraud and mislead. Both the firm and Godinez pleaded guilty to selling reserpine tablets that failed to meet specifications for content uniformity. Both were fined \$1,000 and Godinez was sentenced to 30 days in jail.

The district also requested an injunction against the firm and two of its officers because it was consistently violating FDA's Good Manufacturing Practice regulations. The defendants agreed to a consent decree of permanent injunction that would prohibit them from manufacturing drug products in the future except under the strict supervision of a qualified person. At the time the injunction was signed, however, Marshall Pharmacal Corp. had gone out of business.

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

Summaries of Court Actions



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

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

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

SEIZURE ACTIONS

Foods/Contamination, Spoilage, Insanitary Handling

PRODUCT: Cheese, cheddar, at Los Angeles, C. Dist. Calif.; Civil No. 79-04793-R.

CHARGED 12-11-79: When shipped by Timber Lake Cheese Co., Timber Lake, S.D., the article had been prepared and packed under insanitary conditions—402(a)(4).

DISPOSITION: Pursuant to stipulation, the time for the shipper to file a claim for the article was extended to permit recently retained counsel to discuss the matter. Subsequently, the shipper claimed the article, denied the charge, and demanded a trial by jury. The claimant also requested the production of government inspection reports for the past September and October, analytical worksheets, and other specified documents. The claimant served written interrogatories on the government. Meanwhile, the government discovered that a 752-box lot of the claimant's cheese had been seized, but not the 802-box lot of cheese charged in the complaint for forfeiture. A complaint for forfeiture against the 752-box lot of cheese was thereafter filed, both lots of cheese were seized, and the actions were consolidated for trial.

Subsequently, pursuant to stipulation, the actions were dismissed as to certain cheese manufactured in October, and a consent decree of condemnation was entered against adulterated cheese produced by the claimant on Sept. 24-28. The consent decree authorized release of such adulterated cheese to the claimant for the purpose of either diverting the cheese from human consumption or disposing of it by destruction. Ultimately, the adulterated cheese was released and the conditions of the consent decree were met. (F.D.C. No. 62714; S. No. 80-198-209; S.J. No. 1)

PRODUCT: Dates, at Superior, W. Dist. Wis.; Civil No. 84C-946-C.

CHARGED 11-29-84: When shipped by Great Date In The Morning, Coachella, Calif., the article contained insect filth—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64412; S. No. 85-488-032; S.J. No. 2)

PRODUCT: Hoisin sauce, at Chicago, N. Dist. Ill.; Civil No. 85-C-2140.

CHARGED 3-14-85: When imported from Hong Kong, China, the article (labeled "Hoisin Sauce . . . Packed by: Koon Chun Hing Kee Soy and Sauce Fty. . . Hong Kong") contained animal hairs and feather fragments—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64541; S. No. 85-485-467; S.J. No. 3)

PRODUCT: Oregano leaves, black pepper, coffee beans, sesame seeds, basil leaves, fennel seeds, niger seeds, and filbert nuts, at Brooklyn, E. Dist. N.Y.; Civil No. CV-84-2869.

CHARGED 7-6-84: While held by International Terminal Operations, Brooklyn, N.Y., the article had been held under insanitary conditions—402(a)(4); and the oregano leaves, pepper, coffee beans, basil leaves, fennel seeds and niger seeds contained rodent and/or bird filth—402(a)(3).

DISPOSITION: The black pepper was claimed by the dealer. A decree of condemnation authorized release to the dealer of the black pepper and ordered the destruction of the other articles. (F.D.C. No. 64288; S. No. 84-400-781; S.J. No. 4)

PRODUCT: Peanuts, at Courtland, E. Dist. Va.; Civil No. 82-526-N.

CHARGED on or about 7-21-82: While held by Hancock Peanut Co. Inc., Courtland, Va., the article had been held under insanitary conditions—402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 63740; S. No. 82-339-103 et al.; S.J. No. 5)

PRODUCT: Peanuts, shelled, at Suffolk, E. Dist. Va.; Civil No. 85-31-N.

CHARGED 1-9-85: While held for sale, the article had been held under insanitary conditions—402(a)(4).

