

FDA
CONSUMER

April 1982



Tan Now, Pay Later?

For Nantiles



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More than 90,000 breast implants are performed annually with silicone. Sometimes this strictly cosmetic surgery can lead to problems.

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These squishy, translucent pillows are actually silicone implants of the type used in thousands of breast enhancement operations each year. Silicone envelopes filled with silicone gel are in the foreground. Empty envelopes that will be filled with saline, using the needle and catheter shown in the center, appear in the background. For more on silicone implants and the body's reactions to them, see The Body Doesn't Always Take Kindly to Breast Implants beginning on page 4.

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Section 705 [375] of the Food, Drug, and Cosmetic Act:

(a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of charge and the disposition thereof.

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

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Updates

Feingold Diet Limited

The so-called Feingold diet, widely used to treat hyperactive children, should not be universally applied at this time, a panel of experts recently concluded. While recognizing that an initial trial or continuation of the diet may be warranted in patients who seem to benefit, the group said dietary treatment should not be started until after a thorough and appropriate evaluation of the child and his family and full consideration of all therapeutic options.

The 13-member panel, representing a wide range of medical specialties including biomedical research, pediatrics, immunology, clinical pharmacy and the behavioral sciences participated in a National Institutes of Health Consensus Development Conference in early January. The conference focused on the following: a definition of hyperactivity, what constitutes a "defined diet," any evidence that the diet works, a possible explanation of how it works, when the diet should be used, and finally, directions for research.

Hyperactivity is not a single disease nor is there a single cause, the panel noted in the draft of its conclusions. According to the American Psychiatric Association, the essential features are "signs of developmentally inappropriate inattention, impulsivity and hyperactivity." Other diagnostic conditions include onset by the age of 7, duration of no less than six months and a proven absence of mental illness or mental retardation.

The diet introduced by Dr. Ben Feingold in 1973 eliminates two groups of food: those with high levels of naturally occurring salicylates (almonds, cucumbers, tomatoes, berries, apples, oranges) and those containing artificial colors and flavors. Other defined diets are modifications of the Feingold diet.

Dramatic improvements have been observed in many hyperactive children on these diets, the panel said, but such improvements were not established in the controlled trials presented to them. Since there was insufficient evidence to identify the small group of children who do respond to the diet, the panel said it cannot answer unequivocally the question of when the diet should be used.

The group called for more epidemiological research including the development of standardized diagnostic criteria, studies of the causes and risk factors for hyperactivity and research on its natural history. Investigation of family dynamics also is essential, the group said.

The Consensus Development Conference on Defined Diets and Childhood Hyperactivity, part of a program started at NIH in 1977, was co-sponsored by the National Institute of Allergy and Infectious Dis-

eases and the National Institute of Child Health and Human Development.

A fuller explanation of the Feingold diet and how it is perceived to work was the subject of "Food Additives and Hyperactive Children" in the March 1977 *FDA Consumer*. A brief summary of a study done for FDA's Interagency Collaborative Group on Hyperkinesis which tended to refute the Feingold theory appeared in the Update section of the May 1979 issue.

Laetrile: Ineffective, Toxic

The latest word on Laetrile, the controversial drug made from apricot pits, is that it is not effective as a cancer treatment but is toxic and poses a danger to patients. These were the conclusions from a National Cancer Institute study announced last April and reported in January.

In the study, 178 patients with cancer but in good general condition received Laetrile and the diet usually prescribed with it. "No substantive benefit was observed," the scientists, headed by Charles G. Moertel of the Mayo Clinic, say. They add that although Laetrile has been advertised to the public, state legislatures and courts as non-toxic, "our results demonstrate that oral Laetrile is a toxic drug. Several patients had symptomatic toxicity or high levels of blood cyanide or both; the cyanide levels approached levels known to kill animals and reached levels that have been reported in fatal cases of poisoning in human beings."

Precautions against fatal poisoning were built into the institute study, the scientists say, but have not been incorporated into the practices of Laetrile therapists who, indeed, sometimes encourage double dosing or other practices that could increase the risk of poisonings. "Physicians using such products must accept the associated liabilities," the scientists warn.

"Certainly, the now established toxicity of Laetrile must be considered by persons in state legislatures and the federal courts who are charged with protecting the public safety."

About half of the states have laws making Laetrile legal within their borders, and Laetrile has been available nationally under an affidavit system established by the District Court for the Western District of Oklahoma to patients who are certified by their physicians to be terminally ill. FDA has been seeking review (and elimination) of the affidavit system.

Laetrile has been the subject of a number of articles, Updates and news items. The most recent article was "The Courts, Terminal Patients and Unapproved Drugs" in the November 1979 issue of *FDA Consumer*.

New Drugs Listed

FDA approved 27 "totally new" drugs last year—the most new chemicals approved for use as drugs since enactment of the 1962 legislation governing drug approval.

The category of new drug chemicals represents one of the most innovative of the six types of new drug approvals. The other types: new salts of previously ap-

proved drugs, new dosage forms, combinations, drugs being marketed by a new firm and drugs being marketed for new purposes. How new chemical entities get on the fast track for FDA approval was discussed in "Providing a Breakthrough for Drugs With Promise" in the July-August 1979 issue of *FDA Consumer*.

The 27 new drugs approved in 1981:

| Generic Name | Trade Name | Indication |
|-------------------------------|---------------------------------------|--|
| Albuterol | Schering's Proventil | Bronchodilator |
| Alprazolam | Upjohn's Xanax | Anti-anxiety |
| Alprostadil | Upjohn's Prostin VR | Palliative therapy to maintain ductus arteriosus in newborns |
| Amiloride hydrochloride | Merck's Midamor | Anti-hypertensive |
| Atenolol | ICI Americas' Tenormin | Anti-hypertensive |
| Bethanidine sulfate | A. H. Robins' Tenathan | Anti-hypertensive |
| Buprenorphine | Eaton's Buprenex | Narcotic analgesic |
| Captopril | Squibb's Capoten | Anti-hypertensive |
| Cefotaxime sodium | Hoechst-Roussel's Claforan | Antibiotic |
| Ceruletide | Adria's Tymtran | Anti-ulcer |
| Estramustine phosphate sodium | Hoffmann-LaRoche's Emcyt | Anti-neoplastic |
| Flunisolide | Syntex's Nasalide | Symptoms of seasonal rhinitis |
| Gemfibrozil | Warner-Lambert's Lipid | Lipid regulating agent |
| Halazepam | Schering's Paxipam | Anti-anxiety agent |
| Isosulfan blue | Hirsch Industries' Lymphazurin | Lymphatic contrast agent |
| Ketoconazole | Janssen's Nizoral | Anti-fungal (internal) |
| Mezlocillin | Miles' Mezlin | Antibiotic |
| Moralactam disodium | Lilly's Moxam | Antibiotic |
| Nifedipine | Pfizer's Procardia | For angina |
| Piperacillin sodium | Lederle's Pipracil | Anti-bacterial |
| Saralasin acetate | Norwich-Eaton's Sarenin | Detection of angiotension II-dependent hypertension |
| Secretin | Kabi Group's Secretin-Kabi | Pancreatic diagnostic |
| Sucralfate | Marion's Carafate | Anti-ulcer |
| Sulfadoxine (Pyrimethamine) | Hoffmann-LaRoche's Fansidar | Anti-malarial |
| Temazepam | Sandoz's Restoril | For insomnia |
| Trazodone | Mead Johnson's Desyrel | Anti-depressant |
| Verapamil | Knoll's Isoptin and Searle's Calan | Supraventricular tachyarrhythmias |

The Body Doesn't Always Take Kindly To

Breast Implants

by Paul Tilton and Louise Fenner

Every year thousands of women undergo cosmetic surgery to enlarge their breasts. The results can range from very rewarding to painfully disappointing. Surgery is the only method promoted for breast enlargement that can produce results—unlike the potions, suction devices and exercise machines advertised in many magazines—but it also carries some risks. Women who are aware of these risks will be better able to decide whether surgery is right for them.

The use of surgical techniques to enlarge the breasts is not a new idea. Many methods have been tried since the early 1900s, but only one has been successful—implanting a silicone envelope containing saline or silicone gel under the breast tissue or muscle. Since silicone implants arrived on the medical scene 20 years ago, they have become so widely accepted that an estimated 72,000 surgical breast augmentations take place in the United States every year. The American Society of Plastic and Reconstructive Surgeons based this estimate on a 1980-81 membership survey. Breast reconstructions following mastectomies (breast removals) account for another 20,000 implant procedures annually.

Other than breast reconstruction patients, women who receive silicone implants have healthy breasts that they believe are too small or otherwise undesirably shaped. Some may have breasts that shrank following weight loss or pregnancy or that do not match in size. Others may desire larger breasts for personal or professional reasons—showgirls, for instance. Many of these women undergo the operation with no

complications and are happy with the results. However, problems arising from the body's reaction to the breast implant still cause concern for a significant number of patients—problems that remain unsolved.

In the early years, surgical breast enhancement was fraught with complications. Liquid paraffin, used early in the century, sometimes migrated from breast tissue into arteries and caused obstructions that resulted in blindness and pulmonary embolisms (blood clots in the lungs). There were also reports of inflammatory reactions, necrosis (dead breast tissue) and formation of soft-tissue tumors called granulomas.

In the 1950s and 1960s, some physicians turned to injectable liquid silicone. This material has never been approved by the Food and Drug Administration for use in breast enlargement, not even for experimental purposes. Serious injury and several deaths have been attributed to silicone injections. Reported reactions include severe pain, swelling, lumpiness (formation of nodules in the breasts), discoloration and infection. Surgical removal of the breasts has been necessary in some cases to prevent gangrene or potentially fatal migration of silicone particles from the breasts to the brain, heart or lungs.

Overwhelming evidence of these dangers finally put a stop to the widespread use of liquid silicone for breast enlargement, although cases are occasionally still reported along with the resulting side effects. Manufacturers are prohibited by FDA from selling or promoting liquid silicone for use in the breast. If promoted or sold for this unapproved medical purpose, liquid

silicone may be seized and legal action taken against the supplier.

The use of implants to augment breast size began in the 1950s, but the failure rate was high until 1963 when two physicians reported successful results with silicone. Three basic types of silicone breast implants are now in use: the silicone gel-filled, the inflatable envelope and the double lumen. On the market the longest, the gel type implant consists of a seamless silicone envelope filled with silicone gel. It is pliable and provides a natural appearance and feel to the breast when in place.

The inflatable implant consists of a silicone envelope that is inflated with sterile saline (salt water) after insertion behind the breast or muscle tissue. It allows the surgeon to adjust the size of the implant by the amount of saline used. Although the inflatable implant was designed to provide a more "natural" postoperative appearance and feel, it has lost popularity since its introduction in the mid-1960s because of numerous reports of delayed spontaneous leakage.

The third type of implant, the double lumen, is a combination of the other two. It consists of two silicone envelopes, most commonly an inner envelope containing silicone gel, surrounded by a second envelope that is filled with saline at the time of surgery. Variations of this silicone/saline combination are also being tried. This type of implant has been in use five or six years.

