

FDA CONSUMER

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

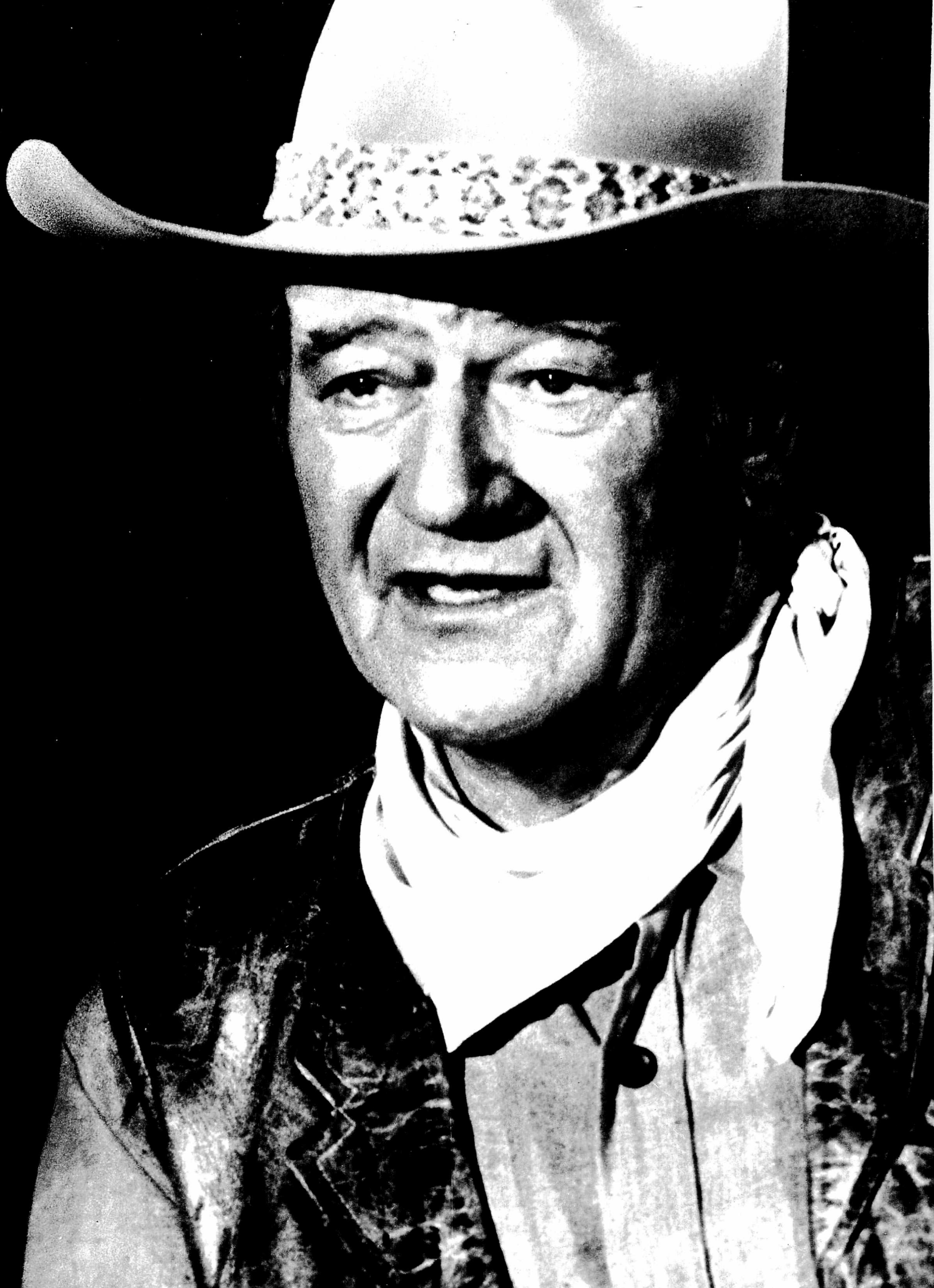
• VOL. 29 NO. 5

JUNE 1995 •

TAMING

**TUMMY
TURMOIL**





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FDA Consumer (ISSN 00362-1332) is published by the Food and Drug Administration (HFI-40), 5600 Fishers Lane, Rockville, MD 20857, U.S. Public Health Service, Department of Health and Human Services. It is published monthly, except for combined issues for July-August and January-February. Use of funds for printing *FDA Consumer* has been approved by the Office of Management and Budget.

Editorial Matters

Address for editorial matters is *FDA Consumer*, Food and Drug Administration (HFI-40), 5600 Fishers Lane, Rockville, MD 20857. Articles in *FDA Consumer* may be republished without permission. Credit to *FDA Consumer* as the source is appreciated. *FDA Consumer* is indexed in the *Reader's Guide to Periodical Literature*. To obtain a copy of the current *FDA Consumer Index*, write to: FDA, HFE-88, 5600 Fishers Lane, Rockville, MD 20857.

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Answers to Consumer Questions About the Food Label

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Since the new food label made its debut about a year ago, consumers have started asking questions about how best to use it. Here are answers to the questions most commonly asked.

An FDA Guide to Choosing Medical Treatments

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Home remedies recommended by friends. "Miracle cures" touted in the tabloids. Experimental therapies still under study. Choosing a medical treatment has never been more baffling. But there are ways to make your choice an educated one.

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New drugs—and new ways of using older drugs—are making urinary tract infections less of a problem for many people. Non-drug measures can also help prevent this malady.

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A number of nonprescription products can ease motion sickness and calm other stomach upsets. But some stomach problems signal that a doctor's care is needed.

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Lung cancer—one of the most deadly forms of the disease—is largely preventable. Yet, in a country where jogging and tooth flossing are common, lung cancer prevention is still too elusive for too many.

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Inside Front Cover Photo: *Movie star John Wayne, a heavy cigarette smoker who often played Western he-man roles, died as a result of lung cancer a number of years ago. For the latest on this deadly disease, see page 24.*

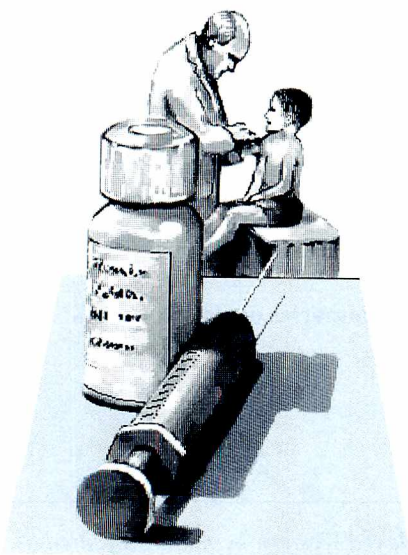


Chickenpox Vaccine Licensed

A vaccine that prevents chickenpox, one of the most common childhood diseases, received a license from FDA last March 17.

In studies over 10 years of approximately 11,000 children and adults who had never had the disease, the vaccine, Varicella Virus Vaccine Live, was 70 to 90 percent effective in preventing chickenpox. Of those who were vaccinated and got the disease, almost all had mild cases. Adverse reactions to the injection were mild and included redness, hardness and swelling at the injection site, fatigue, malaise, and nausea.

A single injection of the vaccine is recommended for children 12 months to 12 years, while two injections four to eight weeks apart are recommended for adolescents and adults who have never had chickenpox. The vaccine has been shown to be safe and effective when administered at the same time as the measles, mumps and rubella vaccines.



An estimated 3.7 million Americans get chickenpox each year, with more than 90 percent of cases in people younger than 15.

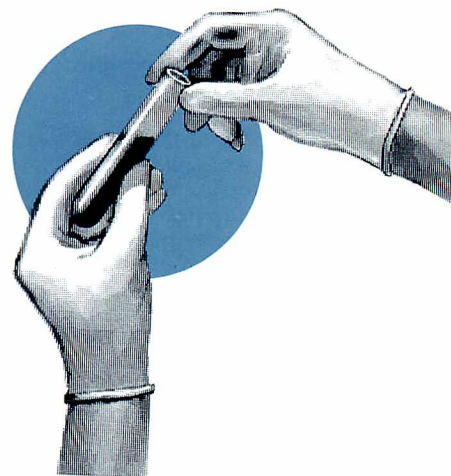
Chickenpox is generally mild and not normally life-threatening. However, some individuals, including adolescents and adults, are at higher risk of serious illness. There are an estimated 9,300 chickenpox-related hospitalizations and 50 to 100 deaths annually, mainly among young children.

Chickenpox is transmitted to others through fluid from broken blisters as well as by coughing or sneezing. A person is contagious from one to two days before the rash appears until all the lesions are dried, which usually takes four to five days. The average incubation period (the time between exposure to the virus and the onset of illness) is 10 to 21 days.

The chickenpox vaccine is manufactured by Merck and Co. Inc., Whitehouse Station, N.J., under the trade name Varivax. At FDA's request, Merck will perform postmarketing studies to determine the long-term effects of the vaccine and possible need for a booster immunization.

Latex Allergy Test Cleared for Marketing

The first laboratory test to help identify people suspected of having allergic reactions to latex received marketing clearance from FDA last March 24. The test, which measures latex antibodies in blood, is not for screening, but it can help prevent future reactions in latex-



sensitive people by alerting them to avoid exposure.

A natural rubber used for medical devices such as catheters and surgical gloves, latex can cause allergic reactions ranging from minor skin reddening to fatal anaphylactic shock. Allergic reactions can occur in sensitive people whenever latex comes in contact with the body, even with no apparent prior signs or allergy symptoms.

Latex sensitivity affects an estimated 1 percent of the population, including up to 15 percent of health workers and others exposed to latex regularly, and 34 to 100 percent of people with spina bifida, who are repeatedly exposed to latex tips on enema bottles during treatment.

FDA based its approval on clinical data showing that the test accurately detected latex sensitivity in 87 to 94 percent of those with an allergy. Previously, diagnoses were based on a physical examination and a history of allergic reaction after latex exposure.

The new test, the AlaSTAT Latex-Specific IgE Allergen Test Kit, can be performed in a hospital laboratory using patient blood specimens. Results are available in a few hours.

Diagnostic Products Corporation of Los Angeles makes the test kits.

New Product for Rh Negative Women

A product that can suppress Rh sensitization of Rh negative pregnant women, to prevent a severe fetal disease, was licensed March 24. It was also licensed to treat an uncommon bleeding disorder.

Marketed as WinRho SD, the product—Rho(D) Immune Globulin Intravenous (Human), or RhIGIV—is the first one licensed by FDA for these uses that incorporates a virus inactivation step in the manufacturing process. The agency encouraged the inclusion of the virus inactivation step as an added safeguard. Immune globulin lots are already tested for hepatitis C, a procedure FDA introduced in December 1994.

Maternal Rh isoimmunization, for which approximately 10 percent of pregnancies are at risk, occurs when an Rh negative mother is exposed to Rh positive blood from her infant at delivery. When a woman becomes Rh sensitized, the antibodies to Rh that develop will cause a severe disease (blue baby syndrome) in future Rh positive fetuses.

The bleeding disorder, idiopathic thrombocytopenic purpura (ITP), affects

100,000 Americans each year. Clinical trials indicated that WinRho SD was effective in treating children and adults with ITP, including ITP associated with HIV infection. It also can be used at lower doses than other nonspecific intravenous immune globulins to treat ITP in Rh positive patients.

FDA has granted orphan drug status for the use of WinRho SD in the treatment of ITP. Orphan drugs are drugs for rare diseases affecting fewer than 200,000 Americans.

WinRho SD is the only U.S.-licensed anti-Rh immune globulin that can be administered intravenously. The product can also be given intramuscularly to suppress Rh sensitization (but only intravenously for ITP). Adverse reactions include soreness at the injection site, chills, fever, and headache.

WinRho SD is manufactured by Rh



Pharmaceuticals Inc. of Winnipeg, Manitoba, Canada, and distributed by Univax Biologics Inc. of Rockville, Md.

New Regimen for Alteplase

A new, accelerated infusion regimen for an already licensed heart attack treatment was approved by FDA April 3.

The regimen calls for giving the medication, Activase (alteplase), through a vein over 90 minutes—half the time of the previous regimen.

Activase is a genetically engineered version of tissue plasminogen activator. It was licensed in 1987 as a blood clot dissolver to reduce heart attack deaths and congestive heart failure and to improve ventricular function. (See "Clot-Busting Drug to Turn Off Heart Attacks," in the February 1988 *FDA Consumer*.) In 1990, it was also licensed to treat pulmonary embolism.

An international trial with more than 41,000 patients included four regimens: infusion with Activase over 90 minutes; two standard-dose regimens with streptokinase, another blood clot dissolver, infused over 60 minutes; and a combination of Activase and a lower dose of streptokinase infused over 60 minutes.

The death rate for the accelerated Activase infusion was 6.3 percent, which was significantly lower than the rates for the two standard-dose streptokinase regimens, 7.2 and 7.4 percent. The experimental combination regimen offered no advantages.

Major safety concerns associated with

using blood clot dissolvers are the potential for bleeding and stroke. In the international trial, stroke incidence for accelerated Activase was 1.6 percent, but higher for the streptokinase standard-dose regimens, at 1.4 and 1.2 percent. However, the combined incidence of death or nonfatal stroke for accelerated Activase, 7.2 percent, was lower than the incidences for the standard-dose streptokinase regimens, which were 8.2 and 8.0 percent.

Activase is not for use in patients who have internal bleeding, a history of cerebrovascular accidents, or severe uncontrolled high blood pressure. The safety and effectiveness of Activase has not been established in pregnant women or children.

Genentech Inc. of South San Francisco manufactures Activase.

Clinton Announces Drug, Device Review Streamlining Initiatives

President Clinton announced a major reinvention initiative for FDA's drug and medical device review programs during a March 16 speech in Arlington, Va.

The measures announced by the president will continue the streamlining of the agency's new product review processes that has been under way since the 1980s.

"The philosophy that guided these changes is pretty simple: Protect people, not bureaucracy; promote results, not rules; get action, not rhetoric," Clinton said.

"Today, Americans don't have to

worry about the safety or effectiveness [of medical products] when they buy anything—from cough syrups to the latest antibiotics or pacemakers. The Food and Drug Administration has made American drugs and medical devices the envy of the world and in demand all over the world. And we should never forget that, either. And we are going to stick with the standards we have; the highest in the world. But strong standards need not mean business as usual in every area," he said.

The proposals Clinton announced would:

- Allow drug and biologic companies to make certain manufacturing changes, such as adding or changing an ingredient without FDA review and approval of the change, if risks are negligible. FDA intends to issue guidance on which types of changes would qualify.
- Eliminate outdated special requirements for manufacturing insulin and antibiotics. These changes would eliminate more than 700 pages in the *Code of Federal Regulations*, eliminate burdens on industry, and may make products available more quickly to consumers.
- Exempt from environmental assessments virtually all applications for human drugs and biologics and animal drugs. This would reduce the burden on industry of submitting such assessments and the burden on FDA of reviewing them.
- Exempt nearly 140 categories of low-risk medical devices from 510(k), or premarket review, requirements, adding to the 441 categories already exempted. Products proposed for exemption range from anesthetic gas masks to powered

finger exercisers. Industry would no longer have to prepare and submit documents, and FDA would not have to process and review an estimated 700 such submissions each year. Public health would not be compromised, because these devices are inherently low risk and would remain subject to good manufacturing practice (GMP) requirements.

- Eliminate the "reference list" of medical device firms and clarify that 510(k) premarket notification of medical devices can be affected only if GMP violations are related to a specific device or if there were systemic violations that would affect the device. FDA would prepare a clear, written policy and set of procedures so that firms would understand the relationship between GMP problems and 510(k) applications, and the steps required for 510(k) clearance.

Caution with Kombucha

A beverage touted as a treatment for AIDS and cancer, among other uses, is not approved by FDA for medical uses and may in fact be harmful.

Kombucha mushroom tea, also known as Manchurian tea and Kargasok tea,



contains considerable quantities of acids that could leach harmful quantities of lead and other toxic elements from some ceramic and painted containers and lead crystal, FDA warned last March. The agency advised against using such containers to store the tea.

FDA studies have shown no evidence of contamination in commercial Kombucha mushroom tea fermented under sterile conditions. However, home-brewed Kombucha mushroom tea may contain microorganisms that can cause serious adverse effects in immune-compromised people, the agency said.