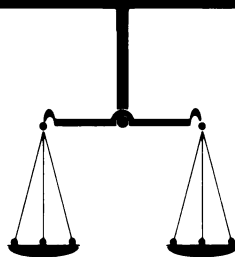
DISPOSITION: Consent—authorized release to Mar-Ja Inc., Suffolk, Va., for salvaging. (F.D.C. No. 64469; S. No. 85-360-848; S.J. No. 6)

Foods/Economic and Labeling Violations

PRODUCT: "Apple juice", at Jersey City, Dist. N.J.; Civil No. 82-3414 (Whipple).

CHARGED 10-12-82: While held for sale, the article (labeled "Rich Harvest Apple Juice . . . Distributed By Natural Juice Mfg. Co., Ltd., Tivoli, N.Y.") had had the valuable constituent apple juice omitted from the article—402(b)(1); the article's labeling was false and misleading as applied to an article that did not consist wholly of apple juice—403(a)(1).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 63847; S. No. 82-312-332; S.J. No. 7)



PRODUCT: **Table Syrups, Clark's Farm**, at Perris, C. Dist. Calif.; Civil No. 55-2111-TJH(KX).

CHARGED 3-27-85: When shipped by Dewey Clark, Philadelphia, Miss., the articles (labeled "Maple Table Syrup" and "Pure Sorghum") had had corn syrup substituted wholly or in part for such articles—402(b)(2); and the article labeled "Raspberry Syrup" had had the artificial color FD&C Red No. 40 added, so as to make the article appear better or of greater value—402(b)(4); the labels of the "maple" and "sorghum" syrups were false and misleading because the products contained little or no maple syrup or sorghum syrup and were, in fact, largely corn syrup—403(a)(1); the "maple" and "sorghum" syrups were foods offered for sale under the name of other foods—403(b); the "maple" and "sorghum" syrups failed to conform to their respective definitions and standards of identity, since the articles consisted wholly or in large part of corn syrup—403(g)(1); and the "raspberry" syrup's labeling failed to state that the article contained FD&C Red No. 40—403(k).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64547; S. No. 85-354-953; S.J. No. 8)

Vitamins/Special Dietary Foods

PRODUCT: **Candies, sugar-free, Sorbee**, at Mineola, E. Dist. N.Y.; Civil No. CV-84-4723.

CHARGED 12-5-84: When shipped by Sorbee International Ltd., Philadelphia, Pa., the articles' labels lacked a statement of the quantity of contents—403(e)(2); the articles' labels lacked required statements concerning dietary usefulness in connection with salt intake, weight control, or tooth decay, although the articles were labeled "sugar-free" and "salt-free"—403(j); and the articles contained artificial coloring, and the labeling failed to state that fact—403(k).

DISPOSITION: Consent—authorized release to the shipper for relabeling. (F.D.C. No. 64420; S. No. 84-419-251; S.J. No. 9)

Foods/Color Additives

PRODUCT: **Almonds coated with sugar and silver**, at Culver City, C. Dist. Calif.; Civil No. 85-1739.

CHARGED 3-13-85: When shipped by Raymond Foods Inc., Niles, Ill., the article contained the nonconforming color additive silver—402(c).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64535; S. No. 85-354-876; S.J. No. 10)

Drugs/Human Use

PRODUCT: **Dextroamphetamine sulfate tablets**, at Philadelphia, E. Dist. Pa.; Civil No. 80-0984.

CHARGED 3-10-80 and amended 10-25-81: While held by Lanett Co. Inc., Philadelphia, Pa., who manufactured the article using interstate d-amphetamine sulfate, the article's quality and purity fell below U.S.P. standards because the article failed U.S.P.

isometric purity requirements and could not be assayed by the U.S.P. method—501(b); the article was a new drug without an effective approved New Drug Application—505(a); the article lacked adequate directions for use and was not exempted due to its new drug status—502(f)(1); and (as amended) when shipped the circumstances of the article's production failed to conform with good manufacturing practices since the labeled expiration date of August 1981 failed to provide assurance that the article met applicable standards—501(a)(2)(B); and while held for sale, the article failed to bear adequate directions for use beyond August 1981—502(f)(1).