Breast implants come in a variety of sizes, but the choice is limited by the degree of stretch that the breast can take. When small breasts have pre-



figure A

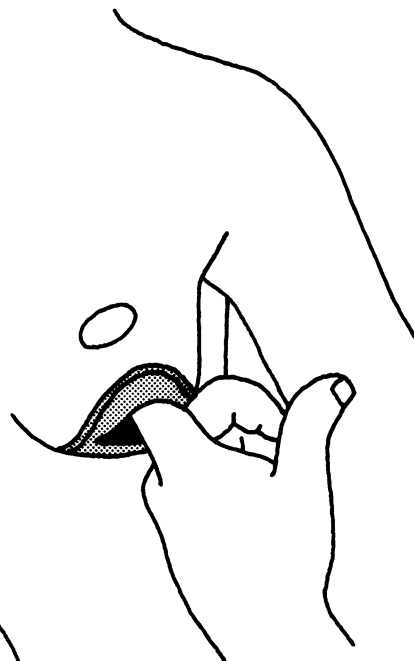
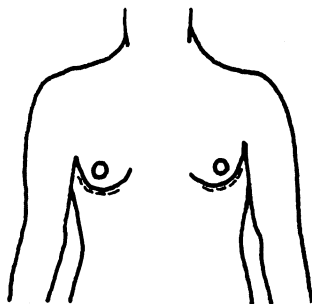


figure B

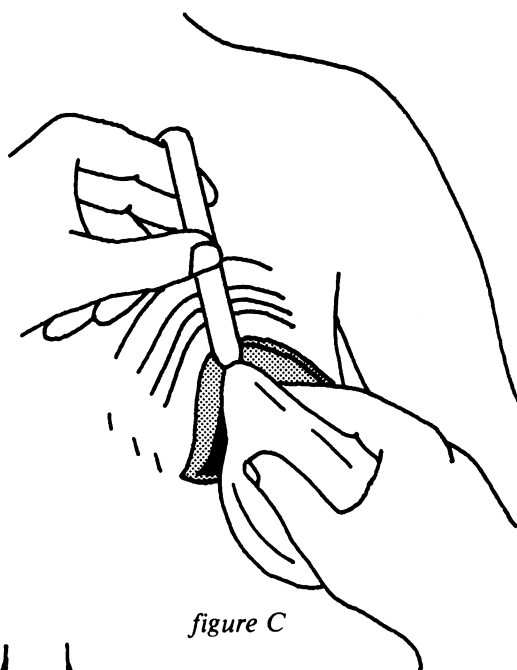
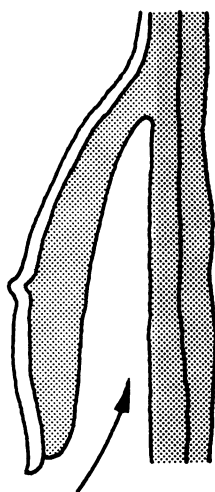
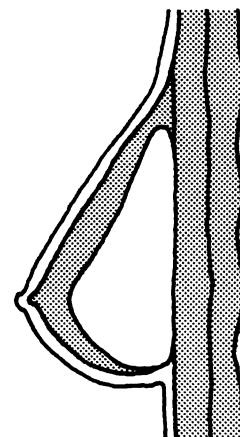
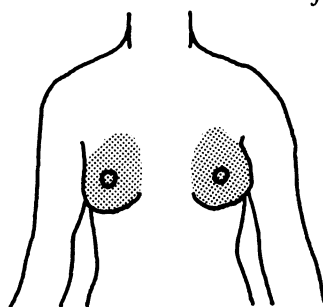


figure C



A typical breast implant operation starts with a silicone bag containing silicone gel (figure A), which will be inserted through incisions made in the crease at the bottom of the breast. Once the incision is made, the physician uses a finger to form a pocket between the breast tissue and the pectoral muscle (figure B). With the aid of a retractor (figure C), the implant is inserted into the pocket and positioned carefully. The incision is then closed with stitches.



viously been larger, as from an earlier pregnancy, their elasticity will permit easier adjustment to larger-sized implants.

Breast implant operations can be done under general or local anesthesia. The site chosen for the incision can also vary. Most surgeons make the incision on the lower outer quadrant of the breast, as this affords easy access for forming a pocket between the breast tissue and the underlying pectoral muscle (the breast tissue itself is not cut into or otherwise invaded). The implant is usually inserted into this pocket, although some surgeons place it underneath the pectoral muscle itself. Scarring from the surgical procedure is minimal—rarely longer than 1½ inches in length—and is concealed by the natural fall of the breast. Other techniques include incisions made in the front portion of the arm pit or around the border of the areola (nipple). Complaints by some patients of sensory loss in the nipple area, plus the possibility of invading the breast tissue, have made the areolar method less popular.

As with all surgery procedures, hemorrhage or infection may occur. Hemorrhage may arise from an unnoticed bleeding point or diffuse oozing of blood from the surface of the pectoral muscle. It usually results in the formation of a hematoma, or blood-filled cavity, which appears as swelling and discoloration of the skin. Hemorrhage is rare, but if it occurs the incision is reopened, the implant removed, and the bleeding brought under control.

Infection is another rare but potentially serious complication. It is manifested by pain, fever and redness of

the suture line. Infection requires antibiotic therapy and, in most cases, removal of the implant.

Implant surgery often presents special problems because of the human system's defenses against the introduction of a foreign body. Most medical authorities agree that in virtually all patients who undergo breast enlargement procedures, a fibrous capsule forms around the implant as part of the

Problems arising from the body's reaction to the breast implant still cause concern for a significant number of patients—problems that remain unsolved.

body's natural defense response. The formation of this capsule is not a problem by itself, but in some cases the fibrous tissue contracts around one or both implants and causes the breasts to become unnaturally firm and uncomfortable. This condition, called capsular contracture, has been reported to occur from a few weeks to several years after the surgery.

Opinions vary widely regarding the incidence of capsular contracture, in part because various physicians may interpret the same symptoms differently. Medical journals have carried articles by doctors who reported contracture rates as low as zero and as high as 74 percent of their patients, although most

reports claim rates that fall between these extremes. According to Dr. Norman Hugo, chairman of the American Society of Plastic and Reconstructive Surgeons' public education committee, a capsular contraction rate of 25 percent to 33 percent can normally be expected. Some contractures are characterized by minimal symptoms that include a feeling of tightness and minor discomfort, while in others, the capsule hardens and causes breast distortion (a round "baseball" shape) and pain.

Capsular contracture can be corrected surgically or non-surgically. The surgical method involves removal and replacement of the implant. In the non-surgical method, the physician manually squeezes the breast until the hardened capsule breaks open, thus releasing the silicone implant and allowing it to resume its original shape. This is done while the patient is under sedation. This "nutcracker" technique is often successful, but it can occasionally result in other complications such as hematomas and rupture or displacement of the implant. If the capsule isn't completely broken open, the implant may partially squeeze through cracks in the capsule and distort the shape of the breast. These complications may then require surgical correction.

Once capsular contracture develops, even when later corrected, the rate of recurrence is very high. Medical authorities are uncertain as to why contracture occurs. Theories and techniques are continually being tested, but no methods have been devised to eliminate this problem.

Silicone gel and inflatable implants are known to have some special quirks. Silicone gel-filled implants "bleed"



minute amounts of gel through the surface of the silicone envelope. (This is not to be confused with leakage or rupture.) Small amounts of this silicone bleeding do not appear to be harmful to body tissues, according to studies so far; however, some medical authorities believe additional studies of the chronic long-term toxicity of silicone are needed. One claimed advantage of the double lumen implant is that the outer saline-filled envelope may act as a barrier to gel "bleed" from the silicone-filled inner bag.

On rare occasions silicone-filled implants have ruptured and leaked, and the gel has migrated into adjacent and even distant soft tissue spaces. A hard blow to the breast or erosion of a fold in the silicone envelope are two possible causes of rupture. Cases have been reported when gel leakage into the tissue necessitated removal of part of the patient's breast. Fortunately, such ruptures are unusual, because implants are designed to withstand pressure. In some versions the use of a thicker, more viscous, silicone gel reduces the chance that the gel will migrate into the tissues if the outer envelope breaks.

As noted in the foregoing, inflatable implants have occasionally been known to leak after being in place for some time. In some cases, this occurred as long as 6½ years after implantation. According to published reports, somewhere between 2 percent and 15 percent of all inflatable implants eventually become deflated from various causes. Because saline is compatible with normal body fluids, the leakage itself is not harmful; but additional surgery is required to replace the defective implants.

Because silicone implants have been in use only about 20 years, many questions are unanswered about the long-term effects of breast implant surgery. Other problems that might arise many years after surgery are simply unknown. One question is whether certain materials implanted in the body can increase the long-term risk of causing cancer. To date, there has not been a demonstrated relationship between the

Because silicone implants have been in use only about 20 years, many questions are unanswered about the long-term effects of breast implant surgery.

silicone implant and the development of breast cancer in humans. However, more extensive long-term patient follow-up studies may be needed before this can be ruled out.

The use of silicone implants for breast reconstruction following cancer surgery has limitations, because a reconstructed breast will not be identical to a normal one. In breast reconstruction, the criterion is generally how a woman looks in a bra or swim suit—not nude—after surgery. Nevertheless, the option is there for the patient. Plastic surgeons are performing successful reconstructions, even in patients who have undergone extensive mastectomies years before.

Silicone implants are regulated by the Food and Drug Administration as medical devices. All silicone implant manufacturers are required to register with FDA and their plants are regularly inspected to determine if they are complying with the Food, Drug, and Cosmetic Act and with FDA's Good Manufacturing Practice regulations. Seven silicone implant manufacturing firms are now registered with FDA.

In January 1982, FDA proposed to classify silicone implants as class III medical devices, a regulatory category requiring premarket approval. (The FD&C Act requires all medical devices to be assigned to one of three categories having varying degrees of regulatory control.) In the classification proposals that appeared in the *Federal Register*, FDA expressed the opinion that not enough information is available about long-term safety and effectiveness of implants to warrant placing them in class II or class I, which have less stringent controls. Final classification decisions will be made after FDA reviews public and industry comments on the proposed classification.

Research continues within the industry, but it is uncertain whether a "perfect" trouble-free implant will be developed because of the basic tolerance problem common to all implants. What's more, each person's reactions to surgery and implantation will be different. Each woman must decide for herself whether it is worth the risk to try to provide what Mother Nature didn't.

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Tan Now, Pay Later?

by Harold Hopkins

In love and romance and other worldly pursuits where personal attractiveness is an asset, one popular method of improving the odds for success is to borrow a bit of coloring from the sun. In other words, get a suntan.

While a suntan—like a kiss—is a temporary thing, some of the undesirable side effects that come with it are longer lasting. The sun damages the skin. Some of the damage may be immediate and obvious: burning and blistering, for example, and various skin rashes or eruptions, as well as eye injury. Other damage may come on the installment plan and may include skin that sags and wrinkles long before it should. Belated damage may also include skin cancer.

Some people are likely to suffer more than others. For many, spending a long time in the sun, when it can be avoided, is rashness beyond reason. Some very fair-skinned people can get severe sunburn from a half hour of exposure in hot summer sun. The elderly, for example, need to take special precautions against overexposure to the sun and high temperatures, as do the obese and people who have diabetes or heart disease. The precaution also extends to people who are taking certain types of drugs, for the sun combined with the drugs can bring on photosensitive or phototoxic effects. A few of the classes of drugs that can create problems when taken along with a heavy dose of sun are certain tranquilizers, anti-emetics (to prevent vomiting), anti-hypertensives, diuretics, tetracycline antibiotics, sulfa drugs, oral diabetic drugs and quinidine. Persons taking any medication, prescribed or over-the-counter, should check with their physicians or pharmacists for possible reactions in strong sunlight.

And when is the sun the strongest?

Some lines from a 1932 stage revue tell us the time of day the heat of the sun should be avoided (and also about some kinds of people who fail to heed the advice):

*Mad dogs and Englishmen go out in the mid-day sun. . . .
In Rangoon the heat of noon is just what the natives shun. . . .
In Bangkok at twelve o'clock they foam at the mouth and run. . . .
In Bengal to move at all is seldom if ever done.*

There is as much science as whimsy in these lines by Noel Coward for the sun is at its strongest and most harmful during the hours from 10 a.m. to 2 p.m. Anyone wishing to minimize the effects of the sun or to avoid heat stroke would do well to confine his or her sunning to other than mid-day hours.

Ultraviolet radiation is worse at these hours, and it's that type of radiation from the sun that causes sunburns, tans the skin and leaves permanent damage. Excessive ultraviolet radiation will cause hardening and thickening of the epidermis (outer skin) of those who tan readily, and blotching or freckling of the skin of those who don't.

Over the long run, the sun's rays will leave the skin tough, leathery, pebbly and dry. Crow's-feet around the eyes may provide a memento of long hours spent squinting under bright sunlight. Other areas of the body exposed for long periods to the sun's radiation may have surface wrinkles much like those in old shoes. Deep creases around the neck are still another legacy of the sun's ravages.

Skins of individuals are affected differently by the sun. It depends on the amount of the naturally occurring skin

pigment, melanin, that an individual's system produces. Persons with darker skins produce larger amounts of melanin. They also tan quicker and with less trouble than those with fair skin. Tanning is especially difficult for those Celtic and other blue-eyed and green-eyed peoples of northern European origins.