Despite its name, the tea is not derived from a mushroom, but from fermentation of various yeasts and bacteria. A starter culture is added to a mixture of black tea and sugar, and the resulting mix is allowed to ferment for a week or more.

No Unexpected Problems With Posilac

Dairy cattle treated with Posilac (recombinant bovine somatotropin, or rbST) showed no unexpected side effects during the first year of marketing, according to an FDA review of reports of adverse reactions.

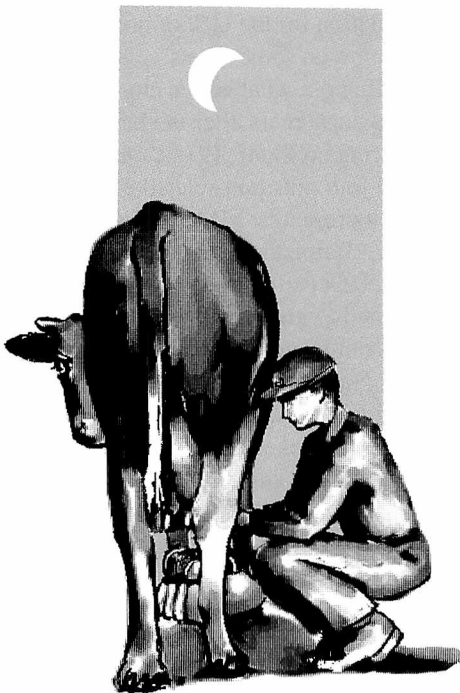
As of March 1995, FDA had reviewed a total of 806 adverse effects in cattle possibly related to use of Posilac to increase milk production.

They included 121 reports of mastitis

(udder infection), 105 of increased white cell counts, 73 of swelling of the udder or abnormal milk, and 89 of reproductive disorders. Other reports relate to digestive disorders and foot or leg problems. All these conditions also occur in cattle not given Posilac.

The findings were consistent with results of pre-approval trials of the drug and raised no new animal health concerns. In addition, before rbST was approved, an FDA advisory committee concluded that use of the product—and any increased use of antibiotics to treat mastitis in cattle given the drug—would not pose a risk to humans.

Posilac is the only recombinant bST product approved by FDA. According to



its manufacturer, Monsanto Co., more than 14 million doses have been sold for use on 13,000 dairy farms, representing about 11 percent of dairy farmers in the United States.

After receiving 96 reports of adverse reactions in cattle in the first six months of marketing, FDA asked Monsanto to submit any references in its records that might relate to an adverse event. After reviewing the reports, the agency found no cause for concern. FDA validated Monsanto's adverse reaction reporting system and investigated some reports with on-farm inspections.

The agency continues to monitor herds treated under field conditions and those in a two-year study of dairy farms of various sizes in different regions of the country.

(For more information about recombinant bST, see "No Human Risks: New Animal Drug Increases Milk Production," in the May 1994 *FDA Consumer*.)

FDA Consumer welcomes comments from readers. Send letters to: Editor, *FDA Consumer*, HFI-40, 5600 Fishers Lane, Rockville, MD 20857.

Answers To Consumer Questions About **THE FOOD LABEL**

by Paula Kurtzweil



Randy Sager of Potomac, Md., turns a box of croutons from side to side, looking for the "Nutrition Facts" panel. Like millions of Americans, she has come to value the information about serving size, calories and nutrients.

The croutons are missing a Nutrition Facts panel and so is a package of baked goods in Sager's grocery cart. Saying she doesn't usually buy foods without nutrition labeling, she adds, "But I'm hungry, so I'm buying it."

Sager is not alone in having come to depend on the Nutrition Facts panel and making decisions based on its presence. According to an *FDA Consumer* poll, missing nutrition information is one of consumers' chief labeling concerns.

It's been about a year since the new food label made its debut on many foods, and with it, mandatory nutrition labeling and a new format for presenting information. Manufacturers had until Aug. 8, 1994, to include the Nutrition Facts panel on labels of packaged food. Food packaged before that date still may

be on the shelves, and this may be one explanation for the lack of nutrition information on some labels.

To find out what issues most concerned consumers after the label started appearing on foods, *FDA Consumer* polled four nutrition-related consumer inquiry programs: FDA's Office of Consumer Affairs, the FDA Seafood Hotline, the U.S. Department of Agriculture's Meat and Poultry Hotline, and the American Dietetic Association's Consumer Nutrition Hot Line.

Here are the questions that the poll showed perplexed consumers the most, along with the answers:

Where can I get more information to help me understand the new food label?

There are several sources for labeling information:

FDA's Office of Consumer Affairs
HFE-88
Rockville, MD 20856

FDA Seafood Hotline
(1-800) FDA-4010
(202) 205-4314 in the Washington, D.C., area
24 hours a day

USDA Meat and Poultry Hotline
(1-800) 535-4555
(202) 720-3333 in the Washington, D.C., area
Recorded messages available 24 hours a day. Home economists and registered dietitians available 10 a.m. to 4 p.m. Eastern time, Monday through Friday.

National Center for Nutrition and Dietetics

American Dietetic Association's
Consumer Nutrition Hot Line
(1-800) 366-1655
Recorded messages available 9 a.m. to 9 p.m. Eastern time, Monday through Friday. Registered dietitians available 10 a.m. to 5 p.m. Eastern time, Monday through Friday.

These sources will provide written

Nutrition Facts

Serving Size 1/2 cup (114g)
Servings Per Container 4

Amount Per	Serving
Calories	from Fat 30
	% Daily Value*

Total Fat	3g	5%
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Saturated Fat	0g	0%
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Cholesterol	0mg	0%
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Sodium	500mg	13%
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Total Carbohydrate	13g	%
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Dietary Fiber		
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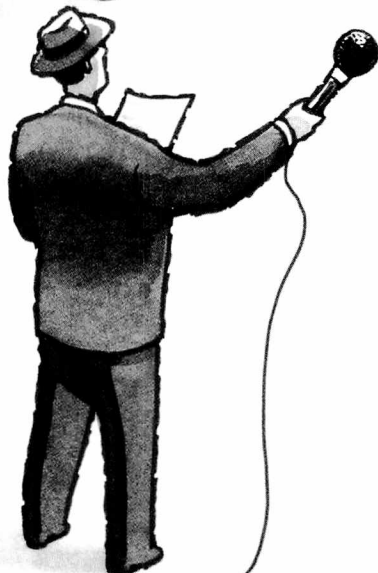
Sugars	3g	
--------	----	--

Protein	3g	
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Vitamin A 80% • Vitamin C 60%

Calcium 4% • Iron 4%

* Percent Daily Values are based on 2000 Calorie diet.



information, as well as answer specific labeling questions.

For information on food labeling educational materials, contact:

FDA/USDA Food Labeling Education
Information Center

National Agricultural Library
10301 Baltimore Blvd., Room 304
Beltsville, MD 20705-2351
(301) 504-5719
facsimile (301) 504-6409

Can a product be labeled “fat-free,” “sugar-free,” or “sodium-free” and still contain those nutrients?

Under FDA and USDA regulations, “free” for various nutrients is defined as:

- sugar-free: less than 0.5 grams (g) per serving

- sodium-free: less than 5 milligrams (mg) per serving

- fat-free: less than 0.5 g of fat per serving

- cholesterol-free: less than 2 mg of cholesterol and 2 g or less of saturated fat per serving

- saturated fat free: less than 0.5 g of saturated fat per serving and less than 0.5 g *trans* fatty acids per serving

- calorie-free: fewer than 5 calories per serving.

FDA and USDA chose these limits because they are the lowest points at which detection of calories or a nutrient can be made. These and lower levels are of no dietary significance.

How can I use the food label to help me follow a low-fat, low-sodium, or other prescribed or modified diet?

If your doctor has prescribed a diet that limits the amount, usually in grams or milligrams, of certain nutrients—for example, a 2,000-mg sodium diet—look at the Nutrition Facts panel, usually on the side or back of the food package. It lists the amount by weight of specific nutrients in a serving of the food. Use these numbers, given in grams or milligrams, to track your daily intake of nutrients.

If you’re trying to follow the Dietary Guidelines for Americans by restricting fat, sodium and cholesterol and increasing fiber to recommended levels, use the %Daily Values. For example, the Dietary Guidelines recommend that fat intake be limited to 30 percent or less of calories. For a 2,000-calorie diet, this amounts to 65 g, the Daily Value for fat used in food labeling. Even though your calorie intake may be higher or lower, you still can use the %Daily Values in a relative way to see how a serving of food contributes to your overall diet.

For specific diet information, you may want to refer to these articles in the *FDA Consumer* series “The New Food Label”:

- “Making It Easier to Shed Pounds,” July–August 1994

- “Scouting for Sodium and Other Nutrients Important to Blood Pressure,” September 1994

- “Coping with Diabetes,” November 1994

- “Help in Preventing Heart Disease,” December 1994

- “Better Information for Special Diets,” January–February 1995.

For further help, see a registered dietitian or nutritionist.

Why is it that the calories I calculate based on protein, carbohydrate and fat amounts don’t match the total calories per serving listing on the food label?

The difference is probably due to rounding rules. Food labeling regulations require manufacturers to round as follows:

- nearest 5-calorie increment up to and including 50 calories. (If it’s less than 5, a listing of zero is OK.)

- nearest 10-calorie increment above 50 calories.

So, the calorie declaration for a food with 12 g of fat that would furnish 108 calories is rounded to 110, while one with 116 calories is rounded to 120.

This is true for “total calories” and “calories from fat.”

The amount by weight of nutrients also is rounded. This can cause some discrepancy between your calculations and the label’s values, too, because the

manufacturer may use the precise numbers to calculate calories.

Overall, though, your figures should come close to the labeled ones.

Why are African American women excluded from the claim on the association between reduced calcium intake and increased risk for osteoporosis?

Based on scientific research, FDA concluded that the general population is not at a significant risk for developing osteoporosis, a bone disease. For example, studies show that despite their generally lower calcium intake, African Americans have higher bone mass at maturity and a very low incidence of osteoporosis-related bone fracture. Thus, the final claim targets those at greatest risk: teen and young adult white and Asian American women. However, calcium is a nutrient everyone needs.

What does “total fat” on the Nutrition Facts panel include?

Total fat refers to all the fat in the food: saturated, polyunsaturated and monounsaturated. Only total fat and saturated fat information is required on the label because high intakes of both are linked to high blood cholesterol, which in turn is linked to increased risk of coronary heart disease. Listing the amount of polyunsaturated and monounsaturated fats in the food is voluntary.

Also, the amounts of saturated, polyunsaturated and monounsaturated fats may not always add up to the full amount declared for total fat because the government-established definitions for those subcategories of fat do not include fatty acids in the *trans* form. So the label value for total fat may be higher than the sum of the subcategories.

Cholesterol is sort of a “cousin” to fat. Both fat and cholesterol belong to a larger family of chemical compounds called lipids. Lowering cholesterol intake, along with saturated fat, may reduce the risk of heart disease. That’s why the amount of cholesterol in a food is required on the label.

Explain the 2,000-calorie basis cited on the food label.

This is the calorie level used to calculate %Daily Values on the label for nutrients whose recommended intakes are based on calorie intake.

In deciding on this number, FDA and USDA referred to the National Academy of Sciences' recommendations on calorie intakes and U.S. Census Bureau data. From these figures, the agencies determined that the mean recommended calorie intake for the American population is about 2,350 calories a day. Based on public comment—and, in part, to make the number user-friendly—the number was rounded to 2,000 calories.

Also, the 2,000-calorie basis gives more appropriate dietary reference numbers for the group that often has the most difficulty obtaining adequate levels of nutrients—older women.

What do the %Daily Values mean?

These show how much of reference daily nutrient intakes a serving of food provides. For example, a food that lists 5 percent as the %Daily Value for fat contributes 5 percent (3 grams), of the maximum amount of fat a person on a 2,000-calorie diet could eat and still be within the Dietary Guidelines' recommendation of 30 percent or less of calories from fat (65 grams of fat or less). The percentage does not mean that the food is made up of 5 percent fat or that 5 percent of the calories come from fat.

How do you interpret "sugars" on the label?

Sugars are part of total carbohydrate and include sugars naturally present in the food (for example, lactose in milk and fructose in fruit), as well as those added to the food, such as table sugar, corn syrup, and dextrose. The label can claim "no sugar added" but still have naturally occurring sugar. An example is fruit juice.

Label Accuracy

Can you trust the nutrition information on the label?

In most cases, yes, suggests an FDA study of 300 food products off store shelves. The study, conducted last fall—during the first six months of the labeling regulations' implementation—found that about 87 percent of eight or more nutrients measured were within regulatory limits.

For fat, 94 percent of the analyses showed that the amount listed on the label accurately reflected what was in the food. For calories, it was 93 percent.

FDA also found that products with new labels appeared to have a higher rate of conformance—88 percent of 1,680 new labels—than old labels—83 percent of 411 old labels.

"These results show that consumers can trust what it says on the new food label," said FDA Commissioner David A. Kessler, M.D. ■

—P.K.

Why do some labels lack nutrition information?

In addition to the possibility that the food may have been packaged before the August 1994 deadline, there are several other possible explanations. The Nutrition Labeling and Education Act of 1990—the law on which the food labeling regulations are based—specifically exempts some foods from nutrition labeling. These include:

- food produced by small businesses. FDA and USDA's definitions for a small business are based, in part, on the number of employees and amount of product produced.
- food in small packages that don't carry nutrient claims. Under FDA rules, a package of less than 12 square inches doesn't have to give nutrition information. However, it must provide an address or telephone number for consumers to get the required information. USDA exempts individually wrapped products weighing less than half an ounce.
- food served for immediate consumption, such as that served in restaurants, hospital cafeterias and airplanes, and that sold by food service vendors (for example, mall cookie counters, sidewalk vendors, and vending machines)
- ready-to-eat food that is not for immediate consumption but is prepared primarily on site (for example, bakery, deli and candy store items)

- medical foods—that is, those used to address the recognized nutritional requirements associated with particular diseases

- plain coffee and tea, some spices, and other foods that contain no significant amounts of any nutrients.

You also may find nutrition information missing on some odd-shaped packages. Only those that have received FDA's permission not to carry nutrition information because the shape makes it impractical are allowed this exemption. But these products must generally provide an address or telephone number for consumers to get the required information.

If you see a product without nutrition information that doesn't fit into these categories, it may be in violation of the law. Between Sept. 19 and Dec. 31, 1994—during the first six months of the law's implementation—FDA notified 625 food importers and 630 domestic companies that their food products were improperly labeled. The majority of them were missing nutrition information.

Consumers who believe a product is improperly labeled and in violation of the law may report this information to their local FDA office. ■

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

AN FDA GUIDE TO CHOOSING

MEDICAL TREATMENTS

by Isadora B. Stehlin

Medical treatments come in many shapes and sizes. There are “home remedies” shared among families and friends. There are prescription medicines, available only from a pharmacist, and only when ordered by a physician. There are over-the-counter drugs that you can buy—almost anywhere—without a doctor’s order. Of growing interest and attention in recent years are so-called alternative treatments, not yet approved for sale because they are still undergoing scientific research to see if they really are safe and effective. And, of course, there are those “miracle” products sold through “back-of-the-magazine” ads and TV infomercials.

How can you tell which of these may really help treat your medical condition, and which will only make you worse off—financially, physically, or both?

Many advocates of unproven treatments and cures contend that people have the right to try whatever may offer them hope, even if others believe the remedy is worthless. This argument is especially compelling for people with AIDS or other life-threatening diseases with no known cure.

Clinical Trials

Before gaining Food and Drug Administration marketing approval, new drugs, biologics, and medical devices must be proven safe and effective by controlled clinical trials.

In a clinical trial, results observed in patients getting the treatment are compared with the results in similar patients receiving a different treatment or pla-

cebo (inactive) treatment. Preferably, neither patients nor researchers know who is receiving the therapy under study.

To FDA, it doesn’t matter whether the product or treatment is labeled alternative or falls under the auspices of mainstream American medical practice. (Mainstream American medicine essentially includes the practices and products the majority of medical doctors in this country follow and use.) It must meet the agency’s safety and effectiveness criteria before being allowed on the market.

In addition, just because something is undergoing a clinical trial doesn’t mean it works or FDA considers it to be a proven therapy, says Donald Pohl, of FDA’s Office of AIDS and Special Health Issues. “You can’t jump to that conclusion,” he says. A trial can fail to prove that the product is effective, he explains. And that’s not just true for alternative products. Even when the major drug companies sponsor clinical trials for mainstream products, only a small fraction are proven safe and effective.

