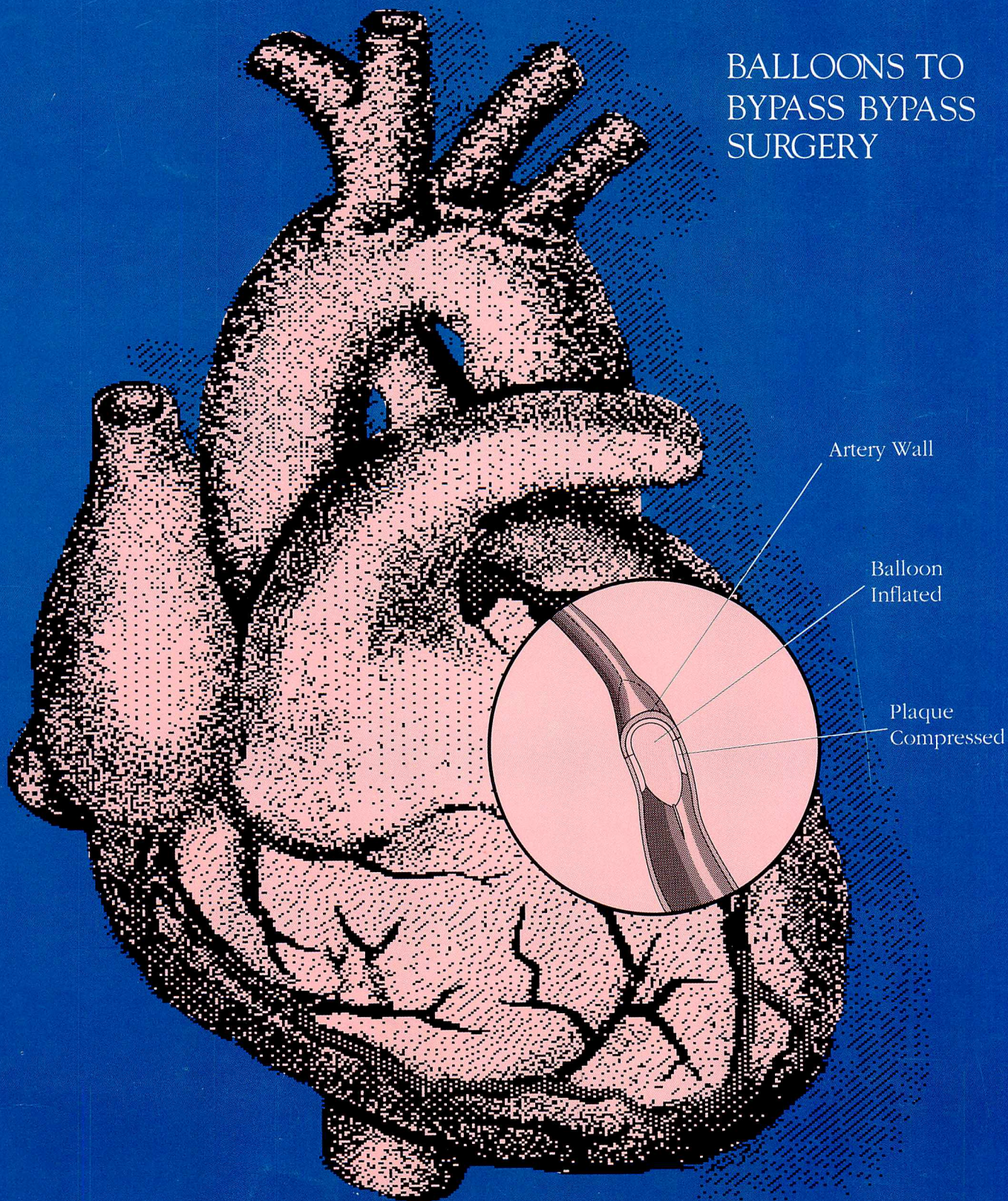


# FDA CONSUMER

• VOL. 22 NO. 4

MAY 1988 •

## BALLOONS TO BYPASS BYPASS SURGERY









# FDA CONSUMER

VOL. 22 NO. 4

MAY 1988

## Experimental Drugs for the Desperately Ill: A Progress Report 2

Three potentially life-saving drugs are now available to certain critically ill patients, thanks to a regulation established last year. FDA Commissioner Frank Young discusses these therapies and whom they might help.

## We're Getting the Message about Diet-Disease Links 6

Sodium and hypertension . . . cholesterol and heart disease . . . fat and cancer. Consumers are seeing a bumper crop of information about how diet can affect health. Are these messages changing the way we eat? Many consumers tell FDA the answer is yes.

## Fruit: Something Good That's Not Illegal, Immoral or Fattening 10

Food technologists are always trying to concoct new foods that are low-calorie, nutritious and tasty. For inspiration, they might want to visit the fruit section of their supermarket.

## Fish Stories: The Catch to the Catch of the Day 14

There might be something fishy with the fish names next time you're in the market for seafood. FDA has found that what is called sole, or flounder, or orange roughy, for instance, may be something else entirely.

## The Silent Epidemic of Hip Fractures 18

Elderly women are the main victims of the growing but largely unpublicized problem of hip fractures. There are new treatments for this crippling condition, but — even better — there are ways to help prevent it.

## Balloons to Bypass Bypass Surgery 24

Thousands of heart patients are able to avoid coronary bypass surgery, thanks to a half-inch-long balloon that looks like a tiny hot dog.

## Brushing Off Dandruff and Other Flaky Afflictions 28

When flakes start to fall and it isn't snowing, you've got dandruff. Or seborrhea, or psoriasis. There's no need to scratch your head wondering what to do; almost everyone can find relief among the vast array of available treatments.

## Updates 4 Investigators' Reports 33

## The Notebook 32 Summaries of Court Actions 37



A fish by any other name . . . FDA has found that sometimes the fish you order at a market or restaurant is not the fish you get. What's sold as sole or flounder, for example, may be something else entirely. For more on this fishy fish story, turn to page 14. The fish on the facing page can't hide behind phony names. Clockwise from bottom left they are: Spanish mackerel, butterfish, white perch, sea trout, and flounder.

Otis R. Bowen, M.D.  
Secretary, U.S. Department of  
Health and Human Services

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

John A. Norris, J.D., M.B.A.  
Deputy Commissioner of Food  
and Drugs

Jack W. Martin  
Associate Commissioner for  
Public Affairs

William M. Rados/Editor

Jesse R. Nichols/Art Director

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

### Editorial Matters

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

### Subscriptions

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

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

To continue to receive *FDA Consumer* without interruption, please return your renewal notice promptly. If your subscription has expired, simply send your mailing label with \$12.00 (\$15.00 foreign), using the form on the back cover, to Superintendent of Documents, Government Printing Office, Washington, D.C. 20402, and your service will be reinstated.

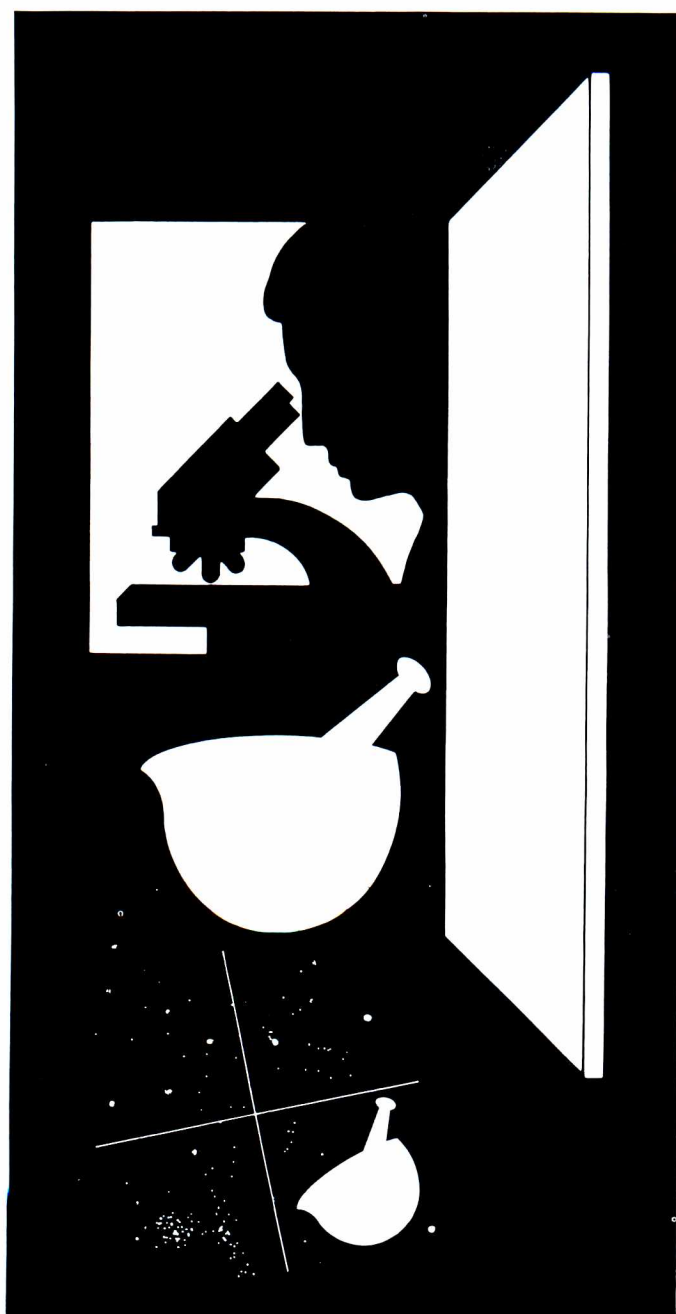




## Health Talk With Dr. Frank Young

### *Experimental Drugs for the Desperately Ill: A Progress Report*

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



Less than a year ago, FDA established a regulation that offers a way to provide promising – but still experimental – drugs to desperately ill patients.

The regulation is known as the “treatment IND” (for investigational new drug) rule. It is based on the premise that there are times when an experimental drug shows such promise – especially for a life-threatening condition for which there is no other hope – that it seems unacceptable to withhold it from desperate patients. (See “Experimental Drugs for the Desperately Ill” in the June 1987 *FDA Consumer*.) The regulation, which went into effect last June 22, makes it possible to bring such promising and important drugs to desperately ill patients much earlier than was previously the case.

As we approach the one-year mark of the treatment IND rule, I am pleased to provide this progress report on its success to date. I think we can be gratified that the regulation has already proven its worth by providing new treatment choices – and potentially life-saving ones at that – for many critically ill patients.

As this column went to press, FDA had approved three important treatment IND requests.

The first approval was given last October to the Massachusetts Department of Public Health for use of a biological product in patients undergoing kidney transplants. FDA felt there was reason to believe that the product, called cytomegalovirus intravenous immune globulin (CMV-IVIG), could prevent potentially life-threatening illnesses in transplant patients whose immune systems are artificially suppressed to prevent rejection of the new kidney.

CMV-IVIG is made from human blood plasma that contains high levels of antibodies to the cytomegalovirus. About half the U.S. adult population has been exposed to CMV. The virus can remain dormant in these infected people and be transferred via a donated kidney to cause severe, uncontrolled infections in the transplant recipient’s lungs, liver, eyes, and other organs. With a suppressed immune system, the transplant patient may be helpless to fight off this normally benign infection.

There are few matched donor kidneys available (those are the only ones for which immune suppression would not be necessary). Since many donors would have encountered CMV infection at some time in their lives, this potential exposure of transplant patients to serious infection can’t usually be avoided. Because there is no currently approved therapy, CMV-IVIG may provide the only protection until the immune system can be allowed to return to normal.

A small percentage of patients who receive CMV-IVIG can be expected to suffer reactions similar to those experienced with other intravenous immune globulins. The reactions tend to be related to the rate at which the immune globulin is administered. Symptoms might include flushing, chills, muscle cramps, back pain, fever, nausea and vomiting. Also, there have been rare reactions similar to anaphylactic shock, with symptoms that include wheezing and a drop in blood pressure.

CMV-IVIG is in very short supply and is available **only** in Massachusetts and Maine, where the plasma used to prepare the product is collected. The producer is working to increase the supply in the coming months, with the goal of being able to distribute it throughout New England and eventually nationwide. Department officials estimate that as many as 3,500 patients across the



country could benefit from the expanded use of CMV-IVIG annually.

FDA has agreed to allow the Massachusetts Department of Public Health to recover its costs of producing CMV-IVIG as provided for in the treatment IND rule. It is not yet certain whether the costs will be passed along to the patients or whether health insurance companies will reimburse these costs.

The second treatment IND, requested by the National Cancer Institute (NCI), was approved last December. It provides a new treatment option to patients suffering from a form of cancer called refractory germ cell carcinoma. This cancer affects the testes, ovaries, and other tissues.

Under the NCI protocol, patients who fail to respond to conventional chemotherapy will be given a combination of four drugs. (In some cases, surgery will be done as well.) Two of the drugs — cisplatin and either vinblastine or etoposide — are already approved for use in cancer treatment. They'll be used with two experimental drugs — ifosfamide and mesna. Ifosfamide is an anti-cancer drug. Mesna is used to prevent a major side effect of ifosfamide — bladder inflammation with bleeding.

As with cancer therapies in general, this multi-drug experimental treatment does have potential side effects. The more common of these include: nausea, vomiting, loss of appetite, hearing loss, hair loss, kidney damage, low blood pressure, fever, chills, and bone marrow suppression (which can lead to anemia, infections, bruising or bleeding). Less common side effects include mouth sores, redness of the skin, confusion, fatigue, neurological toxicity, liver damage, allergic reactions, and chemical abnormalities in the blood. In extremely rare cases, patients treated with ifosfamide have suffered irreversible coma. The extent and severity of the side effects cannot be totally predicted, and the treatment could be fatal. As with any experimental treatment, unforeseen risks may occur.

A study at Indiana University has shown complete remission (meaning the tumor was no longer detectable though it could recur) in about one-third of the more than 50 patients treated with this regimen. Fifteen percent to 20 percent were in complete remission for more than a year. (Recurrences after a year are uncommon.) An estimated 250 patients a year in the United States may be eligible for the new experimental treatment.

The third, and most recent, treatment IND, approved in February, is for a potentially life-threatening infection that often strikes patients with acquired immune deficiency syndrome, or AIDS. The drug, trimetrexate, can be used to combat *Pneumocystis carinii* pneumonia in patients who have had severe adverse reactions to the drugs normally used against this lung infection.

The approval of the treatment IND for trimetrexate reaffirms FDA's commitment to broaden early access for patients to promising experimental treatments for people with AIDS and AIDS-associated conditions. The approval is another step forward in treating one of the most devastating infections seen with AIDS. It also enables community physicians to select the most appropriate therapies for their patients with AIDS.

The drug is being made available through the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

Trimetrexate was originally developed as an anti-cancer drug; its use as a potential treatment for *Pneumocystis carinii* pneumonia was proposed by scientists at the National Cancer Institute in 1985. After promising results from human studies at NCI, NIAID

asked FDA for permission to distribute the drug under a treatment IND.

Trimetrexate is one of a type of medications known as anti-folate drugs. It is toxic to bone marrow cells and the gastrointestinal tract and potentially lethal at the doses needed to treat *Pneumocystis carinii* pneumonia. So it must be administered concurrently with a drug called leucovorin, which protects against the harmful effects of anti-folate drugs. Furthermore, patients must be carefully monitored while taking trimetrexate to ensure their safety.

There are two approved drugs for treating *Pneumocystis carinii* pneumonia — injectable pentamidine and trimethoprim/sulfamethoxazole. But scientists have been interested in trimetrexate because, when used with leucovorin, it may be less toxic than those standard therapies and may be effective in patients who suffer such severe adverse reactions to the approved drugs that treatment must be stopped.

Those three approvals of treatment INDs since last summer offer precious hope to patients and their families.

The challenge — and the opportunity — to make promising experimental drugs available to those who most urgently need them demands the very best from FDA and from the medical community at large. It demands that we be prepared to make tough decisions concerning medical practice and ethics. It demands that we give careful and enlightened consideration to the rights and welfare of patients who are willing — indeed, often desperate — to receive an experimental drug that may offer hope in the face of a devastating disease.

We will continue to use *FDA Consumer* to alert physicians, patients and families to newly approved treatment INDs. FDA also will issue press releases and other public notices about the availability of experimental drugs.

As we make decisions on treatment INDs, we will need to be flexible in weighing the risks against the benefits. But we also will continue to recognize that there will never be a "no-risk" decision. I think our record thus far shows that these tough decisions can be made so that the greatest number of patients benefit — as soon as possible — from the advances of medical science. ■

## For More Information

Patients who feel they may benefit from one of the experimental drugs mentioned in this column should discuss the matter with their doctors. Physicians can obtain more information about these drugs by contacting the following sources:

- Cytomegalovirus intravenous immune globulin for kidney transplant patients — Director of Biologic Laboratories, Massachusetts Department of Public Health: 617-522-3700, Ext. 261.
- Ifosfamide and mesna for germ cell carcinoma — National Cancer Institute: 1-800-4-CANCER.
- Trimetrexate for AIDS-related *Pneumocystis carinii* pneumonia — National Institute of Allergy and Infectious Diseases Hot Line: 1-800-426-7527 within the United States (except in Michigan, where the number is 1-800-833-0014) from 8 a.m. to 8 p.m. (Eastern Standard Time), Monday through Friday.





## Updates

### Retin-A Risky, Unproven for Wrinkles

Tretinoin (Retin-A), an FDA-approved drug for treating acne, has given new hope to consumers searching for the ever-elusive Fountain of Youth. The topical drug, manufactured by Ortho Pharmaceutical Corp., of Raritan, N.J., has recently been reported to reverse premature wrinkling of the skin due to sun damage (photo-aging). But FDA cautions that any benefits may come at the cost of side effects and serious long-term risks.

According to a report in the Jan. 22, 1988, *Journal of the American Medical Association*, all 30 patients in a study by Jonathan Weiss, M.D., and his colleagues at the University of Michigan Medical Center in Ann Arbor showed significant improvements in sun-related skin aging on their forearms treated with Retin-A, as compared with forearms treated with a drug-free cream. The scientists also reported at least slight overall improvement in 14 of 15 patients who used the drug on their faces.

Retin-A is not approved for treating skin aging, but clinical trials of the drug's safety and effectiveness for this purpose are being conducted by Ortho and will be evaluated by FDA when the company submits a new drug application for this additional use. Although doctors can prescribe an approved drug for an unapproved use, many doctors and patients prefer not to use a drug until it has been approved for a new use.

FDA Commissioner Frank E. Young, M.D., Ph.D., cautions that no drug is without side effects. Tretinoin can cause redness, blistering, severe local swelling, and peeling in some patients. Current labeling of the drug also warns that long-term animal studies to determine the carcinogenic (cancer-causing) potential of tretinoin have not been performed and that studies in mice suggest that the drug might accelerate the risk of cancer from ultraviolet radiation. In addition, tretinoin is a compound derived from vitamin A. Other vitamin A-derived drugs and large doses of vitamin A itself have been associated with birth defects, although birth defects are not known to be a problem with vitamin A creams.

For more on wrinkle removers, see "Erasing Wrinkles: Easier Said Than Done" in *FDA Consumer*, July-August 1987.

### Food Irradiation Labeling Extension Proposed

FDA's current labeling requirements for foods that have been treated with irradiation would be extended to April 18, 1990, under a regulation proposed Feb. 18, 1988, in the *Federal Register*.

A regulation adopted by FDA on April 18, 1986, requires that packaged foods approved for irradiation treatment state on the label that they have been "treated with radiation" or "treated by irradiation." In addition,



the label must display a special international logo to alert consumers to irradiated foods. FDA allows certain foods to be irradiated to give them longer shelf life and protect them against insects.

Manufacturers would have been allowed to drop the wording, using just the logo after April 18 of this year had FDA not proposed the extension. The agency decided to propose extending the mandatory labeling language requirement because few companies are producing irradiated food products. "Very few consumers will have seen irradiated food with the required wording before this wording requirement expires," the agency explained, thus they would not know the meaning of the logo by itself.

For more about food irradiation, see "The Growing Use of Irradiation to Preserve Food" in the July-August 1986 *FDA Consumer*.

### Sales Boom for Monoclonal Antibodies

Development and marketing of medical products based on monoclonal antibodies (MAbs) will become a multi-billion-dollar industry by 1993, according to a study published by Frost & Sullivan, Inc., a New York-based market research firm.

MAbs are produced from cell clones, making them identical and highly purified. They are of interest in medical research and treatment because they are able to search out and attach themselves to specific targets, making them useful in both diagnosing and treating diseases. In tumor and cancer research, experimental MAb products had sales of \$10 million in 1987. With FDA approval of additional MAb-based products, sales are expected to reach \$710 million in 1988 and \$4.2 billion in five years, the study says.

Modest capital requirements for the specialized equipment and facilities necessary to manufacture some types of MAbs now in use should attract investors, the study claims.

While in vitro (laboratory) MAb applications are well established, notably for diagnostic testing, the speed at





which the market will grow depends on FDA's rate of approval of products for in vivo (in the body) use, the report points out.

For all applications, both in vivo and in vitro, total sales of MAb-based products amounted to \$275 million in 1986 and \$536.2 million in 1987. By 1993, sales of MAb-based products are expected to total \$8.3 billion.

### **Permanent Reye Warning Proposed**

FDA has proposed that the Reye syndrome warning on aspirin and products containing aspirin become a permanent fixture. The warning was first required on these products in June 1986 as a temporary regulation until the Public Health Service could conclude an epidemiological study confirming the association between aspirin use and Reye syndrome. The temporary regulation expires in June 1988.

The study, carried out from 1984 to 1986 and published in the April 10, 1987, *Journal of the American Medical Association*, verified results of earlier studies that suggested an association between aspirin use by teenagers and children and the development of Reye syndrome. Reye syndrome — characterized by severe tiredness, beligerence and excessive vomiting just when a child or teenager seems to be recovering from the flu — is fatal in 20 percent to 30 percent of cases. Some survivors suffer permanent brain damage.

FDA Commissioner Frank E. Young, M.D., Ph.D., said that the PHS study reinforces the concern over the use of aspirin in children and teenagers with chicken pox and flu-like illnesses. He concluded that the warning label for aspirin products should be made a permanent requirement.

Current aspirin labeling says: "Warning: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome, a rare but serious illness." The proposal to make the label warning permanent appeared in the Jan. 22, 1988, *Federal Register*.

### **Boom Seen in Vitamin, Mineral Sales**

Americans will spend nearly \$2.4 billion a year on vitamin and mineral supplements by 1991, according to a new marketing report by Frost & Sullivan, Inc., of New York City. This figure, up from \$1.95 billion in 1986 and \$2.1 billion in 1987, represents factory-to-distributor sales, so retail mark-ups will take the total even higher.