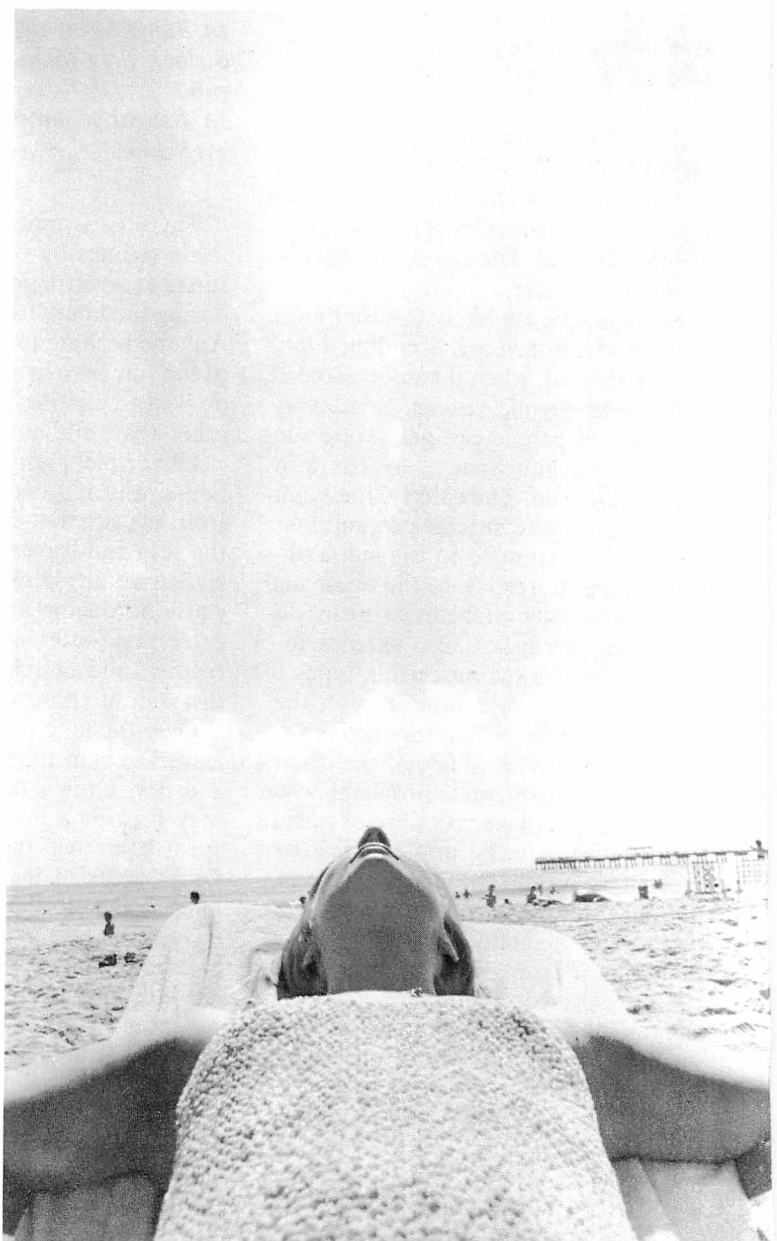
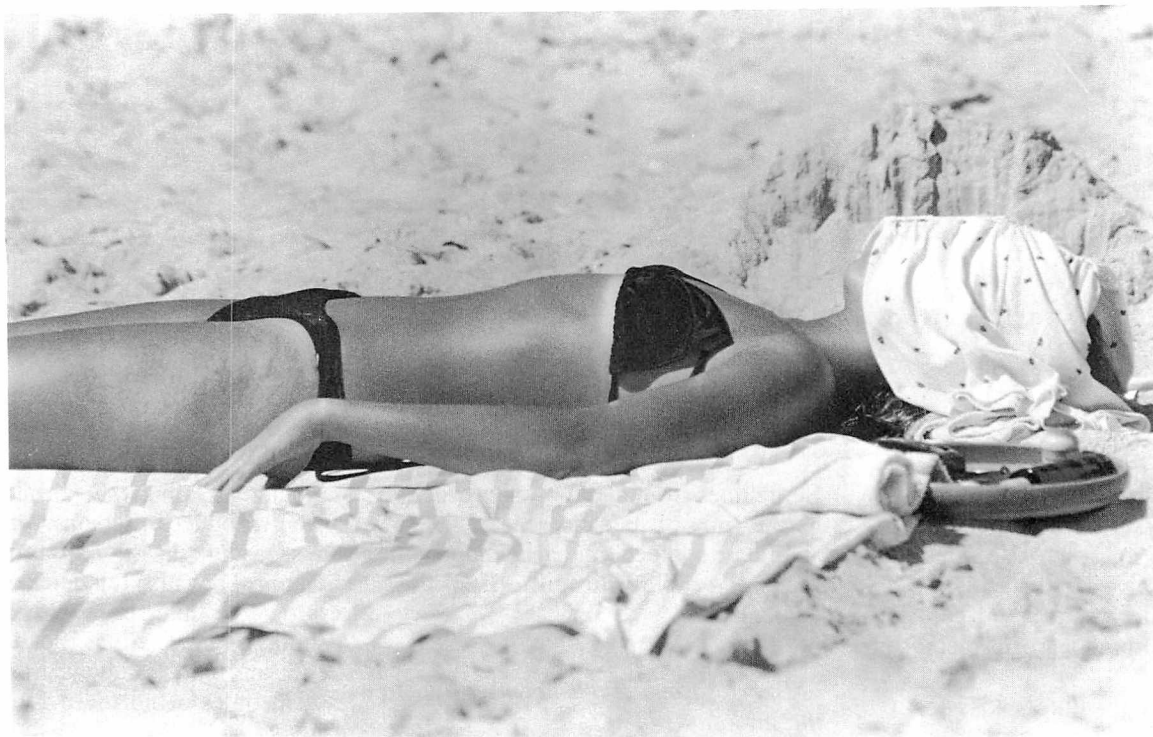
But even those who do tan readily and flaunt their ability to do so may pay dearly for it in the future. Premature aging of the skin is only a part of these deferred payments. The most dreaded long-term effect is the accelerated potential to develop skin cancer.

Ultraviolet radiation from the sun or other sources is the leading cause of skin cancer in people. People who freckle and sunburn easily are especially vulnerable to skin cancer. Most dermatologists consider excessive sunbathing downright foolhardy. They believe the risk of cancer developing from ultraviolet radiation is there, whether one is sunburned or suntanned.

The two most common types of skin cancer—basal cell and squamous cell carcinomas—have been induced in test animals by application of ultraviolet radiation. Each year, according to estimates by the National Cancer Institute, more than 300,000 cases of these two types of skin cancer occur in the United States.

The third type of skin cancer—melanoma—is much more deadly than the others. It has a 40 percent to 50 percent fatality rate, but it is not nearly as common, there being only about 9,000 cases a year. It's not as clear that ultraviolet rays cause melanoma as it is that they cause basal cell and squamous cell cancer, although it's strongly suspected that they do.

Of all types of skin cancer taken together, not more than 2 percent are fatal.



In a 1971-72 study made in several areas of the country by the National Cancer Institute, there were 2.5 times as many cases of non-melanomic cancer in the sunny Dallas-Fort Worth area (latitude 32.8° N) as in the Minneapolis-St. Paul area (latitude 44.9° N), where the sun is less potent. Although skin cancers rarely develop in persons under 20, the incidence increases gradually with advancing age and peaks at about age 75.

The potential for short-term and long-term injury is there whether the ultraviolet radiation comes from the sun or other sources. Sunlamps employing ultraviolet light have long been a favorite for persons seeking a tan in winter or those without access to the sun at other times. More recent has been the popularity, in some parts of the country, of tanning booths or huts, which the customer uses for a fee. All such ultraviolet radiation devices must adhere to FDA design and performance standards, which include requirements for timers, goggles and label directions to help prevent short-term injury.

A panel of scientific experts was engaged by FDA to study a category of over-the-counter drugs that includes sun protectant (screening) products. The panel's report said that liberal, regular use of sunscreen products may help reduce the high incidence of skin cancer and help protect susceptible persons from sunburn. The experts recommended that the labels of such products warn that overexposure to the sun may cause premature aging of the skin and skin cancer and state that sunscreens may provide possible protection against these harmful effects. A minority held that the evidence for sunscreens providing any protection against skin cancer was insufficient and recommended more cautious labeling.

The panel agreed that 21 chemical ingredients marketed in over-the-counter sunscreen products are safe and effective in the prevention of sunburn when properly used. The experts made it clear that they know of no such thing as a perfect prevention for sunburn and said sunscreen products merely extend the time it takes for the sun to cause a burn.



They suggested that sunbathers expose themselves to the sun's rays gradually, while using a suitable sunscreen product.

They recommended that American manufacturers of sunscreen products adopt a numerical system already in use in Europe, called "sun protection factor" (SPF), to designate the relative effectiveness of and the limitations of sunscreens. This numerical rating system in fact is already in wide use among manufacturers in this country and consumers are becoming familiar with and using the system to select sunscreen products to fit their needs.

The rating values are as follows:

- SPF 2 to 4: minimal protection from sunburning; permits suntanning; recommended for people who rarely burn and tan easily and deeply.
- SPF 4 to 6: moderate protection from sunburning; permits some suntanning; recommended for people who tan well with minimal burn.
- SPF 6 to 8: extra protection from sunburning; permits limited suntanning; recommended for people who burn moderately and tan gradually.
- SPF 8 to under 15: maximal protection from sunburning; permits little or no suntanning; recommended for people who always burn easily and tan minimally.
- SPF 15 or greater: ultra protection from sunburn, offers most protection; permits no suntanning; recom-

mended for people who burn easily and never tan.

The range of products marketed under this rating system makes it possible for practically every person to be reasonably well protected from sunburn and to obtain the optimum amount of suntan possible in his or her individual case. Obviously, these screens will not work or will not work as effectively if they are washed off by swimming or diluted by sweating and should be reapplied for safety.

The 21 ingredients the panel found to be safe and effective for use in sunscreen products:

Aminobenzoic acid
Cinoxate
Diethanolamine p-methoxycinnamate
Digalloyl trioleate
Dioxybenzone
Ethyl 4-[bis (hydroxypropyl)] amino-
benzoate
2-Ethylhexyl 2-cyano-3, 3-diphenyl-
acrylate
Ethylhexyl-p-methoxycinnamate
2-Ethylhexylsalicylate
Glyceryl aminobenzoate
Homosalate
Lawsone with dihydroxyacetone
Menthyl anthranilate
Oxybenzone
Padimate A
Padimate O
2-Phenylbenzimidazole-5-sulfonic acid
Red petrolatum
Sulisobenzene
Titanium dioxide
Triethanolamine salicylate

Harold Hopkins is editorial director of FDA Consumer magazine.

Does Your Medicine Chest Need First Aid?

by Annabel Hecht



A bleary-eyed man rummages through the bathroom cabinet, tossing various bottles and boxes aside until, with a sigh of relief, he finds the remedy for his indisposition.

This scene, enacted frequently in television commercials, may help sell the sponsor's product, but is not one to be recommended for the viewers' home. What's basically wrong with the picture is that the bathroom is not the proper place to store medicines. Bathroom cabinets are usually right over the sink and too accessible to young children. What's more, the warm moist atmosphere of the bathroom can cause some drugs to deteriorate. Not only that, but the clutter Mr. Bleary Eyes found in his cabinet, which obviously made it difficult for him to find what he wanted, suggests that he probably had more drug products there than he really needed.

Of course, it's a good idea to have useful medical supplies on hand for emergencies and to treat minor ills, but the family medicine chest does not have to be a mini drug store. What should be kept in the average household will depend on the makeup of the family. For instance, when there are young children, the medicine chest might include baby aspirin, anti-bacterial topical ointments and medicine to treat symptoms of diarrhea. For that family, syrup of ipecac to induce vomiting and activated charcoal are important for emergency treatment for some accidental poisonings. Persons who are likely to use or administer them, however, should understand the types of poisoning for which they should not be used, as when a caustic agent has been swallowed, for instance.

If there are teenagers, the medicine chest might include acne preparations. An older family member might have a special need for liniment. An adult in reasonably good health may have little use for most over-the-counter medicines.

Generally, medicine chests should include only those health care products likely to be used on a regular basis. A

person rarely bothered by constipation, for instance, would have little need for a laxative.