Many people with serious illnesses are unable to find a cure, or even temporary relief, from the available mainstream treatments that have been rigorously studied and proven safe and effective. For many conditions, such as arthritis or even cancer, what’s effective for one patient may not help another.

Real Alternatives

“It is best not to abandon conventional therapy when there is a known response

[in the effectiveness of that therapy],” says Joseph Jacobs, M.D., former director of the National Institutes of Health’s Office of Alternative Medicine, which was established in October 1992. As an example he cites childhood leukemia, which has an 80 percent cure rate with conventional therapy.

But what if conventional therapy holds little promise?

Many physicians believe it is not unreasonable for someone in the last stages of an incurable cancer to try something unproven. But, for example, if a woman with an early stage of breast cancer wanted to try shark cartilage (an unproven treatment that may inhibit the growth of cancer tumors, currently undergoing clinical trials), those same doctors would probably say, “Don’t do it,” because there are so many effective conventional treatments.

Jacobs warns that, “If an alternative practitioner does not want to work with a regular doctor, then he’s suspect.”

Alternative medicine is often described as any medical practice or intervention that:

- lacks sufficient documentation of its safety and effectiveness against specific diseases and conditions
- is not generally taught in U.S. medical schools
- is not generally reimbursable by health insurance providers.

According to a study in the Jan. 28, 1993, *New England Journal of Medicine*, 1 in 3 patients used alternative therapy in 1990. More than 80 percent of those who use alternative therapies

used conventional medicine at the same time, but did not tell their doctors about the alternative treatments. The study's authors concluded this lack of communication between doctors and patients "is not in the best interest of the patients, since the use of unconventional therapy, especially if it is totally unsupervised, may be harmful." The study concluded that medical doctors should ask their patients about any use of unconventional treatment as part of a medical history.

Many doctors are interested in learning more about alternative therapies, according to Brian Berman, M.D., a family practitioner with the University of Maryland School of Medicine in Baltimore. Berman says his own interest began when "I found that I wasn't getting all the results that I would have liked with conventional medicine, especially in patients with chronic diseases.

"What I've found at the University of Maryland is a healthy skepticism among my colleagues, but a real willingness to collaborate. We have a lot of people from different departments who are saying, let's see how we can develop scientifically rigorous studies that are also sensitive to the particular therapies that we're working with."

Anyone who wants to be treated with an alternative therapy should try to do so through participation in a clinical trial. Clinical trials are regulated by FDA and provide safeguards to protect patients, such as monitoring of adverse reactions. In fact, FDA is interested in assisting investigators who want to study alternative therapies under carefully controlled clinical trials.

Some of the alternative therapies currently under study with grants from NIH include:

- acupuncture to treat depression, attention-deficit hyperactivity disorder, osteoarthritis, and postoperative dental pain
- hypnosis for chronic low back pain and accelerated fracture healing
- Ayurvedic herbals for Parkinson's disease. (Ayurvedic medicine is a holistic system based on the belief that herbals, massage, and other stress relievers help the body make its own natural drugs.)
- biofeedback for diabetes, low back pain, and face and mouth pain caused by jaw disorders. (Biofeedback is the con-

Anyone who wants to be treated with an alternative therapy should try to do so through participation in a clinical trial.

scious control of biological functions, such as those of the heart and blood vessels, normally controlled involuntarily.)

- electric currents to treat tumors
- imagery for asthma and breast cancer.

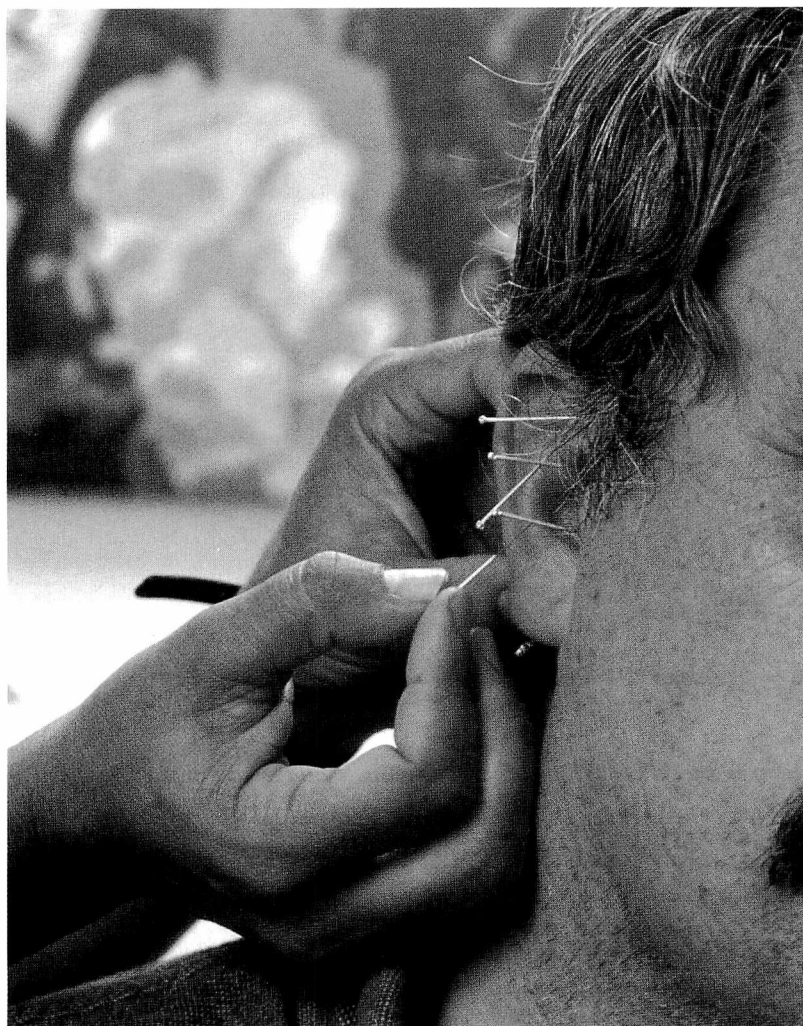
(With imagery, patients are guided to see themselves in a different physical, emotional or spiritual state. For example, patients might be guided to imagine themselves in a state of vibrant health and the disease organisms as weak and destructible.)

While these alternative therapies are the subject of scientifically valid research, it's important to remember that at this time their safety and effectiveness are still unproven.

Avoiding Fraud

FDA defines health fraud as the promotion, advertisement, distribution, or sale of articles, intended for human or animal use, that are represented as being effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), or provide a beneficial effect on health, but which have not been scientifically proven safe and effective for such purposes. Such practices may be deliberately deceptive, or done without adequate knowledge or understanding of the article.

Health fraud costs Americans an estimated \$30 billion a year. However, the costs are not just economic, according to



Acupuncture is one "alternative" therapy currently under study with grants from the National Institutes of Health.

Images provided by © 1994 PhotoDisc, Inc.

Tip-Offs to Rip-Offs

New health frauds pop up all the time, but the promoters usually fall back on the same old clichés and tricks to gain your trust and get your money. According to FDA, some red flags to watch out for include:

- claims the product works by a secret formula. (Legitimate scientists share their knowledge so their peers can review their data.)
- publicity only in the back pages of magazines, over the phone, by direct mail, in newspaper ads in the format of news stories, or 30-minute commercials in talk show format. (Results of studies on bona fide treatments are generally reported first in medical journals.)

- claims the product is an amazing or miraculous breakthrough. (Real medical breakthroughs are few and far between, and when they happen, they're not touted as "amazing" or "miraculous" by any responsible scientist or journalist.)
- promises of easy weight loss. (For most people, the only way to lose weight is to eat less and exercise more.)
- promises of a quick, painless, guaranteed cure
- testimonials from satisfied customers. (These people may never have had the disease the product is supposed to cure, may be paid representatives, or may simply not exist. Often they're identified only by initials or first names.) ■

John Renner, M.D., a Kansas City-based champion of quality health care for the elderly. "The hidden costs—death, disability—are unbelievable," he says.

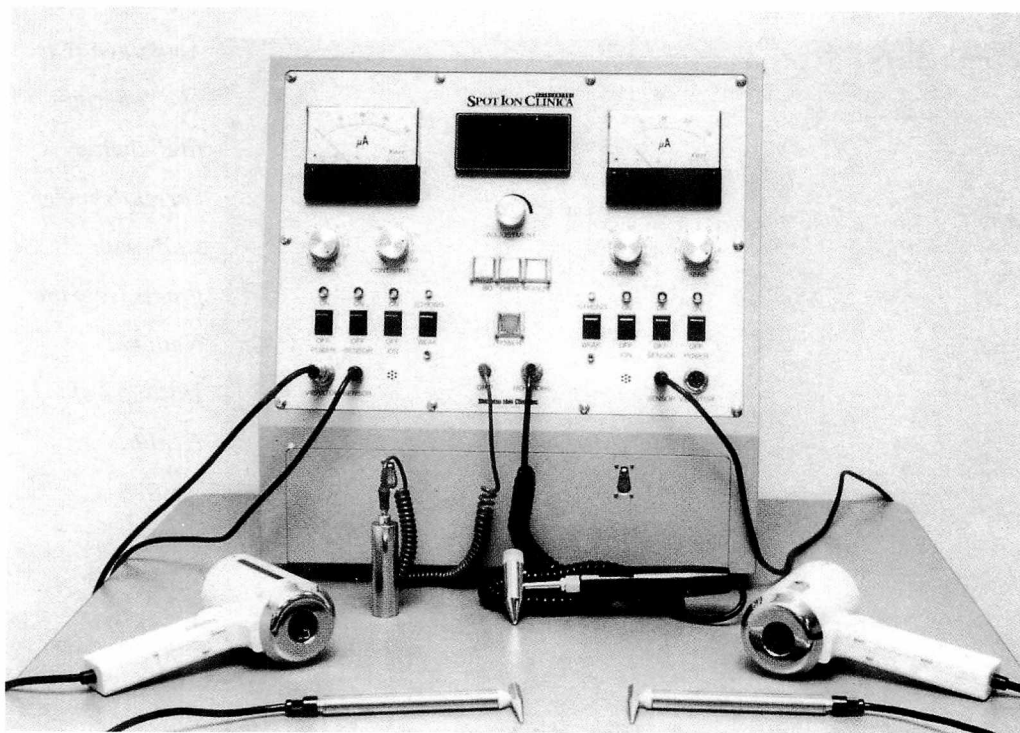
To combat health fraud, FDA established its National Health Fraud Unit in 1988. The unit works with the National Association of Attorneys General and the Association of Food and Drug Officials to coordinate federal, state and local regulatory actions against specific health frauds.

Regulatory actions may be necessary in many cases because products that have not been shown to be safe and effective pose potential hazards for consumers both directly and indirectly. The agency's priorities for regulatory action depend on the situation; direct risks to health come first.

Unproven products cause direct health hazards when their use results in injuries or adverse reactions. For example, a medical device called the InnerQuest Brain Wave Synchronizer was promoted to alter brain waves and relieve stress. It consisted of an audio cassette and eyeglasses that emitted sounds and flashing lights. It caused epileptic seizures in some users. As a result of a court order requested by FDA, 78 cartons of the devices, valued at \$200,000, were seized by U.S. marshals and destroyed in June 1993.

Indirectly harmful products are those that do not themselves cause injury, but may lead people to delay or reject proven remedies, possibly worsening their condition. For example, if cancer patients reject proven drug therapies in favor of unproven ones and the unproven ones turn out not to work, their disease may advance beyond the point where proven therapies can help.

"What you see out there is the promotion of products claiming to cure or prevent AIDS, multiple sclerosis, cancer, and a list of other diseases that goes on and on," says Joel Aronson, director of FDA's Health Fraud Staff, in the agency's Center for Drug Evaluation and Research. For example, he says, several skin cream products promise to prevent transmission of HIV (the virus that causes AIDS) and herpes viruses. They are promoted especially to health-care workers. Many of the creams con-



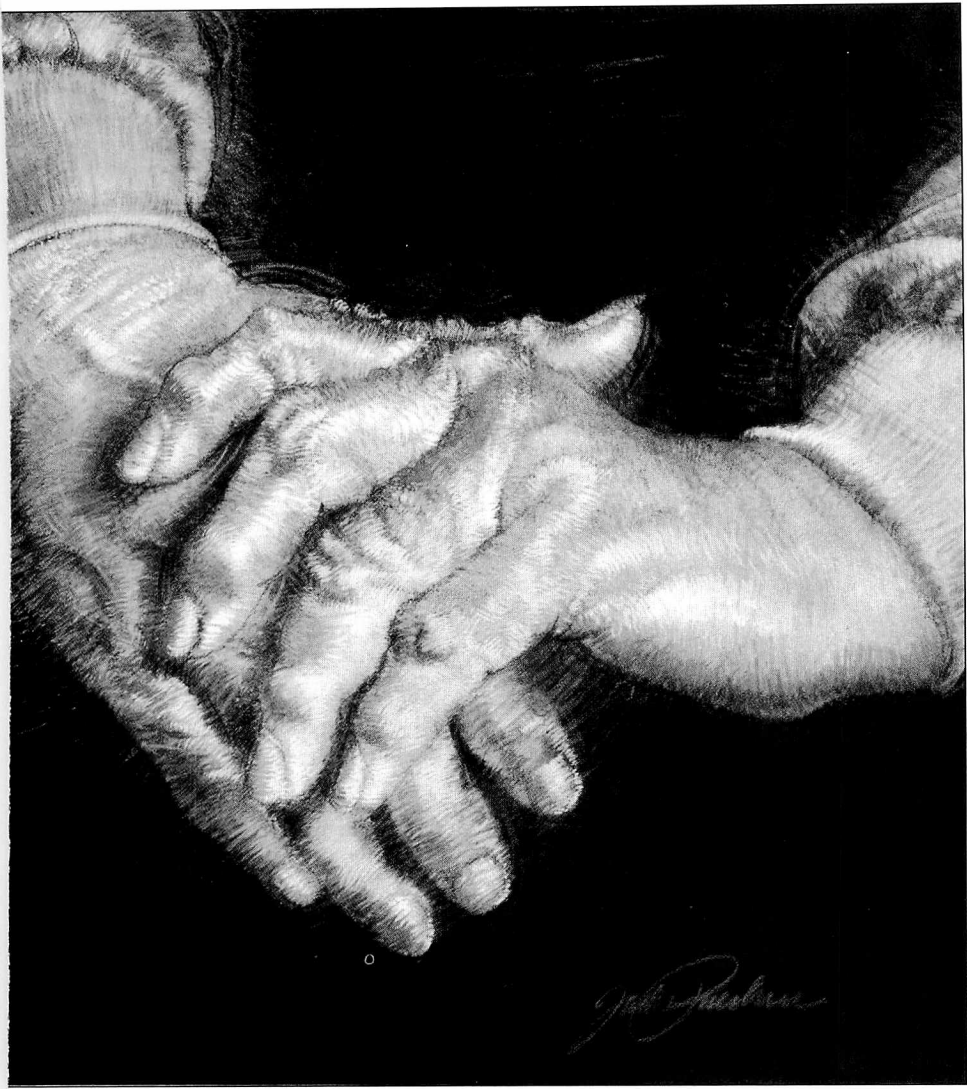
Promoters promised that this "High Genki" machine could treat diabetes, high blood pressure, muscular pain, and arthritis. FDA said it was an unapproved medical device, and on Nov. 9, 1993, the government seized this machine and several similar devices in Hawaii. "It beeped, buzzed, gave a mild electric shock, and that was about all," said Cindy Wolodkin, a public affairs specialist in FDA's San Francisco office.

Approaching Alternative Therapies

The NIH Office of Alternative Medicine recommends the following before getting involved in any alternative therapy:

- Obtain objective information about the therapy. Besides talking with the person promoting the approach, speak with people who have gone through the treatment—preferably both those who were treated recently and those treated in the past. Ask about the advantages and disadvantages, risks, side effects, costs, results, and over what time span results can be expected.
- Inquire about the training and expertise of the person administering the treatment (for example, certification).
- Consider the costs. Alternative treatments may not be reimbursable by health insurance.
- Discuss all treatments with your primary care provider, who needs this information in order to have a complete picture of your treatment plan.