In analyzing producers with the greatest share of the market, the firm notes that "there are probably more vitamin and mineral manufacturers than there are over-the-counter drug or toiletry manufacturers."

The report examines 13 categories of supplements. Multivitamins and multiminerals accounted for 18 percent of 1987 sales, but Frost & Sullivan forecasts their

growth to be slower than the market average as individual nutrients gain. Calcium and iron are among those predicted to become the fastest growing: 5 percent increases each year. "The barrage of new products and heavy advertising" are cited as the main reasons for the surge in calcium products. As examples, Frost & Sullivan points to an orange juice now fortified with calcium, the market-testing of other calcium-bolstered foods, publicity about the bone-weakening disease osteoporosis, and the tendency to avoid foods naturally high in calcium — such as cheese — because they're also high in fat. The firm attributes the expected increase in iron supplements to the fact that "anemia is recognized as the nation's most widespread nutritional deficiency."

### **Artificial Insemination Precautions**

The Public Health Service has recommended additional precautions for preventing transmission of the AIDS virus through sperm donated for artificial insemination.

Because the virus can be transmitted through sperm, PHS has recommended since 1985 that all prospective sperm donors be tested for the presence of AIDS virus antibodies in the blood. However, there is a period of several months when an AIDS-infected person may test negative because enough antibodies have not yet developed to be detected by the blood test.

Therefore, PHS is recommending that, except in some instances when donated semen is from a donor in a mutually monogamous relationship with the recipient, fresh sperm should not be used for artificial insemination. Instead, FDA, the Centers for Disease Control, and private organizations concerned with sperm banking and artificial insemination now recommend that sperm donated for this procedure be frozen for a minimum of six months before use. The donor should be tested for AIDS at the time the sperm is collected and again at least six months after collection. The frozen sperm should be used only if both tests are negative for AIDS antibodies.

The new recommendation was reported in the Feb. 5, 1988, issue of CDC's *Morbidity and Mortality Weekly Report*.

### **Correction: Safety of Electrical Medical Devices**

FDA's decision not to pursue the establishment of uniform standards for electrical medical devices ("The Notebook," February 1988 *FDA Consumer*) applies only to the electrical safety of these devices. While the agency has determined that the voluntary standards currently being followed by manufacturers already are sufficient to protect patients from electrical hazards, other performance standards may still be required to insure the effectiveness of these devices.



# We're Getting the Message About Diet-Disease Links

by Chris Lecos



During the last 10 years, Americans have been the targets of a growing amount of information about how the foods that they eat, or don't eat, may help reduce their risk of three major killer diseases — heart disease, cancer, and high blood pressure.

This educational outpouring is partly a result of the efforts of various federal agencies and health organizations. But the principal task of spreading the word falls on the shoulders of the mass media, says James T. Heimbach, head of the consumer research staff at FDA's Center for Food Safety and Applied Nutrition. "The government depends heavily on the mass media to carry the message," he said.

One way of measuring the success of these efforts, and the media's impact on the dietary habits of Americans, is FDA's health and diet surveys, which are conducted every two years.

---

## MANY CHANGE FOOD CHOICES

---

In general, says Heimbach, FDA's surveys show that many Americans *do* make changes in what they eat as they gain knowledge about the role that a healthy diet can play in reducing the risk of certain diseases.

The survey data show, for example, that better than 6 out of 10 Americans reported in 1986 that they had made a "major" change in their diets during the previous two years. Although there is a tendency for some consumers participating in surveys to overstate behavior changes, Heimbach added that industry sales data seem to confirm the changes in American eating patterns.

"Sales data show declining consumption of salt, red meat, butter, whole milk, and eggs and increased consumption of such foods as fresh produce and high-fiber cereals," he said. "Our survey data show that consumers in fact give prevention of cancer or cardiovascular disease as the reason for making these changes."

One of the more widely publicized diet/health issues of the 1980s has been the link between sodium and high blood pressure (hypertension), a condition that afflicts an estimated 60 million Americans, leaving them at risk of heart disease, stroke, and other serious illness. Sodium is not the only factor in hypertension, and not everyone's blood pressure is sensitive to sodium. However, FDA felt the evidence of a sodium-hypertension link was strong enough to encourage Americans to reduce their sodium intake through an

*Everywhere they turn, consumers are finding more and more information about diet and health, especially at the supermarket. FDA has found that this health information explosion is affecting many Americans' food choices.*

information campaign started in 1981.

Part of this effort included the adoption of a regulation, which went into effect in July 1986, requiring sodium content information on the labels of packaged foods that include other nutrition information. The regulation also allows manufacturers to voluntarily disclose the amount of sodium in a product, even when nutrition labeling is not required. (For more about FDA's sodium labeling regulation, see "New Regulation to Help Sodium-Conscious Consumers" in the May 1986 *FDA Consumer*.)

---

## PRESENT IN MOST FOODS

---

However, the surveys indicate that most consumers erroneously believe sodium is simply the technical term for salt. Salt, or sodium chloride, is composed of 40 per-

*(Continued on page 9)*



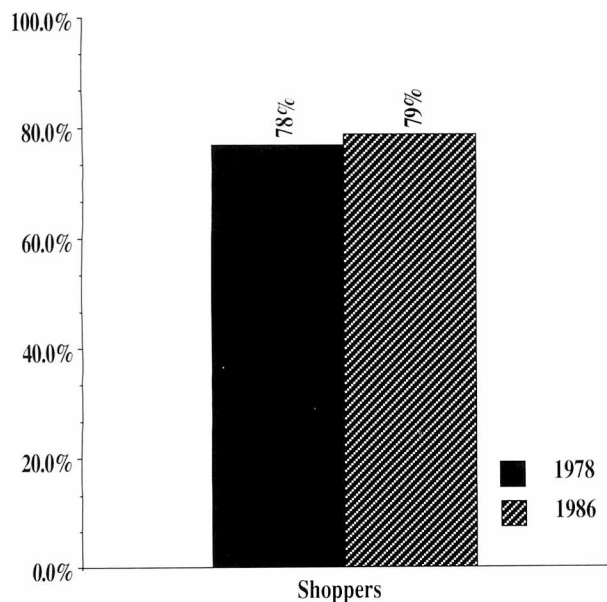
## FDA Surveys Show Diet-Health Trends

The following tables and charts show some of the results of FDA's diet and health surveys of U.S. consumers during recent years. The results point out the impact of various diet-health education efforts by federal agencies and other health organizations.

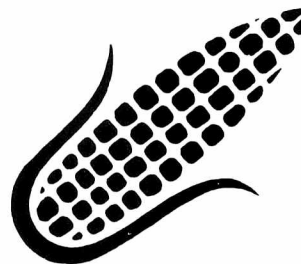
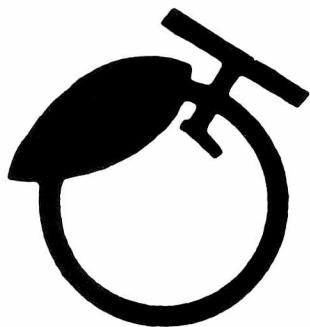
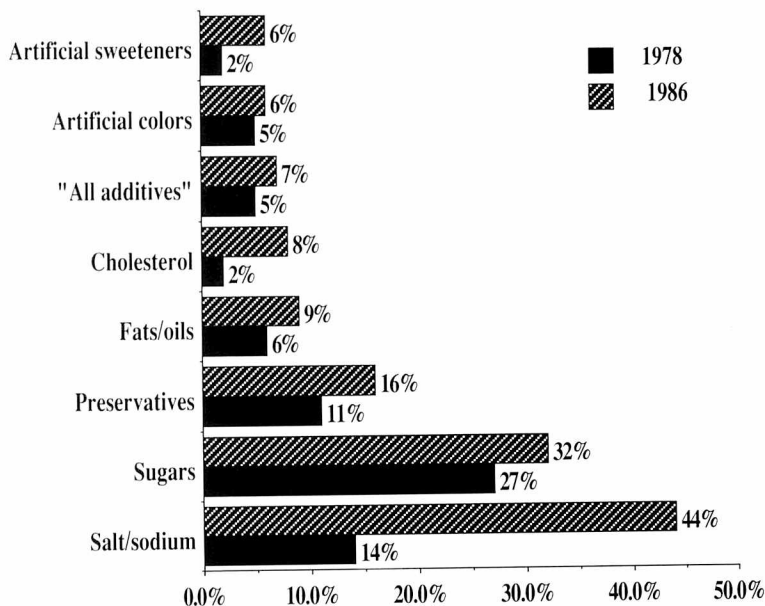


### How Do Shoppers Use Ingredient Lists?

*Shoppers who "pay attention" to ingredient lists*

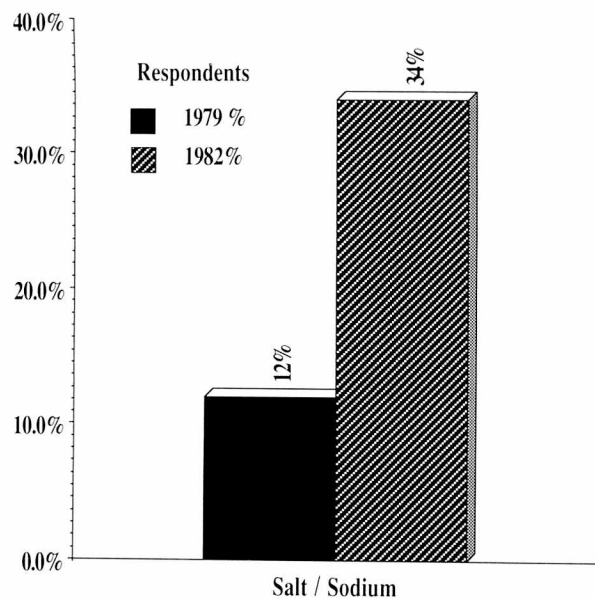


*Shoppers who use lists to "avoid" or limit*

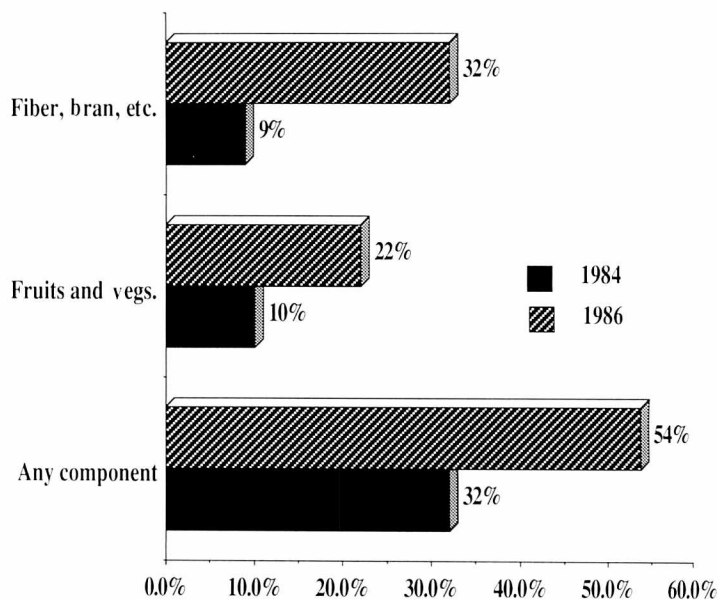




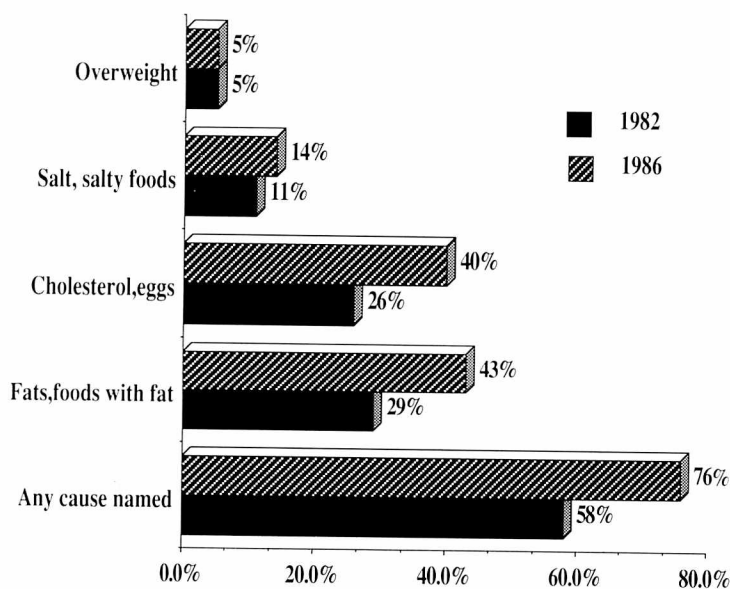
### Survey respondents who perceived salt or sodium as a cause of high blood pressure



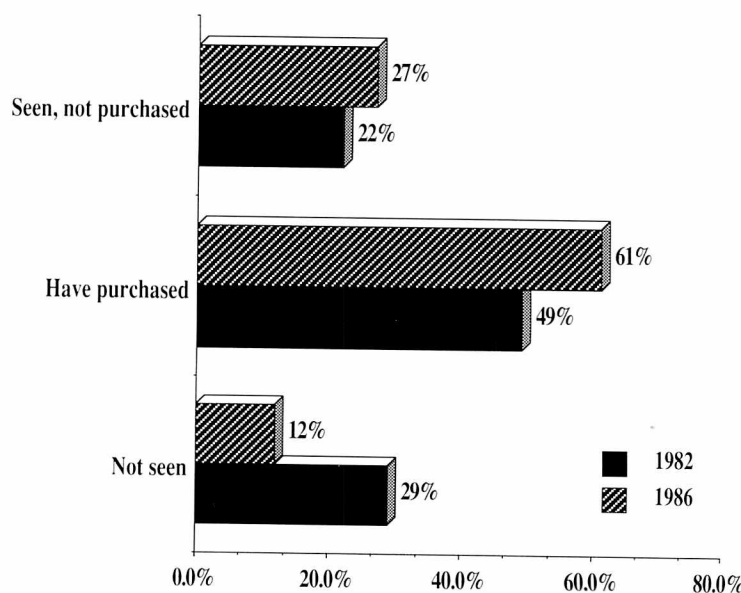
### Dietary Components Believed to Prevent Cancer



### Major Perceived Causes of Heart Disease



### Shoppers' Awareness and Purchase of Low-Sodium Products





(Continued from page 6)

cent sodium and is the most common source of sodium in most people's diets. But sodium — often in forms other than salt — is present in almost all foods.

In 1979, before there was a concerted effort to make people more aware of sodium, only about 12 percent of those surveyed indicated any knowledge of sodium's possible role in high blood pressure. By 1982, the number had nearly tripled, to 34 percent. The campaign's effectiveness was also evident from the responses people gave when asked what food substances they were trying to avoid or limit. In 1978, 14 percent mentioned salt or sodium; by 1986, the number reached 44 percent.

The food industry, at the urging of FDA, started introducing products with less sodium. By 1986, 88 percent of the consumers said they had seen the new products on store shelves, and 61 percent said they had purchased them at least once. Some 16 percent described themselves as regular buyers of sodium-reduced foods.

---

## CHOLESTEROL AWARENESS GROWS

---

In 1982, the focus of the surveys shifted to public perceptions of the major dietary causes of heart disease. That year, 29 percent of the respondents singled out foods with fat, followed by 26 percent who identified cholesterol and eggs. Four years later, the number citing fatty foods jumped to 43 percent, and the number who now felt that cholesterol was a potential dietary villain climbed to 40 percent.

Most of the increase in those percentages could well be due to the spreading of the diet-heart disease messages.

For some years now, heart experts have been urging Americans to eat less fat, particularly saturated fat, and cholesterol to help lower their risk of coronary heart disease.

At the federal level, the National Heart, Lung, and Blood Institute (NHLBI) is coordinating a National Cholesterol Education Program. Also, last October, NHLBI released a report prepared by a panel of experts in blood cholesterol control that called upon all adults 20 or older to have their cholesterol levels checked. In general, the report suggested diet changes as the primary means for controlling and reducing cholesterol levels, but drug treatment as well for those with high blood cholesterol levels that are not reduced through diet changes alone.

While FDA's surveys show a growing public awareness of the dietary links to coronary disease, the surveys also suggest

that many people need to be better informed about this admittedly complex issue. For example, one important way to reduce the risk of heart disease is to eat less saturated fat. Yet the terms that describe the different types of fat are easily misunderstood by consumers.

One example is the word "hydrogenation," a process by which a fat becomes more saturated. Only 11 percent of those surveyed in 1984 and 1986 correctly indicated that hydrogenation made a fat more saturated. Twenty-seven percent thought it meant a fat was less saturated. And only 29 percent knew that a product described as cholesterol-free could still be high in saturated fat.

In 1986, when asked where cholesterol is found, only about one-third correctly indicated it is present only in foods of animal origin (meat, eggs and dairy products). Almost half thought cholesterol was present in anything that contained fat or oil. Such perceptions, however, could change as the public receives more information.

In November 1986, FDA proposed a regulation that would define the terms that could be used on packaged food labels to show cholesterol content. Among the terms of the proposal is a requirement that manufacturers identifying cholesterol content also would have to show the amount of the various types of fat in their products. (See "Cutting Cholesterol? Look to the Label," in the February 1987 *FDA Consumer*.)

In 1984, before heavy publicity — and advertising — about a possible link between high fat and low fiber consumption and various types of cancer, about one-fourth of those surveyed said they were most concerned about food additives as a major dietary cause of cancer; only 12 percent mentioned meat and fats. Two years later, the latter had increased to 19 percent, while 21 percent were mentioning additives, residues and contaminants as the most worrisome dietary cause of cancer.

---

## AD CAMPAIGN SUCCESSFUL

---

The public's perception of the role that diet can play in reducing the risk of cancer sharpened measurably after the Kellogg Co. launched a major advertising campaign in October 1984 promoting its high-fiber cereal. Just before the company's campaign, only about one-third of those surveyed said they had ever heard of any dietary components that might help prevent cancer. Two years later, this rose to 54 percent.

Heimbach said there was little doubt that Kellogg's campaign helped fuel public awareness of the potential benefits of a high-fiber diet and the public's greater interest in high-fiber foods. "The major role in communicating the National Cancer Institute's suggestion of a low-fat, high-fiber diet as a means of preventing certain forms of cancer was . . . left to cereal manufacturers," he said. "That reveals itself when you ask people what are good sources of fiber. Far and away the leading answer — by over two-thirds of the public — is breakfast cereals."

Although the diet/health surveys clearly indicate that many Americans are willing to make changes in their diets if they think doing so will lessen their chances of contracting a major disease, not all the changes are for the better, said Heimbach.

"While many Americans have undoubtedly changed their diets for the better, these changes may be producing distortions in some diets," he said. "The government's overall diet recommendations . . . emphasize the nutrition fundamentals of variety and moderation, but, too often, advice to 'moderate' consumption of a food is translated in the mind of the consumer to 'eliminate' such things as salt, fat, cholesterol, and so forth, in the diet. Some Americans seem to become single-issue dieters, focusing on one or two dietary components, to the detriment of overall good nutrition."

---

## GOOD SOURCES OF CALCIUM

---

Dietitians and nutritionists point out that eggs, meat and dairy products — while generally high in fat and cholesterol — are good sources of calcium, iron and other essential minerals and vitamins. Moderation in the amounts that are eaten is what's important. "The point is that, while reducing fat, cholesterol and sodium may be useful goals," said Heimbach, "they cannot be treated [by consumers] as if they existed in a vacuum."

Also disturbing is the tendency of many consumers to be "more and more controlled by risk avoidance, almost by fear of their food," he continued. "This attitude may cause some people to approach meals and meal planning with grim intensity. What has been lost from nearly all American dietary advice, no matter how well intentioned, is the principle expressed in the Japanese dietary guidelines for health promotion — 'Make All Activities Pertaining to Food and Eating Pleasurable Ones.' "■

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







# FRUIT

Something  
Good  
That's Not  
Illegal,  
Immoral  
Or  
Fattening

by Marian Segal

Is New York the Big Potato? Is life just a bowl of sweet peas? Was Nellie Forbush as normal as sweet potato pie? Of course not. We're talking about fruit, here — apples, cherries, blueberries, peaches, oranges, melons, grapes — the foods that are good for you and taste good, too. Fruits are an important part of a well-balanced diet. They provide fiber and some vitamins and minerals essential to good health. Best of all, most people *like* fruit, countering the myth that anything good is either illegal, immoral or fattening.

---

## EAT FRUIT, NOT FAT

---

Fruits contain carbohydrates and a small amount of protein, but very little, if any, fat. (Most fruits contain less than one gram of fat per serving. Avocados are an exception, with about 31 grams per fruit.) Carbohydrates (starches and sugars) and fats are the primary sources of energy (calories) in the diet. Calories in fruits come mostly from simple carbohydrates; that is, sugars such as fructose, sucrose and glucose. Compared with the early 1900s, Americans today eat more fatty foods and fewer starchy foods, such as breads and other grain products. This trend has doubtlessly helped to contribute pounds and pounds to the shapes of our citizens, because, ounce for ounce, fats contain more than twice as many calories as carbohydrates. In *Dietary Guidelines for Americans*, the U.S. Department of Agriculture and the Department of Health and Human Services recommend reversing the trend, advising that Americans avoid too much fat and eat more foods with fiber and starch, such as whole-grain breads and cereals, vegetables such as

***It's probably a safe bet that little Renee Watkins doesn't know or care that the banana she's about to bite into is a good source of potassium and vitamin A. It looks like the good taste is what she's after. It's the combination of good taste and good nutrition that makes many kinds of fruit appealing snacks.***

dried beans and peas, and fruits.

Of all these foods, fruits have the distinction of being called "nature's own desserts." This is a fitting appellation because, according to a 1987 survey by Market Facts, Inc., snack time is when 43 percent of the people surveyed said they most often ate fresh fruit. Lunch, breakfast and dinner followed at 22 percent, 20 percent, and 14 percent, respectively. The survey also showed that people are eating more fruit than they were a year ago, and the number one reason is snacking, cited by 79 percent of the respondents. Other reasons given were concerns about a well-balanced diet (73 percent), nutrition (61 percent), and calories (61 percent), and getting good value for the money (48 percent).

Bananas, apples, and seedless grapes are the most popular snack fruits, in that order. Kiwi fruit leads the list of fruits people tried for the very first time in 1986, followed by mangoes, papayas, and Granny Smith apples.

---

## VITAMINS AND MINERALS — FRUIT IS GOOD FOOD

---

Why eat berries instead of bonbons? Because fruits contribute fiber and nutrients to the diet, as well as sweetness — and all that without adding lots of calories.