Overstocking drugs in the household should be avoided. Some drug products lose their potency on the shelf in time, especially after they are opened. Other drugs change in consistency. Milk of magnesia, for instance, dries out if it remains on the shelf for a while after opening. Buying the large "family size" of a product not used frequently may seem like a bargain, but it's poor economy if it has to be thrown out before the contents are used up. Ideally, supplies in the medicine chest should be bought to last over a period of no more than six to 12 months.

Obviously, selecting health care items for the family medicine chest is a matter of common sense. Here are some suggested items that will meet the needs of most families:

Non-drug products

Adhesive bandages of assorted sizes

Sterile gauze in pads and a roll

Absorbent cotton

Adhesive tape

Elastic bandage

Small blunt-end scissors

Tweezers

Fever thermometer including rectal type for a young child

Hot water bottle

Heating pad

Eye cup for flushing objects out of the eye

Ice bag

Dosage spoon (common household teaspoons are rarely the correct dosage size)

Vaporizer or humidifier

First aid manual

Drug items

Analgesic—Aspirin and/or acetaminophen. Both reduce fever and relieve pain, but only aspirin can reduce inflammation.

Emetic—syrup of ipecac to induce vomiting and activated charcoal. Read the instructions on how to use these products.

Antacid

Antiseptic solution

Hydrocortisone creams for skin problems

Calamine for poison ivy and other skin irritations

Petroleum jelly as a lubricant

Anti-diarrhetic

Cough syrup—non-suppressant type

Decongestant

Burn ointment

Anti-bacterial topical ointment

The medicine chest might also include anti-nausea medication if any family member is prone to motion sickness, a laxative and some liniment. Seasonal items, such as insect repellents and sunscreens round out the list.

When it comes to storing these health care items the cardinal rule is to keep all medicines out of the reach of children. In addition, be sure all medications have child-resistant caps. Elderly people who have difficulty opening such caps can ask the druggist for regular closure. However, they should be extra careful to see that young visitors can't get to these drugs.

Both prescription and non-prescription drugs should be kept in a cool, dry place away from foods and other household products. Some drugs may need to be kept in the refrigerator. This should be indicated on the label. If in doubt, ask the pharmacist.

Many people keep medicines on a high shelf in a hall or bedroom closet.

Some experts suggest using a locking box. A tackle box might do. A word of warning, however: Be sure all responsible adults in the family know where the key is kept.

To avoid confusion keep prescription and non-prescription drugs in separate boxes clearly labeled to distinguish one type of drug from the other. A list of what's in each box, attached to the outside if possible, will make it easier to find specific items, particularly in an emergency.

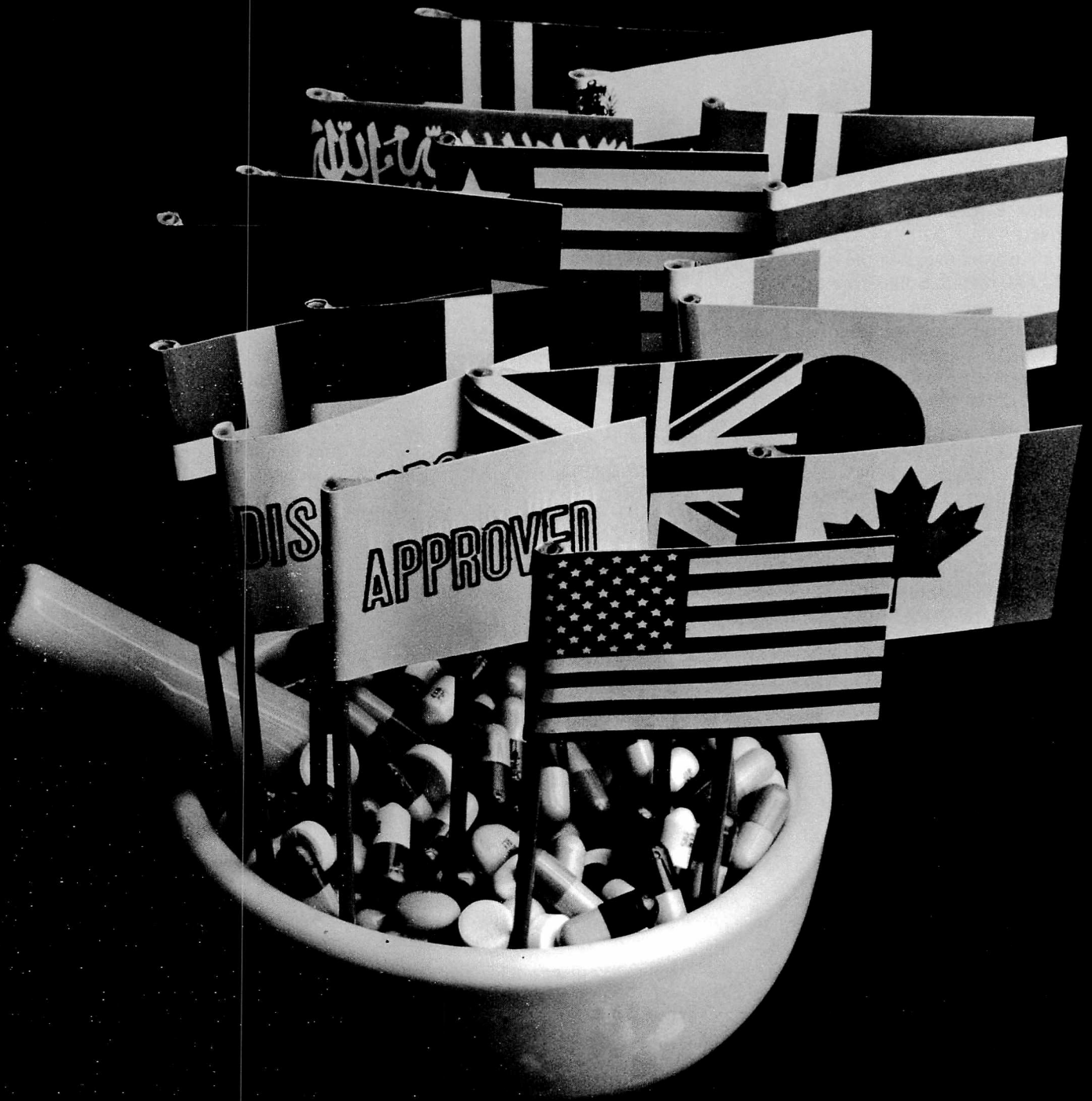
The medicine chest should be checked periodically to be sure supplies haven't run low and to get rid of drugs that may have gone bad or become outdated. Many drug labels have an expiration date beyond which the product should not be used. If there isn't a date, put a label on the container with the date of purchase and the date it was first opened. Then, if there are any questions in the future, a pharmacist can tell whether the product is safe to use.

Tablets that have become crumbly, medicines that have changed color, odor or consistency, or are outdated, should be destroyed. Empty the bottle of medicine into the toilet, flush it down, and rinse out the bottle. Don't put leftover drugs in the trash basket where they can be dug out by inquisitive youngsters. Newly purchased drug products that don't look right should be returned to the pharmacy. Drug products that have lost their labels also should be destroyed.

Keep the telephone numbers of the local poison control center, physician, hospital, rescue squad, fire and police departments near every phone in the house. Tape the emergency phone list inside the bathroom medicine cabinet door and also keep it with the emergency supplies.

Each family's medicine chest is bound to contain some different items. For help in selecting appropriate health care products, check with a physician and a pharmacist.

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

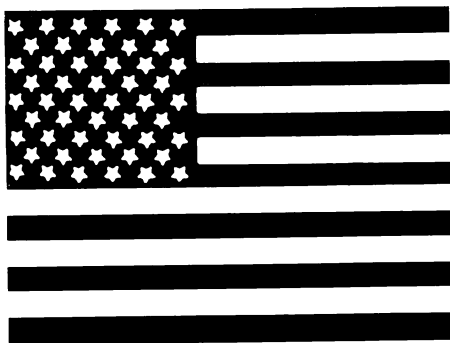


A Global Look At Drug Approvals

by Christopher Smith

Drugs are chemicals or combinations of chemicals that, for the most part, are unusual to the human body. They are allowed to enter into human beings for therapeutic purposes—to cure a disease or minimize its impact, or to restore a lost function. But only some chemicals or chemical combinations should be allowed to enter into the human system. Which should be permitted access and which should be kept out? The answer to that question is deceptively simple: Only those drugs (read: chemicals) that are safe and effective should be given access.

But the average citizen, in the United States or West Germany or South Africa or wherever, cannot make the safety and efficacy decision on a particular chemical. So he must look to the government to do so. Just how the government does that varies by country.



In this country, the drug approval process is divided into two parts: the testing phase and the review phase.

During the testing phase, the Food and Drug Administration requires that animal studies be performed before human testing can begin. If the animal tests indicate that the drug can be used safely in man, and may be therapeutically useful, the drug

manufacturer or sponsor submits to FDA a Notice of Claimed Investigational Exemption for a New Drug, called an IND. This filing includes information about the drug's chemical composition, how it is made, and a description of the plan for testing it in humans. Unless FDA raises objections within 30 days, the manufacturer may begin the drug tests.

FDA reviews the IND to make sure that patients will not be subjected to unwarranted risks during the tests and to see that the tests will yield significant results. FDA also monitors these tests and requires that review boards be established in the universities, hospitals and other institutions where the drug research is being done. These institutional review boards, as they are called, are composed of local professional people who are responsible for assuring that patients treated with experimental drugs have given their consent and that the possible benefits are worth the expected risks for the patients who take part in the testing.

In Germany, a law that became effective in 1978 also requires that new drugs be shown to be both safe and effective before approval. There, the *Institut für Arzneimittel Bundesgesundheitsamt* does the job of approving new drugs. Unlike the U.S. system, no review of the pharmacological and toxicological pre-testing of the chemical is done by the agency before a sponsor is allowed to test the drug in patients. Before beginning, the drug sponsor simply turns over sealed packages to the government describing the results of these tests. The packages are opened only if problems arise at some later time. During this investigational phase, the German institute does not require that institutional review boards be present to help assure the patient's protection.

In Canada, the drug approval function is the responsibility of the Health Protection Branch of the National Health and Welfare Department. Just



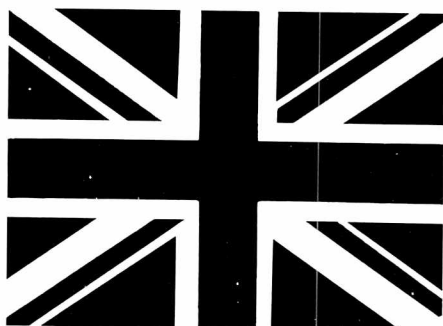
as in the United States, a manufacturer must submit an IND before beginning clinical studies. This IND is reviewed by the authorities for much the same reasons as it is looked at here. A difference exists, however, in the time required for this review. Whereas FDA allows the experiments to begin in 30 days or less, in Canada the drug sponsor usually must wait about 90 days. As with the German system, the Health Protection Branch has no regulatory authority to require review by institutional boards or to require informed consent of the patients in studies of investigational drugs.

Great Britain recently changed its requirements for investigating drugs in humans. A sponsor had been required to apply for a license to study new drugs in patients other than healthy volunteers. The application was complicated and the British regulators took as long as nine months to grant approval for the testing. The drug industry objected to the controls and the Medicines Division of the Department of Health and Social Security responded with a "Clinical Trial Exemption" similar to the IND. Upon filing of the exemption, the

British agency has 35 days to consider the application and advise the company whether it objects to the trials.

Once begun, the time taken to carry out investigational tests on new drugs also varies from country to country. This is not only because of differences in requirements among regulatory agencies, but also because of the nature of the drugs themselves. Very effective drugs that may be beneficial to large populations, such as penicillin for patients with pneumonia, may require testing and careful observation of a limited number of patients before effectiveness can be demonstrated. Drugs of marginal or borderline effectiveness require larger numbers of patients in the clinical studies. In these cases, the larger number of subjects will allow both the drug manufacturer and the regulatory agency to determine more easily whether the drug was truly effective. In other cases, drugs may require years of observation of patients. Sometimes the expectation of great therapeutic benefit may justify making the drug available before all of the answers are known.

The disease being treated can also play a role in the time it takes for the drug's testing. For example, a drug manufacturer obviously must study the effects of a drug for the treatment of a particular tropical disease in countries where that disease is prevalent. Other factors that affect early drug testing are the period the drug will have to be used by the patient; population characteristics such as ethnic background, general health and state of nutrition; and differences in the practice of medicine.