For everyone—consumers, physicians and other health-care providers, and government regulators—FDA has the same advice when it comes to weeding out the hopeless from the hopeful: Be open-minded, but don't fall into the abyss of accepting anything at all. For there are—as there have been for centuries—countless products that are nothing more than fraud. ■



tain antibacterial ingredients but, "there is no substantiation at all on whether or not [the skin creams] work" against HIV, says Aronson. FDA has warned the manufacturers of these creams to stop the misleading promotions.

People at Risk

Teenagers and the elderly are two prime targets for health fraud promoters.

Teenagers concerned about their appearance and susceptible to peer pressure may fall for such products as fraudulent diet pills, breast developers, and muscle-building pills.

Older Americans may be especially vulnerable to health fraud because approximately 80 percent of them have at least one chronic health problem, according to Renner. Many of these problems, such as arthritis, have no cure and, for some people, no effective treatment. He says their pain and disability lead to

despair, making them excellent targets for deception.

Arthritis

Although there is no cure for arthritis, the symptoms may come and go with no explanation. According to the Arthritis Foundation, "You may think a new remedy worked because you took it when your symptoms were going away."

Some commonly touted unproven treatments for arthritis are harmful, according to the foundation, including snake venom and DMSO (dimethyl sulfoxide), an industrial solvent similar to turpentine. FDA has approved a sterile form of DMSO called Rimso-50, which is administered directly into the bladder for treatment of a rare bladder condition called interstitial cystitis. However, the DMSO sold to arthritis sufferers may contain bacterial toxins. DMSO is readily absorbed through the skin into

Medical Guides

Whether looking for an alternative therapy or checking the legitimacy of something you've heard about, some of the best sources are advocacy groups, including local patient support groups. Those groups include:

American Cancer Society
1599 Clifton Road, N.E.
Atlanta, GA 30329
(404) 320-3333, (1-800) ACS-2345

Arthritis Foundation
P.O. Box 19000
Atlanta, GA 30326
(1-800) 283-7800

National Multiple Sclerosis Society
733 Third Ave.
New York, NY 10017-3288
(212) 986-3240, (1-800) 344-4867

HIV/AIDS Treatment Information Service
P.O. Box 6303
Rockville, MD 20849-6303.
(1-800) 448-0440, TDD/Deaf Access: (1-800) 243-7012

Federal government resources on health fraud and alternative medicine are:

FDA (HFE-88)
Rockville, MD 20857
(301) 443-3170

Office of Alternative Medicine/NIH Information Center
6120 Executive Blvd., EPS
Suite 450
Rockville, MD 20852
(301) 402-2466

U.S. Postal Inspection Service
(monitors products purchased by mail)
Office of Criminal Investigation
Washington, DC 20260-2166
(202) 268-4272

Federal Trade Commission
(regarding false advertising)
Room 421
6th St. and Pennsylvania Ave., N.W.
Washington, DC 20580
(202) 326-2222

Other agencies that may have information and offer assistance include local Better Business Bureaus, state and municipal consumer affairs offices, and state attorneys general offices. ■

the bloodstream, and these toxins enter the bloodstream along with it. It can be especially dangerous if used as an enema, as some of its promoters recommend.

Treatments the foundation considers harmless but ineffective include copper bracelets, mineral springs, and spas.

Cancer and AIDS

Cancer treatment is complicated because in some types of cancer there are no symptoms, and in other types symptoms may disappear by themselves, at least temporarily. Use of an unconventional treatment coinciding with remission (lessening of symptoms) could be simply coincidental. There's no way of knowing, without a controlled clinical trial, what effect the treatment had on the outcome. The danger comes when this false security causes patients to forgo approved treatment that has shown real benefit.

Some unapproved cancer treatments not only have no proven benefits, they have actually been proven dangerous. These include Laetrile, which may cause cyanide poisoning and has been found ineffective in clinical trials, and coffee enemas, which, when used excessively, have killed patients. (See "Hope or Hoax? Unproven Cancer Treatments" in the March 1992 *FDA Consumer*.)

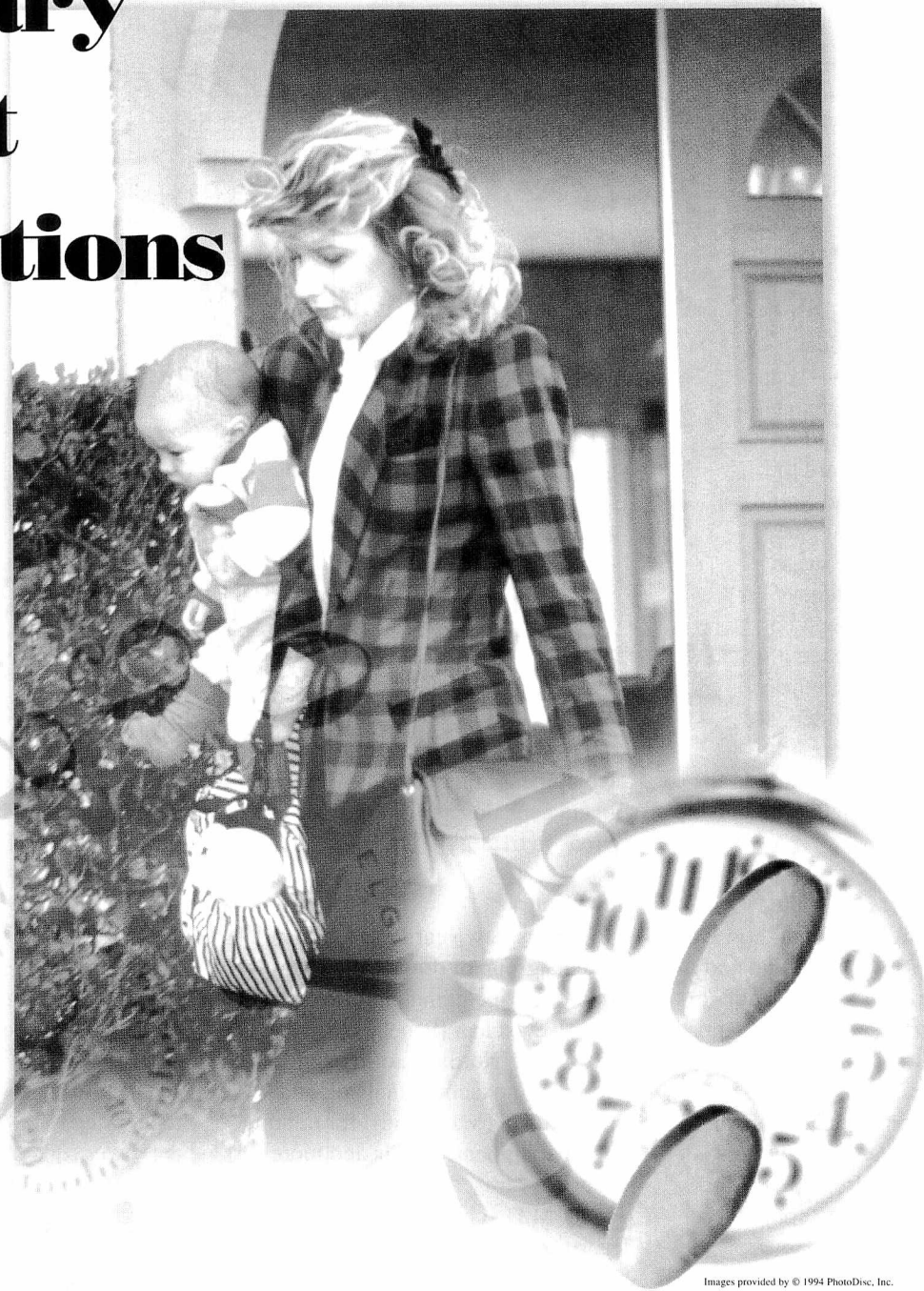
Ozone generators, which produce a toxic form of oxygen gas, have been touted as being able to cure AIDS. To date this is still unproven, and FDA considers ozone to be an unapproved drug and these generators to be unapproved medical devices. At least three deaths have been connected to the use of these generators. Four British citizens were indicted in 1991 for selling fraudulent ozone generators in the United States. Two of the defendants fled to Great Britain, but the other two pleaded guilty and served time in U.S. federal prisons.

The bottom line in deciding whether a certain treatment you've read or heard about might be right for you: Talk to your doctor. And keep in mind the old adage: If it sounds too good to be true, it probably is. ■

Isadora B. Stehlin is a staff writer for FDA Consumer.

New Help for Urinary Tract Infections

by Evelyn Zamula



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Though men don't escape urinary tract infections—especially as they age and their prostates cause problems—women get the lion's share of UTIs, about 25 times more often than men. Most of these infections are uncomplicated: They occur in otherwise healthy women and girls who have normal urinary tracts and normal urinary functioning and no underlying physical problems.

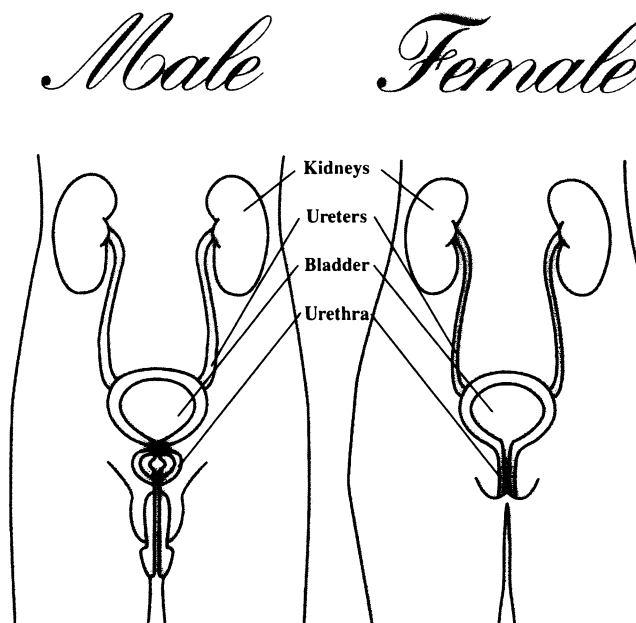
The National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health estimates that by age 30, half of all women experience at least one UTI, and about 20 percent of these women will have recurrent UTIs. Each year, UTIs are responsible for more than 6 million doctor visits and about \$4.5 billion in health-care costs. Only upper respiratory tract infections account for more absenteeism in working women.

The urinary tract consists of the kidneys, ureters, bladder, and urethra. The kidneys—bean-shaped organs weighing about 4 to 6 ounces in the adult and located below the ribs toward the middle of the back—filter liquid waste from the blood that passes through them to produce urine. Urine passes from the kidneys down through two narrow tubes called ureters to the bladder, a triangular-shaped organ in the lower abdomen. The bladder acts as a reservoir for urine until it is emptied out through the urethra, a tube leading from the bladder to outside the body.

When limited to the urethra, an infection of the urinary tract is called urethritis. More often than not, however, bacteria travel up a woman's one-and-a-half-inch-long urethra to the bladder, where they may cause cystitis, the most common urinary tract infection. A more serious condition called pyelonephritis results when bacteria from the bladder ascend to the kidneys via the ureters.

Before the modern drug era, doctors prescribed the urinary antiseptic Mandelamine (methenamine mandelate), cranberry juice, and diets that acidified the urine to prevent and treat recurrent UTIs. In many cases, this treatment was ineffective, and women who had recurrent UTIs ultimately suffered kidney failure. By the 1940s, the antimicrobial sulfa drugs had been introduced and proved very effective in treating UTIs. The explosive development of broad-spectrum antibiotics that began about the same time with the discovery of penicillin—and continued with the

Urinary Tract



The kidneys filter liquid waste to produce urine, which passes through the ureters to the bladder. The bladder acts as a reservoir for urine until it leaves the body through the urethra. Infections can occur anywhere in the urinary tract, but are most common in the bladder.

development of tetracyclines, erythromycin and cephalosporins—provided more options in treating UTIs.

New Drugs

In the last few years, FDA has approved a group of drugs called quinolones (including ciprofloxacin [Cipro], enoxacin [Penetrex], norfloxacin [Noroxin], ofloxacin [Floxin], cinoxacin [Cinobac], and lomefloxacin [Maxaquin]) for treating both uncomplicated UTIs and more serious urinary tract disorders. Philip Hanno, M.D., chairman of the urology department and professor of urology at Temple University, Philadelphia, Pa., says that with quinolones, "... you don't have to bring people into the hospital to get good levels of antibiotics that can treat pseudomonas and other gram-negative organisms. Previously, we had to use parenteral antibiotics [intravenous medications]. I do think they're overused, though, and resistance to them is developing."

Each group of drugs affects bacteria in the urine differently, either by interfering

with reproduction, or depriving them of certain enzymes necessary for their growth. Successful treatment depends on the concentration of the bacteria-fighting drug in the urine.

Normal urine is sterile. An average adult passes about 3 pints of urine each day, but the amount varies, depending on how much food and drink are consumed.

The urinary system is constructed to repel infection. Valve-like structures at the lower ends of the ureters prevent urine from backing up (called vesicoureteral reflux) into the kidneys, where it could cause damage. When infection occurs, urination helps wash bacteria out of the bladder.

Symptoms of Infection

Sometimes a person can have a UTI without having symptoms. But usually UTIs are accompanied by such discomforts as pain and a burning sensation during urination, frequent urination—often passing no more than a few drops at a time—and a feeling that the bladder doesn't feel empty even after urinating.

How Women Can Prevent UTIs

Here are some suggestions to help prevent UTIs:

- Drink at least eight glasses of water a day, in addition to the coffee, tea, cola drinks, and other beverages you normally drink. Frequent urination flushes bacteria out of the bladder and makes urinary symptoms, if you get a UTI, more bearable. Some doctors advise drinking large amounts of cranberry juice, which acidifies the urine and makes it less hospitable to bacteria.
- Wipe from front to back to prevent bacteria in the anal area from entering the vagina and urethra.
- Empty the bladder shortly before and after sex.
- Wash the genital area before sex with plenty of warm water. Bacteria from the vaginal, anal and perineal areas can be introduced into the urethra during sex.
- Check with your gynecologist if you suspect a diaphragm is contributing to your problems. You may need another size, or perhaps another method of birth control.
- Use some sort of water-soluble lubricant, such as a vaginal jelly (not petroleum jelly), if your vagina feels dry and uncomfortable during sex, especially if you're past menopause. Bruised tissues may become irritated, even infected.
- Avoid using feminine hygiene products, such as sprays, deodorants or douches, which may irritate the urethra.
- Change sanitary pads and tampons frequently during menstruation.



- Avoid using hot tubs—because the water is not hot enough to kill bacteria—and highly chlorinated pools, because too much chlorine may irritate the genital area.
- Don't use perfumed toilet paper, heavily scented soaps and powders in the vaginal area, or bubble baths. (Some bubble bath products warn that they can cause urinary tract irritation.) Some laundry detergents, bleaches, and fabric softeners leave residues that can be irritating or cause allergic reactions. Try unscented laundry detergents or soaps if you are sensitive.
- Take showers instead of baths, because showers wash bacteria away.
- Avoid wearing tight jeans, bodysuits and pantyhose. The heat generated by tight clothing makes it easier for bacteria in your genital area to grow. Replace nylon underclothing with cotton underwear. ■

—E.Z.

The urine may look cloudy, or may have a bloody tinge. A person with a UTI may feel tired and shaky, sick all over. Often, women feel pressure above the pubic bone and men feel fullness in the rectum. Chills and fever, flank pain, nausea, and vomiting suggest kidney involvement.

Common Culprits

Many bacteria can cause UTIs in women, but the most common are *Escherichia coli* (*E. coli*), responsible for over 80 percent of infections. Normally, these bacteria reside in the gastrointestinal tract, but they may also be present in the vaginal and rectal areas, and on the skin of the perineum, the band of flesh between the anus and the vagina. Sexually transmitted microorganisms *Chlamydia trachomatis* and *T. mycoplasma* (*Ureaplasma*) can cause UTIs in both men and women. These infections are usually confined to the urethra and reproductive organs.