Peaches, apricots, cantaloupes, bananas, nectarines, mangoes and watermelon are sources of carotene, a precursor of vitamin A, an essential vitamin.

Grapefruits, oranges and other citrus fruits and juices, melons, berries, papayas, and kiwi fruit are sources of vitamin C. Among other things, vitamin C helps bind body cells together and increase iron absorption from foods.

Dried fruits — raisins, dates, prunes, and dried apricots — are good sources of iron and potassium; bananas, oranges, and other fruits also provide potassium. Iron

combines with protein to make hemoglobin, which carries the oxygen in red blood cells from the lungs to cells throughout the body.

Many fruits also provide folic acid and magnesium. Folic acid is essential for several chemical processes in the body, including synthesis of the nucleic acids DNA and RNA, and formation of certain amino acids and hemoglobin. Magnesium is involved in cellular metabolism, protein digestion, and nervous system functions.

---

## FRUIT AND FIBER

---

Eating fruit is a good way to add dietary fiber, too. Fiber is the parts of plants that are not digested by humans. The undigested food residue forms bulk for the stool. The skin, seeds and pulp in fruits contribute dietary fiber.

Eating foods high in fiber can promote normal bowel function and is useful in the prevention and treatment of constipation. On the basis of potential benefits, an expert panel of the Federation of American Societies for Experimental Biology (FASEB) has recommended a dietary fiber intake range of 20 to 35 grams per day or 10 to 13 grams per 1,000 calories for healthy adults. (The panel emphasized that this range of intakes may not be appropriate for children, the elderly, or persons on special diets.)

Data on the dietary fiber content of foods are incomplete, but it is known that the American diet is relatively low in fiber. At a USDA/FDA-sponsored conference on food safety and nutrition held in Washington, D.C., last October, Susan Welsh, director of USDA's Nutrition Education Division, cited a 1986 USDA survey showing that women aged 19 to 50 consume an average of 12 grams of fiber a day, with only 1 in 20 women consuming 20 grams. A 1985 USDA survey found that men are doing better at 18 grams a day, but are still below the range recommended by FASEB.

In addition, in all but 12 percent of the women in the 1986 survey, fat intake averaged 37 percent of total daily calories, exceeding the 30 percent level advised by both the National Cancer Institute and the



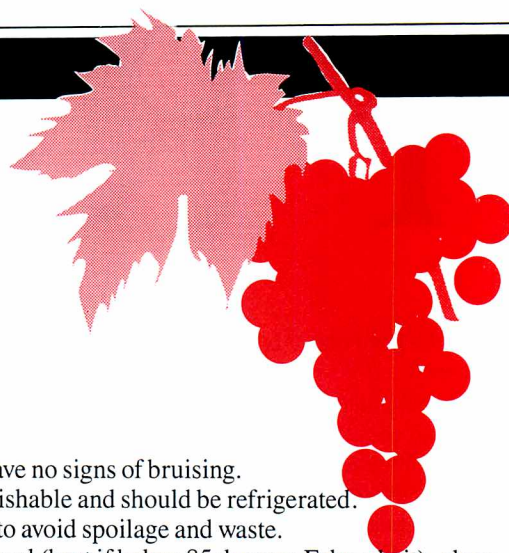
American Heart Association. High-fat (especially saturated fats) and high-cholesterol diets can contribute to an elevated blood cholesterol level, which is a risk factor for heart disease. There is some indication that some forms of dietary fiber may play a role in helping to lower blood cholesterol. It's not yet known whether fiber extracted from food has the same effect as that from intact food, and different forms of fiber have varying physiological effects. The USDA/HHS guidelines and the FASEB panel both advise that the best way to increase fiber intake is to eat a variety of foods and more of those that contain fiber.

The health news about fruit gets better and better because, besides providing some vitamins, minerals and fiber, fruits have no cholesterol and little or no fat or sodium. Whole fresh fruits provide the most fiber. For example, a whole apple with peel provides two grams of fiber, while one-half cup of applesauce provides 0.65 gram of fiber, and three-quarters of a cup of apple juice supplies only 0.25 gram of fiber.

#### **FRESH, FROZEN OR CANNED?**

Processing fruits can cause some nutrient losses. Current information is limited, and variations can occur depending on the product and the processing conditions. Freezing, canning and drying can result in variable losses of vitamin C and vitamin A. Also, canned and frozen fruits are often packed in sweetened syrups, which add extra calories. However, more and more fruits are being packed in water, juice or light syrup.

In defense of canning, National Food Processors Association vice president Roger Coleman claims in the July 1987 issue of the trade magazine *Progressive Grocer* that "one of the biggest misconceptions that people have about canned fruit is that it is full of additives and less nutritious than fresh fruit." He notes that fresh fruits can lose a lot of nutrients between the time they are picked and when they reach the table. However, proper handling both in shipment and at home can help reduce such losses. In the same article, Dan Thornton, marketing manager at Tri/Valley Growers, San Francisco, points out increasing consumer interest in low-sugar, low-calorie products. This is evidenced by a 17.8 percent increase in sales of "light" fruit in cans over last year, and their 24 percent share of all canned fruit sales.



## **Fruity Ideas**

- Select fresh fruits that have no signs of bruising.
- Most fresh fruits are perishable and should be refrigerated.
- Use fresh fruits quickly to avoid spoilage and waste.
- Store canned fruits in a cool (best if below 85 degrees Fahrenheit), clean, dry place.
- Fruits that are cut up should be served just after preparing to prevent vitamin loss. ■

## **Favorite Fruits**

Grapes are the leading fruit crop of the world and the number two crop in the United States. But the majority (57 percent) of grapes grown in this country end up in wine bottles instead of fresh fruit bowls.

Although playing second fiddle to grapes in world production, the fruit that is the top banana of fruit sales in American supermarkets is — you guessed it — the banana.

Coming in third in world fruit production is the apple. There are 7,500 varieties of apples worldwide, with 2,500 varieties available in the United States. The colonists introduced the apple to North America in the 1620s, and the United States is now the second largest producer of this fruit, after the Soviet Union. ■

## **Vitamin A and C Losses in Processed Fruits\***

Processing Method	Loss of Vitamins Compared to Fresh Produce**	
	Vitamin A	Vitamin C
	(%)	(%)
Frozen	37 (0-78)	18 (0-50)
Canned, solids and liquid	39 (0-68)	56 (11-86)

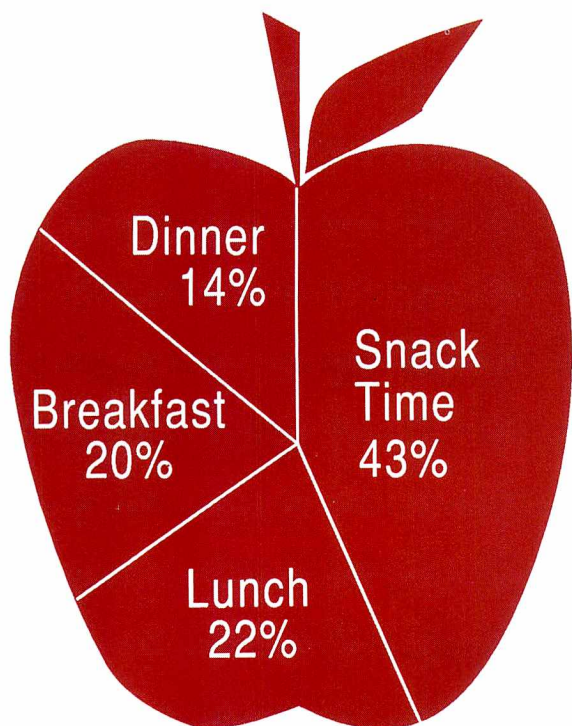
\* Apples, apricots, blueberries, cherries, orange juice concentrate, peaches, raspberries and strawberries.

\*\* Top value is average percentage loss; values in parentheses represent the range of percentage loss.

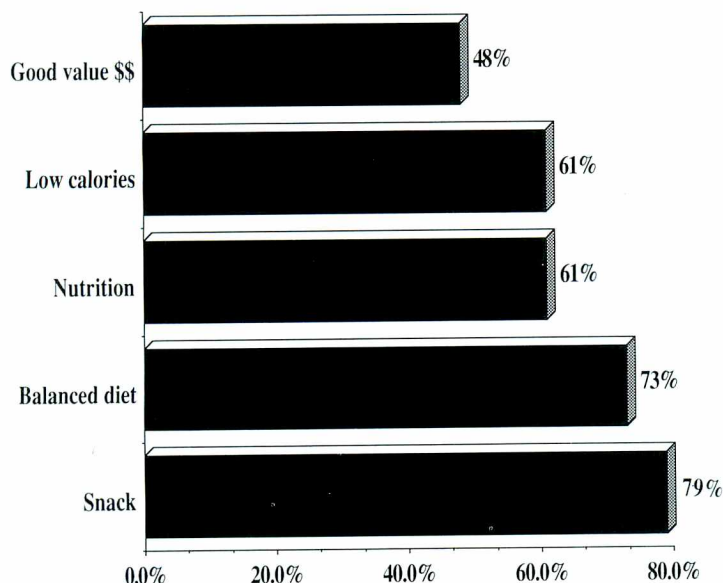
Source: USDA Handbook No. 8, 1963.



## When Do People Eat Fresh Fruit?



## Why Are People Eating More Fresh Fruit?



Source: *The Packer Newspaper* (Focus 1986-1987 supplement), Vance Publishing Corp.

Consumers should read labels carefully, though. Although the word "light" or "lite" on a food label often means it is low or reduced in calories, it can refer to other properties of the food. In canned fruit, "light" syrup refers to its density, determined by the amount of liquid and sweeteners used.

FDA has established standards of identity that apply to many processed fruit products. They include requirements for what may be identified as a particular canned fruit, fruit juice, fruit jelly, or frozen fruit pie, for example, and also requirements for how these foods are to be labeled. In addition, the agency sets minimum standards of quality for some canned fruits, with specific attention, for example, to tenderness, color, and freedom from defects. Other standards regulate how full a container must be to avoid deceptive practices.

Dried fruits have a high concentration of sugar because most of their water content has been removed. Also, drying fruits can destroy vitamin C and carotene unless they are sulfured first, a process in which the fruit is exposed to fumes from burning sulfur or dipped in a sulfate solution. (Sulfites can cause allergic reactions, so people sensitive to these preservatives should read ingredient labels carefully. FDA has required since January 1987 that sulfites be listed on ingredient labels of packaged foods that contain them.)

When buying fresh fruits, consumers should look for bruising because the chemical reactions that occur from bruising cause loss of some nutrients. Nutrients can also be lost by paring, slicing or dicing fruits. Little Bobby may be fascinated by Mom's talent for paring an apple with one continuous intact peel, but without the peel, Bobby's not getting the most from that apple. In fact, the area just under the skin of fruits is usually richer in nutrients than the insides. Slicing, dicing, chopping and mashing can also rob fruits of some of their vitamins by exposing the surfaces to air and light. Breaking up the cells of fruits can account for a significant loss of some vitamins, and the longer the fruit stands, the greater the loss.

Almost any way you cut it, though, fruit has a lot to offer in terms of good taste and good nutrition. ■

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



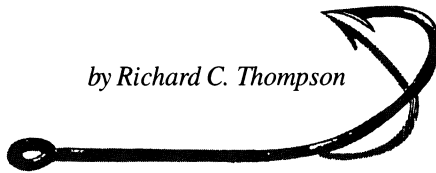




# Fish Stories:

## The Catch to the Catch of the Day

by Richard C. Thompson



There is no such fish as “Cape Haddie,” but somehow six tons of this nonexistent species managed to make its way into the United States, reportedly from Spain, in the hold of a freezer ship early in 1987.

Shore Crest Foods of Norwood, Mass., a subsidiary of a Canadian conglomerate, accepted the import and stored the fish in a warehouse in Perth Amboy, N.J. Shore Crest then sold the shipment to Greenwood Packing of Middletown, N.Y., which paid the Perth Amboy firm to relabel the boxes as “Canadian flounder.”

Now selling at flounder prices, a portion of the shipment went to a wholesaler in Charlotte, N.C. The wholesaler in good faith sold some to local restaurants, then had to take it back when diners objected that it wasn't flounder. Wanting to recover its money, the wholesaler complained to FDA that mislabeled fish had been sent in interstate commerce.

That was the end of the line for the “Cape Haddie flounder.” U.S. marshals seized 1,800 pounds in storage in Charlotte, another 800 pounds at Greenwood's in Middletown, and 10,000 pounds at Perth Amboy. If anyone claims it, they could “recondition” the fish by relabeling the boxes with the proper name. But that would reveal what it really is and where it came from. If no one steps forward to make a claim — in effect, denying any role in these transactions — the seized fish in the various locations could be donated by the courts to local charities as wholesome but mislabeled food.

The agency is not obliged to determine what the fish *is*. That is up to the owner. What matters is that the fish *is not* what it is labeled.

Unfortunately for American seafood lovers, “fishy” fish names are an all too common problem nowadays, sometimes offering consumers more confusion than satisfaction. For unwitting shoppers and

even restaurant diners, there may be a “catch” to the catch of the day.

The law under which the “Cape Haddie” fish was seized is the Federal Food, Drug, and Cosmetic Act, enforced by FDA. This law requires that foods bear labels identifying the product — in this case, fish — by its “common or usual name” as used in the United States. If there is none, a descriptive term that reveals the nature and identity of the food is permitted. No part of the label can be false or misleading. But FDA has no pre-market approval over labels; it is only when a product is offered for sale that the agency can take action.

By FDA definition, the “common or usual name” or “an appropriately descriptive term” is a name used and understood by ordinary consumers in the United States. It does not matter what a fish is called in its country of origin or elsewhere; in the United States it must be labeled with the name by which it is known here.

Mary I. Snyder, of the office of compliance in FDA's Center for Food Safety and Applied Nutrition, is the agency expert on fish names and labeling. She says the requirement is very simple: “Fish must be labeled for what they are. The packer or shipper or distributor must not disguise or upgrade the fish by giving it a more attractive and more marketable name.”

But the industry has trouble meeting that requirement. A visit to supermarkets in Michigan and Indiana reported in *Seafood Business* shows what consumers face in choosing seafood. People making their purchases — many of them inexperienced — will find Atlantic pollock sold as blue cod, Boston bluefish, or blue scrod, depending on the shipper or packer. Then there is *Lophius piscatorius*, which is found off the New England coast and might appear in the markets as monkfish, goosefish, lotte, anglerfish, and sea devil.

How can buyers even guess what they are getting?

“Nomenclature is the single most confusing issue when it comes to seafood,” says industry analyst A.D. Chandler in the trade paper *Seafood Leader*. “Consumers are so frustrated they don't even ask questions anymore, and there's no consumer confidence. The seafood industry has got to come to grips with this.”

One basic problem is that the seafood industry has long believed that the reason one fish sells and another does not is because of the name it carries. There may be some truth to this, but the industry is partly to blame. For years the marketers would talk up certain fish and put down others. Now some of the fish they had promoted, such as cod, sole and ocean perch, are in short supply, while the ones they had ridiculed, such as hake and pollock, are plentiful but have bad reputations. The temptation is to market the latter with the names of more attractive species or to invent a new name altogether.

But a supermarket operator in Michigan found that calling fish what they are did not affect sales. “Changing the name from whitefish to Atlantic hake,” he said, “did not hurt us at all. In one store, it's our top seller. It's the quality, appearance, and our knowledge about the fish that helps it sell.”

FDA and the National Marine Fisheries Service (NMFS) use several references to determine whether a marketed fish or shellfish has an acceptable name. The two most important are:

- The common or usual names established by law or regulation in FDA's Title 21 or NMFS's Title 50 of the *Code of Federal Regulations* and
- The names listed in *Common and Scientific Names of Fishes from the U.S. and Canada*, compiled by the American Fisheries Society and being revised to cover the world.

(Continued on page 17)



# A Fish by Any Other Name...

An entrepreneur in Florida has taken a fish from the genus tilapia — a popular and plentiful food fish — and by cross-breeding has changed it from its natural pink to dark red. He has named it “Cherry Snapper,” saying in his promotional flyers that “red snapper consistently gets the best market prices.” He convinced the U.S. Patent and Trademark Office that his success at imitating red snapper entitled him to a trademark for “Cherry Snapper.”

But he will have difficulty selling it as a food fish in interstate commerce because the Federal Food, Drug, and Cosmetic (FD&C) Act does not permit one genus (in this case, tilapia) to be called by the name of another (in this case, snapper). By calling it snapper, he is representing the tilapia as being a more desirable fish.

That he managed to obtain a trademark is irrelevant, because it was his responsibility to be certain his product complied with the law. “Using the trademark ‘snapper’ on a fish that is not a snapper,” he was told by FDA fish expert Mary Snyder, “is misleading to the American consumer and a violation of the FD&C Act. This agency cannot condone your trading on the popularity and recognition of the food fish snapper to promote your tilapia.”

Tilapia figures in another matter that is getting Snyder's attention.

An import firm in Atlanta is bringing into the United States pond-grown tilapia from Israel that is being sold and promoted as “St. Peter's fish,” the name it is given there. In pseudo-Biblical language, the sales material tells of the fisherman Peter going down to the Sea of Galilee “where he did reel in a wondrous fish whose like there was not other; a beautiful sight to behold and whose flavor was out of this world, and Peter named this fish for himself . . .

“All the people did flock to St. Peter for his scrumptious fish,” says the promotion, adding that tourists returning to America were saddened that they could not find this fish in their markets. But now it comes to the United States “like manna unto the people.”

All well and good, said Mary Snyder in a published comment requested by the trade paper *Seafood Leader*, “but St. Peter's there is tilapia here.”

“In Germany,” she continues, “it is

**Copy of advertisement touting “St. Peter's fish,” which FDA says should be called by its more mundane U.S. name, “tilapia.”**

And it came to pass in the Land of Israel, in the suburbs of Tiberias that a fisherman arose and his name was St. Peter. And St. Peter went down unto the Sea of Galilee that was a fresh water sea, and did reel in a wondrous fish unto whose like there was no other. For the fish was succulent and did taste delicious, yea heavenly unto every last bite.

And St. Peter consumed the fish and it was good . . . yea, it was better than good, it was divine. And St. Peter did know his way around a kitchen, for with the skilled hands of a fisherman he did deftly slice and trim the fish. And the naked fish was a beautiful sight to behold and the flavor was out of this world.

And he named the fish St. Peter's fish after himself and the filet, St. Peter's filet, just for the heck of it.

And though he was a hungry man, to the fish put not weight on St. Peter, and he was exceedingly glad. For he counted his calories and did jog religiously along the banks of the sparkling sea at least thrice a week. And behold the fish was only 2% fat thereof and great in protein.

#### News Traveler's Fast

And the word spread forth across the land (which was not exactly large) and all the people, the men and the women, the married and the single, the professionals, middle management, working women, yea even the yuppies, all did flock to St. Peter for his scrumptious fish. And on Fridays, so great was the number, the line stretched East as far as

## The Miracle of St. Peter's Fish

the Babylonian/Jericho intersection.

#### No Fish Doth Compare

Now it came to pass that there was a strange land far to the West and its name was America. And the people there knew not St. Peter's fish from the Galilee. Indeed only travelers who journeyed to the land of Israel had tasted this fish saying, “WOW! This fish tasteth great!” Yet upon their return their eyes were downcast, for they could not find genuine St. Peter's fish neither in the fish store, nor in the supermarket, nor in the gourmet shops and fancy restaurants. And with heavy hearts they ate their salmon and their trout and their sole and all manner of fish for they were sorely depressed.

#### A New Brand Did Arrive

And more than 1900 and four-score years had come and gone when happily there appeared a new name in fine fish. Yea, and that name was called Harvest Fresh. For behold the people's desire to enjoy freshly-tasted, home-grown St. Peter's fish did now extend from the shores of Israel to the distant land of Georgia USA. And, verily, this desire begat Covenant Aquaculture. And Covenant Aquaculture begat Harvest Fresh.

And the name Harvest Fresh was on everyone's lips and on their T-shirts, too. And Covenant Aquaculture took pity on America and all those people who had missed St. Peter's fishing boat.

#### Wonder of Wonders

And behold in the era of Reagan, in the fifth year of his reign, the folks at Covenant Aquaculture did hear the cry of America and caused a great miracle to happen. Lo, before the eyes of the children of Israel and the adults of Israel, St. Peter's fish did fly.

And the flight was first class. Yea just as the fish had feasted like Kings in the deep, so did they fly royally on a VII-IV-VII Jumbo in a special section which did maintain their cool and their freshness. And the temperature therein was 38° neither more nor less. For otherwise would be an abomination to Harvest Fresh.

#### Fresher Than Thine

And the fish flew non-stop to the land of America and the people rejoiced. For St. Peter's fish was like manna unto them . . . both whole and filet. And St. Peter's fish was on the tables of America the very next day, yea, far faster than ‘fresh’ fish from the Atlantic. For, think on this: How fresh is fish that sitteth for an entire week, gutted and packed like sardines in the hold of a fishy boat, before it idles to port?

For verily, though the whole world was created in but six days, the so-called ‘fresh’ fish taketh longer to get to the fish store.

#### Rejoice, Ye People

And St. Peter's fish found favor in the tummies of all and they did eat their fill of

filet . . . even unto the highest epicures in the land and the chefs of the five star restaurants (even the French). And St. Peter's fish, a.k.a. Galilee fish, was

easy to prepare and could be cooked in many wondrous ways. And the people proclaimed: This fish beareth all others, for with thinly sliced onions, a clove of garlic and just a twist of lemon, it maketh our mouths water. And in the wilderness of their backyards, the people of America did Bar-B-Q St. Peter's fish . . . for there was no tastier fish under the sun.

And they did eat to their hearts' and their wallets' content, for the fish cost not an arm and a leg.

And the fish was consumed throughout the land, from the big cities to the small towns and in the provinces, too. And whosoever serveth it to the stranger in his midst was a heavenly host.

#### And Thou Shalt Demand the Best

So harken unto the rumbling in thy stomachs and when ye enter the local fish store, market or eating establishment, demand thy fish, St. Peter's fish and filet. And when thy fish be served whole, seek out the seal that is affixed thereon. For without the seal it is just a fish.

And verily, all the people across America, both young and old shall agree, that no man knew his fish like St. Peter.

If thou requireth knowledge of the multitude of wondrous ways to cook St. Peter's fish, send thy stamped, self-addressed envelope to:

Covenant Aquaculture  
1936 North Druid Hills Road, N.E.  
Suite 100  
Atlanta, Georgia 30319  
(404) 636-8909



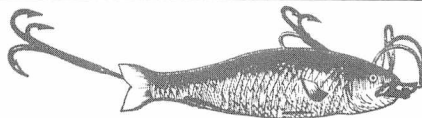
tilapien, in Japan telapia, and in Sweden munravate. In Egypt in the year 2000 B.C. — even before St. Peter — it was known as ‘bulti.’ Should we say the name is ‘bulti’ yet today?