DISPOSITION: The article was claimed by the shipper, who denied the charges. Upon stipulation of the parties, the claimant filed an amended answer which asserted that the court lacked jurisdiction insofar as the article was alleged to be a new drug since the drug was being held by the claimant in quarantine and had not been shipped in interstate commerce. Upon the uncontested motion of the government, the court authorized post-seizure sampling of the article. Ultimately, since the labeled expiration date of the article had passed, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 62856; S. No. 79-203-473; S.J. No. 11)

PRODUCT: **Liquid for the disorders of children**, at Bronx, S. Dist. N.Y.; Civil No. 84-Civ. 7855.

CHARGED 10-30-84: When imported, the article (labeled "Woodward's Gripe Water For . . . Gripes, Flatulence and other complaints . . . Sodium Bicarbonate . . . Concentrated Dill Water . . . Ginger Tincture . . . Alcohol . . . Prepared in Canada for W. Woodward Ltd., London, England, Distributors Julius Schmid of Canada Ltd., Scarborough, Ontario") was a new drug without an effective approved New Drug Application—505(a).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64352; S. No. 84-400-513; S.J. No. 12)

Cosmetics

PRODUCT: **Toilet water in self-pressurized spray bottles, Climat**, at North Miami, S. Dist. Fla.; Civil No. 84-0929-CIV-WMH.

CHARGED 4-13-84: When shipped from Paris, France, the article (labeled "Climat Eau De Toilette Atomiseur Lancome Paris") contained a poisonous and deleterious substance, a chlorofluorocarbon propellant that was prohibited—601(a); the labeling of the article was misleading in failing to reveal material facts concerning conditions of use, since required warning statements were lacking—602(a); and the article was also in violation of the Fair Packaging and Labeling Act, as follows: the immediate container label and the outer carton label of the article lacked a quantity of contents declaration in terms of U.S. fluid ounces—15 U.S.C. 1453(a)(3)(A)(i); and the label of the outer container of the article failed to declare each ingredient in descending order of predominance—15 U.S.C. 1454(c)(3)(B).



DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64242; S. No. 84-373-708; S.J. No. 13)

Medical Devices

PRODUCT: **Leg magnets for horses, neck collars with magnets, and foot boots with magnets**, at Ruidoso, Dist. N.M.; Civil No. 83-1409 JB.

CHARGED 8-31-83: The articles, which were manufactured by Big M Magnetic Bandage Co. Inc., Ruidoso, N.M., were accompanied by an instruction sheet, "Equine Magnetic Training Aids," containing false and misleading claims for bucked or sensitive shins, lightly damaged tendons and ligaments, Green Osselets, arthritis, joint injuries, reducing swelling, dissolving cholesterol, increasing blood circulation, serving as an aid to better performance, endurance, vitality, hair, and respiration, and relieving soreness—502(f)(1); and the article's labeling failed to bear adequate directions for such uses, since adequate directions for such uses could not be written—502(f)(1).

DISPOSITION: The articles were claimed by the manufacturer, who denied the charges. The government served written interrogatories on the claimant. Ultimately, a consent decree ordered destruction of the articles, except for 12 sets of the articles to be delivered to FDA for educational and exhibit purposes. (F.D.C. No. 64051; S. No. 83-331-883; S.J. No. 14)

CRIMINAL ACTIONS

DEFENDANT: **Richard B. Knapp, M.D.**, clinical investigator, Morgantown, N. Dist. W.Va.; Criminal No. 84-00037-E.

CHARGED 3-22-84: That the defendant had signed a Statement of Investigator (Form FD-1572) to conduct a study of the new drug Talwin-APAP (pentazocine with acetaminophen); that the defendant had knowingly submitted, to such drug's sponsor, a patient case report containing the alleged results of a human study which contained false data; and that the defendant knew that the investigation had not been conducted as represented, and that the patient case report was false—18 U.S.C. 1001.

DISPOSITION: Guilty plea; probation for one year. (F.D.C. No. 63743; S.J. No. 15)

DEFENDANT: **Tally-Ann Baking Co., and Domenic Mastrangelo**, president, Philadelphia, E. Dist. Pa.; Criminal No. 84-453.