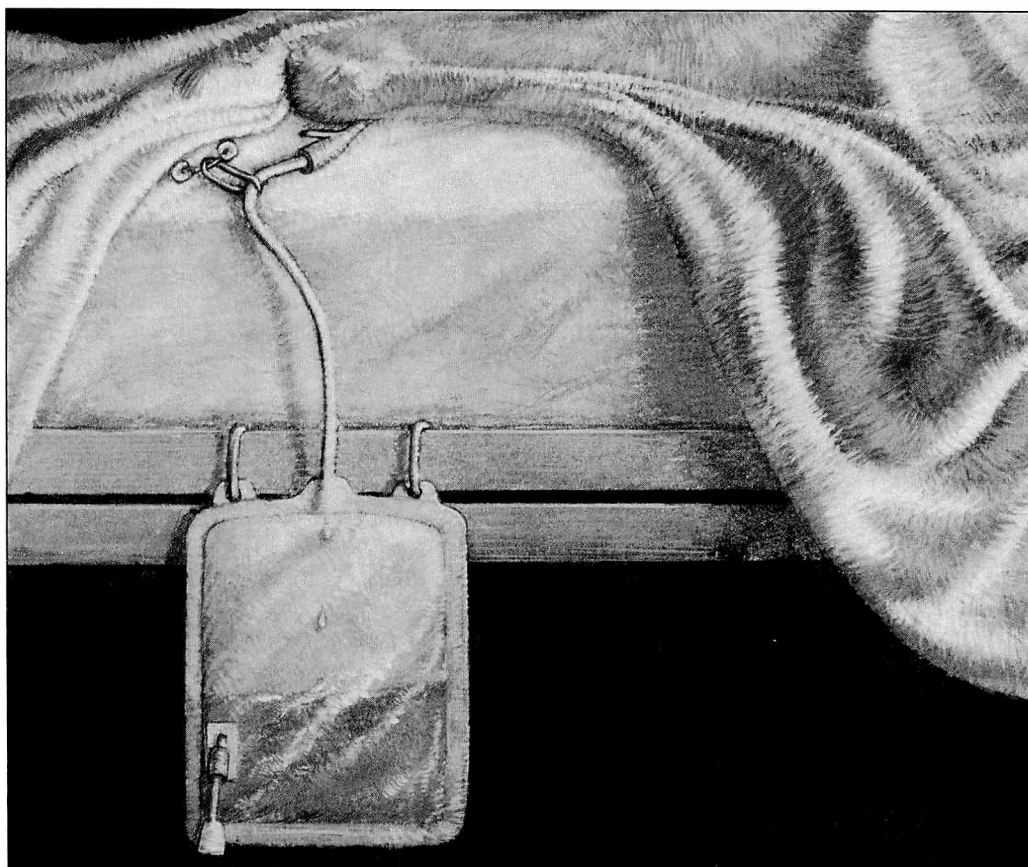
Women can acquire UTIs after sexual intercourse. Many women have their first bout of cystitis after they become sexually active; in fact, "honeymoon cystitis" was once a common name for this affliction. Data from a variety of studies suggest that during sexual intercourse, bacteria in the vaginal area can be pushed into the urethral opening and move up into the bladder, making it one of the most important risk factors for developing uncomplicated UTIs.

Using a diaphragm for contraception can be an additional risk factor for UTIs. The diaphragm may press on the neck of the bladder, preventing it from emptying completely and leaving a pool of stagnant urine for bacteria to grow in. Bacteria may also enter the urinary tract when the diaphragm is inserted and removed and when it is left in place longer than recommended by the labeling or the doctor. Recently, researchers found an association between UTIs and sexual intercourse when women use a spermicide or a diaphragm/spermicide or when their

partners use a condom with spermicidal foam. Thomas Hooton, M.D., and Walter Stamm, M.D., in the March 1991 issue of *Medical Clinics of North America* report that spermicides increase colonization of the vagina with bacteria, thus increasing risk of bladder infection.

Pregnant women get about the same number of UTIs as nonpregnant, sexually active women of childbearing age. However, when a pregnant woman gets a UTI, it is more likely to travel upwards to the kidneys. Since a woman can have

in the bladder to drain off urine when a patient is unconscious, very ill, recovering from surgery, or incontinent. About 900,000 UTIs are contracted in hospitals each year, and up to 90 percent of these infections are associated with indwelling catheters. Avoiding unnecessary catheterization is the best way to prevent such UTIs. When a catheter is necessary, strict antiseptic techniques must be used by medical personnel when inserting and maintaining this device to prevent the introduction of bacteria into the bladder.



bacteria in her urine, but no symptoms, it's important that urine cultures be performed on the first prenatal visit and at intervals thereafter. Studies have shown an association between bacteria in the urine in the first trimester and the subsequent development of acute pyelonephritis. Pregnant women with UTIs can be treated with antibiotics, but, as always, the drug's effectiveness, the stage of pregnancy, the mother's health, and the potential effects on the fetus have to be carefully considered.

Not all UTIs are a result of sexual activity. Another common source of infection is the catheter, a tube that is placed

A common source of urinary infection is a catheter (tube) inserted in the bladder to drain urine during hospitalization.

Diabetics run a higher risk of UTIs because their immune systems are suppressed. Additionally, their urine is rich in glucose, which is a good growing medium for any bacteria that enter the bladder.

Diagnosis

Though a urinalysis can tell the doctor bacteria are present in the urine, only a urine culture can identify the particular organism. Which drug will be effective and the length of time it is used depend both on the patient's history and what the culture reveals. Since a UTI can cause excruciating discomfort—and since many medications are effective against a UTI—most doctors prefer to treat patients with symptoms without waiting the 48 hours or so for culture results. The medication can be changed at that time, if necessary.

Doctors may treat routine, uncomplicated UTIs with trimethoprim (Trimex), trimethoprim/sulfamethoxazole (Bactrim, Septra, Cotrim), amoxicillin (Amoxil, Trimox, Wymox), nitrofurantoin (Macrochantin, Furadantin), ampicillin, and other drugs. Many of these drugs cause side effects, such as rash, itching, nausea, diarrhea, abdominal cramping, difficulty in breathing, and sensitivity to sunlight. Tetracyclines, cotrimoxazole, nitrofurantoin, and quinolones are not recommended for pregnant women. Patients should report all known allergies, such as an allergy to penicillin or sulfa drugs, to the doctor before treatment begins.

Types of Therapy

Doctors can use single-dose therapy, a three-day course of drugs, or a longer regimen. Studies have shown that a single dose of trimethoprim or cotrimoxazole, for instance, is effective in treating uncomplicated bacterial cystitis and asymptomatic bacterial infections in sexually active women and in girls with normal urinary tracts. Not only do single-dose therapies save money, but they are simple to take—thus promoting compliance—well-tolerated, and preferred by patients. In addition, they produce fewer side effects and less risk of developing resistant organisms. And, for pregnant women, a single dose of some drugs also poses less danger to the fetus.

Not all urologists like single-dose therapy. “I rarely use it,” says Hanno, “unless it’s someone who’s very responsive and has not had symptoms for a long time—generally people who are on self-treatment programs—and won’t panic if symptoms don’t go away after one dose. Then they can take one dose of medicine and that’s it. But since it usually takes two or three days for the symptoms to go away even if you sterilize their urine with one dose, you know that they’re going to call you back after taking one pill. I find it makes more sense to put people on the three-day therapy.”

Urologists deal with recurrent UTIs in several ways. When women have three or more symptomatic UTIs a year, some urologists may prescribe low doses of an antimicrobial drug, such as trimethoprim/sulfamethoxazole or nitrofurantoin, to be taken daily for six months or longer as a preventative. Taken at bedtime, the drug remains in the bladder the whole night and is thus more effective. Other urologists prefer to give their patients medications to be taken on alternate nights or even three nights a week. When sexual intercourse is the culprit, one dose of an antibiotic after sex has proved a safe, effective and inexpensive treatment for preventing recurrent urinary tract infections.

Since illness is apt to strike at inconvenient times, women subject to recurrent UTIs often panic when they feel symptoms coming on and don’t have immediate access to a doctor. “What most urologists do, once we have established that it’s a recurrent urinary infection from reinfection—which makes up about 99 percent of UTIs in women—is give them a prescription to keep with them,” says Hanno. “At the first sign of infection they take antibiotics for three days. If symptoms don’t get better in three days, then it’s worthwhile to do a urine culture, to see if something unusual is going on.”

UTIs in Men

Men have lower rates of uncomplicated UTIs than women for various reasons. The longer male urethra, the greater distance between the urethral opening and the anus (the usual source of bacteria), and the drier environment

surrounding the urethra present less opportunity for bacteria to enter the urinary tract. Another plus is that the prostate secretes fluid with antibacterial properties.

“UTIs are uncommon in men,” says Hanno. “They usually reflect some anatomic abnormality or bladder dysfunction, and they’re usually related to a deep-seated problem.”

The male prostate is often involved in UTIs. An enlarged prostate can slow urine flow by squeezing the urethra, which it surrounds, thus setting the stage for a UTI. It works the other way, too. When the prostate is infected (prostatitis), the infection soon spreads to the bladder. UTIs in males are usually treated by long-course therapy of 14 to 21 days, especially when the prostate is involved.

When infections in either men or women persist despite treatment and are caused by the same strain of bacteria, the doctor checks for problems in the urinary system. The intravenous urogram (often incorrectly called the intravenous pyelogram) is an important diagnostic tool: The radiologist injects an iodine-containing liquid dye into the veins. As the dye concentrates in the kidneys and urine and flows through the ureters and bladder, x-ray pictures are taken that outline the urinary tract and reveal any abnormalities.

Another valuable test—especially for babies and people who cannot tolerate the dye used in the intravenous urogram—is done by ultrasound, which gives pictures from the echo patterns of sound waves bounced back from the urinary organs. Doctors may also perform a cystoscopy, where they look into the bladder with a cystoscope, an instrument made of a hollow tube with several lenses and a light source. The doctor can see tumors or other lesions in the bladder, or sediment from urinary stones.

Fortunately, most UTIs don’t require such measures. Most healthy adults with normally functioning urinary tracts who have UTIs can be safely and effectively treated with a variety of medications. And, with prompt treatment, they will experience no long-term damage to the urinary system. ■

Evelyn Zamula is a freelance writer in Potomac, Md.

OTC Options



TAMING TUMMY TURMOIL

by Dixie Farley

(This article is one in a series of articles on nonprescription drugs.)

A vague queasiness stirs in your stomach. Queasy quickly turns to severely nauseated. A sour bubble rises in your throat, and you dash for the bathroom in a cold sweat.

Whatever the cause, the nausea and vomiting of an upset stomach are nasty. Upset stomachs caused by motion or too much food or drink may respond to over-the-counter (OTC) medicines. For other upset stomachs, professional care and no medication often are best.

Motion Sickness

Paleness, yawning and restlessness often precede the nausea, vomiting and dizziness that occur in motion sickness, which most frequently strikes youngsters ages 2 to 12, but may occur at any age.

The primary culprit in this condition is excess stimulation to the inner ear's maze of fluid-filled canals, responsible for maintaining the body's balance. Poor ventilation, anxiety or other emotional upset, and visual stimuli may contribute to motion sickness.

Because motion sickness is easier to prevent than to treat once it has begun, it may help to take an OTC drug to prevent symptoms 30 to 60 minutes before traveling and then continue doses during travel.

The Food and Drug Administration considers four active ingredients to be safe and effective for use in OTC drugs for motion sickness, says Gerald Rachanow, deputy director of the monograph review staff in FDA's Office of OTC Drug Evaluation. The ingredients are cyclizine (Marezine and others), dimenhydrinate (Dramamine and others), diphenhydramine (Benadryl and others), and meclizine (Bonine and others).

The active ingredients in these drugs are antihistamines. Their main side effect is drowsiness. Alcohol, tranquilizers

and sedatives may increase this effect. Rachanow says anyone taking a drug for motion sickness should use caution when driving a vehicle or operating machinery and should avoid alcoholic beverages.

In large doses, OTC drugs for motion sickness may cause dry mouth and, rarely, blurred vision. "People with breathing problems such as emphysema or chronic bronchitis, glaucoma, or urinating difficulty due to an enlarged prostate should not take these drugs unless directed to do so by a doctor," Rachanow says.

OTC drugs for motion sickness have the following age restrictions:

- cyclizine—not for use under age 6
- dimenhydrinate—not for use under age 2
- diphenhydramine—not for use under age 6
- meclizine—not for use under age 12.

Before trying these drugs, or along with them, the following measures may also help stave off motion sickness:

- Don't read during travel.
- Keep your line of vision fairly straight ahead.
- Avoid excess food or alcohol before and during extended travel. Avoid all food and drinks on short trips.
- Stay where motion is felt the least—the front seat of a car, near the wings of an airplane, or amidship (preferably on deck).
- Avoid tobacco smoke and other odors, particularly from food.

Heartburn

Last April, FDA approved the first drug for OTC use that works systemically to reduce the amount of stomach acid produced. The drug, famotidine, has been sold at higher dosage levels by prescription since 1986 to treat gastrointestinal illnesses such as ulcers. It will be marketed OTC as Pepcid AC Acid Controller to treat and prevent occasional heartburn, acid indigestion, and

OTC Drugs for Upset Stomachs

Motion Sickness (Antibistamines)

Drug	Common Brands	Possible Side Effects
cyclizine	Marezine	drowsiness; dry mouth; rarely, blurred vision
dimenhydrinate	Dramamine	same
diphenhydramine	Benadryl	same
meclizine	Bonine	same

Heartburn, Indigestion (Antacids)

Drug	Common Brands	Possible Side Effects
sodium salts	Alka-Seltzer Bromo Seltzer	interference with salt-restricted diet; with sodium bicarbonate to be dissolved in water, risk of stomach rupture if product is not fully dissolved
calcium salts	Alka-2, Calcium Rich Rolaids, Titalac, Tums	with extended heavy use, kidney stones, reduced kidney function
aluminum salts	ALternaGEL, Amphogel, Rolaids	constipation; with overuse, weakened bones
magnesium salts	Camalox, Gelusil, Maalox, Mylanta	laxative effect; with prolonged use, kidney stones; with excessive blood magnesium, problems of the heart, central nervous system, and kidneys

Heartburn, Indigestion, Sour Stomach (Acid Reducers)

Drug	Common Brands	Possible Side Effects
famotidine	Pepcid AC Acid Controller	headache, dizziness, constipation, diarrhea—mostly at higher dosages

Overindulgence

Drug	Common Brands	Possible Side Effects
bismuth subsalicylate	Pepto-Bismol	temporary, harmless darkening of the tongue or stool; risk of Reye syndrome in children or teenagers who have or are recovering from flu or chickenpox; with overuse, ringing in the ears

sour stomach in people age 12 and older. It may also be taken as a preventative before consuming food and beverages expected to cause these symptoms.

In nonprescription use, people should take no more than two Pepcid AC tablets in 24 hours and consult a doctor if they have swallowing difficulty or persistent abdominal pain, as these symptoms may indicate a more serious condition.

Most other products approved to relieve heartburn, indigestion, or upset stomach from too much food or drink are antacids, which neutralize gastric acidity.

Antacids may contain various active ingredients. The four general categories, with common brands and potential side effects, are:

- **Sodium salts** (Alka-Seltzer, Bromo Seltzer, and others)—People on a salt-restricted diet, especially if being treated for high blood pressure, should only take sodium antacids under a doctor's orders. FDA requires labels of all OTC antacids to give the sodium content. Because a risk of stomach rupture has been associated with sodium bicarbonate intended to be dissolved in water, FDA has proposed a "Stomach Warning" in product labeling: "To avoid serious injury, do not take until [insert product dosage form, e.g., "tablet," "powder"] is completely dissolved. It is very important not to take this product when overly full from food or drink. Consult a doctor if severe stomach pain occurs after taking this product."

- **Calcium salts** (Alka-2, Rolaids [Calcium Rich], Titalac, Tums, and others)—Extended heavy use of calcium antacids (20 grams or more daily for a prolonged period) may cause excess calcium in the blood, which can lead to kidney stones and reduced kidney function. People who already have impaired kidneys may develop milk-alkali syndrome (causing symptoms such as nausea, vomiting, mental confusion, and loss of appetite) with as little as 4 grams a day.

- **Aluminum salts** (ALternaGEL, Amphogel, Rolaids, and others)—Aluminum salts can constipate, so they're usually combined with magnesium salts to counter this effect. Overuse can weaken bones, especially in people with impaired kidney function, leading to

conditions such as osteomalacia (softening of the bones, which causes symptoms such as tenderness, muscular weakness, and weight loss).

- **Magnesium salts** (Camalox, Gelusil, Maalox, Mylanta, and others)—These salts have a laxative effect, so they're usually combined with aluminum salts; Camalox also has calcium salts. Very prolonged use may cause kidney stones. Too much magnesium in the blood can cause heart, central nervous system, and kidney problems.