“Verily I say, the FDA careth not what a fish may be called in foreign lands. Whence the fish sets fin in this land, it shall be known as tilapia and as tilapia shall be sold. Not Nile perch, not sunshine

snapper, not St. Peter's fish, not butterball.

“Further, there is already a fish esteemed throughout the world as ‘St. Peter's fish’ and ‘St. Pierre,’ for it bears on its body two dark spots where St. Peter gripped it returning it to the sea. But its name is John Dory, and when this fish crosses into our land it becomes Dory and as Dory it is sold.” ■





(Continued from page 15)

Other lesser sources include the *Multilingual Dictionary of Fish and Fish Products*, *Fishes of the World*, the common names cited in the *Food and Agriculture Organization Yearbook of Fishery Statistics*, market names most often used in the seafood industry, and names suggested by those exporting fish to the United States that properly describe the species, but do not trade on the established name of another species.

America's liking for seafood has made it a prime market for imported fish, and quick freezing and overnight air freight have made it easy to fill that demand from anywhere in the world. FDA's experience with orange roughy from New Zealand illustrates the name games that can be played with fish imports.

Orange roughy came to the U.S. market six years ago as an unknown import from Down Under. Its scientific name is *Hoplostethus atlanticus*, and it is similar to the species *Hoplostethus mediterraneus*, whose common name is "slime head." It would be difficult to market any fish under that name. Because orange roughy was properly descriptive and the name used in New Zealand — and not like any name already in use in the United States — it was accepted by FDA for labeling.

As orange roughy became popular with Americans, less expensive fish began showing up with orange roughy labels to be sold at roughy prices. FDA's Minneapolis district office has investigated several such cases, one involving "golden roughy," which turned out to be croaker and "Pacific roughy," which was grouper chunks.

It's no coincidence that these cases are clustered in that region, because residents of the upper midwest and central states

have developed a liking for imported seafood, in particular New Zealand's orange roughy.

One result of this popularity is that meat dealers and distributors with little knowledge of seafood began adding this and other imported fish to their product lines. These dealers were often easy marks for deceitful distributors, who could exploit the local demand for orange roughy as well as the dealers' lack of knowledge.

The problem of mislabeled orange roughy was shown when a responsible broker offered some at the going rate to one of his accounts in 1987. The Minneapolis dealer said he couldn't use it; he had just taken a shipment from a Florida supplier at 40 cents a pound under the market price.

Roughy prices don't vary that much. What the dealer had was oreo dory, a less choice New Zealand fish that sells at half the price of roughy. In fact, the packages bore counterfeit labels that misspelled the name of Skeggs, the New Zealand packer, as Skeegs.

Snyder, FDA's expert on fish names, obtained frozen samples of genuine orange roughy and oreo dory from New Zealand. Then the agency's Boston laboratory used a precise laboratory technique (isoelectric focusing) to compare the protein bands of the suspect fish with the two samples. (Protein bands are as unique to species of fish as fingerprints are to humans.)

The Florida supplier's "roughy" was confirmed as oreo dory and was seized by FDA for mislabeling. It was later claimed by and returned to the supplier, who insisted he had "bought it as orange roughy and sold it that way."

In another case, Marketing Services International of Minneapolis in mid-1985 purchased several lots of frozen grouper

fillets in bulk and packaged them in retail boxes as "Pacific Ruffie," a nonexistent species that might command orange roughy prices.

When FDA investigators showed interest, MSI took the fish out of the boxes, put them in unlabeled plastic bags, and shipped them as "orange ruffie" (close enough to roughy) to a California broker. But when the broker discovered it was not roughy and the fillets were actually pieces, he rejected the entire shipment. The fish were kept in cold storage in California for almost six months, then returned to Minneapolis.

Knowing the history of the product, FDA's Minneapolis office asked that the fish be seized, saying that "MSI seems willing to put any label on this product if that will help it sell." The seizure was carried out by U.S. marshals. When the fish — edible but mislabeled — went unclaimed, the court donated the lot to a local charity.

FDA's Snyder continues to get complaints about bogus orange roughy, most coming from small distributors in the central and midwest states. And in the mail with those complaints was a product list from a supplier offering "rainbow roughy," a new one to Snyder. "They're calling it '*Arcus pluvius*,' whatever that means," she said. "The fish is certainly not a roughy and we are looking into it."

Although FDA cannot intercept all, or even most, of the misnamed fish — domestic and import — that find their way onto the market, the industry is on notice that FDA is serious about its responsibilities and will act to protect the consumer from this kind of economic fraud. ■

*Richard C. Thompson recently retired from FDA's public affairs staff.*



# *The Silent Epidemic of Hip Fractures*

by Dori Stehlin

A silent epidemic may be hard to imagine. But that is how William G. Winter, M.D., describes the increasing number of hip fractures suffered by older people every year.

Winter, chief of orthopedics at the Denver Veterans Administration Hospital, feels other health problems that are frequently called epidemics get more attention because they affect younger people. "By the time people get around to breaking their hips, they are in the shadows of their lifetimes," he said. "Those people are no longer the focus of society."

But that doesn't mean the epidemic isn't there. Currently, over 200,000 hip fractures occur every year in the United States. Of those, almost 50 percent occur in persons who are 80 or older. Winter points out that "although [hip fractures] have always been a health problem, increasing numbers of older people will incur these injuries as our society steadily greys. We now have the ability to survive until our bones give out."

Most of those people will be women. According to Jennifer Kelsey, M.D., director of epidemiology at the Columbia University School of Public Health in New York, women account for 75 percent to 80 percent of all hip fractures, mainly because of the bone-weakening effects of osteoporosis, a disfiguring, often crippling condition that strikes women far more often than men. (This is due to hormone changes that occur in women after menopause.)

While medical technology offers an array of devices to help repair a broken hip, the best treatment is still prevention. Whether they occur in men or women, fractures of the hip are associated with more deaths, disability, and medical costs

than all other fractures due to osteoporosis combined, according to Kelsey.

The National Center for Health Statistics reports that out of 112,000 people in nursing homes because of fractures in 1985, more than half — 62,200 — had suffered hip fractures.

One out of five of those who do not recover normal function after a hip fracture will die within a year. Of the people who survive hip fractures, 15 percent to 25 percent must remain in nursing homes for at least one year after the fracture. Even for those who are able to return home, about a third of them cannot get around on their own, but must depend on other people or special devices.

---

## **REPAIRING OR REPLACING THE FRACTURE**

---

There are medical devices — complete hips or parts of them — that can replace the damaged bones. These devices are especially important for older people whose bones can no longer grow back together or would take too long to do so.

But the decision to replace the real thing is not taken lightly. "The rule of thumb is whatever they can save, they save," says FDA's orthopedic devices branch director, Thomas Callahan, Ph.D. He says that in a young person whose otherwise healthy bone was broken in a fall, replacement might not be necessary at all — the fracture could be repaired by holding the bone together with a pin.

"That young person is one extreme," says Callahan. "The other extreme is the older patient who has advanced stages of a disease such as osteoarthritis, and all three elements [of the hip] are damaged. Then the physicians will probably go for a total

hip replacement. Then there is a group of people in the middle where it is up to the physician to decide whether the bones that aren't replaced are good enough to last much longer."

Callahan says the trend is towards total hip replacements in the elderly. Winter, of the Denver VA Hospital, agrees. "For those people not strong enough to use crutches, a total replacement will allow them to walk a little without waiting for a fracture to heal," he said.

The three bones these devices replace are the shaft of the femur (thigh bone), the head of the femur, and the acetabular cup. The devices are made of metal, such as stainless steel, or alloys of cobalt, chrome and titanium.

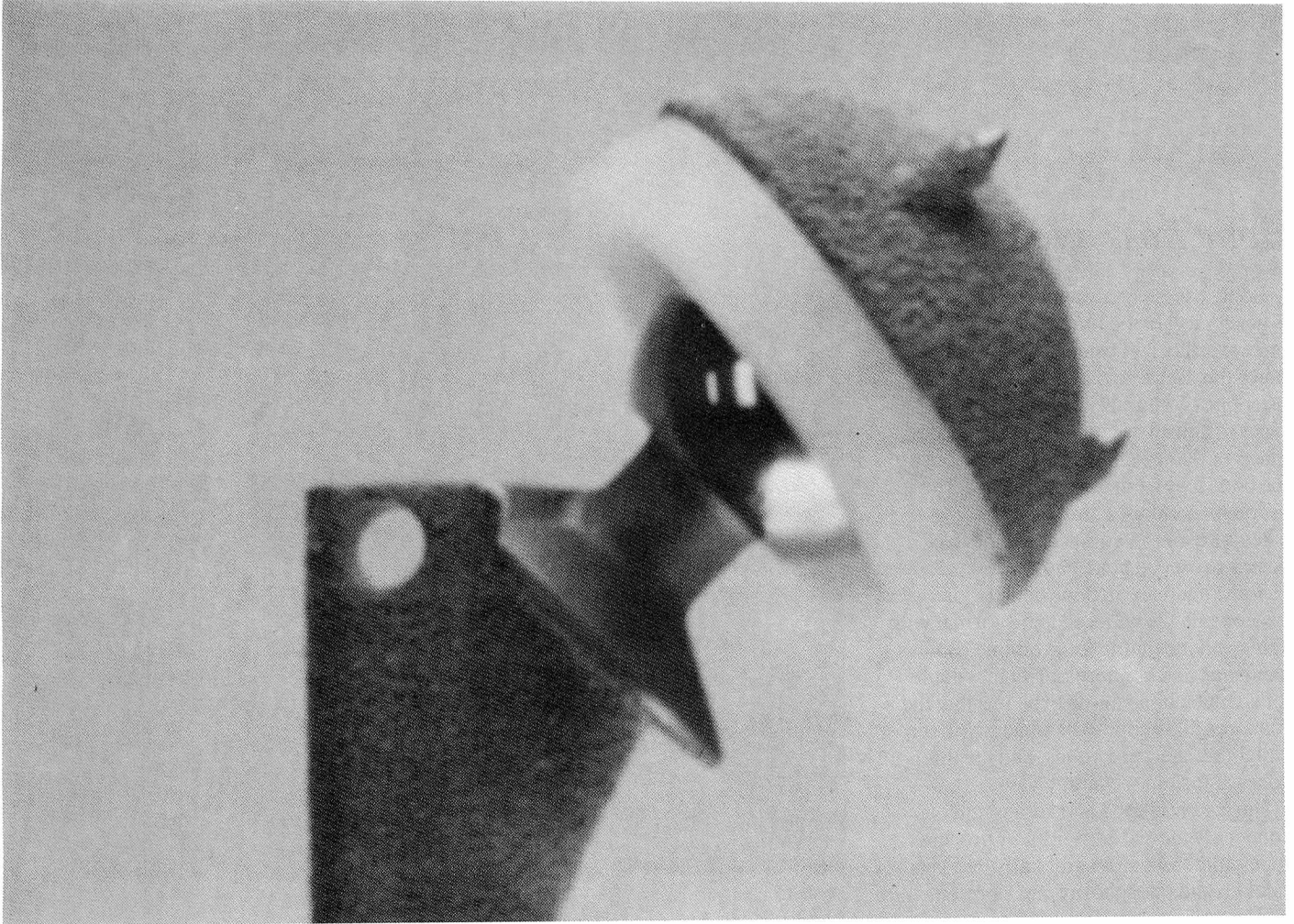
Most of these prosthetic hips have smooth surfaces and must be anchored with a special bone cement. While they work well at first, the cement can loosen over time. "There is still a controversy in the field on whether it's the fault only of the bone cement itself or the fault of the bone cement in combination with the bone-cementing technique, but in either case the cement very often lets go after seven to 10 years," says Callahan.

However, a new hip replacement — the porous, coated prosthetic hip — is being used without cement. These hip-replacement devices have rough surfaces that allow healthy bones to grow into them and hold them in place. "The idea is that if the bone can grow into it, it might make a more stable prosthesis [than the cemented hip] in the long run," says Callahan.

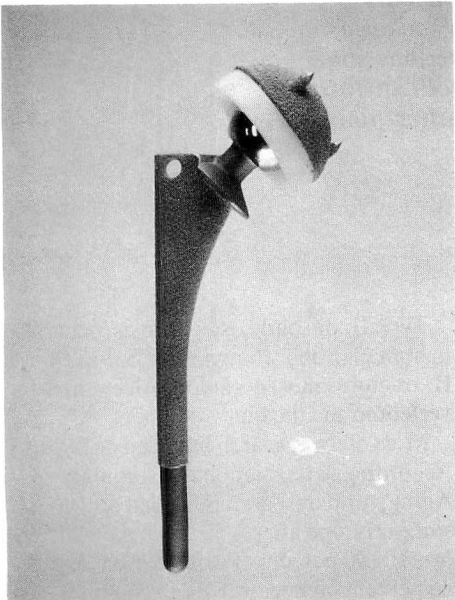
But that is only a theory. So far, the porous, coated hips are working as well as the cemented ones. However, "so far" is only five years, and problems with the

*(Continued on page 21)*





*This porous, coated hip prosthesis has a rough, bead-like surface that, theoretically, allows healthy bones to grow into it and hold it in place. However, questions still remain on whether the bone growth is permanent. (Source: DePuy, a division of Boehringer Mannheim Corp., Warsaw, Ind.)*





## Bone Loss and Gain

Bone loss is not always bad. In fact, it is necessary. In the living bone tissue, one type of cell — osteoclasts — breaks down the tissue, and another type — osteoblasts — builds it back up. These types of cells work together — the osteoblasts build new bone tissue in response to the bone loss from the osteoclasts. The problem — and the cause of osteoporosis — occurs when bone loss begins to exceed bone gain.

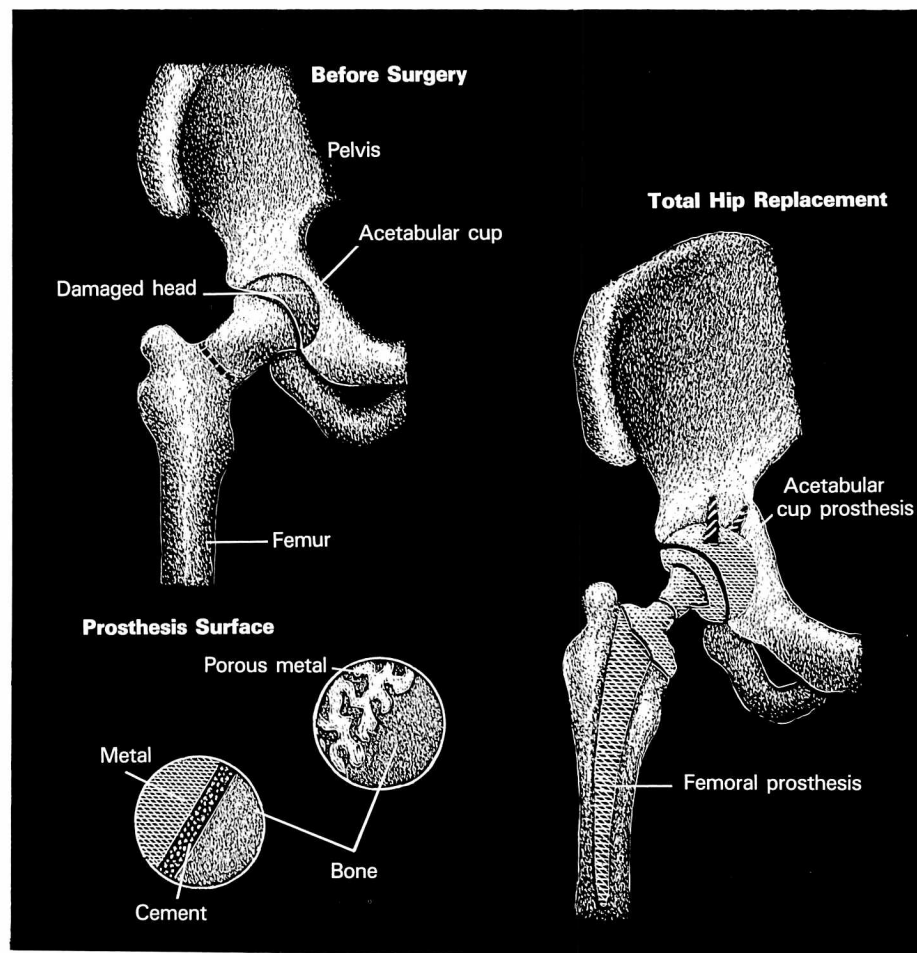
Some decrease in bone density, or “osteopenia,” is believed to be normal with aging and inevitable for everyone. But it’s abnormal and not necessarily inevitable for so much bone tissue to be lost that the fractures of osteoporosis — mainly in the vertebrae, the wrist bones, and the thigh-bones at the hip — occur.

During childhood and adolescence, bone mass increases rapidly. A process called mineralization gradually deposits calcium and phosphorus into a protein framework made by the bone-forming cells. The body’s total bone mass continues increasing this way until the skeleton reaches maturity in a person’s mid-30s. After a short period when the loss and gain of bone tissue is equal, bone loss will begin to win out.

While the mid-30s are the starting point for a gradual increase in bone loss in both sexes, the first few years after natural or surgical menopause can result in very rapid bone loss — and osteoporosis — for some women.

Men and black women are at less risk than white women of developing osteoporosis. One reason may be that they generally have more bone mass at maturity (men have about 30 percent more than women, blacks about 10 percent more than whites). People with greater bone mass presumably must lose more bone than people with less bone mass before the fractures of osteoporosis occur.

B. Lawrence Riggs, M.D., a consultant in endocrinology at the Mayo Clinic in



***A complete hip replacement prosthesis replaces the shaft of the femur (thigh bone), the head of the femur (the part actually damaged in this drawing), and the acetabular cup (the socket of the ball-and-socket joint). The cross sections show how the two kinds of prostheses—smooth surface (lower left) and porous, coated—look after placement next to healthy bone.***

Used with permission from *Postgraduate Medicine*, copyright by McGraw-Hill.

Rochester, Minn., has proposed that there are at least two distinct types of osteoporosis. Type I occurs predominantly in women within the first 15 to 20 years after menopause, and the bones of the lower vertebrae are the most common fracture sites. As vertebrae collapse and wedge together, they cause the rib cage to tilt forward toward the hipbones, forcing the stomach to protrude and the upper spine to curve outward in the familiar dowager’s hump.

Type II, or senile osteoporosis, occurs in both men and women over 75. In Type II, fractures most commonly occur in the vertebrae and the hip.

Most of the research has been on Type I. According to the National Institute on Aging, more research is needed on Type II since this type affects 50 percent of women overall, 90 percent of women over 75, and 25 percent of men over 75. In contrast, Type I affects only 5 percent to 10 percent of postmenopausal women. ■



*(Continued from page 18)*

cemented ones usually don't surface until the seventh year.

FDA is watching the performance of the porous, coated hips. The agency has approved only one such device, which has a rough bead-like surface. In addition, the Orthopedic and Rehabilitation Devices Panel, an FDA advisory committee, has recommended that the agency approve another hip that is covered in a metallic mesh.

The panel said it is not yet clear whether the bone actually holds the prosthesis in place or whether the device stays put because it is pressed very tightly in the femoral canal (a femur — thighbone — that has been surgically hollowed out). The panel also said any bone growth into the prosthesis may not be permanent. Blood vessels, necessary to nourish the bone, may not grow in with the bone or even if they do they might not be functional. This can cause the bone to be broken down by the body (see accompanying article).

Determining the success of the bone growth into the porous, coated hip replacements is difficult. Any bone that might grow into the device is very difficult to see on an X-ray, so growth can only be measured if surgery is required for another reason or the patient dies.

The panel added that it hadn't seen any evidence that the porous hips were any better or worse than cemented ones.

In the meantime, research on all kinds of hip prostheses continues. According to the New York marketing research firm of Frost & Sullivan, Inc., new collagen-based materials, designed to induce bone regeneration, are the focus of a great deal of that research. FDA's Callahan says that the idea behind coating the prosthesis with collagen — a protein that is the chief consti-

tuent of skin, connective tissue, and bone — is to dupe the body into thinking the surface of the hip replacement is really bone. This allows the bone to grow into intimate contact with the prosthesis. Other research is looking into better cementing techniques and modular prostheses with interchangeable components to allow mixing and matching to fit individual patient needs.

"I think we'll see a wave of [new products] very soon," says Callahan.

But traditional devices are still very important and useful, according to Carl Larson, director of FDA's division of surgical and rehabilitation devices. Larson says that of all the people who might benefit from a hip replacement, 80 percent will get more traditional treatment.

---

### LEARNING TO WALK AGAIN

---

Without the surgeon's work — repairing or replacing the damaged bone — a person with a hip fracture might never walk again. But even with surgery, a person who wants to walk must go through months of physical therapy after the operation.

How long does it take someone to get on their feet again? "It depends more on the patient than the device," says Fran Preidis of the National Hospital for Orthopaedics and Rehabilitation in Arlington, Va. Preidis, a clinical specialist in joint replacement, says that health and age can affect the length of recovery, as well as motivation.

Even in the highly motivated, it takes approximately three months for the patient to return to a normal level of activity — and that is with therapy that begins the very first day after surgery.

If there are no complications from the

surgery, patients are encouraged to sit up on the side of the bed the day after the operation. By day two, they should try to stand. How much standing they should do and how much weight should be put on the leg depends on the type of prosthesis.

With cemented hip replacements, patients can put the amount of weight on the leg that feels comfortable to them whenever they want. This is because the cement fixes the prosthesis in place immediately.