CHARGED 11-5-84 by grand jury: Flour (count 1) was held under insanitary conditions in an area infested with rodents and insects and was contaminated with insect filth—402(a)(3), 402(a)(4); and, when shipped to Pennsauken, N.J., kaiser rolls (count 2) contained rodent excreta—402(a)(3); submarine rolls (counts 3 and 5) and kaiser rolls (counts 4 and 7) contained insect and rodent filth and had been prepared and packed under insanitary conditions—402(a)(3), 402(a)(4); and bread (counts 6 and 8) contained insect fragments and had been prepared and packed under

insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Guilty plea by corporation; \$8,000 fine. Guilty plea by individual; 3 years' probation. (F.D.C. No. 64130; S. No. 83-355-020 et al.; S.J. No. 16)

INJUNCTION ACTIONS

DEFENDANT: **Springboro Bennett Drugs, Inc., t/a Bennett Rexall Drugs, and Phillip A. Rotman**, president and chief pharmacist, Springboro, S. Dist. Ohio; Civil No. C-1-84-0173.

CHARGED 1-31-84 in a complaint for injunction: That the defendants sold prescription drugs to lay persons without prescriptions (e.g., veterinary prescription drugs—such as Equipose, Task 40, prednisolone acetate suspension—and human prescription drugs—such as Bacitrim Pediatric Suspension and tetracycline capsules); that FDA inspection revealed an unusually large inventory of prescription veterinary drugs but only four legitimate veterinary prescriptions filled in the last four months; that all of the specified prescription drugs (except the tetracycline capsules, which were sold in a wholly unlabeled vial) bore warnings that federal law restricted their use except on prescription or order of a licensed veterinarian or physician; that the defendants' act, in selling prescription drugs to lay persons without a prescription, was in violation of the law; and that the individual defendant was well aware that his actions were in violation of the law—503(b)(1)(B) and 502(f)(1).

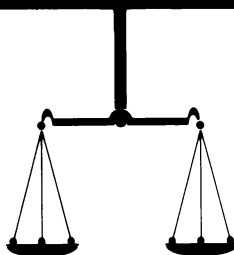
DISPOSITION: The defendants denied the charges. Subsequently, the defendants consented to a consent decree of permanent injunction which enjoined the complained-of violations and enjoined any further sale of prescription drugs unless and until specified conditions were met, including establishing records to document the sale of all prescription drugs, the preparation of an accurate inventory of all prescription drugs in stock, and notice by FDA to the court of the defendants' compliance. (Inj. No. 1054; S. No. 83-340-120 et al.; S.J. No. 17)

MISCELLANEOUS ACTIONS

SUBJECT: **DES premixes and implants for cattle and sheep and FDA's withdrawal of approval for NADAs for animal drugs containing DES**, at Washington, Dist. Columbia; two actions, D.C. Court of Appeals, Nos. 79-1694 and 79-1706.

PETITIONED 7-3-79 by Rhone-Poulenc Inc. (Hess & Clark Divisions) against FDA and 7-6-79 by Vineland Laboratories Inc. (subsidiary of Damon Corp.) against FDA and acting FDA Commissioner Sherwin Gardner: That the Court of Appeals should set aside the FDA order of June 29, 1979, withdrawing approval of specified new animal drug applications for DES implants and DES liquid and dry premixes for use in feeds for cattle and sheep.

The petitioners filed motions for various stays of the FDA orders, but the motions were denied and the actions were consolidated upon the joint motion of the petitioners. On Nov. 24,



1980, the Court of Appeals denied the petitions. Although FDA had originally approved the use of DES in animals because it was believed that, properly administered, the drug would not remain in any edible portions of the receiving animals, more sophisticated tests showed that small amounts of DES were present. The petitioners had contended that DES was similar to naturally occurring human estrogens and that the amount of DES residue was insignificant.