As this list shows, some antacid products contain a combination of antacid ingredients. Some also contain simethicone, which breaks up gas bubbles, making them easier to eliminate from the body.

"Antacids are fast-acting drugs," says Hugo Gallo-Torres, M.D., a medical officer in FDA's division of gastrointestinal and coagulation drug products.

"They should bring relief within 15 to 20 minutes of each episode. If, after several episodes, there is no relief, then something else may be going on, something that requires a physician's evaluation."

Antacids may interact with many drugs. Gallo-Torres advises consulting a doctor before using antacids if you have a condition that requires adjusting sodium in your diet, or if you are taking a prescription medicine.

Overindulgence

Bismuth subsalicylate is recommended for overeating and drinking excessively. Bismuth also has some antibacterial effect. The product, sold as Pepto-Bismol and generic brands, may cause a temporary, harmless darkening of the tongue or stool.

FDA has proposed that products containing bismuth subsalicylate have labeling warning not to give the drug to children and teenagers who have or are recovering from chickenpox, flu symptoms (nausea, vomiting or fever), or flu. The warning is needed because, like aspirin, bismuth subsalicylate is a salicylate and may be associated with an increased risk of Reye syndrome, a rare but serious illness that can occur in children and teenagers with those illnesses.

Other proposed warnings advise users

not to take the drug if they're allergic to any salicylate, and to consult a doctor first if they have diabetes, gout or arthritis or if they take blood-thinning medicine.

Users are also advised to stop taking the drug if they have ringing in the ears. Rachanow explains: "This may happen when too much drug is taken or when another salicylate, such as aspirin, is taken at the same time."

Viral Infection

Nausea, vomiting and diarrhea may also be due to mild viral gastrointestinal infection. Children are especially susceptible. A doctor should be consulted if vomiting or diarrhea recur or persist, because dehydration or a chemical imbalance may result and require treatment. It is very important that patients recovering from viral gastrointestinal infection drink plenty of fluids.

General Advice

With stomach upsets in general, it's a good idea to call the doctor if symptoms last more than a few days. A doctor should be called if symptoms become severe—for instance:

- continuous vomiting or diarrhea
- extreme discomfort or pain in the gastrointestinal tract
- black stool (unless the drug you took, such as Pepto Bismol, contains bismuth subsalicylate)
- visible blood in the stool
- vomiting of blood or material that looks like coffee grounds, but which is actually digested blood.

Prolonged self-treatment may mask a more serious condition, such as an ulcer or cancer.

Women who are pregnant or breastfeeding should consult their doctors before taking any drugs.

Fortunately, most upset stomachs get better by themselves or require minimal treatment. As with any medicine, it's important to read an OTC drug's entire label and follow directions carefully. And, as with any illness, it's important to know when to call the doctor. ■

Dixie Farley is a staff writer for FDA Consumer.



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Prevention Best Treating Lung Cancer

by Margie Patlak

Lung cancer is the leading cause of cancer death in this country.

Americans are known the world over as preventive health enthusiasts. We jog for fitness, floss and take fluoride to prevent tooth decay, and eat low-fat products to reduce the risk of heart disease. Even the rarest environmental pollutant is likely to provoke public outrage and regulatory action if it is found to increase cancer risk.

Yet it's not uncommon for people who engage in such healthful activities to also engage in another activity known unmistakably to cause lung cancer: cigarette smoking.

Lung cancer is the leading cause of cancer death in this country. The lung cancer death rate recently surpassed that of breast cancer in women, according to the national Centers for Disease Control and Prevention, and continues to climb. Yet the vast majority of lung cancer cases are highly preventable.

FDA is responsible for ensuring the safety and effectiveness of the devices or drugs used to diagnose or treat lung cancer.

Smoke Gets in Your Lungs

The constant assault of cigarette smoke wears away cilia, the tiny hair-like structures that line the lungs' air passages and sweep out foreign material trapped inside by mucus. Without this cleaning mechanism, the lungs are particularly vulnerable to compounds brought into air passages. Most lung cancers crop up in the cells that are directly exposed to inhaled air.

People who smoke or who live with a smoker breathe air that may harbor more than 50 cancer-fostering chemicals, including benzopyrene and formal-

dehyde, as well as a radioactive compound called polonium-210. One researcher, in the September 1993 edition of the journal *Pediatrics*, estimates that the lungs of a person who smokes a pack of cigarettes a day, are exposed to as much radiation a year as they would absorb from 250 chest x-rays.

The risk of developing lung cancer increases with the number of cigarettes smoked and the number of years of smoking. People who smoke filtered low-tar cigarettes may have a somewhat lower lung cancer risk than those who smoke regular cigarettes. However, according to the National Cancer Institute (NCI), people may smoke more cigarettes if the nicotine content is reduced (as it is in low-tar cigarettes), so these smokers still have a substantial risk of lung cancer.

Cigar and pipe smoking can also boost the risk of developing lung cancer, but because people usually inhale less smoke with this type of tobacco use, it is not as high a lung cancer risk as cigarette smoking. However, these forms of smoking, as well as chewing tobacco, cause other types of cancer. The tobacco smoke nonsmokers breathe, also called "secondhand smoke," has been classified by the Environmental Protection Agency as one of the most dangerous environmental contaminants.

Other Causes of Lung Cancer

Exposure at high levels to certain compounds encountered in various mining or manufacturing jobs also can trigger lung cancer. These compounds include asbestos, nickel, chromium, coal gas, mustard gas, arsenic, vinyl chloride,

beryllium, hydrocarbons, ionizing radiation, and the radon byproducts of uranium mining.

Such compounds are more apt to cause lung cancer in smokers than nonsmokers. Asbestos workers who smoke cigarettes, for example, are 30 times more likely to develop lung cancer than asbestos workers who don't smoke. They have

cancer by eating more fruits and vegetables. More studies need to be done, however, to confirm this hypothesis.

By far the most effective way to avoid lung cancer is to steer clear of tobacco smoke, experts agree. Studies show that lung cancer risk gradually declines after stopping smoking. One study cited by CDC found that 10 years after quitting

Sometimes symptoms may be caused by hormones made by lung cancer cells. Certain lung cancer cells, for example, produce a hormone that causes a sharp drop in the level of salt in the body. This can produce many symptoms, including concentrated urine, confusion, fatigue, or coma.

Doctors diagnose the presence, type or extent of lung cancer with a series of tests. The first is a chest x-ray to detect any abnormal spots on the lungs. Doctors may also require other x-ray tests, such as a tomogram or a CT (computed

THE THREE MAIN WEAPONS DOCTORS CAN WIELD AGAINST LUNG CANCER ARE SURGERY, RADIATION AND CHEMOTHERAPY.

90 times the lung cancer risk of people who neither smoke nor work with asbestos, according to NCI.

Although radon produced by the decay of uranium in soil and rocks is present in low levels in many houses, it is not certain whether such low-level radon exposure can cause lung cancer.

Some smokers may feel they are genetically protected from lung cancer because their mothers or fathers smoked and never got the disease. But this could be "a fatal mistake," points out M. Miles Braun, M.D., a senior research investigator at NCI. His recent study of twins suggests that for most people, heredity plays little or no role in the development of lung cancer.

The study found that pairs of identical twins died less often of lung disease than pairs of fraternal twins. This finding is opposite what would be expected if a susceptibility to lung cancer was inherited because fraternal twins share only some of the same genes, unlike identical twins, who inherit identical genes.

There also is no firm evidence that vitamin supplements can protect smokers from the disease. According to NCI, some human studies suggest smokers might be able to lower their risk of lung

smoking, people who had smoked for less than 20 years had almost the same risk of lung cancer as lifelong nonsmokers.

Difficult to Detect

Few cases of lung cancer are detected early enough to achieve the best response to treatment. Coughing and wheezing are the earliest symptoms. But these respiratory annoyances are often dismissed as "smoker's cough"—the hacking many smokers have because smoking prompts their lungs to produce excess mucus—or chronic bronchitis, to which smokers are also prone.

Other early symptoms of lung cancer include coughing up blood, chest pain, and shortness of breath. People with lung cancer may also experience repeated bouts of pneumonia or bronchitis, fever, weakness, weight loss, hoarseness, or swelling of the neck and face.

In some cases, patients first notice symptoms stemming from the spread of the cancer to the brain, bones, or other organs. These symptoms include headaches, blurred vision, dizziness, unsteadiness or difficulty walking, and bone pain.

tomography) scan. Tomograms image thin slices of the lung that can show a small cancer not seen on standard x-rays. CT scans produce an image of a cross-sectional slice of a selected body area and are particularly useful for showing the extent of a lung tumor and whether it has spread into neighboring organs.

Sometimes doctors can detect lung cancer cells in the patient's sputum, examined under a microscope. Additional tests are usually required to determine the tumor's type and location. Doctors usually need to extract cells from the lungs to screen under a microscope for cancer cells. A procedure called a bronchoscopy allows doctors to pluck cells from the inner walls of the bronchi—the two branches of the trachea (windpipe) leading to the lungs. This procedure is generally done in a hospital. The patient is given a local anesthetic, and a flexible thin tube with lighting and magnifying devices called a bronchoscope is threaded through the nose or mouth into the lung.

To collect cells hard to reach with a bronchoscope, doctors perform a needle aspiration biopsy guided by fluoroscopy. Fluoroscopy is an x-ray procedure that

uses a television screen to view internal organs such as the heart and lungs while they are in motion. Using the picture on the screen as a guide, the doctor inserts a long, thin needle into the tumor to withdraw cells for examination.

If lymph nodes in the neck seem enlarged, doctors may remove them to see if cancer cells have spread there. Doctors may also biopsy the lymph nodes between the lungs. Tissue is removed through a small incision in the chest while the patient is under general anesthesia.

Radionuclide scans are sometimes done to find out whether lung cancer has spread to other areas of the body. Technicians inject patients with a small amount of radioactive material. These compounds emit signals a machine translates into a screen image that outlines areas of possible cancer involvement in the bones or other parts of the body.

Spreads Rapidly

Unfortunately, in about 85 percent of patients, by the time lung cancer is diagnosed the disease has spread beyond the lungs.

Lung cancers tend to spread more quickly than most other types of cancer because the lungs are richly supplied by the blood and lymph systems, which carry cells to other parts of the body. This makes lung cancers particularly difficult to treat.

The three main weapons doctors can wield against lung cancer are surgery, radiation directed at the chest, and chemotherapy with anti-cancer drugs.

Surgery involves removing part or all of the lung, depending on the extent of the tumor. Patients recovering from surgery usually need to use an artificial respirator to help them breathe for a few days. Lung cancer surgery frequently

causes disrupted heart functions, such as an abnormal heartbeat. For this reason, patients with advanced heart disease may not tolerate lung cancer surgery well. Also, patients with lung conditions that impair breathing, such as emphysema (also commonly caused by cigarette smoking), may not tolerate lung cancer surgery.

Radiation therapy is usually given five days a week for several weeks and may cause dry and reddened skin in the treated area, unusual tiredness, or a dry or sore throat that can make swallowing painful. These side effects usually disappear in a few weeks after completion of treatment.

Drugs used to treat lung cancer may be given by mouth or by injection into a muscle or vein. Some drugs require patients to stay in the hospital for a few days while doctors monitor their effects.

Other drugs may be taken on a hospital outpatient basis, at the doctor's office, or at home.

Chemotherapy affects not only cancer cells but also other rapidly growing cells, such as blood or hair cells, and cells that line the digestive tract. As a result, it can cause side effects such as anemia, an increased risk of infection or bleeding, hair loss, nausea, and vomiting. Some of these side effects may make patients feel unusually tired during treatment.

Treatment Varies

The treatment plan for lung cancer patients depends on the size, location and

type of lung cancer as well as the patient's general health.

All common types of lung cancer occur more frequently in smokers. Small cell lung cancer (SCLC) is diagnosed almost exclusively in smokers. This form of lung cancer spreads especially quickly to distant parts of the body. Consequently, treatment with surgery or radiation, both of which target localized disease, is almost never effective in controlling it.

Doctors commonly treat patients with SCLC with a combination of several anti-cancer drugs or with anti-cancer drugs plus radiation to the chest. For patients whose SCLC does not appear to have spread extensively beyond the lung, chemotherapy following surgical removal of the lung tumor may be an option.

Doctors usually treat patients with

nonsmall cell lung cancer (NSCLC) not detected in the lymph nodes or other organs with surgery that removes part or all of the cancerous lung. Doctors may also prescribe radiation therapy if patients cannot have surgery because of other medical problems.

Doctors usually treat NSCLC patients whose cancer has spread to nearby tissue or lymph nodes with radiation therapy, which is sometimes combined with surgery or chemotherapy. Radiation is also used to temporarily shrink the tumors and relieve symptoms of patients with NSCLC that has spread to distant parts of the body.

Lung cancer often spreads to the brain,

THE RISK OF DEVELOPING LUNG CANCER INCREASES WITH THE NUMBER OF CIGARETTES SMOKED AND THE NUMBER OF YEARS OF SMOKING.

Smoking Gun

Lung cancer was a rare disease at the turn of the century when Americans smoked an average of only 50 cigarettes per capita a year and tobacco was mainly used for cigars, pipes, or chewing tobacco. Twenty-five years later, the popularity of cigarette smoking mushroomed, boosting the average number of cigarettes smoked to over 1,000 per capita a year.

It often takes more than 20 years for the effects of cigarette smoke to develop into a detectable malignancy. By 1950, the country's annual lung cancer death toll had reached 18,000 (six times the amount in 1930). This set off an alarm in the public health community.

Cancer experts suspected cigarette smoke, but other factors, such as urban pollution and occupational exposures that also might have prompted the rise in lung cancer, clouded the issue. Then, in the 1960s, scientists had enough evidence to say with certainty that cigarette smoke was the "smoking gun" behind the rise in lung cancer deaths. By then,

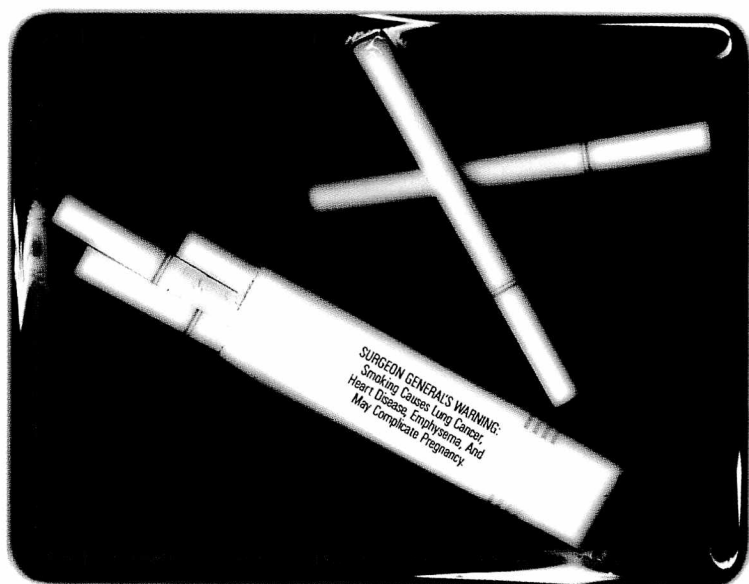
nearly half of all Americans smoked.

In 1964, the landmark *Smoking and Health Report of the Advisory Committee to the Surgeon General* greatly increased public awareness that cigarette smoking causes lung cancer. Numerous studies done over the past two decades have shown that 9 out of 10 cases of lung cancer are caused by smoking. Even daily exposure to secondhand cigarette smoke can boost one's chances of developing lung cancer by as much as 30 percent, according to the National Research Council.

Despite these scary statistics and the Surgeon General's plea for a "smoke-free society" by the year 2,000, 1 out of 4 Americans

still smokes. Many of these smokers have tried to quit—some more than once—but are stymied by the addictive nature of nicotine. Others either don't believe the health information about cigarette smoking or enjoy the image of being a high risk-taker. ■

—M.P.



where it can do substantial damage before it is detected. Doctors may recommend that patients whose SCLC hasn't spread extensively receive prophylactic radiation treatments directed at the brain in addition to surgery, chemotherapy, or radiation therapy for the chest region. Such radiation of the brain, however, may cause permanent side effects, according to the National Cancer Institute, including impaired memory and thinking abilities.