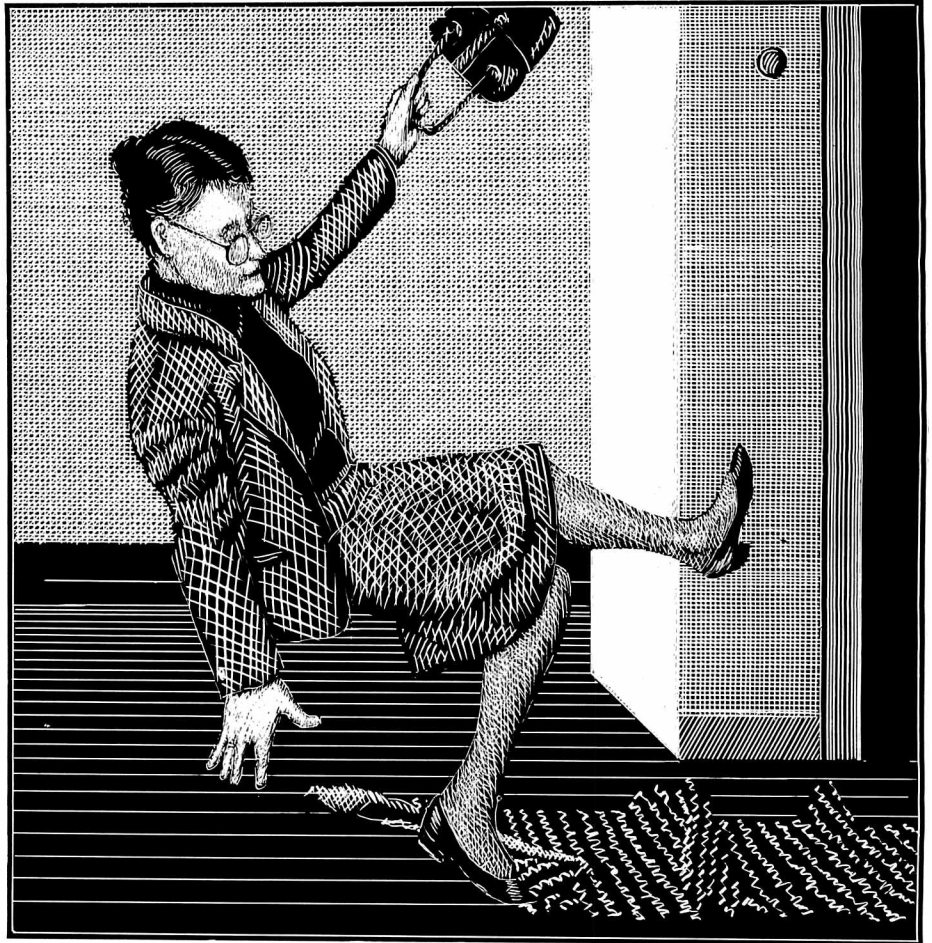
With non-cemented hip replacements, however, bone growth is desired to hold the prosthesis in place, so patients must limit the amount of weight they put on their hips until the support is firm. Usually, therapy begins with six weeks on crutches or a walker, followed by one crutch for four weeks, and two weeks with a cane.

Patients with cemented hips may need to use crutches, too, but usually they're walking sooner than those with non-cemented prostheses.

How much weight should be placed on the hip at what time isn't based solely on the type of prosthesis. "It's up to the physician," says Preidis. "He knows what he has put in and what he wants the patient to accomplish."

Preidis says that some doctors have patients with porous-coated prostheses putting as much weight as possible on their legs as soon as possible after surgery to stimulate bone growth. At the same time, Preidis says that many physicians and therapists are changing the current practice for cemented hips and limiting the initial amount of weight allowed on the leg. This would allow the cement time to set, and any minor damage to the bone

*(Continued on page 23)*



*Recommendations for home safety measures to prevent falls in the elderly*

- Provide handy light switches and good illumination
- Consider night light
- Eliminate extension cords by installing sufficient number of electrical outlets
- Provide toilet facility on same floor near bedroom
- Install high toilet seat
- Install handrails for toilet, bath, and stairways
- Remove castors from furniture; if castors are essential, put furniture against wall
- Make floors, bathtub, and carpets nonslip
- If possible, have home without steps inside or out, or have stairs with small gradient
- Make last step (up and down) a different color



(Continued from page 21)

from the cement, which must be hot when applied to have the proper consistency, would have time to heal.

With both types of implants, exercise, such as riding a stationary bike and swimming, is added to the walking therapy after the first six weeks. These kinds of exercises are needed to increase the range of motion of the joint and strengthen the muscles.

---

### BEFORE THE FALL

---

No matter what the advances in treatment, the best solution is to prevent hip fractures in the first place. The simplest form of prevention is to remove physical hazards from the home. The Office of Disease Prevention and Health Promotion, part of the U.S. Public Health Service, recommends that all staircases have handrails and that halls and staircases be well lit. Hazards caused by loose rugs, unstable furniture, and loose wires underfoot should be corrected. Medical conditions may also lead to falls. "Properly fitted eyeglasses and adequate podiatric [foot] care could reduce the risk of falls," the office said.

Preventing the fragile bones that result from osteoporosis is a more difficult task. Proper calcium intake and exercise early in life can best prevent osteoporosis; however, there are steps that older people can take to slow bone loss.

"The most effective method of reducing postmenopausal bone loss is estrogen replacement," William E. Peck, M.D., professor of medicine at the Washington University School of Medicine in St. Louis, said at a February 1987 workshop on osteoporosis sponsored by the National Institutes of Health. Peck added that

recent studies have shown that oral use of short-acting estrogen preparations (ones that are absorbed and have an effect within a day or two) reduces postmenopausal bone loss throughout the body, including the vertebrae, the hips, and the wrists.

A study reported in the Nov. 5, 1987, *New England Journal of Medicine* established that taking estrogens at any time after menopause cuts the risk of hip fracture by a third. The risk is cut to two-thirds after taking estrogens for two years. While the authors felt that the evidence of estrogen's protective effects was strong, they were unable "to determine the ideal duration and dose" of estrogen replacement.

However, estrogen use may be accompanied by side effects, the major one being an increased risk of endometrial cancer. Taking a second hormone, progesterin, along with the estrogen reduces this risk, but Peck recommends even this combination therapy only for women at high risk of osteoporosis who have not had other medical problems such as breast or endometrial cancer, stroke, or unexplained vaginal bleeding. He adds that women who take estrogen must be conscientious about keeping appointments with their doctors to catch any side effects early.

Peck also promotes calcium and exercise. He says 1,500 milligrams of calcium daily and a program of frequent exercise may reduce the doses of oral estrogen needed to retard bone loss.

The best sources of calcium are dairy products. In addition to calcium, milk contains lactose and vitamin D, both of which help the body to absorb the calcium. Milk also contains magnesium and phosphorus, which are essential to bone growth.

"Drinking milk allows you to get more of these essential nutrients in the right

proportions," says Mona Calvo, a staff fellow in experimental clinical nutrition at FDA's Center for Food Safety and Applied Nutrition. She adds that the same benefits that apply to milk apply to other dairy products.

In addition to dairy products, foods such as canned sardines (with bones), collards, broccoli, and canned salmon (with bones) are also good sources of calcium. The problem with getting enough calcium with foods is that a lot of calories come along for the ride. Those calories may be the reason that many people turn to calcium supplements. However, those supplements have their own set of problems.

Supplements made from bone meal and dolomite, which come from natural sources, can be contaminated with lead and other toxic trace elements. Also, some supplements don't dissolve quickly enough, and the calcium passes right through the body without ever being absorbed.

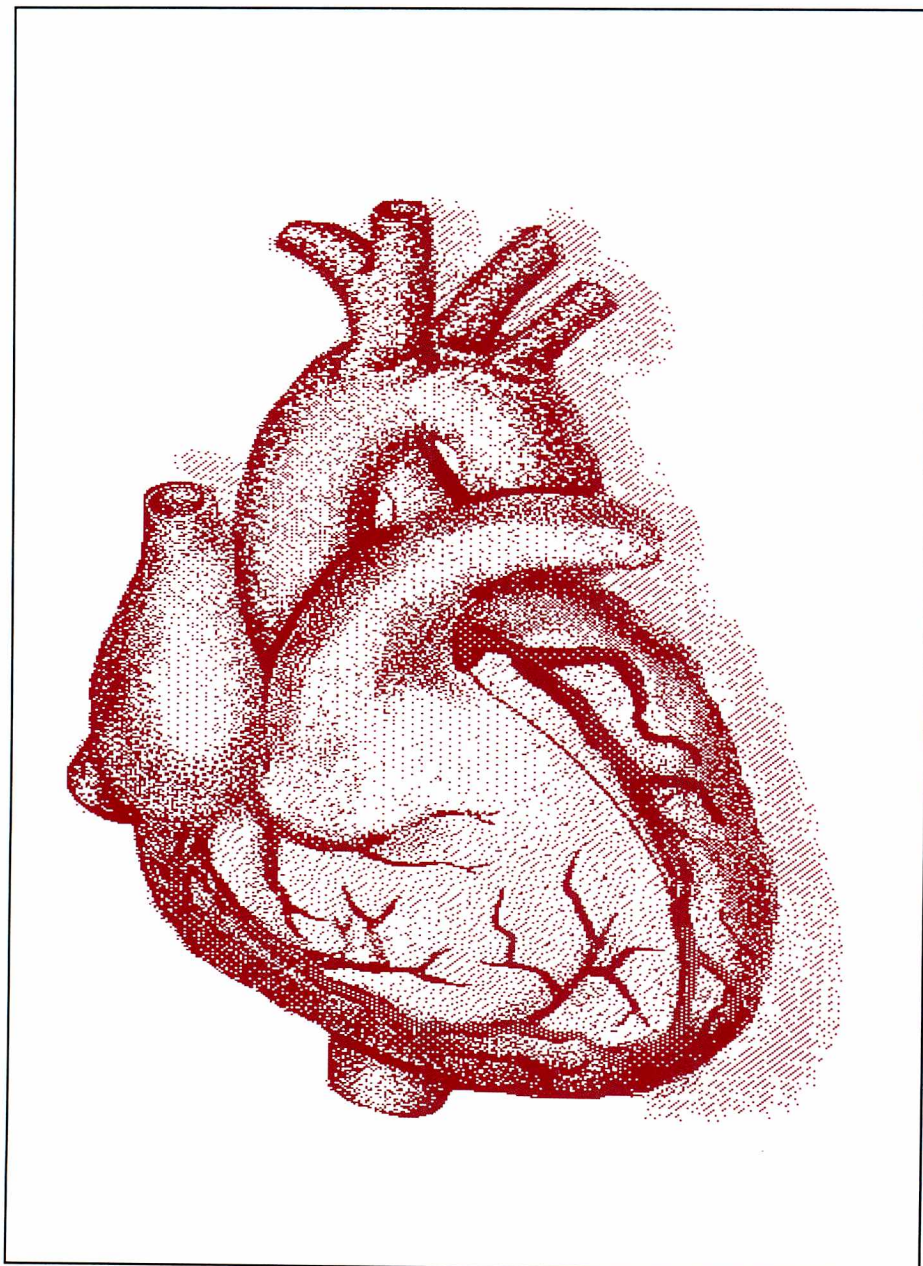
Even as research continues, however, Winter's silent epidemic of hip fractures should not be considered an unavoidable consequence of age. According to Winter, "Orthopedists need reminding that weakened osteoporotic bones might be preventable and that steady advances in osteoporosis investigations and management are occurring. But a fall is also an element responsible for most hip fractures; the consequences of this epidemic of falls in aged people should be examined, just as occupational safety and health experts might evaluate an industrial problem of similar magnitude." ■

*Dori Stehlin is a member of FDA's public affairs staff.*

---

# Balloons to Bypass Bypass Surgery

by Evelyn Zamula



**P**ercutaneous transluminal coronary angioplasty. Quite a mouthful to say and practically impossible to remember. A more common name for the procedure, balloon angioplasty, is not only easier to pronounce, but gives us a clue as to what's involved. A half-inch-long balloon that looks like a tiny hot dog when inflated plays a crucial role in this medical technique.

Balloon angioplasty is an increasingly important alternative to coronary bypass surgery for improving blood flow to the heart. Although angioplasty probably won't ever entirely replace bypass surgery, it is being done more and more each year. Figures from the National Center for Health Statistics show that nearly seven times as many angioplasties were done in 1985 as in 1982; 82,000, up from 12,000. Although many more people have bypass surgery — 170,000 in 1982 and 23,000 in 1985, the rate of increase is much lower. And it's very likely that the number of angioplasties will continue to rise dramatically. So, what is this procedure and why is it so popular?

To pump blood, the heart muscle itself requires a large supply of oxygen-rich blood that is delivered through the coronary arteries. When one or more of these arteries becomes clogged with deposits of fat, the heart may not receive enough blood to do its job properly. Balloon angioplasty widens the artery's channel, helping to improve the blood supply to the heart, while relieving pain and lessening the chances of having a heart attack.

The procedure demands a high degree of skill on the part of the doctor. With the patient under local anesthesia, the physician gently threads a guiding catheter (a thin, flexible tube) toward the heart by



---

*Balloon angioplasty is an increasingly important alternative to coronary bypass surgery.*

entering and passing it through an artery in the leg. The physician carefully watches the catheter's progress on an X-ray screen. A second catheter, tipped with a deflated balloon, is introduced through the guiding catheter and advanced to the constricted area. When the tip reaches the blockage, the tiny balloon is blown up, compressing the soft, fatty deposits against the artery's inner walls. If necessary, the balloon can be inflated more than once. It's then deflated, and the catheter is slowly withdrawn from the body. In the hands of an expert (such as the physician who developed balloon angioplasty, the late Dr. Andreas Gruentzig of Emory University Hospital in Atlanta), the procedure can take as little as 20 minutes. In a day or so, the patient can go home.

Balloon-tipped catheters used in coronary angioplasty are regulated by FDA's Center for Devices and Radiological Health. The first such catheter received FDA approval in March 1980.

Balloon angioplasty seems like a miracle compared to the much more complicated bypass surgery, which involves taking a vein from another part of the body — usually the leg — and sewing it at one end to the aorta (the largest artery coming from the heart) and at the other end to the diseased coronary artery “downstream” from the blockage, thus bypassing the obstruction. This surgery requires general anesthesia, many hours on the operating table, use of a heart-lung machine, and a longer recuperative stay in the hospital.

Neither procedure would be necessary if arteries leading to the heart didn't clog up to begin with. Atherosclerosis — the buildup of fatty deposits known as plaque on the inside artery wall — is a progressive

disease, usually connected with aging, though the process may begin early in life. (Fatty streaks have been found in the arteries of children, and autopsies of young men dying of other causes revealed many cases of advanced atherosclerosis.)

No one knows exactly what causes atherosclerosis. What is known is that people at greatest risk are those who smoke, have high blood pressure, or have high levels of cholesterol in the blood. Other risk factors are diabetes, a sedentary lifestyle, a family history of heart disease, and being male. (In people under 45, coronary artery disease is 10 times more prevalent in men than in women.) Coronary artery disease is the major cause of heart attacks, suffered by almost 700,000 Americans each year.

Besides the coronary arteries, other arteries in the body may be affected by atherosclerosis. When narrowed arteries in the head and neck impair blood flow to the brain, a stroke may occur. Clogged arteries in the legs and feet can cause pain and difficulty in walking. Left untreated, these obstructions interfere with circulation so severely as to cause gangrene, leading to amputation. Insufficient blood flow to the kidneys can cause high blood pressure.

A chilling fact is that many people with coronary artery disease don't know they have it. That's because the heart doesn't begin to complain until its blood supply is severely disturbed. It takes a sizable narrowing — more than 50 percent — of at least one artery before the heart sends out warning signals.

Chest pains are most often the first symptom. They occur when the heart needs more oxygen, usually on exertion, signaling that the blood supply to the heart is

inadequate. This temporary lack of oxygen causes no permanent damage; medicine can relieve the pain known as angina, and permit many sufferers to live normal lives.

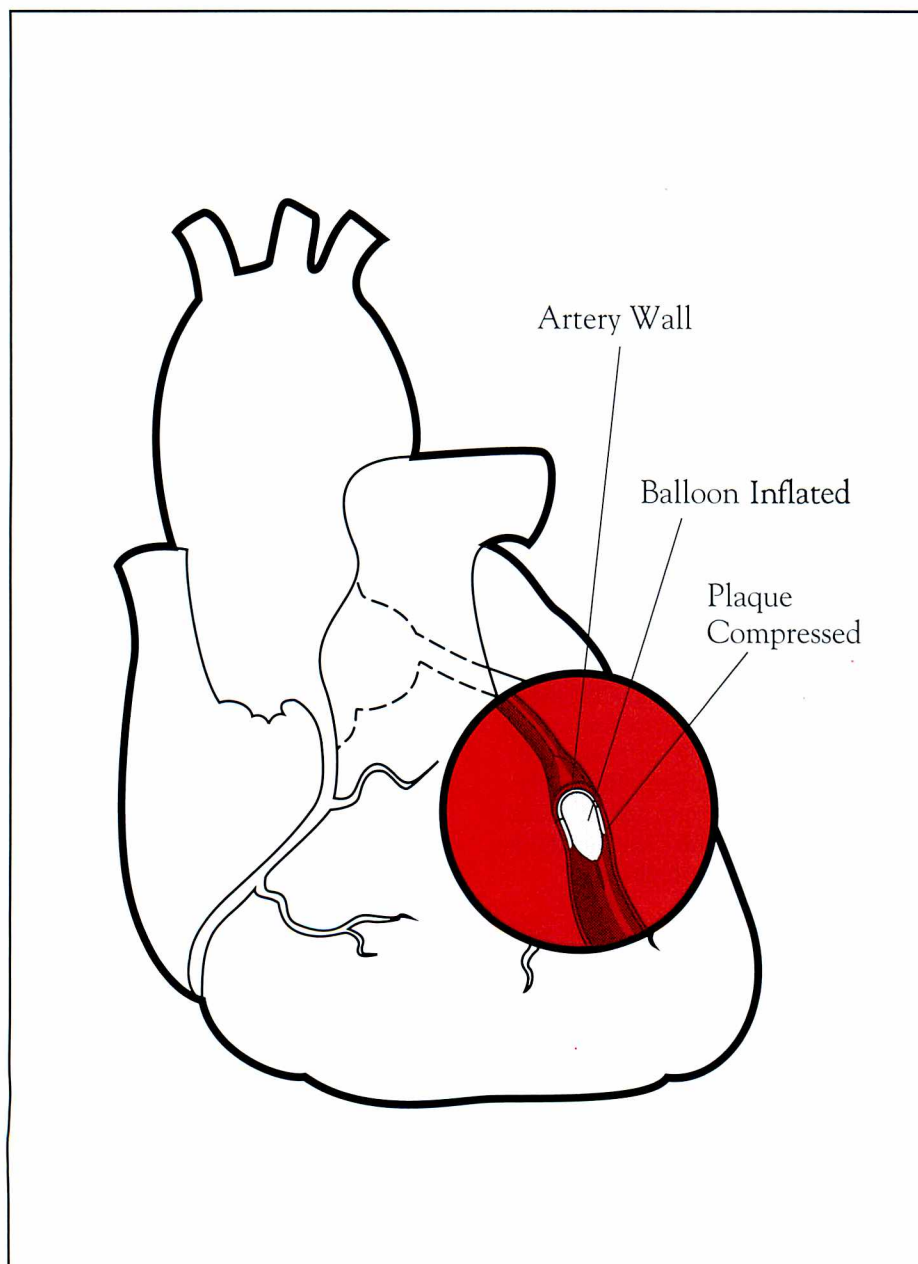
But in time the clogging may become so severe that medication can't control the symptoms. Pain may occur at rest as well as on exertion; the chances of complete blockage and heart attack increase. At that point, the patient may require more aggressive treatment — bypass surgery or balloon angioplasty.

Patient selection is very important. The procedure works best on people who have had angina less than a year, who are under 65, and who have only one obstruction in one artery (though angioplasty is now being done on people with multiple obstructions in all three of the main coronary arteries). The procedure is generally less successful in women than in men. As with any technical procedure, a physician who has done many balloon angioplasties is more likely to have a higher success rate.

Many people are not candidates for angioplasty because the procedure has some limitations. Over half the people with coronary artery disease can't undergo angioplasty because the blockage(s) is too severe or because the heart has been damaged by past heart attacks. Those with an obstruction in the left main artery usually don't qualify either, because angioplasty of this artery — which supplies the largest amount of heart muscle with blood — allows for no mistakes. A nick in the left main artery could cause heart attack or sudden death. Also, plaque that has become calcified (hardened by calcium) may rule some people out, since the balloon doesn't work as well when deposits are hard.

*(Continued on next page)*

Balloon angioplasty opens clogged coronary arteries (as shown below) by compressing the deposits of fat — called plaque — that block the flow of blood to the heart muscle. About 82,000 balloon procedures were done in 1985.



(Continued from previous page)

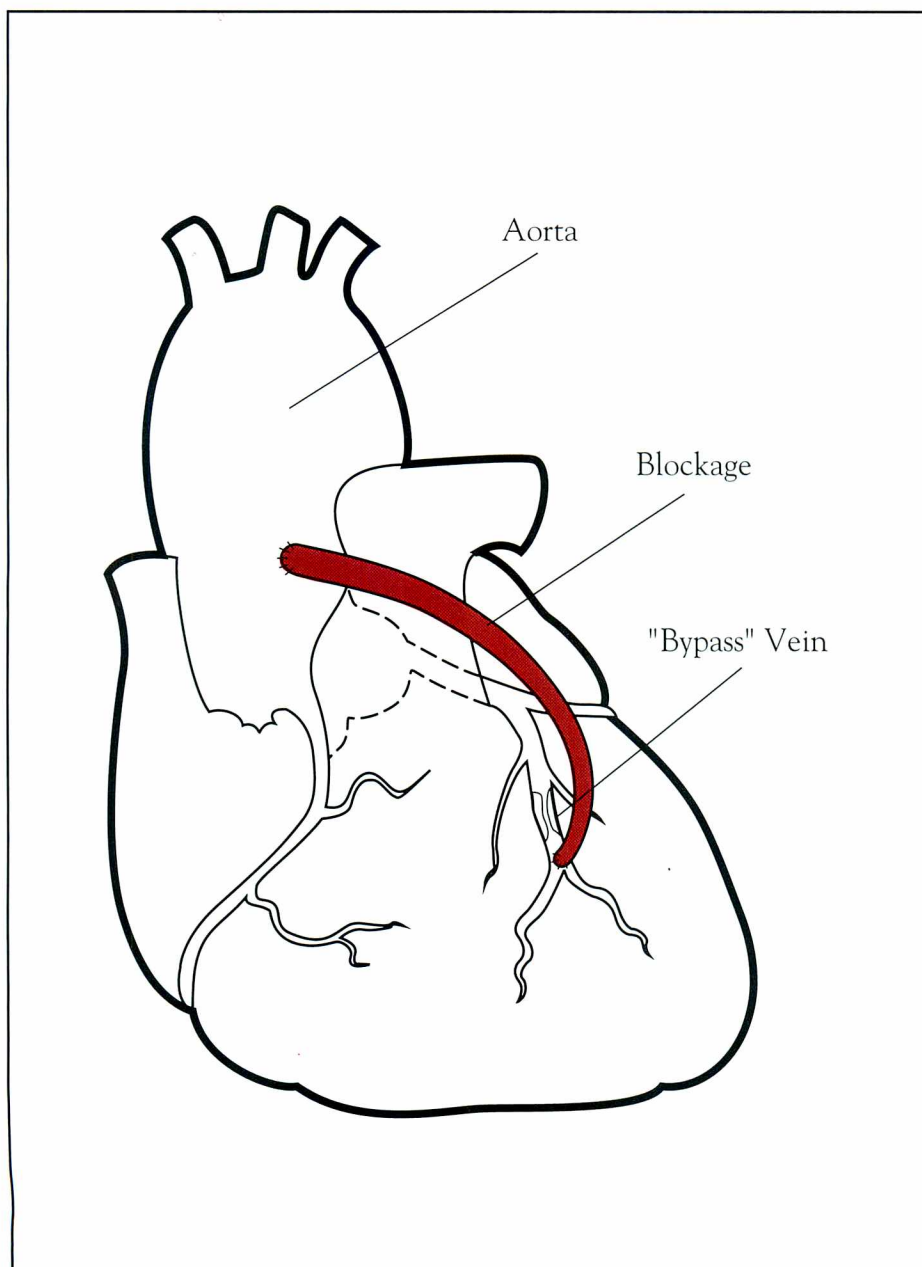
However, doctors are now using a laser device to remove even hardened blockages in leg arteries. Should it prove to be safe and effective in destroying blockages in coronary arteries, FDA could approve it for that use as well. Occlusions must also be accessible by catheter. Even with improved catheters, many blocked areas just can't be reached, especially those located at or after sharp bends in the artery or where the artery separates into two branches. Clogged areas longer than three-fifths of an inch are not suitable for dilation because of an increased risk of damaging the artery with the catheter guidewire. In all, fewer than one-third of persons with coronary artery disease are eligible for the procedure.