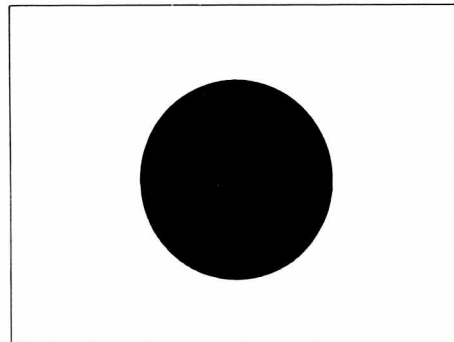


The second major phase of drug development involves the approval of the drug for marketing. In the United States, the application for this approval is called a New Drug Application, or NDA. The NDA contains all the information the sponsor has about the drug and usually runs into thousands of pages. As each application makes its way through the FDA approval process, it is seen by physicians, pharmacologists, chemists and statisticians. In some cases, specialists such as microbiologists may also review the submission. These scientists must ascertain whether the drug is safe and effective, what its labeling should say, and whether the sponsor can manufacture the drug properly. At times, FDA is assisted in this review by 15 advisory committees composed of outside experts in specific drug areas.

In Sweden, this process is carried out by the Department of Drugs. Like the U.S. requirements, Swedish law demands a full report of all studies, including those done outside of Sweden. The data may be summarized by the sponsor and is reviewed by the physicians, pharmacists and chemists of the department in much the same way FDA review teams go over NDAs.

Canada also requires that studies be submitted to document a drug's safety and effectiveness. Many times Canadian authorities review not only summaries of the investigational results but also individual patient records to assure the adequacy of the testing. Like FDA, Canada's Health Protection Branch requires that these studies be well controlled and that they adequately substantiate the claims made for the new drug.

In Japan, new drugs are reviewed in a complicated system of government appointed committees and subcommittees. These outside reviewers comprise 68 committees of senior experts and eminent specialists from universities, hospitals and research centers throughout the country. After the review a recommendation is made to the regulatory agency regarding the drug's approval. No new drug from outside the country can be approved in



Japan unless the drug has been sanctioned for use first in the country of origin. The Ministry of Health and Welfare also requires that certain tests be carried out in Japan before the drug will be considered for approval in that country. The data are then collected and submitted to the committees, usually in a summarized form only. No individual patient records are required.

In some countries, such as Algeria, Bolivia and Uruguay, no guidelines exist to assist the drug sponsor in obtaining licensing approval. Indeed, many countries have no specially designed system to register a drug for the market.

When a manufacturer submits a New Drug Application to FDA, the law allows 180 days for the agency to conduct its review and approve or not approve the drug for marketing. Most NDAs, however, are not approved after this first review cycle because of deficiencies in one or more areas of the application. Eventually about 85 percent of the NDAs are approved, usually after the second or third cycle. The total approval times from initial submission to final approval vary from six months to several years. During 1981 FDA approved 96 New Drug Applications including 27 for chemicals never before used in this country as drugs. FDA's average time for approval of New Drug Applications was shortened from almost three years in 1979 to less than two years in 1981.

In some countries it's fairly easy for sponsors to gain approval for marketing new drugs. This is especially true in many underdeveloped areas of the world such as Latin America and

Africa. Approvals generally take longer in countries such as Germany, Sweden, Canada, Great Britain and Japan, which have well-developed regulatory systems. In Sweden, the time period for approval has risen steadily over the last decade and is now 2½ years. The German regulatory agency has four months to decide on approval once the data are submitted. Additional information can be requested of the sponsor and, once that is submitted, the regulations allow three additional months for the review. The average time for approval in Germany is about 10 months. In England, a new drug approval takes about a year. There, the Medicines Division has 120 days in the first cycle but when new information is requested, additional review periods can be allowed.

Canadian law requires that the Health Protection Branch answer a sponsor's request for approval within 120 days. Clearance time for an application after the necessary review and any additional requests by the sponsor is now estimated at about 11 months. Approval in Japan can take from one to three years. Japan has no time limit restrictions.

In most countries approval is accompanied by a licensing arrangement that requires periodic renewal. In Germany and the United Kingdom, registration is granted for five years. The same is true in Czechoslovakia, Israel and Greece. In South Africa, it is one year. In Egypt, licenses are granted for 10 years. Many of the countries also charge fees for relicensing after that period has expired. The United States, Sweden and Canada do not require renewals or charge fees.

Differences also exist among countries in how drugs are monitored once on the market. After a drug is in wide use, the data that show the balance between its benefits and risks may change. Previously undetected adverse effects may be discovered, or particular groups of patients may turn up who are more or less likely to develop adverse reactions. A drug also may be found effective for uses other than those studied before marketing. When new discoveries are made about a drug, its label

may need revision. Occasionally, if a very serious reaction to or risk from a drug turns up, removal from the market may be necessary.

Once a drug is approved in the United States, the manufacturer is required to report any newly found adverse reactions. FDA participates in many post-marketing surveillance programs involving drug products, including those operated by the United States Pharmacopeia and the World Health Organization. An FDA system for voluntary reporting by health professionals draws some 12,000 reports of adverse reactions annually. Besides these systems, both domestic and foreign scientific literature are constantly reviewed for reports of adverse reaction incidents.



Germany, Sweden and the United Kingdom also operate post-marketing surveillance systems and have requirements for drug experience reporting by drug manufacturers. Collection of adverse reaction data is easier for British authorities in many ways because that country operates a national health insurance program from which data about drug use are retrieved quite readily.

Many South American countries, as well as Portugal, the Netherlands and Hong Kong, have no legal requirements for reporting adverse reactions by drug firms or for monitoring the use of the products after marketing begins.

In addition to the drug regulatory process, other factors affect the drug approval system: the array of marketed drugs varies, the practices of medicine

differ, and the drugs perceived by the industry or by physicians in one country to be worthy of marketing are not the same as those in another. This is why drugs are often introduced in different countries at different times. Just where a drug is introduced may depend on where it was discovered, the research resources available in that country, the disease for which the drug is intended, and the differences in the costs of research in different countries. Also of importance are economic issues such as the value of currency, tax structures and labor costs.

Still other factors that influence drug introduction are differences in the forms of government. In the United States, for example, the government system requires that decision making be for the most part on the record, from congressional hearings to public advisory committee meetings to solicitations for public comment in the *Federal Register*. In addition, the Freedom of Information Act provides access to much of the information on which the drug is evaluated and approved.

Today, the U.S. system for drug evaluation might well be considered at a crossroads. Last September, FDA Commissioner Arthur Hull Hayes Jr. established a task force to conduct a review of the drug approval process. Among the subjects being studied by the group are the amounts of data required by FDA for drug approval, the use of advisory committees, and more use of information from foreign studies. Also being looked at is the handling of so-called breakthrough drugs, those with special promise. In addition, a special committee on the drug approval process has been established by Congress. Consisting of non-government experts, that group will report its findings to the lawmakers.

All of this scrutiny could bode well for the system, as it could result in development of a better way for maintaining the delicate balance between those drugs that are approved too soon and those that arrive too late.

Christopher Smith is a member of FDA's public affairs staff.



How To Ignore Salt And Still Please The Palate

by Roger W. Miller

“People are just overwhelmed with the idea that they have to give up salt. They think they’re being penalized. But you just have to withdraw the idea of salt. You have to adjust flavorings—use lemon, garlic and fresh herbs. I’ve done that with considerable success for years.”

That’s the advice of James Beard, a food connoisseur who has been writing cookbooks for 40 years and revealing his culinary techniques on television for more than a quarter of a century. It’s obvious that a man with these credentials didn’t just misplace his salt shaker. No, the reason Beard foregoes salt is that he is a high blood pressure victim who is on a salt (sodium) restricted diet.

Adding spice to Beard’s sentiments is Craig Claiborne, food editor of the *New York Times* and author of 14 cookbooks including one that features low-sodium recipes. Claiborne is another hypertension or high blood pressure victim. He had been on drugs to control his pressure, but the drugs didn’t work. A low-sodium diet did. Claiborne finds the amount of sodium we add to our food appalling. Today his recipes in the Sunday *New York Times Magazine* invariably include the line:

“Salt, if desired.”

Claiborne thinks there are many ways to ignore salt and still “fool the palate,” and his thoughts are shared by a number of other authors who have turned out low-salt cookbooks. The authors include other gourmets, doctors, scientists and just plain consumers who found themselves ordered to reduce their salt intake.

Too much sodium (salt is 40 percent sodium) is a problem for the estimated 60 million Americans who have high blood pressure or who are marginal hypertensives. Evidence is mounting that those to whom hypertension is a family affair are more likely to intensify the problem with a high-sodium diet.

Americans consume an estimated 2,000 to 6,000 milligrams (mg) of sodium per day. That’s about the same as gulping down one to three teaspoons of salt. Most experts agree that the average adult can get along on 1,000 milligrams or less a day.

Controlling the amount of sodium in the diet is no easy matter. The stuff comes from three sources: some occurs naturally in food and water, some is added in cooking and at the table, and the rest is put into foods during processing for a variety of reasons, mainly for taste and preservation.

The Food and Drug Administration began a major effort in 1981 to enlist the aid of food manufacturers in lowering sodium content and providing better label information of the amounts of sodium in processed foods. In less than a year that effort has paid off with cooperation from such major processors as Del Monte, Quaker Oats, General Foods, Frito-Lay, Beatrice Foods, Campbell Soup, Friday Canning Corp. and Procter & Gamble as well as some supermarket chains such as Stop & Go. Within a year, it is expected that a third of the processed foods regulated by FDA will carry sodium content on their labels. That would be a tripling of such information.

FDA now requires that foods sold as low-sodium items must spell out on the label the number of milligrams of sodium contained in 100 grams of the product, plus the number of milligrams in a serving. To understand this information, the consumer must remember that there are 1,000 milligrams in a gram and 28.4 grams in an ounce.

Waiting in the wings are regulations to define the terms “low sodium,” “moderately low sodium” and “reduced sodium” when used on food labels.

Not too much can be done about the sodium Mother Nature adds to her bounty. However, the pots and pans pundits are ready to offer relief from the kitchen use of salt and other high sodium cooking products such as baking soda, monosodium glutamate (MSG) and soy sauce.

For the average consumer, such relief is not spelled e-a-s-y. It’s not that the cooking is any more difficult, but low-sodium and sodium-free products continue to be more expensive and harder to find on store shelves. Sometimes it seems that the consumer is being asked to pay for what is left out. In testimony before Congress in April 1981, Claiborne said: “The worst thing about trying to maintain a (low-sodium) diet . . . [is] trying to find foods on the supermarket shelf not containing salt.” In reality, the problem is the law of supply and demand. Up to this point there just hasn’t been enough demand for those products.

And the book *How To Live 365 Days a Year—The Salt-Free Way* has a chapter titled “High Adventure in the Supermarket: In Search of Low-Sodium Food.” That book was written in 1977. One would hope that the situation has improved and will continue to do so. However, the authors advise consumers to ask the store manager for low-sodium and sodium-free products and to voice their displeasure when none is available.

It is unrealistic to expect to find any simple salt substitutes. A number of products labeled “salt substitute” are on the market. They usually contain potassium chloride as a partial or complete replacement for sodium chloride (table salt). Some of the cookbook writers have complained about the substitutes, one saying that they distort the flavors of foods. More important, people with certain medical conditions, such as severe liver or kidney disease, must control the amount of potassium they take in. People with a serious desire or concern about potassium intake for other reasons should consult with their physician before using a salt substitute.