Nearly half of all lung cancer patients whose tumors are detected before spreading beyond the lungs live five or more years after diagnosis. But because these patients make up such a small frac-

tion of the total lung cancer cases, only 13 percent of all lung cancer patients live this long, according to the American Cancer Society.

Experimental Treatments

Such dire statistics may prompt lung cancer patients and their doctors to consider new experimental treatments that are investigational and have not been approved by FDA. Examples of these treatments include chemotherapy and "immunotherapies" that use cancer vaccines, monoclonal antibodies, or other biologicals to boost or enhance the patient's anti-cancer immune response or to more selectively direct anti-cancer

drugs or radiation to tumors. Another new technique called photodynamic therapy selectively kills cancer cells with a compound that makes them die when exposed to laser light brought into the lung via a bronchoscope.

It is hoped that some of these experimental treatments will prove to be safe and effective enough to merit FDA approval for general use. However, despite extensive research, the discovery of safe and highly effective treatments for lung cancer remains an elusive goal. ■

Margie Patlak is a writer in Elkins Park, Pa.



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

■ **Meats for NASA space meals** can now be irradiated so they stay fresh as long as the source of radiation is safe and the meats are frozen and packaged, according to an FDA final rule. (FR March 8)

■ **Ethyl alcohol** maximum concentration limits in oral over-the-counter drug products were set in an FDA final rule. The alcohol limits are 0.5 percent in products for children under 6, 5 percent for children between 6 and 12, and 10 percent in products for people over 12. The rule also requires prominent display of the alcohol content on the product label. (FR March 13)

■ **Six new guidelines** are available from FDA and the International Conference on Harmonisation:

- "Text on Validation of Analytical Procedures"
- "Toxicokinetics: Guidance on the Assessment of Systemic Exposure in Toxicity Studies"
- "The Extent of Population Exposure Required to Assess Clinical Safety for Drugs Intended for Long-term Treatment of Non-life-threatening Conditions"

- "Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies"

- "Dose Selection for Carcinogenicity Studies of Pharmaceuticals"

- "Clinical Safety Data Management: Definitions and Standards for Expedited Reporting."

Free copies can be ordered from CDER Executive Secretariat Staff (HFD-8), Center for Drug Evaluation and Research, FDA, 7500 Standish Place, Rockville, MD 20855. (FR March 1)

■ **Mammography facility** inspection fees were set for 1995 by FDA in a March 17 notice. For an annual inspection, FDA will charge each facility \$1,178 for the first mammography unit and \$152 for each additional unit. The agency will charge \$670 for each follow-up inspection. The Mammography Quality Standards Act of 1992 authorizes FDA to inspect, certify, and collect fees for certification of nearly all U.S. mammography facilities. (FR March 17)

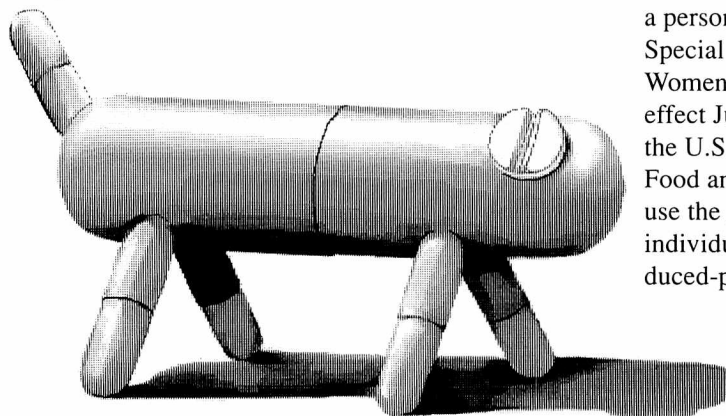
■ **A new animal drug study guideline** is available from FDA's Center for Veterinary Medicine. "Protocol Development Guideline for Clinical Effectiveness and Target Animal Trials" outlines the components necessary for a well-

designed study. For a free copy, request docket number 94D-0356 and send two self-addressed labels to Communications and Education Branch (HFV-12), FDA, 7500 Standish Place, Rockville, MD 20855. (FR March 28)

■ **Bicycle helmet standards** that were voluntary became mandatory in a Consumer Product Safety Commission final rule, effective March 15. The standards contain helmet requirements for construction, labeling, peripheral vision, reducing impact, and strength. The standards include specific requirements for children's helmets. (FR March 23)

■ **New and revised food chemical monographs** are available, according to an FDA notice. The new monographs on acesulfame potassium and glyceryl monooleate, and revised monographs on calcium carbonate, caramel, and carnauba wax were prepared for the National Academy of Sciences/Institute of Medicine Food Chemicals Codex. Send written requests for free copies of the documents to NAS/IOM Committee on Food Chemicals Codex, National Academy of Sciences, 2101 Constitution Ave., N.W., Washington, DC 20418. (FR March 8)

■ **Adjusted poverty income guidelines** for use by state agencies in determining a person's eligibility to participate in the Special Supplemental Food Program for Women, Infants and Children will take effect July 1, according to a notice by the U.S. Department of Agriculture's Food and Consumer Service. Agencies use the guidelines to determine an individual's eligibility for free or reduced-price meals. (FR March 9)





Ice Cream Firm Linked to Salmonella Outbreak

by John Henkel

In September and October 1994, Minnesota's health department logged a sharp rise in the state's *Salmonella* illness cases. A few weeks later, FDA and state officials determined that contaminated ice cream was the likely cause of a *Salmonella* outbreak that may have sickened more than 3,000 people in as many as 41 states.

Schwan's Sales Enterprises of Marshall, Minn., recalled ice cream made at its Marshall plant after learning last Oct. 7 that the products were linked to the illnesses. The recall involved dozens of frozen dairy products, including ice cream, yogurt, dietary desserts, sherbets, cones, and ice cream sandwiches.

Schwan's resumed making and distributing ice cream on Nov. 7, after follow-up tests by FDA and the Minnesota Department of Agriculture (MDA) found no evidence of contamination in the company's plant.

Federal and state officials theorize that *Salmonella* contamination occurred when raw, unpasteurized eggs were hauled in one or more tanker trucks that later carried pasteurized ice cream premix to the Schwan's plant. Raw eggs are a well-known source of *Salmonella* contamination, and because the ice cream premix wasn't pasteurized again after delivery to the plant, the bacteria had a direct route into the final product.

Salmonella poisoning can cause diarrhea, abdominal cramps, fever, and sometimes vomiting. The infection can be life-threatening to infants, the elderly,

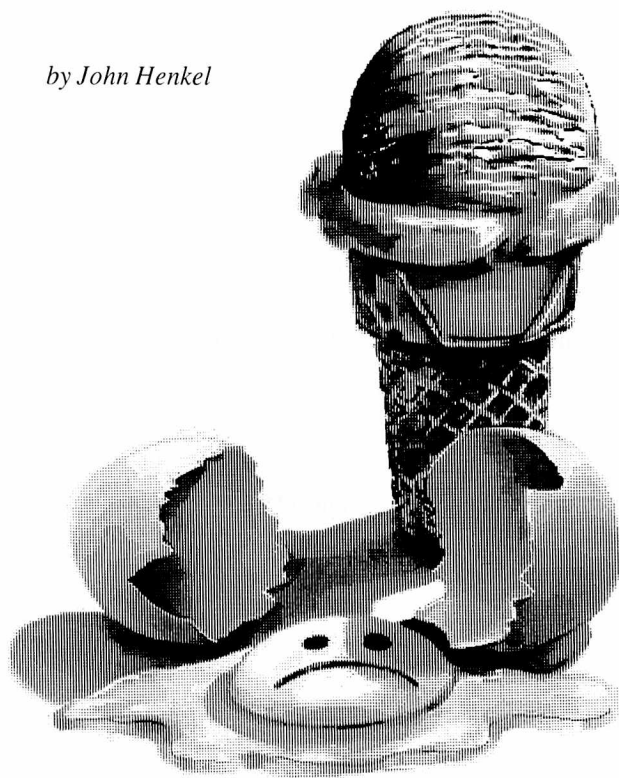
or persons with weakened immunity. The federal Centers for Disease Control and Prevention received reports from 41 states of illness associated with Schwan's products: 740 cases from 30 states were confirmed by cultures, and 41 states reported an additional 3,423 probable or suspected cases, according to CDC reports. No deaths were reported.

Schwan's has about 500 warehouses across the United States from which about 3,000 salespersons distribute the firm's products. The company has about 8,500 wholesale accounts—including schools, nursing homes, cafeterias, and restaurants—as well as over a million individual consumer homes.

From Sept. 19 to Oct. 10, 1994, the

Minnesota Department of Health confirmed 80 cases of *Salmonella* infection in the state. On Oct. 6, the department conducted a telephone survey and found that 18 of 24 Minnesotans with confirmed *Salmonella* illness had eaten Schwan's ice cream within five days of the onset of symptoms.

On Oct. 7, FDA met with state health and agriculture officials and concluded that Schwan's ice cream, contaminated with *Salmonella*, was the most likely cause of the illnesses. Officials informed the company, which voluntarily stopped production and distribution at the Marshall plant, pending investigations, and began a recall of distributed products. Within three weeks, most of the suspect products were recovered and



slated for disposal. FDA inspected the facility, identified Schwan's suppliers, and, with MDA, collected samples for analysis. MDA and FDA's Midwest Laboratory for Microbiological Investigations analyzed hundreds of samples—including raw materials, environmental swabs, and finished ice cream products.

Analysis of egg samples from a tanker, ice cream from the plant, and stool specimens from infected consumers revealed that all contained *Salmo-*

nella of the same genetic type. At an Oct. 20 press conference in Minneapolis, FDA Commissioner David A. Kessler, M.D., stated that contamination of premix transported in inadequately cleaned tanker trucks most likely caused the *Salmonella* outbreak.

To prevent future product contamination, says company president Alfred Schwan, the firm will pasteurize ice cream premix when it arrives at the plant. Schwan's now uses "dedicated"

tankers that carry only the company's ice cream premix.

In addition, Schwan's has set up a Hazard Analysis Critical Control Point program, which FDA has reviewed. The program is designed to identify key points of potential contamination in the production process and institute preventive measures.

John Henkel is a staff writer for FDA Consumer.

Unapproved Products Destroyed

The brochure accompanying Aidex hand cream promised "One million viruses including HIV, Herpes and Hepatitis are inactivated instantly." When the manufacturer refused to substantiate that and other statements in the brochure, as required by FDA, \$20,000 worth of the cream and other products were destroyed last October. But first FDA had to find where the firm president had stashed the products.

Medicine and Applied Sciences, Inc., Sterling, Va., manufactured and distributed several lotions, soaps and creams under the brand name Aidex. These products were unapproved drugs under the Food, Drug, and Cosmetic Act because the brochures that accompanied shipments indicated the products were safe and effective against a number of diseases and would destroy most viruses, bacteria and fungi when applied to the skin. In addition, the firm distributed several products labeled for disinfecting medical devices. These products were found to be in violation of the act.

In January 1988, the president of Medicine and Applied Sciences, Yash Sharma, asked FDA's Center for Drug Evaluation and Research if FDA approval was necessary to market his

products. The center told Sharma his products containing the OTC spermicide nonoxynol-9 as an active ingredient could not be marketed for AIDS prevention without FDA's approval of a new drug application substantiating the AIDS prevention claims.

In July 1989, FDA's Center for Devices and Radiological Health told Sharma that because his firm's disinfectants were devices, the firm was required to register with the agency as a medical device manufacturer.



Sharma never submitted any new drug applications, nor did he register his firm.

FDA inspected the firm in April 1992 after a doctor in Bethesda, Md., asked FDA if the firm's disinfectants were as effective as the promotional literature claimed.

Problems uncovered during the inspection included:

- inadequate written manufacturing procedures and records and no documentation to show that procedures were followed
- no records on the receipt, examination or testing of raw materials, containers or closures
- two conflicting manufacturing procedures for the Aidex product line, one showing the batch size as 4 liters and the other showing a 9.79-liter batch size
- rejected finished products stored along with accepted products
- no written procedures or documentation for cleaning, maintaining or calibrating manufacturing and testing equipment
- no stability data or test procedures to support the two-year expiration date
- no approved new drug applications
- no approved 510(k) or Investigational Device Exemption/Premarket Approval.

In addition, the investigators could not get documentation for receipt of nonoxynol-9 or the antibacterial

PCMX—both active ingredients listed in Medicine and Applied Sciences' products. FDA laboratory analysis of samples showed widely varying amounts of the two ingredients, and some samples contained no PCMX or nonoxynol-9. However, mold and insects were found in several samples.

According to the investigators, when they informed Sharma that his products were not in compliance with agency regulations, he told them he did not consider his products to be drugs or devices, nor did he consider himself to be a manufacturer.

In an April 29 letter to the agency's Baltimore district office, Sharma said he would cooperate with the agency if FDA determined that the products were new drugs and devices. But he argued that he did not believe his products were under FDA's regulatory control because the labels did not promote them as effective in preventing disease. In addition, he did not indicate that he would correct any of the problems found during the inspection.

Because of extensive manufacturing violations and continued disregard for the Food, Drug, and Cosmetic Act and FDA's drug and device regulations, the agency's Baltimore district office, on July 10, recommended the firm's products be seized.

While FDA headquarters reviewed the recommendation, the investigators returned to the firm to try and convince Sharma to conduct a voluntary recall. Sharma agreed to the recall, but denied there was anything wrong with his products and complained that the investigators had ruined his business. The recall plan, received at FDA on Oct. 20, was inadequate both in scope and in explaining the reason for the recall. The recall was never carried out.

FDA investigators returned to Medicine and Applied Sciences on March 3,

1993. They found only about \$500 worth of an original \$20,000 of finished products, raw materials, and product literature that had been listed in the seizure recommendation. Sharma said he had sold everything else, including the firm. When the investigators asked for details about the sale, he threatened to have them arrested if they ever returned.

On May 13, at FDA's request, a seizure complaint was filed in the Eastern District of Virginia. When an FDA investigator went to the firm on July 14 to make sure there was something left to seize, he found no products. Instead, he found copies of invoices indicating that all of the firm's inventory was being stored at a warehouse in Jessup, Md.

On March 18, 1994, a seizure complaint was filed for the products in the Jessup, Md., warehouse, and on March 21, the products found there were seized. The products were destroyed Oct. 25.

—Dori Stehlin

Hair-Raising Claims Lead to Shampoo Ban

A federal judge recently ordered a Rhode Island hair-care products distributor to stop selling two products it claimed would stimulate hair growth and prevent hair loss.

On Sept. 26, 1994, Judge Raymond J. Pettine, of the U.S. District Court for the District of Rhode Island, permanently enjoined Kasz Enterprises, Inc., of Warwick, R.I., and its owner and president James Kaszyk from marketing "Solution 109 Herbal Shampoo" and "Solution 109 Herbal Cosmetic Scalp Cleanser." The court found the products were new drugs being marketed without FDA approval. In addition, the court found the products were misbranded because they lacked adequate directions for use.

Kasz argued that the shampoo and scalp cleanser were cosmetics, not drugs, and therefore not subject to the agency's drug application and labeling requirements.

FDA maintained that the products were drugs, however, because Kasz promoted them with drug claims, such as causing hair growth and preventing hair loss, rather than only with cosmetic claims, such as making hair appear fuller or thicker.

The judge agreed with FDA and accepted the agency's position that merely ordering a halt to the therapeutic claims would not be a sufficient remedy. In light of the substantial market that had already been created for the products based on the hair growth claims, the court believed that unless marketing were halted altogether, buyers would continue to associate the products with hair restoration, and Kasz would continue to profit from its past illegal activity.

FDA investigator John Biello, of the East Providence, R.I., resident post, and investigator Debra Cooper and public affairs specialist Joseph Raulinaitis, of the Boston district office, gathered the required evidence of Kasz's illegal promotional claims.

Biello first inspected Kasz Enterprises on Feb. 12, 1991, in response to reports from consumers and government health agencies that the firm was promoting its products for baldness and thinning hair. He found promotional materials for Solutions 109 that included testimonials from Kasz customers. Examples included:

- A booklet entitled *Kasz Enterprises, Inc.: Solution 109*, containing a testimonial stating, "With Solution 109, I've stopped losing my hair and it's actually growing back, even in places that were totally bald before," and a claim that, "Usually in one to three months, most

customers report their hair is regrowing and their hair loss has stopped.”