Another requirement for balloon angioplasty is that the patient must also be able to undergo bypass surgery. In about 3 percent to 5 percent of patients, the dilated artery immediately closes up again after the catheter is removed, and bypass surgery must be performed right away to prevent a heart attack. For this reason, a bypass surgical team should always be on standby.

Physicians who perform angioplasty must also be prepared for other emergencies, because if an artery is accidentally punctured, blood may fill the sac that contains the heart (the pericardium), causing a buildup of pressure on the heart (cardiac tamponade). Heart failure may result. A heart attack may also occur if a clot forms in the dilated area, or if an artery goes into spasm.



Despite the growing popularity of balloon angioplasty, some 230,000 coronary bypass operations were performed in 1985. As shown below, bypass surgery involves taking a vein — usually from the leg — and sewing one end to the aorta and the other end to the diseased coronary artery, "downstream" from the blockage, bypassing the obstruction.



One problem that is frustrating to some individuals — and their cardiologists — is reblockage of arteries that have been widened by angioplasty. This happens — unpredictably — to about one-third of the patients within a year of the balloon treatment. The reasons for recurrent blockages are unknown. Often angioplasty will have to be repeated — it has been done as often as four times in the same artery — or coronary bypass surgery will have to be performed.

Balloon angioplasty does not cure coronary artery disease. It aims to relieve pain and improve blood flow to the heart, and is successful in about 85 percent to 90 percent of cases. Death following the procedure or death associated with bypass surgery after unsuccessful angioplasty occurs in about 1 percent to 2 percent of the patients, the same as for bypass surgery alone.

Since 1968, the mortality rate from cardiovascular disease has declined about 2 percent a year, according to the *Morbidity and Mortality Weekly Report* (Oct. 24, 1986), published by the U.S. Centers for Disease Control in Atlanta. It may be that changes in lifestyle — increased attention to a healthful diet, exercise, and reduction in smoking — are making a difference. Certainly playing a part are the development of drugs that dissolve blood clots in the heart and arteries, better diagnostic tests, better surgical procedures, and new techniques, such as balloon angioplasty. ■

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

# Brushing Off Dandruff and Other Flaky Afflictions

by Ellen Hale

It's the day of your big job interview. You put on a crisp white shirt and your best dark suit, ready to take on the world. You finally get into that inner sanctum to see your prospective boss, and glance down at your suit.

Oh no. Dandruff.

It's not life-threatening, doesn't make you sick, and says nothing about the state of your health. But for millions of Americans, dandruff and other similar scalp conditions are problems that can be annoying, embarrassing, and even socially devastating.

The good news is that something can be done for nearly everyone who has dandruff or its related disorders, seborrheic dermatitis and psoriasis.

"I haven't seen a patient for whom there is no help," says Dr. C. Carnot Evans, group leader in dermatology in the Food and Drug Administration's division of anti-infective drugs. "Some cases are more difficult than others, but we have such an array of products that we can almost always offer some relief."

Caused not by a dry scalp, as is commonly assumed, these conditions are actually the result of abnormal shedding of the top layers of the scalp's skin cells, or epidermal cells, says Dr. Nia Terezakis, clinical associate professor of dermatology at Tulane Medical School in New Orleans.

---

## SHEDDING CELLS

---

These cells normally form continuously in the lowest layer of the epidermis and work their way to the skin's surface within about two weeks. As they reach the surface, the epidermal cells die gradually and, through normal wear and tear, are routinely shed from the scalp. For most people, this shedding is continuous and imperceptible. For others, however, the rate of shedding is greatly accelerated, resulting in noticeable flaking and scaling.

Dandruff appears with shedding of white or gray scales from small round patches, usually on the crown of the head, but sometimes extending to cover the entire scalp. Itching may be a problem occasionally, but the most common complaint is the unsightly flaking. Dandruff seems to be seasonal, becoming milder in

summer months and more severe from October through December.

"No one knows how many people suffer from dandruff, but certainly millions do," says FDA's Evans. Gender makes no difference in your chances of getting dandruff, nor have any clear familial associations been found. It does, however, appear to occur more commonly in people with oily skin or acne.

Few cases are seen in children between 2 and 10 years, but the condition is common in adolescents. Scaling increases rapidly with puberty and peaks in the early 20s. It diminishes in middle and old age.

Despite its common occurrence and the mental trauma it can bring, no one has yet been able to discover what causes dandruff. Some researchers have attributed it to improper diet, hormonal imbalances, or vitamin deficiencies. A controversial but as yet unproven theory implicates a yeast-like fungus known as *Pityrosporum ovale* (*P. ovale*), but the studies implicating it are less than convincing, argue many researchers. *P. ovale* is a common fungus, and virtually everyone harbors it. Some people with high levels of the yeast, however, appear more likely to suffer dandruff.

---

## SEBORRHEIC DERMATITIS

---

In seborrheic dermatitis, the turnover rate of skin cells is much higher than with dandruff, making it an even more annoying and embarrassing problem. In addition, this condition is marked by inflammation that can cause itching more often than does dandruff. Its characteristic shedding of skin affects not only the scalp but often the eyebrows and eyelashes, external ear canal, behind the ears, in the nasal folds, mid-chest, armpits, between the shoulder blades, and in the pubic and groin area. Like dandruff, no one knows the cause of seborrheic dermatitis, but it appears to run in families, and its severity fluctuates over the years.

A harmless form of seborrhea that occurs in infants and which many new parents become concerned about is commonly known as "cradle cap." The scaly inflammation on the scalp is very common in the first week or two of life, but can occur at any time during infancy. It usually

clears within a month and does not recur, although it occasionally can become severe.

---

## PSORIASIS

---

Psoriasis is a chronic inflammatory skin disease whose symptoms include distinct pink or dull red areas covered with silvery scales. Psoriasis, which strikes the skin and scalp, may persist indefinitely or go into remission for brief periods. From 1 million to 3 million Americans have psoriasis, and the disorder is more common in whites than blacks. Scientists know psoriasis is hereditary; what they don't know is why some people predisposed to it don't develop symptoms.

Stress and anxiety may trigger outbreaks of psoriasis, as can some infections. Some people think emotional trauma may also worsen dandruff or seborrhea, but there's no scientific evidence it does. Certain medicines, such as malaria pills, lithium and propranolol, can worsen it. The condition often clears during pregnancy, only to recur after birth, suggesting that hormones may play a role.

Like dandruff and seborrheic dermatitis, psoriasis usually first appears between the ages of 10 and 30, and, except in severe cases, does not usually affect a person's general health.

Although there are no cures for these skin conditions, dandruff, seborrheic dermatitis, and psoriasis usually respond to treatment, which is often similar for all three. Most cases can be controlled with simple topical treatments, although severe cases of seborrhea or psoriasis may require more intensive therapies.

---

## HAIR IN THE WAY

---

In recent years, psoriasis sufferers have found relief in a new medical treatment using long-wave ultraviolet radiation in combination with psoralen, a drug that enhances the skin's sensitivity to the light. These PUVA treatments, as they are called (for psoralen and ultraviolet-A), effectively control psoriasis, but do not cure it. PUVA typically is used as a last resort for patients who have not responded to other therapies. (See "PUVA's Double Whammy" (Continued on page 30))



*Dandruff, seborrhea and psoriasis result from an abnormal shedding of cells from the top layers of the skin—the epidermis. Shedding of epidermal cells is normal and, for most people, continuous and imperceptible. But for those with dandruff or related conditions, the rate of shedding is much faster, resulting in noticeable flaking and scaling.*

An area of skin  
in cross section

Epidermis

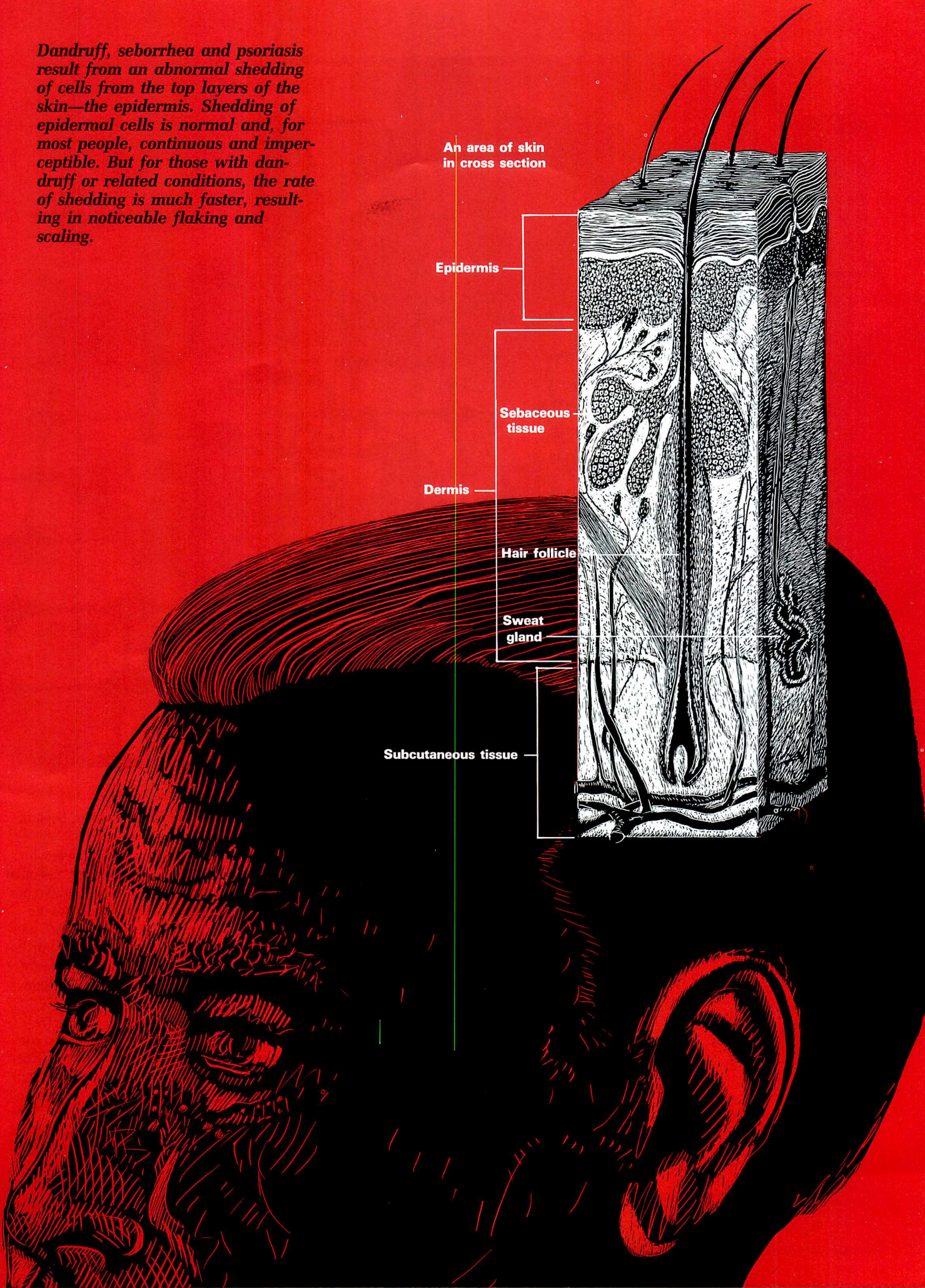
Sebaceous  
tissue

Dermis

Hair follicle

Sweat  
gland

Subcutaneous tissue







*Sometimes ordinary shampoos can control dandruff and related conditions, but when they don't, medicated shampoos and other over-the-counter drugs, such as cortisone creams and lotions, are available. Some experts believe that cortisone preparations shouldn't be used for more than a month without consulting a doctor.*

*(Continued from page 28)*

on Psoriasis" in *FDA Consumer*, September 1982.)

PUVA is of little value for people with conventional dandruff, however, and often does not work for those with psoriasis of the scalp. "That's probably because the hair gets in the way of the treatment," says Dr. Alan Moshell, director of the skin disease program at the National Institute of Arthritis and Musculoskeletal and Skin Diseases in Bethesda, Md.

"Plain dandruff may just require frequent shampooing" — often with just conventional shampoos, says Moshell. Other self-treatment options include medicated shampoos and other over-the-counter drugs. At best, these drugs and shampoos only control the scaling and flaking of scalp conditions, and they must be used regularly to work, stresses Moshell.

Such self-treatment products fit into a number of categories, although some may



*Dandruff, seborrhea and psoriasis result from an abnormal shedding of cells from the top layers of the skin—the epidermis. Shedding of epidermal cells is normal and, for most people, continuous and imperceptible. But for those with dandruff or related conditions, the rate of shedding is much faster, resulting in noticeable flaking and scaling.*

An area of skin  
in cross section

Epidermis

Sebaceous  
tissue

Dermis

Hair follicle

Sweat  
gland

Subcutaneous tissue







*Sometimes ordinary shampoos can control dandruff and related conditions, but when they don't, medicated shampoos and other over-the-counter drugs, such as cortisone creams and lotions, are available. Some experts believe that cortisone preparations shouldn't be used for more than a month without consulting a doctor.*

*(Continued from page 28)*

on Psoriasis" in *FDA Consumer*, September 1982.)

PUVA is of little value for people with conventional dandruff, however, and often does not work for those with psoriasis of the scalp. "That's probably because the hair gets in the way of the treatment," says Dr. Alan Moshell, director of the skin disease program at the National Institute of Arthritis and Musculoskeletal and Skin Diseases in Bethesda, Md.

"Plain dandruff may just require frequent shampooing" — often with just conventional shampoos, says Moshell. Other self-treatment options include medicated shampoos and other over-the-counter drugs. At best, these drugs and shampoos only control the scaling and flaking of scalp conditions, and they must be used regularly to work, stresses Moshell.

Such self-treatment products fit into a number of categories, although some may



contain more than one active ingredient. The active ingredients include coal-tar preparations, salicylic acid, selenium sulfide, sulfur, and zinc pyrithione. Usually, they are found in "pre-shampoo" preparations, shampoos, rinses and hair dressings. (For more information, see the FDA-proposed monograph on over-the-counter drug products for control of dandruff, seborrheic dermatitis, and psoriasis, published in the July 30, 1986, *Federal Register*.)

---

### DRUG TREATMENTS

---

The treatment categories of over-the-counter products for these conditions include:

- **Antimicrobials:** The effectiveness of these products is based on the theory that microorganisms like *P. ovale* are the cause of scalp disorders and that the hair "traps" them. However, researchers have yet to prove that dandruff-like problems are caused by such microorganisms. Shampoos containing zinc pyrithione are intended to fight such microbes, and they do appear to control embarrassing scalp conditions, but scientists don't know exactly how they work.
- **Keratolytics:** These products don't prevent scales from being formed, but do appear to loosen scales and allow them to be more easily washed away. Lotions containing salicylic acid fit into this group, as do those with precipitated sulfur.
- **Antipruritics:** These products curb the pain and itching that sometimes accompany scalp conditions and, therefore, supposedly slow down the flaking and scaling. Before corticosteroids became widely used, these were much more commonly employed than they are now. Menthol is one active ingredient in antipruritic products.
- **Corticosteroids:** Now among the most commonly used anti-dandruff treatments, corticosteroids, or cortisone preparations, work as antipruritics, relieving itching and thereby slowing down flaking. However, they have the added benefit of being anti-inflammatory, reducing the redness and swelling that contribute to scalp conditions. Cortisone preparations are a relatively new weapon in the fight against dandruff and other scalp conditions. Some experts believe they shouldn't be used continually for more than a month without consulting a doctor.
- **Coal-tar solutions and extracts:** These preparations — formulated with a

byproduct of treated bituminous coal — have been used for thousands of years to treat the skin. Precisely how they work is unclear, but several theories have been proposed. One holds that coal tar takes oxygen from the skin, thereby inhibiting cell reproduction and causing a decrease in the number of cells that can be shed from the scalp. Coal tars in various soaps and shampoos may also work by penetrating the outer skin layers and removing scales.

Because coal tars are messy and smelly and stain the skin and hair, they were initially put into lotions, shampoos, bath oils, and liniments, with other ingredients to help mask these problems. More recently, manufacturers have emulsified tar into a gel that is not only effective but much more cosmetically acceptable. Coal tars tend to increase susceptibility to sunburn, however, so specialists warn that users should avoid exposing their skin to sunlight for 24 hours after use. Nor should coal-tar products be used for prolonged periods without consulting a doctor, and they shouldn't be used with psoriasis therapies, such as PUVA, without first consulting a physician.

---

### ALTERNATE TREATMENTS

---

"For severe forms of dandruff, coal tars, salicylic acid, and zinc pyrithione seem to work best," says Tulane's Terezakis, who adds "people tend to respond better if they alternate the various types."

She also offers this advice:

"Don't scratch your scalp. Many people have a tendency to scrape or scrub seborrhea out of the scalp, which only makes it worse. The more they scratch, the thicker the skin will get and the more it itches. Avoid too vigorous scrubbing, which won't get the seborrhea out and actually may make it worse."

It's impossible to prevent seborrhea, but it can be kept under control by regular use of over-the-counter tar shampoos that are worked into the scalp and left on for several hours and then washed out. Also, she says, begin to treat it as soon as you notice it.

For the many people who are not helped by over-the-counter treatments, prescription drugs are available. Most popular, according to FDA's Evans, is a selenium sulfide suspension, a topical product used in place of shampoo to cut down on scaling, itching and other signs and symptoms of dandruff and other scalp conditions.

The concentration of selenium sulfide in this suspension is higher than that allowed in over-the-counter preparations.

Some scientists believe selenium sulfide is one of the most effective medications against *P. ovale*. Possibly, they propose, it is converted into ions that block the enzymes responsible for the growth of cells on the outer layer of the scalp. Whatever its mechanism, it does apparently slow the rate of cell turnover and reduce scaling when used in concentrations of 2.5 percent — the prescription strength. Over-the-counter dandruff shampoos contain up to 1 percent concentrations of selenium sulfide; these products are used to control milder cases of scalp disorders.

The second most common prescription medications are steroid lotions that reduce inflammation and suppress itching. These products have long been widely used to treat a number of skin problems.

---

### NEW ANTI-FUNGAL CREAM

---

Recently, FDA approved a new anti-fungal cream, called ketoconazole, available only by prescription, which has been shown to be effective in treating dandruff. Again, researchers believe the cream works by acting on the *P. ovale* organism. Yet, according to Evans, some of the patients who had the best results with ketoconazole had the least reduction of *P. ovale* on their scalp.

As with all drugs, there may be side effects from use of dandruff-controlling agents, warns FDA's Evans. People using selenium products sometimes complain they discolor their hair. Some people using prescription products have complained of excessive dryness of the hair, itching, and even hair loss.

But, says Evans, "it's hard to know what is cause and what is effect here. What we tell people is that they should discontinue the product and see a physician if itching or discomfort result."

For most dandruff sufferers, however, a little discomfort is worth it to get relief from a problem that ranks low on the list of the world's health issues, but high on the embarrassment scale.

Says Evans: "Dandruff may not be a major health problem, but it's certainly annoying and something you definitely want treated if you have it." ■

*Ellen Hale is a free-lance writer in Washington, D.C.*



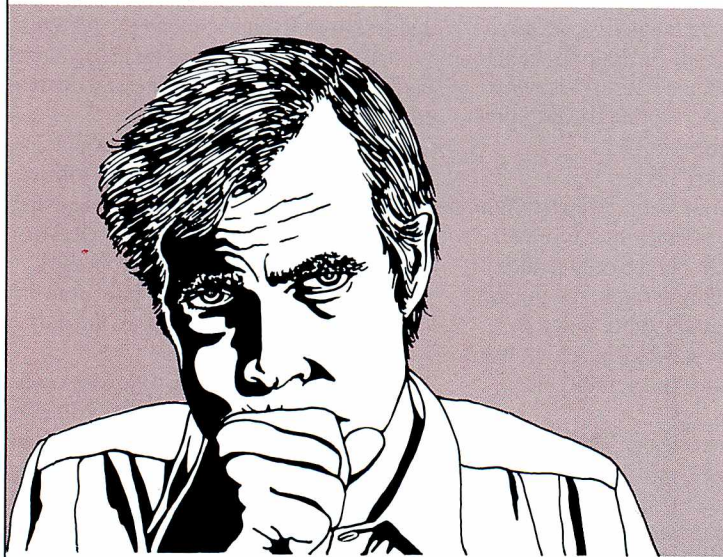
## The Notebook

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

■ **FDA's bioequivalence requirements for generic drugs** are scientifically sound and do not require any major changes, according to a report by the agency's Bioequivalence Task Force. The report is available from the Dockets Management Branch, FDA, Room 4-62, 5600 Fishers Lane, Rockville, Md. 20857 (FR Feb. 29).

■ FDA has established a new division that will be primarily responsible for reviewing potential anti-viral and other anti-infective treatments for AIDS and infections associated with the disease. This **division of anti-viral drug products** will review all other anti-viral agents as well.