However, as James Beard noted, there are flavorings that can often be substituted for salt, and some of these are natural seasonings for the foods. The American Heart Association’s cookbook, *Cooking Without Your Salt Shaker*, offers a simple guide for flavor combinations. That guide is printed in a box adjoining this article. Some of the

How To Ignore Salt

From the American Heart Association's cookbook *Cooking Without Your Salt Shaker*, here's a simple guide for substituting herbs and spices for salt in a variety of foods:

Meat & Fish & Poultry

| | |
|----------|--|
| Beef: | Bay leaf, dry mustard powder, green pepper, marjoram, fresh mushrooms, nutmeg, onion, pepper, sage, thyme. |
| Chicken: | Green pepper, lemon juice, marjoram, fresh mushrooms, paprika, parsley, poultry seasoning, sage, thyme. |
| Fish: | Bay leaf, curry powder, dry mustard powder, green pepper, lemon juice, marjoram, fresh mushrooms, paprika. |
| Lamb: | Curry powder, garlic, mint, mint jelly, pineapple, rosemary. |
| Pork: | Apple, applesauce, garlic, onion, sage. |
| Veal: | Apricot, bay leaf, curry powder, ginger, marjoram, oregano. |

Vegetables

| | |
|--------------|--|
| Asparagus: | Garlic, lemon juice, onion, vinegar. |
| Corn: | Green pepper, pimiento, fresh tomato. |
| Cucumbers: | Chives, dill, garlic, vinegar. |
| Green Beans: | Dill, lemon juice, marjoram, nutmeg, pimiento. |
| Greens: | Onion, pepper, vinegar. |
| Peas: | Green pepper, mint, fresh mushrooms, onion, parsley. |
| Potatoes: | Green pepper, mace, onion, paprika, parsley. |
| Rice: | Chives, green pepper, onion, pimiento, saffron. |
| Squash: | Brown sugar, cinnamon, ginger, mace, nutmeg, onion. |
| Tomatoes: | Basil, marjoram, onion, oregano. |
| Soups: | A pinch of dry mustard powder in bean soup; allspice, a small amount of vinegar or a dash of sugar in vegetable soup; peppercorns in skim milk chowders; bay leaf and parsley in pea soup. |

Salt-Free Books

Following are some books that people interested in maintaining a sodium-restricted diet may obtain. The list is not meant to be comprehensive in the subject area, nor does the listing constitute an endorsement of the books by FDA or this magazine. They are listed alphabetically by title.

Cooking Without a Grain of Salt, by Elma W. Bragg, Bantam Books, New York, N.Y. Also published in hardback by Doubleday & Co.

Cooking Without Your Salt Shaker, American Heart Association, Dallas, Texas.

Craig Claiborne's Gourmet Diet, Ballantine Books, New York, N.Y. Also published in hardback by Random House.

The Dell Color-Coded Low-Salt-Living Guide, by Janet James and Lois Goulder, Dell Publishing Co., New York, N.Y.

The Dictionary of Sodium, Fats, and Cholesterol, by Barbara Kraus, Grosset & Dunlap, New York, N.Y.

The Dieter's Gourmet Cookbook, by Francine Prince, Cornerstone Library, New York, N.Y.

Dr. Rechtschaffen's Diet for Lifetime Weight Control & Better Health, Random House, New York, N.Y.

Gourmet Cooking Without Salt, by Eleanor P. Brenner, Doubleday & Co., Garden City, N.Y.

How to Live 365 Days a Year the Salt-Free Way, by J. Peter Brunswick, Dorothy Love and Assa Weinberg, M.D., Bantam Books, New York, N.Y.

Living Salt Free & Easy, by Anna Houston Thorburn with Phyllis Turner, New American Library, Inc., New York, N.Y. Also published in hardcover by Douglas-West Publishers, New York, N.Y.

Salt-Free Cooking With Herbs and Spices, by June Roth, Contemporary Books, Chicago, Ill.

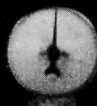
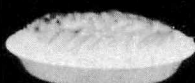
Secrets of Salt-Free Cooking, by Jeanne Jones, 101 Productions, San Francisco, Calif.

Sodium Content of Your Food, which is referred to in the article, is available free of charge by sending a postcard to: FDA Consumer Communications HFE-88 5600 Fishers Lane Rockville, Md. 20857

It lists the sodium content of 789 foods and food products as well as a number of popular non-prescription drugs.

Dieter's Gourmet Cookbook

FRANCINE PRINCE



The Dell Color-Coded Low-Salt-Living Guide

From the Dell Color-Coded Low-Salt-Living Guide

HOW TO LIVE 365 DAYS A YEAR THE SALT-FREE WAY

GOURMET COOKING WITHOUT SALT



Over 300 low-salt recipes for people who love to eat well

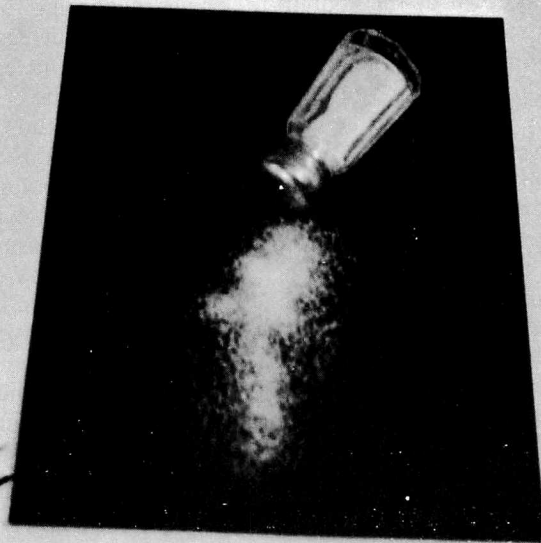
THE DICTIONARY OF SODIUM, FATS, AND CHOLESTEROL

HOW TO MANAGE YOUR DIET AND YOUR HEALTH

How to use the dictionary

DR. RECHTSCHAFFEN'S DIET FOR LIFETIME WEIGHT CONTROL & BETTER HEALTH

CRAIG CLAIBORNE SAYS, I can live with all the convenience of my modern diet and give myself the best of both worlds. And with this perfect



LIVING SALT FREE & EASY

other cookbooks offer more detailed listings.

Despite Nature's penchant for incorporating sodium in food and water, living on or cooking for a low-sodium diet usually means using fresh vegetables whenever possible. For examples see the U.S. Department of Agriculture's booklet *The Sodium Content of Your Food*. It reveals that a cup of cooked fresh corn contains only one milligram of sodium, while a cup of frozen has seven and a cup of canned 671. The ratios are much the same for most vegetables. Frozen dinners also tend to be high in sodium, according to information supplied by manufacturers to *The Dell Color-Coded Low-Salt-Living Guide*. Most of 14 dinners listed in that book had more than 1,000 mg of sodium, topped by the 1,615 in the fried chicken serving. Most of the sodium is added in the processing.

There are some quirks in the raw-is-good maxim. Celery, for example, runs 25 mg of sodium to a stalk (but less when cooked sans salt because some sodium is lost in the cooking). Likewise, regular milk and fresh meat contain moderately low amounts of sodium. One cup of whole milk has 122 mg, while an ounce of cheddar cheese (to which salt is added in processing) provides 176 mg. Most raw meats are moderately low in sodium, but the sodium counts go up considerably when the meats are corned, smoked, dried, cured or processed in other ways.

Needless to say, fish from salt water runs higher in sodium than fresh water fish. Again, most fish, including frozen forms, are higher when processed. Three ounces of raw shrimp contains about 137 mg. However, when canned it contains 1,955 mg of sodium, according to the USDA publication. And smoked herring runs up to 5,234 mg of sodium for three ounces.

Of course, some other salty items are well known: canned sauerkraut, 1,554 mg per cup; dry roasted, salted peanuts, 986 mg per cup; one dill pickle, 928 mg and a frankfurter, 639 mg.

Not so well known are Manhattan style condensed clam chowder with water, 1,808 mg per cup; catsup, 156 mg for a tablespoon; pancake mix, 2,036 mg in a cup.

The amount of sodium that occurs in a community's drinking water will vary by areas. Usually a call to the local water department will give a quick sodium headcount, a couple of writers noted. *The Dictionary of Sodium, Fats, and Cholesterol* has a state-by-state breakdown of the sodium content of municipal water supplies ranging from Birmingham, Ala. (0.5 mg per cup) to Milwaukee, Wis. (1.0 mg per cup). The highest listing is 46.9 mg/cup for one of the plants serving Long Beach, Calif.

Eating out can present special problems for those who have to restrict their sodium intake. Several of the books offer advice on how to get along on the fewest milligrams while so far from the home range. In *The Secrets of Salt Free Cooking*, the author starts out with this advice about restaurant dining: "The first assumption you must make is that your waiter doesn't know anything about low-sodium diets." From then on, it's a matter of choosing foods wisely, avoiding known salty items such as soups, most sauces and salad dressings, and making sure meats and fish are fresh—not frozen or processed. For the traveler, most airlines will provide a low-sodium meal if notified in advance, and hotels will often equip a room with a small refrigerator for stocking low-sodium items.

Fast food restaurants are, generally speaking, a no man's land in the battle to reduce sodium consumption. According to the figures supplied by the chains, the sodium contents of the items run: 393 mg for a Burger Chef hamburger, 960 for a Big Mac and 2,285 for a Kentucky Fried Chicken Original Recipe dinner. A hamburger, french fries and a chocolate shake will total 965 mg of sodium, according to *The Dell Color-Coded Low-Salt-Living Guide*.

The American Council on Science and Health, which describes itself as an "independent educational association promoting scientifically balanced evaluations of food, chemicals, the environment, and human health," recently published a booklet called *Fast Food and the American Diet*. The booklet includes this advice:

"Individuals who are under a physician's orders to reduce their sodium intake (common advice to people who have high blood pressure) should be aware that many fast foods are relatively high in sodium due to their high content of salt (sodium chloride). It may be impossible to fit some menu items into sodium-restricted diets. . . .

"Condiments such as pickles, catsup and mustard also contain substantial amounts of sodium. Consumers who add salt to fast food items before eating further increase the food's sodium content."

However, there are signs of hope for those people who love fast foods but need to know sodium content. Arby's restaurants are providing nutrition composition information, including sodium quantities, for foods listed on their menus. McDonald's has also done pilot tests on a nutrition listing program.

In commenting to *FDA Consumer* about living without added salt, James Beard said the only taste he missed was bread made with salt. But the authors of the various salt-free cookbooks offer a variety of salt-free breads, ranging from apple juice rye bread (1 mg sodium) in *The Dieter's Gourmet Cookbook* to Claiborne's hamburger buns to the low-sodium white bread in *Cooking Without A Grain of Salt*. The heart association's saltless cookbook lists two dozen items under the heading of "breads."

Some say it's impossible to eat a hard boiled egg without putting salt on it. But boiled, poached or fried eggs can be seasoned delightfully with the pepper shaker. Other egg dishes can be seasoned with paprika, tarragon, savory and chives, according to the book *Salt-Free Cooking With Herbs and Spices*. But eggs in themselves are not exactly low-sodium food. One egg contains about 60 mg of sodium, 51 of that in the whites.

A scientific study done for FDA on sodium concluded that the aggregate consumption of sodium should be lowered. In other words, all of us should cut down on the amount we use. Recent scientific evidence indicates that people with slightly raised blood pressure will usually benefit from sodium-restricted diets, as do those who take prescribed drugs for their hypertension. Less sodium in the diet tends to make the drugs more effective and results in fewer and less severe side effects.

Diseases of the heart are the nation's No. 1 killer. Hypertension is often an accessory in those deaths. So, even though that recipe may call for just a pinch of salt, remember that a few pinches can add up to a considerable ouch.

Roger W. Miller is editor of *FDA Consumer*.

Death Helped Write The Biologics Law

by Ramunas A. Kondratas

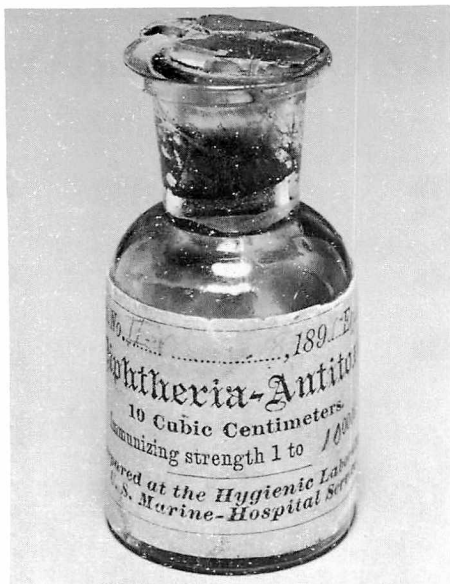
It was nearly 80 years ago, on July 1, 1902, that President Theodore Roosevelt signed into law "an act to regulate the sale of viruses, serums, toxins, and analogous products in the District of Columbia, to regulate interstate traffic in said articles, and for other purposes." The new federal law attempted to control the interstate and foreign sale of a specific class of drugs in the United States preceding by four years the first Food and Drugs Act.