- A newspaper article reprint entitled “Is this the Solution to hair loss problem?” containing testimonials from radio personalities regarding the products’ hair growing effects.
- A memorandum entitled “From the Office of the President,” stating, “There are many products today claiming to help people with a hair loss problem. Only Kasz Enterprises gives you: 90% satisfaction rate [and] proven results with local celebrities ...”

Radio advertisements broadcast around the time of the inspection stated, “There’s a proven effective product that people are claiming regrows their hair. It’s called Solution 109 by Kasz Enterprises. Kasz only claims to make hair fuller and thicker; the results confirm that Solution 109 far exceeds its claims.”

FDA sent a warning letter to Kasz on Aug. 12, 1991, alerting the company that its claims of therapeutic effect were drug claims and that the two products were misbranded and unapproved new drugs. The letter also stated that continuing to sell the products as baldness remedies might lead to FDA enforcement action.

On Sept. 5, 1991, FDA representatives met with Kasz’s attorney, at his request, and reiterated FDA’s position.

Despite FDA’s warnings, Kasz continued to sell the solutions. As a result of the continued sales and drug claims, on April 10, 1992, the government seized 30 bottles of the products from a Burlington, Mass., hair salon and subsequently destroyed them.

Cooper and Raulinaitis inspected the company on Sept. 9, 1992, and April 16, 1993, and found that Kasz was still making therapeutic claims for the products.

Cooper visited one of Kasz’s hair salon distributors on April 27, 1993. The salon had a sign in the window stating,



“Solutions 109 Available Here,” and, at Kasz’s request, dispensed promotional literature containing hair restoration claims.

Because of the company’s continued violations, FDA sought an injunction to stop Kasz from selling the hair products unless the firm submitted new drug applications and the products received FDA approval.

In court, Kasz argued that it had made no claims of therapeutic effect for Solutions 109, and thus the products were not drugs. Kasz said that, while promotional literature did include statements from third parties crediting Solutions 109 with hair restoration, the company only claimed that the products made hair fuller and thicker.

In granting the injunction, the court referred to Kasz’s using third-party statements rather than its own as “linguistic game-playing.” The court said that, because Kasz clearly intended people to buy Solutions 109 to treat or prevent hair loss, the products were drugs, regardless of the claims being third-party “testimonials.” Judge Pettine said Kasz should have simply removed all references to hair growth in its promotions. “They have not done so,” the judge said, “doubtless because they know that consumers will not purchase normal shampoo for the \$100 price, now

being charged for Solutions 109 unless they believe that it will grow hair.”

Under Judge Pettine’s ruling, Kasz was ordered to:

- stop selling Solutions 109 or similar products with hair growth claims
- notify all customers and distributors by letter that Solutions 109 could no longer be marketed because they were unapproved new drugs and misbranded drugs
- refrain from marketing any hair or scalp treatments using the Solutions 109 logo, the color or shape of the Solutions 109 bottle, or the Solutions 109 graphic design.

As a follow-up, FDA investigator Diane Reitz, of the East Providence resident post, inspected Kasz Enterprises on Jan. 26, 1995. According to Reitz, Kasz continues to market hair-care products, but is apparently complying with the court’s order. Kasz’s new “Herbal Whiz Scalp Cleanser” and “Herbal Whiz Shampoo” are packaged in bottles that look substantially different from the Solutions 109 bottles. The FDA investigator found no use of drug claims to promote the products. The Herbal Whiz bottle labels say: “the scientific miracle in a bottle,” a claim that FDA regards as mere “puffery.”

—Tamar Nordenberg

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 alleged to be adulterated or misbranded or otherwise violative of the law when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce.

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

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

SEIZURE ACTIONS

Food/Contamination, Spoilage, Insanitary Handling

PRODUCT: Cheeses, yogurt, at Chicago, IL (N.D. Ill.); Civil No. 94C-5880.

CHARGED 9-27-94: While held at Midwest Vending Supplies, Inc., Chicago, Ill., the articles were adulterated while held for sale after shipment in interstate commerce, in that they contained a poisonous and deleterious substance, *Listeria monocytogenes*, which might render them injurious to health—402(a)(1); they were misbranded in that nutrition information on the label failed to conform to specified requirements and material facts—403(a)(1); and they were misbranded in that the labeling was not in English, and the ingredient declaration, and name and place of business of the manufacturer, packer or distributor were not prominently placed—403(f).

DISPOSITION: Default—destroyed. (F.D.C. No. 67013; S. No. 94-710-490; S.J. No. 1)

PRODUCT: Tuna, chunk white, at Baltimore, MD (D. Md.); Civil No. 94-1199.

CHARGED 5-6-94: While held at The Belt's Corporation, Baltimore, Md., the articles were adulterated in that they consisted in part of decomposed fish—402(a)(3).

DISPOSITION: A consent decree of condemnation and exportation authorized release to claimant for relabeling as "For Export Only". (F.D.C. No. 66956; S. No. 94-656-774; S.J. No. 2)

PRODUCT: Tuna, yellow fin, at Seattle, WA (W.D. Wash.); Civil No. 94-707.

CHARGED 5-10-94: While held at Cityice Cold Storage Company, Seattle, Wash., the articles were adulterated in that they contained a poisonous and deleterious substance which might render them injurious to health—402(a)(1); the articles were adulterated in that they consisted in part of decomposed fish—402(a)(3).

DISPOSITION: Default—destroyed. (F.D.C. No. 66967; S. No. 94-629-609; S.J. No. 3)

PRODUCT: Tuna, yellow fin, at Seattle, WA (W.D. Wash.); Civil No. 94-04152.

CHARGED 3-22-94: While held at Cityice Cold Storage Company, Seattle, Wash., the articles were adulterated in that they consisted in part of decomposed fish—402(a)(3).

DISPOSITION: Consent—destroyed. (F.D.C. No. 66947; S. No. 94-629-602; S.J. No. 4)

Food Additives

PRODUCT: Evening Primrose Oil, at Urbana, IL (C.D. Ill.); Civil No. 88-2398.

CHARGED 11-8-88: While held at Hutchcraft North American Van Lines (public storage), Urbana, Ill., for the account of Traco Labs, Inc., Champaign, Ill., the article is adulterated because it is a food which bears or contains a food additive (black currant oil) which is unsafe—402(a)(2)(C); and the additive is unsafe because there is no regulation under Section 348 prescribing the conditions under which it may be safely used, and there is no exemption in effect for its use or intended use—348(a).

DISPOSITION: *District Court*—The government contended that the black currant oil was an unsafe food additive because it was intended for use as a component of a dietary supplement, that it was not generally recognized as safe for that use, and that there is no food additive regulation permitting such use. The court ruled that the government had not made a sufficient showing to establish the intended "additive" use of the product. The court granted the summary judgment motion filed by Traco Labs, Inc., and entered judgment against the government. The court found that the seized article was not a "component" of food when encapsulated by itself or with a preservative into dietary supplements.

Court of Appeals—The Court of Appeals affirmed the judgment of the district court, holding that the seized article—black currant oil claimed by Traco Labs and marketed in a gelatin and glycerin capsule as a dietary supplement—is not a

“food additive” within the meaning of the statutory definition. According to the court, the seized article is a single active ingredient that does not alter the food’s characteristics, thus requiring FDA to prove that the article is injurious to health before it can be considered adulterated and condemned.

An application under the Equal Access to Justice Act was filed by Traco Labs, seeking legal fees and expenses. The government opposed. The district court awarded to the applicant, refusing to grant an upward adjustment for expertise in food and drug law or any expenses. (F.D.C. No. 65558; S. No. 88-433-394; S.J. No. 5)

Drugs/Human Use

PRODUCT: **Acitibine, brand of Yohimbine HCl Tablets**, at Brewster, NY (S.D. N.Y.); Civil No. 90-5747.

CHARGED 9-6-90: While held at Consolidated Midland Corporation, Brewster, N.Y., the articles were adulterated because the methods used in, and the facilities and controls used for, their processing, packing and holding did not conform to and were not operated and administered in conformity with current good manufacturing practice—501(a)(2)(B).

DISPOSITION: Consent—destroyed. (F.D.C. No. 65909; S. No. 90-544-792; S.J. No. 6)

PRODUCT: **Benzotropine Mesylate Tablets**, at Salt Lake City, UT (E.D. Utah); Civil No. 91C-896.

CHARGED 8-22-91: While held at Bergen Brunswick Drug Company, Salt Lake City, Utah, the articles were misbranded because their labeling was false or misleading since it failed to reveal material facts—502(a).

DISPOSITION: Default—destroyed. (F.D.C. No. 66196; S. No. 91-487-122; S.J. No. 7)

PRODUCT: **Oxygen, U.S.P., liquid, in cylinders**, at Ventura, CA (C.D. Calif.); Civil No. 93-3443.

CHARGED 6-11-93: While held at Primedica, Inc., d/b/a Crest H.R. Medical, Ventura, Calif., the articles (labeled “AIRCO *** OXYGEN*** REFRIGERATED LIQUID U.S.P.”) were adulterated because the methods used in, and the facilities and controls used for, their manufacture and holding did not conform to and were not operated and administered in conformity with current good manufacturing practice—501(a)(2)(B).

DISPOSITION: Consent—reconditioned. (F.D.C. No. 66676; S. No. 93-425-596/7; S.J. No. 8)

PRODUCT: **Oxygen, U.S.P., liquid, in cylinders**, at Crest

Medical, Santa Barbara, CA (C.D. Calif.); Civil No. 93-3439. CHARGED 6-11-93: While held at Crest Medical, Santa Barbara, Calif., the articles, which were labeled “*** Penox *** LIQUID OXYGEN U.S.P. ***”, were adulterated because the methods used in, and the facilities and controls used for, their manufacture and holding did not conform to and were not operated and administered in conformity with current good manufacturing practice—501(a)(2)(B).

DISPOSITION: Consent—destroyed. (F.D.C. No. 66677; S. No. 93-663-380; S.J. No. 9)

PRODUCT: **Pedolatum, wart, corn, and callus remover**, at Dallas, TX (N.D. Texas); Civil No. 3-93CV2106.

CHARGED 10-19-93: While held at King Laboratories, Inc., Dallas, Texas, for introduction into interstate commerce, the article was misbranded in that it was a “new drug” which may not be introduced or delivered for introduction into interstate commerce pursuant to 21 U.S.C. § 321(p)—505(a); it had no approval of an application filed—505(b); and it was misbranded because its label failed to bear adequate directions for use—502(f)(1).

DISPOSITION: Articles destroyed. (F.D.C. No. 66731; S. No. 93-666-223; S.J. No. 10)

Drugs/Veterinary

PRODUCT: **Mecadox, article of veterinary drug**, at Hillsboro, IN (S.D. Ind.); Civil No. 90-1526.

CHARGED 6-28-90: While held for sale after shipment in interstate commerce, the articles located at Pro-Gain, Inc., Hillsboro, Ind., labeled “Mecadox 10 TYPE A MEDICATED ARTICLE Active Drug Ingredient: Carbadox ...” and “*** MGA 200 Premix (Type A Medicated Article) *** Active Drug Ingredient Melengesrol Acetate ... 20 mg ***” were adulterated because they had not been processed or held in conformity with current good manufacturing practice—501(a)(2)(B); and they were adulterated because they were manufactured without an approved medicated feed application or because the medicated feed consisted of a combination of drugs not provided for by regulation—501(a)(6).

DISPOSITION: Consent—destroyed. (F.D.C. No. 65859; S. No. 90-550-572/7 et al.; S.J. No. 11)

Medical Devices

PRODUCT: **Capnographs, electronic, fragile medical instrument**, at Lenexa, KS (D. Kansas); Civil No. 91-2448.

CHARGED 12-4-91: While held at PPG Industries, Inc.,

SUMMARIES OF COURT ACTIONS (continued)

Lenexa, Kan., the articles labeled “FRAGILE MEDICAL INSTRUMENT SARA PPG Biomedical Systems *** (device) ***O.R. SARAcap *** PPG Biomedical Systems ***” were adulterated because the methods used in, and the facilities and controls used for, their manufacture, packing, storage, and installation were not in conformity with current good manufacturing practice requirements for devices—501(h).

DISPOSITION: Consent—reconditioned. (F.D.C. No. 66252; S. No. 91-597-567; S.J. No. 12)

PRODUCT: **Electrosurgical Generator Units**, at Chicago, IL (N.D. Ill.); Civil No. 93C-5350.

CHARGED 8-27-93: While held at Cameron-Miller, Inc., Chicago, Ill., the articles were adulterated in that they were classified as class III devices, which are required to have in effect an approved application for premarket approval or an investigational device exemption pursuant to 21 U.S.C. 360j(g). No such approvals or exemptions were in effect—501(f)(1)(B).

DISPOSITION: Consent—reconditioned. (F.D.C. No. 66721; S. No. 93-662-287; S.J. No. 13)

PRODUCT: **Lab-Tek and Flaskette Tissue Culture Chamber Slides**, at Naperville, IL (N.D. Ill.); Civil No. 93C-7477.

CHARGED 12-10-93: While held at Nunc, Inc., Naperville, Ill., the devices were adulterated because the methods used in, and the facilities and controls used for, their manufacture, packing and storage were not in conformity with current good manufacturing practices for medical devices—501(h).

DISPOSITION: Consent—destroyed. (F.D.C. No. 66719; S. No. 93-661-761; S.J. No. 14)

PRODUCT: **NeuroSearch 4, electroencephalograph**, at Rock Springs, WY (D. Wyo.); Civil No. 93-CV0076.

CHARGED 3-3-93: While held at the private residence of Larry K. Hill, Ed.D., Rock Springs, Wyo., the article was adulterated because it was a class III device that lacked an approved application for premarket approval—501(f)(1)(B); it was also adulterated because the methods used in, and the facilities and controls used for, its manufacture, packing and storage were not in conformity with good manufacturing practice requirements for devices—501(h); the article was misbranded because the labeling failed to bear adequate directions for use for the purpose for which it was intended—502(f)(1).

DISPOSITION: Default—destroyed. (F.D.C. No. 66608; S. No. 92-586-688; S.J. No. 15)

INJUNCTION ACTIONS

DEFENDANT: **Richard B. Aronsohn, M.D.**, a professional

corporation, at Los Angeles, CA (C. Dist. Calif.); Civil No. 92-2780.

CHARGED 5-8-92 in a complaint for injunction: That the defendant used and promoted liquid injectable silicone, a class III medical device without a premarket approval or an approved investigational device exemption—332(a).

DISPOSITION: Consent decree of permanent injunction—goods surrendered to FDA. (Inj. 1279; S. No. 92-5663-574; S.J. No. 16)

DEFENDANT: **George Zabadal**, an independent cattle dealer, Binghamton, NY (N. D. N.Y.); Civil No. 94-CV-0847.

CHARGED 7-7-94 in a complaint for injunction: That the defendant had been and was delivering and causing the delivery of adulterated beef into interstate commerce—301(a); and analyses performed by the U.S. Department of Agriculture showed illegal antibiotic drug residues in cattle sold. Food is considered to be adulterated if it contains new animal drug residues above the tolerances established by FDA, or in amounts that indicate that the pre-slaughter drug withdrawal period was not adhered to—402(a)(2)(D).

DISPOSITION: A consent decree of permanent injunction required the defendant to establish and implement an FDA-approved written record-keeping system. This record-keeping system is designed to prevent the defendant from marketing cattle to slaughterhouse with illegal animal drug residues. It also required the defendant to obtain from the seller of any medicated animal a signed drug-free certificate. (Inj. No. 1354; S. No. 94-672-468; S.J. No. 17)

MISCELLANEOUS ACTIONS

SUBJECT: **Dr. Dilip Shah**, at Washington, DC (Dist. D.C.); Civil No. 93-1715.

CHARGED 10-27-93: In a petition for review, for conduct relating to the development or approval of a drug product, and relating to the regulation of a drug product under the FD&C Act—335a(a).

DISPOSITION: The U.S. Court of Appeals for the District of Columbia granted the petitioner's motion to dismiss his appeal of an FDA order that permanently debars him from providing services in any capacity to a person with an approval or pending drug product application. In his appeal, Dr. Shah had argued that FDA's order violated procedural and substantive due process and the double jeopardy and *ex post facto* clauses of the Constitution. In addition to the conviction that provided the basis for the debarment, Dr. Shah was convicted of one count of making false statements, for which he was sentenced to 46 months in prison and a \$15,000 fine. (Misc. 1006; S.J. No. 18)

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