The Court of Appeals found no reason to overturn the commissioner's evaluation of the risks and benefits of DES, and agreed with the commissioner that the manufacturers (the petitioners) had failed to present sufficient evidence concerning the health and economic benefits of DES. Accordingly, the Court of Appeals affirmed that the benefits of DES had not been shown to outweigh its risks. In addition, the Court of Appeals also upheld the commissioner's failure to issue an environmental impact statement based on the commissioner's conclusion that banning DES would not significantly affect the quality of the human environment. (Misc. No. 545; S.J. No. 18)

SUBJECT: Reye syndrome and aspirin warning label, at Boston, Dist. Mass.; Civil No. 82-3554-N.

CHARGED 11-22-82 in a complaint for injunction (amended 1-18-83) by Heinz F. Eichenwald, M.D., John Baum, M.D., Harvey L. Chernoff, M.D., Joseph Fitzgerald, M.D., Burton H. Harris, M.D., Robert A. Hoekelmann, M.D., David J. Lang, M.D., James P. Orlowski, M.D., and the Committee on the Care of Children (an unincorporated association), Boston, Mass., against HHS Secretary Richard S. Schweiker, Surgeon General C. Everett Koop, M.D., FDA Commissioner Arthur Hull Hayes Jr., M.D., and the director of the Centers for Disease Control, William H. Foege, M.D.: That the defendants had undertaken a publicity campaign to advise the public that there was an undefined "association" between the use of aspirin and Reye syndrome; that such campaign had been initiated after initial review of highly criticized studies and after the HHS secretary had stated that FDA was going to adopt a regulation requiring warning labels on aspirin; that the proposed regulation had been withdrawn because of the dispute as to the drug studies; that the secretary was arbitrary and capricious in continuing this campaign; that the campaign placed sick children at risk because physicians and patients would refuse to use aspirin and would use acetaminophen (a potentially more harmful drug in certain situations); that ordering and continuing the campaign was arbitrary and capricious; that, in the absence of an imminent health hazard, the defendants lacked authority to implement the campaign; that the campaign was in direct conflict to the HHS secretary's findings that HHS could not proceed with the proposed warning-label rules; that the campaign violated the Administrative Procedure Act, the FTC Act, and the Food, Drug, and Cosmetic Act; and that the defendants should be enjoined from the campaign, should be required to publicize insufficient bases concerning aspirin and Reye syndrome, and should be enjoined to establish a panel of experts to review

whether there was any relation between aspirin and Reye syndrome.

DISPOSITION: The court denied the plaintiff's motion for a temporary restraining order and for a preliminary injunction. The government moved to dismiss or for summary judgment. The plaintiffs moved for leave to take depositions; and the court opened discovery in the action but limited all discovery to the issue of exhaustion of administrative remedy. Ultimately, pursuant to stipulations of the parties, the action was dismissed without prejudice and without assessment of costs. (Misc. No. 697; S.J. No. 19)

Statement of Ownership, Management, and Circulation (Required by 39 U.S.C. 3685)

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B. Paid circulation		
1. Sales through dealers and carriers, street vendors, and counter sales	1,199	1,212
2. Mail subscriptions	12,500	12,300
C. Total Paid Circulation (sum of B1 and B2)	13,699	13,512
D. Free distribution by mail, carrier, or other means, samples, complimentary, and other free copies	1,351	1,407
E. Total distribution (sum of C and D)	15,050	14,919
F. Copies not distributed		
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2. Returns from news agents	---	---
G. Total (sum of E, F1, and F2—should equal net press run shown in A)	15,225	15,094

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

William M. Rados, editor

QUACKERY ...The Billion Dollar MIRACLE Business



This year, we Americans will spend billions of dollars on health products that simply do not work and may even harm us. These products promise us we can eat all we want and still lose weight. Or we can grow taller or build a bigger bustline. Or overcome baldness, age, arthritis—even cancer.

It sounds too good to be true, and it is. But how to avoid these rip-offs? A new brochure available from the Food and Drug Administration can help. Published in conjunction with the Federal Trade Commission, the

U.S. Postal Service, and the Pharmaceutical Advertising Council, the brochure offers tips on how you can protect yourself from health fraud. It tells what to watch out for in ads and who to contact if you're suspicious of a product or think you're been "had."

For a free copy of "Quackery . . . The Billion Dollar Miracle Business," write to the Food and Drug Administration, HFE-88, 5600 Fishers Lane, Rockville, Md. 20857. Protect yourself from miracles that never happen.