Identification of microbes as causes of disease, discovery of sources of infection and understanding of the modes of transmission had made it possible for physicians and public health workers during the latter half of the 19th century to develop more specific methods of prevention. Serum therapy and the newly emerging science of immunology were important milestones in developing specific remedies—antitoxins and vaccines—for mass prevention and treatment of many epidemic, communicable diseases that scourged mankind at the turn of the century. Until then vaccination was successful only against smallpox and only a very few specific remedies were known, such as quinine for malaria and mercury compounds for syphilis.

Some of the first specific remedies devised by man came out of Koch's laboratory in Berlin in 1890 where it was found that animals injected with diphtheria and tetanus toxins produced antitoxins that provided immunity to animals or humans inoculated with them. Of more importance, this serum

could actually cure the diseases. Large scale production of diphtheria antitoxin began after Emile Roux reported in 1894 his successful effort at producing antitoxins from horses. Roux's study of serum therapy was based on four years of laboratory experiments and the treatment of hundreds of cases of diphtheria. Under serum therapy, mortality from diphtheria in Paris hospitals was





reduced from 52 percent to less than 25 percent. The clinical success of diphtheria antitoxin in Europe and later in the United States acted as a powerful stimulus for the development of pharmaceutical firms and public health laboratories.

By the spring of 1895, the first samples of diphtheria antitoxin had been produced and tested in New York City and Washington, D.C. The H. K. Mulford Co. of Philadelphia was the first pharmaceutical firm in the United States to manufacture the antitoxin.

Serum therapy opened a broad new field in preventive medicine, but at first there were some serious pitfalls. Lacking were a good working knowledge of bacteriology and the sterile technique for successful production of serums and vaccines. Proper dosage forms and sterile containers had to be designed. Laboratory equipment had to be manufactured or imported. Proper refrigeration was a requisite and stables and animal shelters needed to be kept absolutely clean with the animals free from disease and infection. Most important, standards of purity and potency had to be established and enforced. All had to be done at a reasonable cost and at a time when the science of bacteriology was still in its infancy on American soil.

Diphtheria antitoxin was a powerful new weapon for the physician, but without proper standards and safeguards it could have been misused and could have brought harm to the public and the medical profession. The failure of tuberculin developed by Koch a few years earlier was still fresh in the

minds of many physicians and they viewed with skepticism the glowing reports about diphtheria antitoxin. In Germany competition developed between pharmaceutical manufacturers in the production of serum, with firms boasting of the strength of their serums. Joseph Kinyoun, director of the U.S. Hygienic Laboratory, speculated about what could happen in the United States without government supervision. He wrote:

"... Many persons will, during the ensuing year, commence to prepare the serum as a business enterprise, and there will, without doubt, be many worthless articles called antitoxin thrown upon the market. All the serum for sale should be made and tested by competent persons. Testing, in fact, should be done by disinterested parties. . . ."

Indeed, the Dec. 22, 1894, issue of the *Journal of the American Medical Association* cautioned the medical profession that one or more fraudulent antitoxins for diphtheria were already on the market and that only a few small packages received from Germany were known to be reliable and guaranteed. A few weeks earlier the New York City Board of Health had issued a circular urging that steps be taken to supervise the sale of diphtheria antitoxin in the city by inspecting and scientifically examining the various preparations of antitoxin offered for sale to verify their strength and purity. The board warned that it would institute criminal proceedings in instances of fraud or the marketing of inferior preparations.

In the medical literature and records



of the time several major arguments emerged for regulating biologicals. The purity of serums, toxins, antitoxins and analogous products was considered far more important than that of ordinary drugs because biologicals were normally introduced directly into the circulatory system instead of the digestive tract and could not be withdrawn, once administered. Biologicals were most effectively given in full doses in the early stages of a disease, and if these were worthless or below strength, the loss of time could cost the life of the patient.

Other arguments dealt with inspection. It was noted that there could be no assurance of purity if control was limited to inspection and tests of the final product, as preparations differed between one animal and another. Efforts therefore had to be directed toward licensing the establishments where these products were manufactured.

Before the 1902 act, "any kind of a stable, a little technical skill, and a fair amount of nerve" were all that was needed to produce and sell biologicals, according to a U.S. Senate report. Furthermore, since most of the biologicals were sold in states other than the ones in which they were produced, individual states were powerless to protect themselves against impure and impotent materials without federal supervision.

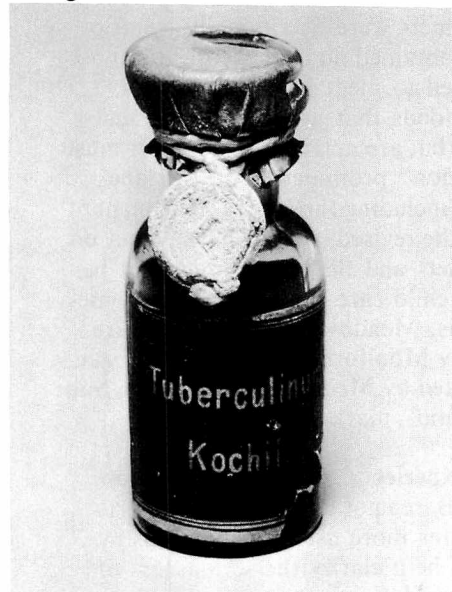
It took a tragedy to mobilize popular and professional opinion and induce the legislators to act. This event occurred in the fall of 1901.

On Oct. 26, 5-year-old Veronica O'Neill died in the St. Louis city hospital from tetanus. She had been admitted nine days earlier and was given two shots of diphtheria antitoxin. Her physician notified the city health department that her death was undoubtedly caused by tetanus-infected antitoxin. The department immediately stopped further distribution of the antitoxin and asked for an investigation. On Oct. 30 it was reported that a horse that over the past three years had furnished over 30 quarts of diphtheria antitoxin had come down with tetanus and had been killed. Two flasks of serum from the dead horse were dumped into the laboratory sink. The next day the *St. Louis Globe Democrat* reported the deaths of four more children, describing them as "antitoxin victims."

More investigations followed. In the

meantime, the number of children's deaths from tetanus rose to 13. On Feb. 12, 1902, a special investigating committee recommended that a consulting bacteriologist who had supervised the antitoxin production and distribution be dismissed and that the city get out of the antitoxin manufacturing business. The city health commissioner complied.

The St. Louis incident was widely reported in the nation's press and some physicians were afraid it would be used by opponents of serum therapy in general. An editorial in *JAMA* warned that "anti-vaccinationists, anti-vivisectionists, 'Christian Scientists,' and crotchety persons in general" would use this incident for "evil purposes." It became clear that action was needed to preserve the confidence of the medical profession and the public in biologicals.



The Medical Society of the District of Columbia took the initiative and in spring 1902 proposed legislation to regulate the sale of biologicals. The District medical society had consulted with the U.S. Public Health Service, which had been considering drafting similar legislation; but the congressional committees did not ask for comments from the Public Health Service nor its parent organization at the time, the Treasury Department. Thus, without much comment or discussion, and without any publicity, the act was signed into law by the president on July 1. This stands in great contrast to the heated debates and deluge of publicity attendant to the enactment of the first Food and Drugs Act four years later.

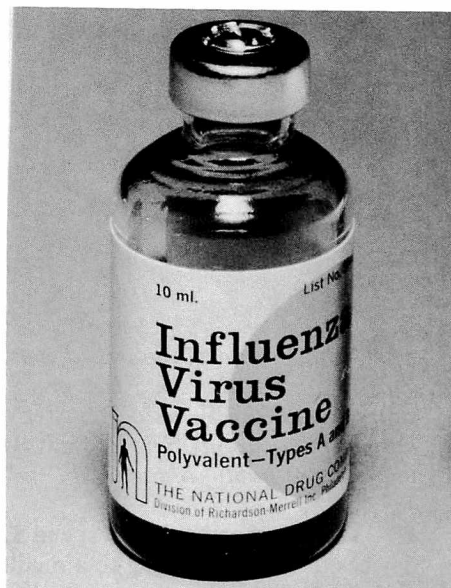
The 1902 act set up a board com-

posed of the surgeon general of the Army, the surgeon general of the Navy, and the supervising surgeon general of the Marine Hospital Service. The board was given authority, with Treasury Department concurrence, to promulgate regulations for licensing companies engaged in the sale and preparation of viruses, serums, toxins, antitoxins and analogous products in interstate or foreign commerce. The act made it unlawful to transport or sell preparations not prepared at a licensed establishment, and not carrying identification of the manufacturer as well as a date beyond which the contents could not be expected to yield "their specific results." The Public Health Service was given power to inspect the premises of any establishment manufacturing these products. The penalty for violations was a fine of up to \$500 or a maximum of a year's imprisonment or both.

There were European precedents for federal regulation. As early as 1895, laws regulating the manufacture, sale and distribution of biologicals had been enacted by the governments of France, Germany, Italy and Russia. They dealt with the licensing and inspection of products by government approved laboratories, proper labeling and the accreditation of manufacturing places.

The first regulations under the new act were promulgated Feb. 21, 1903, and became effective six months later. They dealt with licenses and inspections. Before a license was granted a medical officer from the Public Health Service would make an unannounced visit to the manufacturing establishment and inspect the sanitary condition of the physical plant and the methods of preparing, storing and dispensing the products. His report was sent to the sanitary board of the service, which would make recommendations to the surgeon general and finally to the Secretary of the Treasury for action.

Licenses were issued for a year and could not be re-issued without re-inspection. Licenses could be suspended for 30 days for faulty methods of preparation, faulty construction or administration of the establishments, for impurities, or for lack of potency of products as demonstrated by laboratory examination. If the faults were not corrected within 60 days, the license could be revoked. By 1904 a total of 13 establishments had been inspected and licensed, mostly for the sale of smallpox



vaccine and diphtheria antitoxin. Parke-Davis and Co. received the first license and H. K. Mulford (now part of Merck Sharp & Dohme) the second. By 1921, a total of 41 establishments had been licensed for the interstate sale of 102 biologicals.

The regulations were strictly enforced. Some laboratories were refused a license or their licenses were suspended. Others simply closed down because they couldn't meet the standards. Marked improvement was shown in the quality of the products sold on the open market. Much original scientific work was done in the Hygienic Laboratory to establish the American standard of potency for diphtheria antitoxin and later for other vaccines. Products that did not meet these standards were taken off the market.

The Biologics Control Act of 1902 restored public and professional confidence in biological products by establishing and vigorously enforcing strict standards of purity and potency. It improved the quality of products on the market. It stimulated original research in government and private laboratories. On a more subjective level, it helped develop a relationship of mutual respect and cooperation between the federal government and the pharmaceutical industry. It set the tone for future drug regulation.

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The Notebook

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

■ **Victims of arthritis** will spend \$2 billion on drugs and devices in 1990 according to a medical market report by Frost & Sullivan Inc., an international business research firm. Of this amount \$1.3 billion will be spent on prescription drugs, up from \$660 million in 1980, while OTC drug sales are predicted to go down to \$400 million from a 1980 sales figure of \$470 million. Devices will double in sales, from \$120 million in 1980 to \$240 million in 1990, according to the report.

■ Only 17 percent of the adult population asks physicians to prescribe **generic drugs** and only 20 percent asks pharmacists to fill prescriptions generically, according to a recent report from Arthur D. Little Inc. of Cambridge, Mass. Based on a July 1981 survey of 1,009 people by Opinion Research Corp., the report notes that the people most likely to ask for generic products were those with the most education and highest incomes and those in professional, managerial or owner occupations.

■ **Worldwide sales** of pharmaceutical products in 1981 were estimated at \$76.28 billion, according to IMS-World. Estimates for 1980 were \$76.02 billion, a 13.4 percent gain over 1979.

■ Department of Labor's Occupational Safety and Health Administration is taking a new look at its standards regulating employee exposure to **ethylene oxide** (EtO) in light of new information on possible health hazards of the gas. EtO is used in making antifreeze and heavy duty laundry detergents and is a sterilizing and fumigating agent used in hospitals, medical product and cosmetic manufacturing, in the food industry, beekeeping and dairy packaging (FR Jan. 26).

■ What manufacturers must do if they have to recall **defective infant formula** has been spelled out in a proposed FDA regulation. The rule would require a written evaluation of the health hazard, development of a recall strategy, prompt notification of FDA and progress reports every 14 days. The rule, mandated by the Infant Formula Act of 1980, will become effective 60 days after a final version is published (FR Jan. 15).