■ Because a consumer survey indicates that the terms "bloating," "pressure," "stuffed feeling" and "fullness" are very meaningful to and used by consumers in describing what is commonly, if not accurately, referred to as "gas," FDA has proposed to allow these terms to be used on the **labeling of over-the-counter antiflatulent drug products** (FR Jan. 29).



■ **FDA's action levels for unavoidable added poisonous or deleterious substances** — such as aflatoxin in corn — are guidelines rather than substantive rules, the agency announced. FDA stressed that food producers have never been immune from prosecution just because contaminants are below the action level. Legal action by the federal government depends not only on the action level, but also on other factors, such as the amount of food involved and the risk to health (FR Feb. 19).

■ A guideline for use of the LAL (**limulus ameobocyte lysate**) test to detect bacterial toxins in human injectable drugs, animal injectable drugs, and medical devices is available from FDA's Dockets Management Branch, Room 4-62, 5600 Fishers Lane, Rockville, Md. 20857 (FR Feb. 19).

■ To help protect the rights and safety of **people participating in clinical trials** of drugs, medical devices, and other products regulated by FDA and to insure the quality and integrity of the study data, FDA has developed a guideline for monitoring these tests. "**Guideline for the Monitoring of Clinical Investigations**" is available from the Dockets Management Branch (address above) (FR Feb. 17).

■ FDA also has prepared a draft guideline to help manufacturers ensure that investigational new drug products comply with the agency's current good manufacturing practice regulations. "**Guideline on the Preparation of Investigational New Drug Products**" is available from the Dockets Management Branch (address above) (FR Feb. 26).

■ **Chik-Chek**, a mail-order bacterial test used to detect *Salmonella* bacteria in raw chicken, is neither accurate nor useful, according to the U.S. Department of Agriculture's Food Safety and Inspection Service. In laboratory tests conducted by the department, Chik-Chek gave excessive false negative and false positive results and even indicated that bacteria were present in sterile lab solutions.

■ A cumulative list of designated **orphan drugs and biologicals** (as of Dec. 31, 1987) is available from the Dockets Management Branch (address above) (FR Jan. 29).

■ The Commissioner of Food and Drugs can now deny a **request for a regulatory hearing** before the agency if no "genuine and substantial issue of fact" has been raised by the requester (FR Feb. 17).

■ In a notice of proposed rule-making to establish conditions under which over-the-counter **digestive aid drugs** are generally recognized as safe and effective, FDA is requesting information on digestive aids promoted for people intolerant of foods containing lactose (FR Jan. 29).

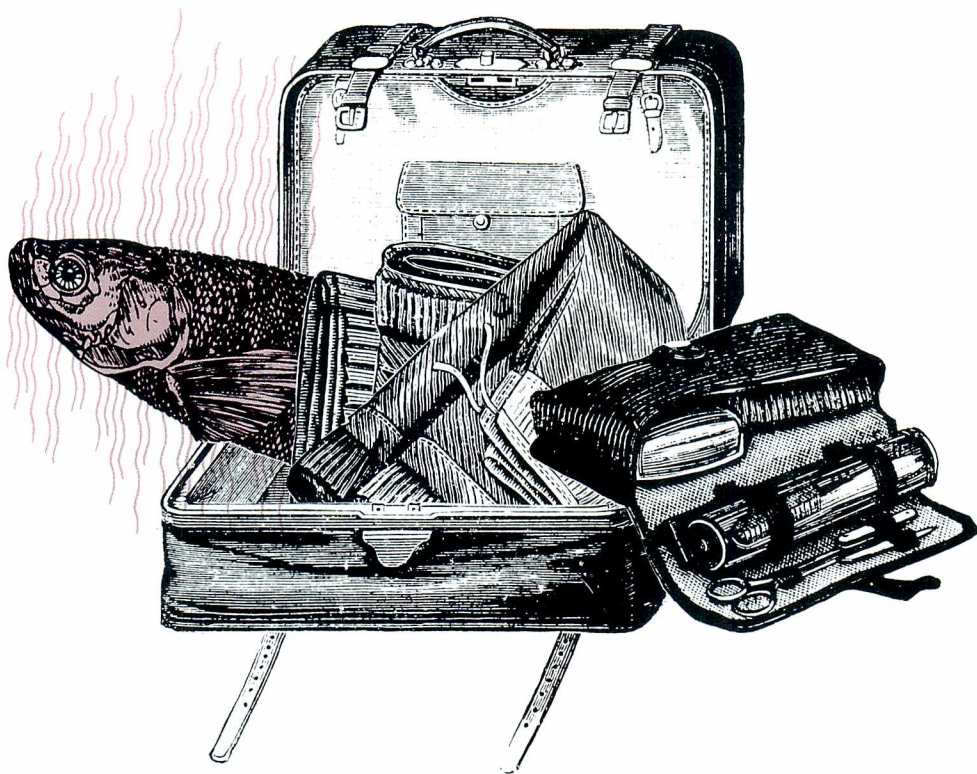




## Investigators' Reports

# Fish 'Delicacy' Causes Botulism Illnesses and Death

by Marian Segal



It so happened last November that partaking of what some consider to be a delicacy resulted in illness in one country and illness and death in another. Before the cases were resolved, government agencies at the federal, state and local levels, as well as a foreign ministry of health and an American embassy, were involved. And by the time it was over, U.S. agencies were moving to remove the product from the market completely.

The delicacy was kapchunka, a salt-cured, air-dried whitefish that is processed and sold uneviscerated (with the guts left inside the fish). Sold also under the names ribeyza, rostov and rybetz, the fish—particularly the guts—may harbor *Clostridium botulinum* bacteria spores, which produce the toxin (botulin) that causes botulism, a potentially fatal food poisoning.

On Nov. 2, the U.S. Centers for Disease Control notified FDA's Division of Emergency and Epidemiological Operations (DEEO) that a man and his 9-year-old son were admitted to a hospital the previous evening with symptoms of botulism,

including abdominal pain, vomiting, diarrhea, and blurred vision. They had reportedly eaten a salted whitefish purchased at a store in Forest Hills, N.Y. FDA's New York district office, in cooperation with New York City and state officials, immediately started an investigation, and by the next day, the fish suspected of causing the illnesses was identified as kapchunka. Working together, the officials got all the kapchunka off the market within two days.

When the initial report came in, FDA had immediately collected samples from the store where the fish was purchased and sent them to FDA's New York Regional Laboratory for analysis. That same evening, the New York City Department of Health seized all fish products (approximately 75 pounds) at the store. FDA was unable to obtain samples of the fish eaten by the father and son because the remaining scraps had been discarded. However, a stool sample from the father later tested positive for the botulin toxin.

The international aspect of the case became apparent on Nov. 3, when FDA and CDC were notified of botulism

poisoning in six people in Israel who had eaten a fish referred to as "rybetz" (later identified as kapchunka). One of them, a 77-year-old woman, died 36 hours after eating the fish. Others who ate the fish became ill but recovered. Visitors to the United States from Israel had purchased the fish in Brooklyn and taken it back home in their flight carry-on luggage.

The Israeli Ministry of Health, the American Embassy, FDA's International Affairs Staff, and DEEO worked to bring the tainted fish sample back to the United States for analysis. Both countries were extremely concerned about transporting the sample because it contained large amounts of the botulin toxin.

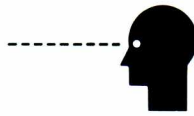
With all health precautions in place, the sample that caused the death of the 77-year-old woman was safely returned to the United States. Unexpectedly, a second sample was also brought back—this from someone who turned two fish in to authorities after hearing Israeli press reports about the botulism incident. Those fish, too, had been purchased in New York and transported to Israel, and samples from both contained the botulin toxin.

By Nov. 4, FDA and the New York State Department of Agriculture and Markets had inspected Arthur's Smoked Fish, the firm that processed the fish, and Gold Star Smoked Fish, the distributor—both located in Brooklyn. During the inspections, the state agency seized all kapchunka at the firms, totaling approximately 2,200 pounds.

FDA's investigation had been complicated by a language barrier that hampered identification of exactly what product or products were involved in the illnesses. Interviews with more than a dozen people eventually revealed that different Russian names were being used to describe the same or similar products. Because of the confusion, FDA visited all 22 stores that had received the uneviscerated fish from Gold Star Smoked Fish and collected 51 samples of several types of products.

Arthur's Smoked Fish's license had been revoked in June 1987, but reinstated in





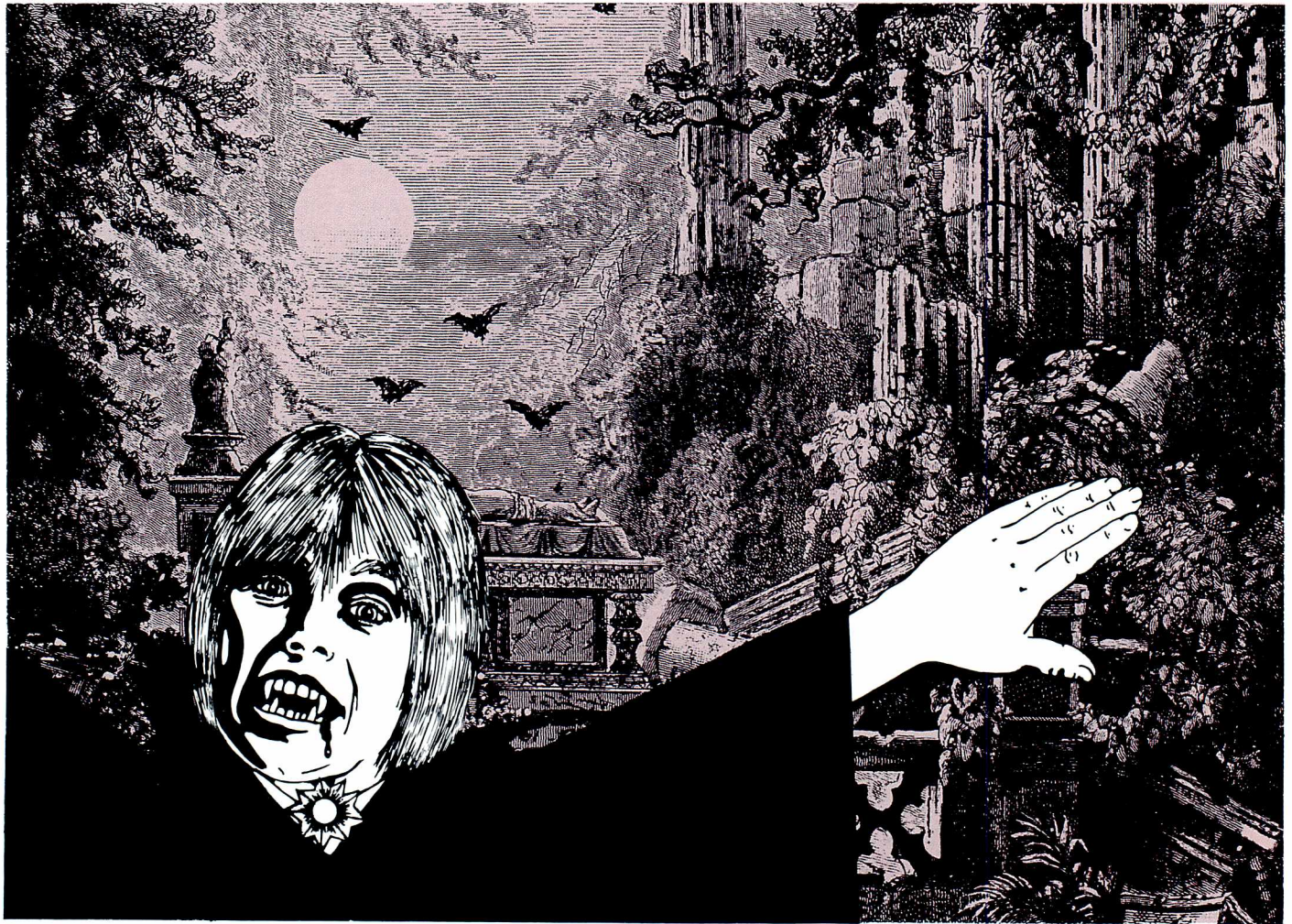
August after the firm passed a New York state inspection.

All kapchunka has been recalled from the market, and its manufacture has been stopped. The New York State Department of Agriculture and Markets has suspended Arthur's license to manufacture the product, and the state is working on new

regulations for processing fish products. New York City is proposing a regulation to prohibit the sale, production and distribution of all uneviscerated, salt-cured, air-dried fish, including kapchunka. And FDA is preparing to publish a notice in the *Federal Register* stating that because there is no known method of processing this

type of fish to guarantee its safety, it is a public health hazard and will be subject to regulatory action if marketed.

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



## The Color of Dracula's Blood

Some illegal color additives came to the attention of FDA's Los Angeles district office in a rather startling way shortly after last Halloween. A physician reported that a 13-year-old boy had apparently suffered an epileptic-type seizure after biting on a Frothing Blood Capsule containing imitation blood. According to the boy's mother, her son had used the capsule to complete his vampire costume for a Halloween party and had the reaction the next morn-

ing. The episode lasted several minutes, and afterwards the boy was dazed for a while. He had had a similar reaction a year earlier, she said, after spraying his hair with red spray color. The boy recovered completely after each episode.

An investigator collected samples of the capsules at California Novelties, Inc., Riverside, Calif., the importer of the product. Frothing Blood Capsules are manufactured in Great Britain and exported in bulk by Jarroy Ltd., London. California Novelties was repacking the

product in blister pack display cards containing four capsules each.

Lab analysis found three illegal color additives in the imitation blood: amaranth (formerly FD&C Red No. 2), ponceau 4R, and carmosine. However, it was not determined if any of the colors might have caused the boy's reaction. FDA received no other complaints involving the product.

When FDA told the firm about the illegal color additives, it agreed to place its warehouse inventory in quarantine — 78,000 capsules on blister cards plus an





additional 55,800 capsules in bulk. The president of the firm authorized a recall letter to be sent to the firm's customers nationwide.

FDA also issued an Import Alert to its district offices stating that if they encountered Frothing Blood Capsules, the product should be tested for illegal color additives and detained if they were detected.

### Salvaging Food for the Needy

Food banks are local neighborhood outlets — a sort of mini-warehouse, often operated by social service, church and welfare groups — where needy families entitled to food assistance can get the items they need. The banks in turn get their foods from distribution centers that serve a city or even a region.

Last November, FDA's Philadelphia district office inspected a number of area food banks and found bags of rice, flour



and other items that had been contaminated by insects and rodents. Since the food bank buildings were clean and intact, the food must have been contaminated when it was received.

The supplier was the Robideau Distribution Center, a contract warehouse that handles surplus and donated foods for the Pennsylvania food assistance program.

Checking through the huge four-story building, FDA and state and local inspectors discovered bags and bales of rice, flour, dry milk, cornmeal, and other foods that were rodent-gnawed and contaminated with rodent stains, nests and droppings. The warehouse itself had structural and storage problems and there was insect infestation.

The food — valued at \$1.5 million — had been donated by the U.S. Department of Agriculture and become contaminated in storage. Since FDA had the clearest jurisdiction, the agency obtained a court order for seizure of two floors-full of the warehouse contents to prevent further distribution of the foods. The seizure was executed Dec. 10 by U.S. marshals. To expedite inspections and laboratory analysis, additional investigators and lab staff were assigned by FDA's Philadelphia office.

Over the next three months, warehouse workers sorted through 140,000 bales of food. As the various lots were salvaged and contaminated food set aside, the reconditioned lots were released to the food banks. Food not suitable for human use was converted to animal feed.

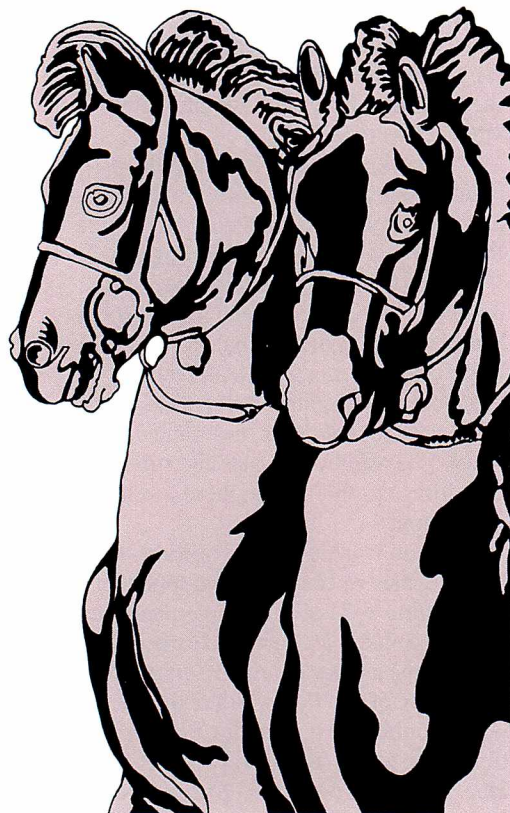
When the sorting and reconditioning were completed, more than 90 percent of the stored food had been salvaged. In the course of the operation, Robideau management cleaned and restored the warehouse, sealing it against further damage from insects and rodents.

### Fake Horse Hormones

Coordinated moves by FDA, the FBI, and other agencies against illegal steroid suppliers have made it difficult for these operators to obtain the drugs they sell from legitimate sources. Consequently, many have turned to counterfeiting existing products or to making products that are outright fakes — even fake and counterfeit veterinary drugs.

Steroids are prescription hormone drugs often abused by athletes and body builders





in hopes of increasing their strength and muscle mass. The many dangers of steroid abuse were described in "Athletes and Steroids: Playing a Deadly Game" in the November 1987 *FDA Consumer*.

Among counterfeit steroids recently seized by FDA in California and the Midwest was "Equipoise," a prescription veterinary drug used legally at horse farms and race tracks around the country. It is an injectable liquid that increases body mass and muscle and can make the animal more aggressive and competitive. However, Equipoise has long been used illegally by body builders and athletes, who commonly refer to it as "horse."

Closer control of steroid sources and prescriptions has made Equipoise harder to obtain, so suppliers of illegal steroids have begun selling their body-building customers counterfeit versions, complete with phony labels and lot numbers. The quality and safety of these counterfeits is suspect; they may contain dangerous impurities and contaminants and, as FDA found with the fake Equipoise, may have no active ingredients.

FDA's Center for Veterinary Medicine is working with Solvay Veterinary, the New Jersey firm that makes the real Equipoise,

to be certain that the useless and perhaps dangerous counterfeits do not find their way into the animal-care market. Staff from FDA's New Brunswick and Camden, N.J., offices have visited Solvay to confirm that the recently seized drugs are not authentic.

It is not yet a problem, but counterfeit Equipoise and other fake veterinary drugs intended for sale to athletes could show up in animal-care uses. FDA's health fraud office points out that selling such drugs for animal use would be less profitable than selling to body builders, but it could happen.

FDA urges that horse trainers, horse owners, and veterinarians protect themselves and their animals by purchasing drugs only through reputable sources. They should carefully check all drug labels and call the manufacturer and FDA if they have any doubts or problems. And body builders and athletes should avoid taking steroids in any form in an effort to build strength and muscle.

## Douches Not for Children

"Vaginal douches have no place in the treatment of infancy and early childhood. Severe damage may be caused to the vagina or other pelvic structures."

That's what FDA's Denver district office told ProCare Industries Ltd., Inc., last October in a letter admonishing the firm for promoting Discreet Woman's Care douche to treat infections in youngsters. Several complaints from a competitor in 1985 about this promotion prompted a lengthy FDA investigation, culminating in the Englewood, Colo., firm's promise to stop making the illegal, dangerous claims.

To gather facts on the marketing history of the over-the-counter (OTC) douche, FDA investigators from the Baltimore, Orlando and Denver offices visited a number of firms and individuals. They learned ProCare bought the rights to the douche in 1983 from its developer, who first marketed the product under another name in 1968.

On June 16, 1987, FDA's Denver office sent an investigator to inspect ProCare. He collected samples, including two different information sheets the firm distributed to its field representatives to instruct sales people. This so-called "educational literature" claimed that the product could be used in children from infancy, that the for-

mula is "geared to combat the four most common forms of bacteria that infect the vagina," and that "when a young child has a fulminating (sudden, severe onset), foul-smelling vaginal discharge, there is no substitute for a douche." FDA medical experts examined the product and its labeling and concluded that ProCare's recommended use for children posed a potentially serious health hazard.

In a letter dated Oct. 19, FDA told ProCare that a "fulminating, foul-smelling vaginal discharge" in a child is usually due to a foreign object in the vagina or an infection, both of which call for immediate attention from a physician, not treatment with an OTC product. FDA said that a youngster could be cut and severely injured when given the douche and that it was "very likely" a health hazard for children. The letter added that FDA considers the douche a new drug because of the claims to treat children and "to combat" vaginal infections. FDA advised that the law requires manufacturers of new drugs to register with FDA and to submit a list of their products, which ProCare had not done.

In a letter dated Oct. 27, ProCare promised to destroy all copies of the illegal literature. FDA followed up with another inspection on Nov. 12. That same day, the firm sent its field representatives letters asking them to destroy the literature and wrote FDA to say that all copies had been destroyed.

The letters from ProCare to its distributors, however, mentioned that the douche could now be marketed as a cosmetic. This was incorrect, so FDA wrote back to say that, while the agency no longer considers Discreet Woman's Care a "new drug" since the illegal claims have been discontinued, it still considers the douche an OTC drug and, so, ProCare and the product are still subject to FDA's registration and listing regulations.

FDA has received no reports of injury associated with using the douche, but will continue to monitor the product and will regularly inspect the company to see whether its manufacturing practices comply with agency regulations.

*— This small sample of reports from the field was prepared by Carol Ballentine, Dixie Farley, Frank Golden, Brenda Holmes, Gordon Scott, and Richard Thompson.*





# Summaries of Court Actions

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

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

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

## SEIZURE ACTIONS

### *Foods/Poisonous and Deleterious Substances*

PRODUCT: **Pecan pieces**, Wilkerson, at Baltimore, Dist. Md.; Civil No. R-87-937.

CHARGED 4-16-87: When shipped by Albany Pecan Sales Co., Inc. (t/a Wilkerson Pecan), Sylvester, Ga., the article contained the added poisonous and deleterious substance aflatoxin, which might render it injurious to health—402(a)(1); and the article had been prepared, packed or held under insanitary conditions—402(a)(4).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65137; S. No. 87-441-679; S.J. No. 1)

### *Foods/Contamination, Spoilage, Insanitary Handling*

PRODUCT: **Apple slices, dried, Del Monte**, 3 seizure actions, at Oklahoma City, W. Dist. Okla.; Keller, N. Dist. Texas; and Carrollton, N. Dist. Texas; Civil Nos. 86-1355-W, 4-86-560-K, and 3-86-1753-F.

CHARGED 6-19-86, 7-1-86, and 6-30-86: When shipped by Del Monte Corp., Topeka and San Jose, Calif., the articles were unfit for food because of obnoxious odors (sulfites)—402(a)(3).

DISPOSITION: Defaults—ordered destroyed. (F.D.C. Nos. 64911, 64924, and 64925; S. Nos. 86-453-949, 86-492-993, and 86-492-994 et al.; S.J. No. 2)

PRODUCT: **Crabmeat, pasteurized**, at Reading, E. Dist. Pa.; Civil No. 86-4038.

CHARGED 7-7-86: While held for sale, the article contained filthy, putrid or decomposed substances, or was otherwise unfit for food—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64912; S. No. 86-451-090; S.J. No. 3)

PRODUCT: **Mackerel, dried, dried mullet, and dried anchovies**, at Norfolk, E. Dist. Va.; Civil No. 87-34-N.

CHARGED 1-26-87: When imported from Manila, Philippines, the dried mackerel and the dried mullet contained insect filth, animal filth, and/or moldy fish—402(a)(3); and while held for sale, the dried anchovies contained moldy fish—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65102; S. No. 87-441-846 et al.; S.J. No. 4)

### *Foods/Economic and Labeling Violations*

PRODUCT: **“Molasses”**, and **“honey”**, at Jonesville, M. Dist. N.C.; Civil No. C87-475-WS.

CHARGED 7-22-87: When shipped by J.H. Pilgrim, DeKalb, Miss., the articles labeled “Pure Molasses Distributed Muncus Bros. Wholesale, Inc. . . . Jonesville, N.C.” and “Sourwood Brand Pure Honey Distributed by Muncus Bros. Wholesale, Inc. . . . Jonesville, N.C.” had had a substance substituted for molasses and honey—402(b)(2); the articles’ labeling was false and misleading because it represented (contrary to fact) that the articles consisted wholly of molasses or honey—403(a)(1); and the articles had been offered for sale under the name of another food (i.e., molasses and honey)—403(b).

DISPOSITION: Default—ordered constructively destroyed by donation to *bona fide* charitable organizations. (F.D.C. No. 65225; S. Nos. 87-508-090/1; S.J. No. 5)

### *Food Additives*

PRODUCT: **“Calcium Pangamate” tablets**, in bulk cartons and in retail bottles, at Hollywood, S. Dist. Fla.; Civil No. 84-6502 Civ.-Paine.

CHARGED 11-2-84: When shipped in bulk by Manhattan Drug Co., Inc., Hillside, N.J., and while being held by Sundown Vitamins, Inc., Hollywood, Fla., the article (which contained a mixture of various amino acids) contained one or more of the nonconforming food additives glycine, lysine and dl-methionine—402(a)(2)(C).

DISPOSITION: Default—ordered disposed of in accordance with the law. (F.D.C. No. 64394; S. No. 84-374-386 et al.; S.J. No. 6)





### *Drugs/Human Use*

**PRODUCT:** Compressed breathing air, nitrous oxide, U.S.P., nitrogen, N.F., and other medical gases, at Memphis, W. Dist. Tenn.; Civil No. 86-2870-GA.

**CHARGED** 11-6-86: While held by Standard Welders Supply Co., Memphis, Tenn., the circumstances used for the article's manufacture, processing, packing and holding failed to conform with current good manufacturing practice—501(a)(2)(B).

**DISPOSITION:** Consent—authorized release to the dealer for bringing into compliance. (F.D.C. No. 64943; S. No. 85-348-736 et al.; S.J. No. 7)

**PRODUCT:** Concentrated cruciferous vegetable capsules, Vital Veggies, at St. Augustine, M. Dist. Fla.; Civil No. 84-635-Civ-J-12.

**CHARGED** 6-19-84: When shipped by Twin Laboratories, Inc., Ronkonkoma, N.Y., the article was a new drug without an effective approved New Drug Application—505(a).

**DISPOSITION:** Default—ordered destroyed. (F.D.C. No. 64252; S. No. 83-271-655; S.J. No. 8)

**PRODUCT:** Ethynodiol diacetate and mestranol combination tablets, 4 seizure actions, at Grand Prairie, N. Dist. Texas; Carson, C. Dist. Calif.; Oxford, N. Dist. Miss.; and Dothan, M. Dist. Ala.; Civil Nos. CA-3-84-1933-R, 84-8873-LEW (Bx), WC-84-248-NB-D, & 84-V-1679-S.

**CHARGED** 11-9-84, 11-19-84, 12-12-84, and 12-31-84: The article was a counterfeit drug labeled (envelope) "Ovulen-21" and (tablets) "401 . . . SEABLE [sic]," since the article, its containers, and its labeling, without authorization, bore the trademark, trade name, imprint and likeness of a drug manufacturer other than the actual manufacturer, packer or distributor—201(g)(2).

**DISPOSITION:** Defaults—ordered destroyed. (F.D.C. Nos. 64425, 64435, 64454, & 64467; S. Nos. 85-361-689, 85-416-095, 85-333-230 & 85-376-746; S.J. No. 9)

**PRODUCT:** Rivixil hair treatment containing hair treatment solution and shampoo, at Denver, Dist. Colo.; Civil No. 86-2-1915.

**CHARGED** 9-17-86: When shipped by Riahom Ltd., Jupiter, Fla., the article was a new drug without an effective approved New Drug Application for the article's recommended use for hair restoration and growth—505(a); the article's label lacked the established name and quantity of each active ingredient (i.e., minoxidil)—502(e)(1)(A)(ii); and the article's labeling lacked adequate directions for use for the article's recommended conditions, and the article was an unapproved new drug for which adequate directions for use could not be written—502(f)(1).

**DISPOSITION:** Default—ordered destroyed. (F.D.C. No. 64979; S. No. 86-369-454; S.J. No. 10)

**PRODUCT:** Various prescription legend tablets and capsules, at Palos Heights, N. Dist. Ill.; Civil No. 84-C-0163.

**CHARGED** 1-10-84: While held by Harry's Prescription Pharmacy, Inc., Palos Heights, Ill., who had repacked the articles, the circumstances used for the articles' processing, packing and holding failed to conform with current good manufacturing practice—501(a)(2)(B); and the articles had been processed in an unregistered establishment—502(o).

**DISPOSITION:** Default—ordered destroyed. (F.D.C. No. 64157; S. No. 84-3382-853 et al.; S.J. No. 11)

### *Drugs/Veterinary*

**PRODUCT:** Levamisole wormer injection and bulk levamisole, at Appleton City, W. Dist. Mo.; Civil No. 86-1340-CV-W-9.

**CHARGED** 12-24-86: When the bulk drug was shipped by Illini Veterinary Service, Pittsfield, Ill., the bulk drug failed to bear adequate directions for use—502(f)(1); and while held by William R. Brownsberger, D.V.M. (t/a Brownsberger Veterinary Clinic, Inc.), Appleton City, Mo., who had manufactured the injectable drug using the bulk levamisole, the injectable drug was a new animal drug, and the manufacturer lacked an approved New Animal Drug Application—501(a)(5).

**DISPOSITION:** Default—ordered destroyed. (F.D.C. No. 65093; S. Nos. 87-262-251/2; S.J. No. 12)

**PRODUCT:** Racemethionine capsules, at St. Louis, E. Dist. Mo.; Civil No. 86-2116-C-B.

**CHARGED** 10-14-86: When shipped by Forest Pharmaceuticals, Inc., Cincinnati, Ohio, the article, labeled "Scent-Free Racemethionine . . . Capsules LeGear a division of O'Neal, Jones & Feldman . . . St. Louis, Mo.," was a new animal drug, and no approval of a New Animal Drug Application was in effect for such drug for veterinary use—501(a)(5).

**DISPOSITION:** Default—ordered destroyed. (F.D.C. No. 65040; S. No. 86-526-727; S.J. No. 13)

### *Cosmetics*

**PRODUCT:** Canthaxanthin tablets for tanning, Riviera, at Ooltewah, E. Dist. Tenn.; Civil No. 1-84-470.

**CHARGED** 7-30-84: When shipped by Holistic Products Corp., Bogota, N.J., the article was not a hair dye, and it contained a nonconforming color additive—601(e).

**DISPOSITION:** Default—ordered destroyed. (F.D.C. No. 64332; S. No. 84-344-740; S.J. No. 14)

**PRODUCT:** Cologne, spray, at St. Thomas, Dist. Virgin Islands; Civil No. 83-33.

**Charged** 2-14-83: When shipped from Miami, Fla., by Parfums Worth, Paris, France, the article, labeled "Je Reviens Cologne





Spray . . . Parfums Worth Paris . . . Made in France,” was a cosmetic in a self-pressurized container that contained a prohibited chlorofluorocarbon propellant—601(a); the article’s immediate container label lacked an accurate quantity of contents statement, and the article’s outer carton label lacked a required net quantity of contents declaration in terms of U.S. fluid ounces—602(b)(2). **DISPOSITION:** Default—ordered destroyed in a manner that complied with the National Environmental Policy Act of 1969. (F.D.C. No. 63934; S. No. 83-347-353; S.J. No. 15)

### CRIMINAL ACTIONS

**DEFENDANTS:** **SmithKline Beckman Corp., Philip J. Tanenbaum, M.D.**, vice president and medical director, **Ralph M. Myerson, M.D.**, group director, and **Theodore Selby, M.D.**, associate medical director, Philadelphia, E. Dist. Pa.; Criminal No. 84-00227.

**CHARGED 6-12-84:** When shipped to Rochester, N.Y.; Stamford, Conn.; Brooklyn, N.Y.; Cincinnati, Ohio; Elizabeth, N.J.; New Castle, Del.; Hialeah, Fla.; Solon, Ohio; Zanesville, Ohio; Bristol, Tenn.; Lincoln, Neb.; West Haven, Conn.; Evansville, Ind.; Florence, S.C.; Knoxville, Tenn.; Elmhurst, N.Y.; St. Petersburg, Fla.; Sioux Falls, S.D.; Columbus, Ohio; and Wauwatosa, Wis., the labeling of Selacryn brand ticrynafen contained false and misleading claims concerning the following: “no causal relationship has been established” between the drug and abnormal liver function tests and jaundice, when (a) Selacryn had been shown to cause and to be capable of causing abnormal liver function tests and jaundice, and (b) such labeling failed to reveal the material facts that hepatic positive rechallenges had been reported with Selacryn and Selacryn had been reported as the probable cause of abnormal liver function tests and jaundice—502(a).

**DISPOSITION:** Nolo contendere pleas; corporation—\$1,000 fine, suspended, and probation for two years with special conditions, including providing 500 hours of volunteer community service and a \$100,000 contribution to a specified civil program; individuals—imposition of sentences suspended, but probations for two years, with special conditions, including 200 hours of community service. (F.D.C. No. 62411; S.J. No. 16)

### INJUNCTION ACTIONS

**DEFENDANTS:** **Alcon Laboratories (Puerto Rico), Inc.** (a subsidiary of **Alcon Laboratories, Inc., of Ft. Worth, Texas**), and **Edgar H. Schollmaier**, president of Alcon Laboratories, Inc., and **John W. Feik**, president of Alcon Laboratories (Puerto Rico), Inc., Humacao, Dist. Puerto Rico; Civil No. 78-2378.

**CHARGED 11-28-78** in a complaint for injunction: That, at the defendants’ plant in Humacao, Puerto Rico, the defendants manufactured, processed, packaged, labeled, held, and distributed

in interstate commerce a number of WANS drug products (i.e., WANS No. 1, WANS No. 2, and WANS Children—combinations of pyrilamine maleate and pentobarbital sodium in a waxy base), which were suppositories claimed to be safe and effective for the symptomatic treatment of nausea and vomiting, and which were new drugs without effective approved New Drug Applications—505(a); and, when shipped, the labeling of the articles lacked adequate directions for use and the articles were not exempt, due to their new drug status—502(f)(1); that FDA had advised that the reconsideration of the new drug status of antihistamine and barbiturate/antihistamine combination products was being planned; that FDA had issued a Regulatory Letter to all manufacturers of fixed combination pyrilamine maleate/pentobarbital sodium antiemetic suppositories; that all such manufacturers, except the defendants (Alcon), had acceded to FDA’s request to cease manufacturing and had recalled all outstanding stocks of such suppositories; that Alcon had responded to FDA’s Regulatory Letter by claiming that the safety and efficacy of the WANS suppositories was supported by published and unpublished scientific data which they enclosed with their response; that, after FDA’s medical personnel had reviewed such data, FDA had advised Alcon that their data did not represent adequate and well-controlled studies demonstrating the safety and effectiveness of the WANS products, and that continued marketing was in violation of the law; that the government had charged that the WANS products were violative (Dist. P.R.; Civil No. 78-1830) and had seized approximately 450,000 dosage units; and that, despite such warnings and such seizure, Alcon continued to manufacture and distribute the WANS products.

**DISPOSITION:** The government’s petition for a temporary restraining order was denied. The injunction action was consolidated with the seizure action mentioned above. Subsequently, the court dissolved the initial seizure and a second seizure (Civil No. 80-0243) of WANS products, denied the government’s motion for a preliminary judgment, and enjoined any enforcement action against WANS or its manufacturer until FDA had held an administrative hearing to determine WANS’ new drug status.

After the court reiterated its ruling, the court remanded the matter to FDA with instructions to defer regulatory action against the WANS products until after a 5 U.S.C. 554 hearing and after an administrative determination of new drug status. Alcon continued to deny that the articles were “new drugs”; and Alcon also claimed protection under the 1962 “grandfather clause,” asserting that regulatory action was premature because there was no significant new information questioning the safety and effectiveness of the drug.

**Initial Appeals**—The government appealed both the dissolution of the seizures and the remand for an administrative hearing, and also moved for a stay of the District Court’s orders pending appeal. The Court of Appeals found that this was an injunction





appealable under 28 U.S.C. 1292(a)(1) and that the order releasing the seized articles pending appeal exceeded the District Court's authority. As to the government's appeal from rulings that the case was to be remanded to FDA for an administrative hearing, the Court of Appeals found for the government and remanded the case to the District Court for a trial on the merits.

**The Trial, Verdict and Judgment**—A trial by jury was held. The testimony was largely a battle of experts. After all of the evidence was submitted, FDA moved for a directed verdict. That motion was denied, as was a motion for a judgment "Notwithstanding the Verdict." The jury had rendered its verdict for the claimant upon special interrogatories, finding Alcon's drugs to be generally recognized by qualified experts as safe and effective and that the drugs were presently intended solely for use under the same conditions prescribed in their 1962 (i.e., grandfathered) labeling. The court entered a judgment for Alcon.

**Appellate Jurisdiction Contested**—Meanwhile, Alcon moved to amend the judgment of the District Court to provide for the return of the WANS products. After the government's Notice of Appeal, Alcon moved that the appeal be dismissed on the ground that the Court of Appeals lacked jurisdiction because the judgment appealed was not final, in view of Alcon's pending motion to amend the judgment. However, the Court of Appeals ruled that appellate jurisdiction was properly vested and that Alcon's motion to the District Court asking for a return of its property was a request for a post-judgment order which would not affect the judgment on the merits and "therefore, had no effect on our appellate jurisdiction."

**Further Motions**—Meanwhile, the District Court heard argument on Alcon's motion to return the seized articles and also on a motion to reimburse Alcon for attorney's fees, expenses and costs. The court granted the claimant's motion for the return of its property and denied the government's motion for a stay of such release. The District Court also considered at length the claimant's motion for fees, expenses and costs. The court concluded that the government's posture, both before and during litigation, was characterized by obdurate obstinacy, and granted both of Alcon's motions. However, the government filed with the Court of Appeals an emergency motion for a stay pending appeal, and the Court of Appeals granted the government's motion for a stay and subsequently ruled in favor of the government on the merits of the action.

**Appeal on the Merits**—The Court of Appeals reversed the judgments in the injunction action, the two seizure actions mentioned above, and two subsequent seizure actions (Civil Nos. 80-2112 and 82-0055) because it concluded that WANS was subject to the Federal Food, Drug, and Cosmetic Act, was not now generally recognized among qualified experts as safe and effective, and was a new drug subject to Section 505. The court noted that WANS was clearly a "new drug" in 1955; that, at FDA's sug-

gestion, changes in WANS' promotional materials had been made in 1967; and that, in 1977, an FDA committee of experts noted a safety issue concerning antiemetics used in children.

The court found that, as a matter of law, Alcon's evidence was insufficient for the following reasons: (A) the conditions for use of WANS in connection with vomiting and nausea had changed significantly since 1962 and WANS was, therefore, not grandfathered, and at least some scientific drug testing prior to 1962 was necessary to fulfill the general recognition requirement of the grandfather clause; and (B) because WANS was not grandfathered, WANS must meet the current requirements, i.e., "generally recognized among experts . . . as safe and effective." Although Alcon had conceded that no investigations of any kind had ever been conducted to test WANS' efficacy, Alcon introduced into evidence three 1968 and 1969 studies of a similar antiemetic, which contained the same amounts of the same active ingredients found in WANS, and Alcon's expert witness offered his theoretical opinion that the clinical effects of the similar antiemetic and WANS would be "identical, or nearly so," although the drugs might not be identical in terms of their inactive ingredients. However, in the absence of testimony specifically addressing the inactive ingredients, the bioequivalence of the similar antiemetic and WANS was, as a matter of law, not demonstrated. Furthermore, the deciding factor on effectiveness was the testimony of Alcon's own expert who testified that the studies of the similar antiemetic "did, for the most part, fail to use some of the methods that most recently . . . have come to be regarded as more important in the [design] of clinical [investigations]."

Since Alcon never submitted a New Drug Application for WANS, it was subject to today's effectiveness standards, and Alcon, as a matter of law, failed to produce the required types of studies demonstrating effectiveness and, as a matter of law, failed to meet the substantial evidence requirement of 505(d) so as to create an issue for a jury.

The judgments in the five cases were reversed, and the District Court was to enter judgments consistent with this opinion.

**Further Applications**—Alcon moved in the Court of Appeals for a stay of the Court of Appeals' mandate, but that application was denied. Alcon filed an application for a stay in the Supreme Court of the United States, and that application was also denied. Nevertheless, Alcon filed a petition for *certiorari* in the Supreme Court. The petition was denied.

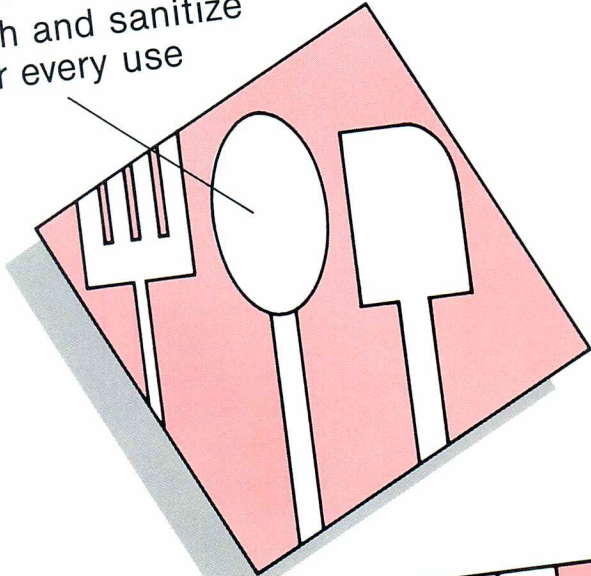
The final judgment of permanent injunction requested by the government was entered, as well as a decree of condemnation as to all four seizure actions. In accordance with such judgment, 527,988 packages of WANS and \$165,037.84 of raw materials were destroyed. In addition, costs of \$5,493.94 were taxed against Alcon. (Inj. No. 879; F.D.C. Nos. 61874, 62774, 63201, and 63620; S. Nos. 78-147-435, 80-157-807, 80-268-264, and 82-281-867; S.J. No. 17)



# CROSS CONTAMINATION

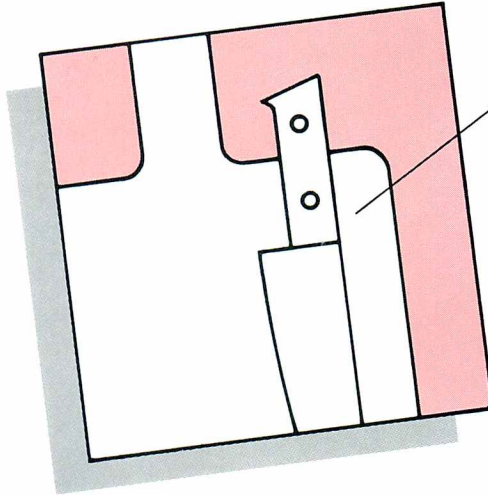
## Utensils

Wash and sanitize  
after every use



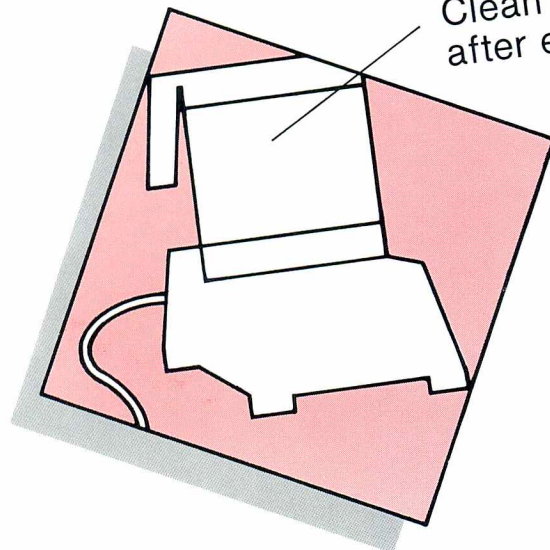
## Cutting Boards

Wash and sanitize  
after every task



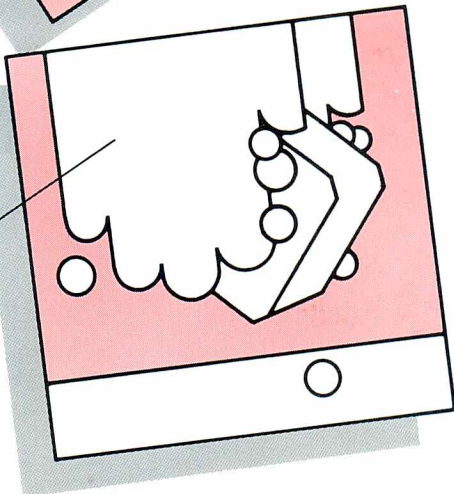
## Equipment

Clean and sanitize  
after every use



## Hands

Wash frequently  
and thoroughly



## Recipe for Danger

Take one knife; use it to cut raw meat and salad greens, not washing in between. May result in cross contamination of the salad and enough harmful bacteria to make the family sick for several days.