■ **Selenium sulfide** and **Selsun**, an anti-dandruff shampoo containing selenium, didn't cause cancer when applied to the skin of mice, but did prove carcinogenic in male and female rats and female mice when administered directly into the stomach. These were the findings of three long-term studies done by the National Toxicology Program and the National Cancer Institute. Results of the studies are available from the Office of Cancer Communications, NCI, Bethesda, Md. 20204 (FR Feb. 5).

■ Labels on **Meadow Fresh imitation dairy products** once claimed the products were nutritionally equal or superior to milk and contained no cholesterol. But those labels have been revised to meet FDA regulations. Among other things, foods that are a substitute and resemble another food but are nutritionally inferior must bear the word "imitation" prominently on the label. Several state agencies, including the Utah Department of Agriculture, accepted the revised labeling but say they do not endorse the products and that they should not be promoted and sold to child care centers, nursing homes and similar institutions. Meadow Fresh products are manufactured by Dairy Monitoring of America, Logan, Utah, and are distributed by Meadow Fresh Farms, Salt Lake City, via "pyramid" marketing.

■ A revised **drug experience reporting** form, now available from FDA's Bureau of Drugs, makes reports of adverse drug reactions more useful for analysis by adding information to help clarify the seriousness of the drug reaction and to determine if a cause and effect relationship exists (FR Jan. 22).

■ A grand total of 519 **medical devices** were classified by FDA for regulatory purposes during the first two months of 1982. The products, ranging from artificial body parts to surgical lasers, clinical testing materials and medical dressings were rated either class I (general controls), class II (performance standards) or class III (premarket approval). Here's a rundown on these latest device classifications. General and plastic surgery devices: I - 23, II - 24, III - 6, both II and III - 1 (FR Jan. 19); ear, nose and throat devices: I - 10, II - 47, III - 10 (FR Jan. 22); ophthalmic devices: I - 45, II - 51, III - 4, both I and II - 19 (FR Jan. 26); radiology devices: I - 7, II - 64, both II and III - 1 and I, II or III - 1 (FR Jan. 29); and clinical chemistry and clinical toxicology devices: I - 31 and II - 175 (FR Feb. 2).

Investigators' Reports

Unwelcome Ingredient

A can of wax beans contained an unpleasant surprise for a consumer in Augusta, Maine—a dead mouse. The consumer complained to the **Maine Department of Agriculture, FDA** became involved, and when the dust settled more than 6,400 cans of wax beans had been buried in the Augusta city dump.

When the State of Maine was presented with a can of beans in which the consumer had found a large foreign object, it asked a contract laboratory to do an analysis. The object turned out to be a mouse that had apparently been cooked with the beans.

After the state notified FDA's **Augusta resident post** of the findings, an agency investigator visited the product distributor, Associated Grocers of Maine Inc. He took 48 sample cans of wax beans marked with the same production code as the one with the mouse. Analysis of the samples at the Boston district laboratory subsequently isolated rodent hairs in 21 of the 48 cans.

Armed with these findings, the state quickly placed an embargo on the entire code lot of wax beans and other codes packed in the same cases. The embargo included beans being returned to the distributor from 323 member retail stores located in Maine. Associated Grocers had initiated a recall in accor-

dance with company policy.

The manufacturer of the beans, C-B Foods, Division of Curtice Burns Inc., of Rochester, N.Y., also was notified. The company replied that it considered the problem to be an isolated incident since its own analysis of beans in stock disclosed no problem, and it believed no further action was needed. FDA then recommended and received approval for seizure of the entire lot of Generic Cut Wax Beans under embargo in the Associated Grocers warehouse.

When notified by the United States attorney of the pending seizure, the manufacturer and distributor agreed to destruction of the lot. While an FDA investigator and the warehouse superintendent of Associated Grocers watched, 267 cases of beans containing 24 cans each were crushed and buried in the Augusta city dump. Their value was estimated by the manufacturer at approximately \$1,468.

FDA had one final job to do. An investigator from the **Buffalo district** office inspected the C-B Foods plant in Alton, N.Y., that had processed and canned the wax beans. A three-day inspection revealed no conditions requiring further legal or administrative action by FDA; however, the company made some changes in its processing operations to reduce the possibility of similar problems with its canned products in the future.

Lost Appetite Solved

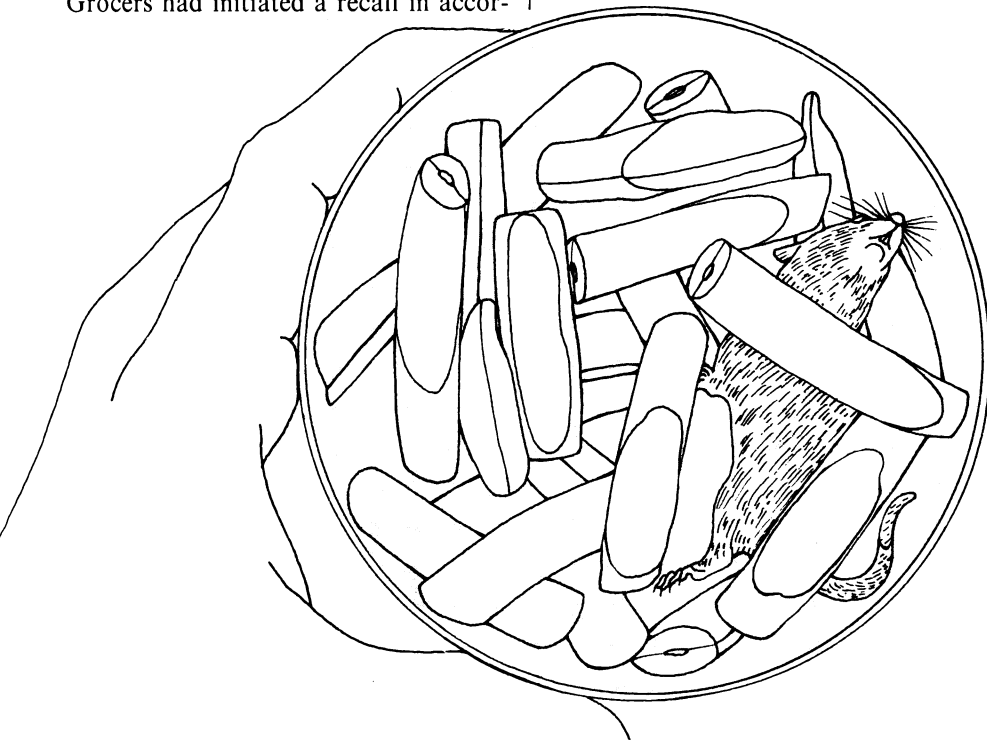
Some dairy farmers in eastern Canada, puzzled that their cattle were reluctant to eat and that milk production was down, asked advice from government farm experts. The experts decided that the magnesium oxide supplement sprinkled on the feed didn't look right, and probably didn't taste right to the cattle. It should have been creamy white; instead it was dark gray. Besides that, the label on the bags did not give the percentage of analysis (how much magnesium) as required by regulations.

The labels showed that the bags had been shipped by the Westmin Co. of Quincy, Ill. Canadian officials told FDA's **Chicago district** office about the problem, and FDA's **Springfield (Ill.) resident post** was asked to look into it.

The resident post investigators found that Westmin was hauling discarded fire brick from steel mills in Harbor, Ind., to Solomon Grind-Chem Service right there in Springfield. Solomon would grind up the bricks, then bag, store and ship the powder labeled as magnesium oxide to various distributors in several midwest states and Canada. The oxide was then sold to farmers as a feed supplement.

Samples of Solomon's bagged oxide were sent by investigators to FDA's laboratory in Cincinnati for analysis. The lab found that the percentage of magnesium oxide was substandard and varied from bag to bag. Toxic heavy metals were also found in the samples. In addition, there was an amber oily residue that the lab could not identify. The residue was sent to FDA's Detroit laboratory for further analysis. The Detroit laboratory separated the residue into five compounds, each of which was found to be an organic, cancer-causing substance. These findings of heavy metals and carcinogens made the ground-up bricks unsuitable as an animal feed supplement, because animals eating the feed would be harmed, and humans who consumed the milk or meat of the animals could also be affected.

The fire brick, made with special clays and a high metallic content, had been used to line the steel mill furnaces. The white-hot temperatures in these



furnaces normally vaporize the organic (oily) compounds that FDA's laboratories found. But some bricks, because they were damaged or defective, had not been used in the furnaces and so had not been exposed to the intense heat. They were tossed into the discard pile, then hauled away by Westmin along with the used brick. The carcinogens in the oxide grind came from these unused bricks.

Neither Westmin nor Solomon would, at first, cooperate with FDA by providing shipping records to help locate interstate shipments. But by checking with contract truckers and other sources, FDA identified purchasers of the supplement in several states. Samples of the bagged supplement in those shipments showed the same general mix of magnesium, heavy metals and carcinogens.

Informed that the feed supplement violated the Food, Drug, and Cosmetic Act, Westmin recalled all outstanding shipments, totaling some two million pounds, for possible reconditioning as an industrial powder.

2-Legged vs. 4-Legged

Spotting insects is part of the routine in an FDA warehouse inspection and is one of the reasons FDA exists. Working their way through the stored goods, FDA investigators stay alert for signs of six-legged and eight-or-more-legged creatures, for beetle droppings, and other evidences of entomological infestation of food or food packaging.

But an investigator from FDA's **Atlanta district** found something four-legged while inspecting a Revco Co. warehouse in North Augusta, S.C. The Georgia Department of Agriculture had told the district staff that chocolate candy containing insect fragments had been showing up in Revco drug stores in the Atlanta area. An FDA investigator was dispatched to check out the warehouse from where the candy shipments had been stored.

The investigator's search through boxes of chocolate bars and grape candy failed to reveal a significant insect problem, but there was a four-legged one: Mice were found in the food storage area along with three rodent

nests (two with baby mice). The problem was serious enough to warrant seizure and destruction of approximately 221 cases of candy, valued at \$5,599.

Sardine Saga

During eviction proceedings against a tenant of a Brooklyn warehouse, the New York City marshal's office found about 300 cases of canned sardines in the building's basement. Signs posted over the merchandise read, "Poison. Do Not Touch."

An investigator from the FDA's **New York district** office took 50 sample cans of sardines from the warehouse basement and turned them over to the New York regional laboratory for analysis. The findings: 12 of the 50 cans, or nearly 25 percent, were swollen, and some improperly formed can seams were evident. No microorganisms were found; the swelling was due to overfilling (as much as 20 percent) and to the presence of carbon dioxide and hydrogen gases.

Back at the warehouse, the landlord who had instituted the eviction said he was unwilling to pay for disposing of the sardines—that it was the original purchaser's or FDA's problem. The New York district tracked down the attorney representing the owner of the merchandise, a clothing textile remnant salvage operator who had decided to try food salvaging as a sideline. At least, that was his intention when he bought the sardines four or five years earlier, but they had remained in the warehouse ever since. Eventually he noticed that some cans were swelling and posted the "poison" signs, apparently deciding to abandon his salvaging enterprise.

At FDA's request the State of New York placed the sardines under embargo to prevent movement until they were destroyed.

Dripdown in Dodge City

A Kansas meat packer has decided that it will never again store anything on the large concrete slab that covers its million-gallon underground water tank.

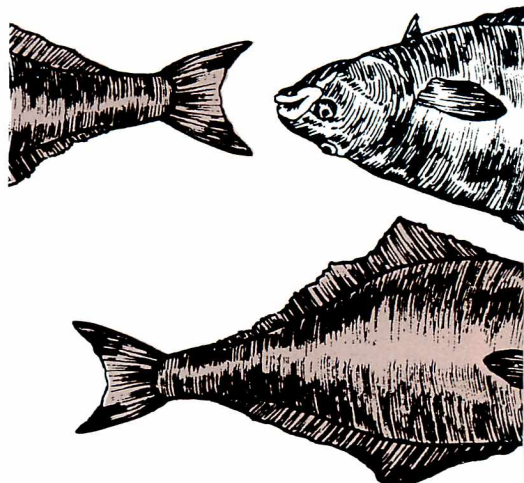
The packer, Missouri Beef of Dodge City, had been stacking drums of in-

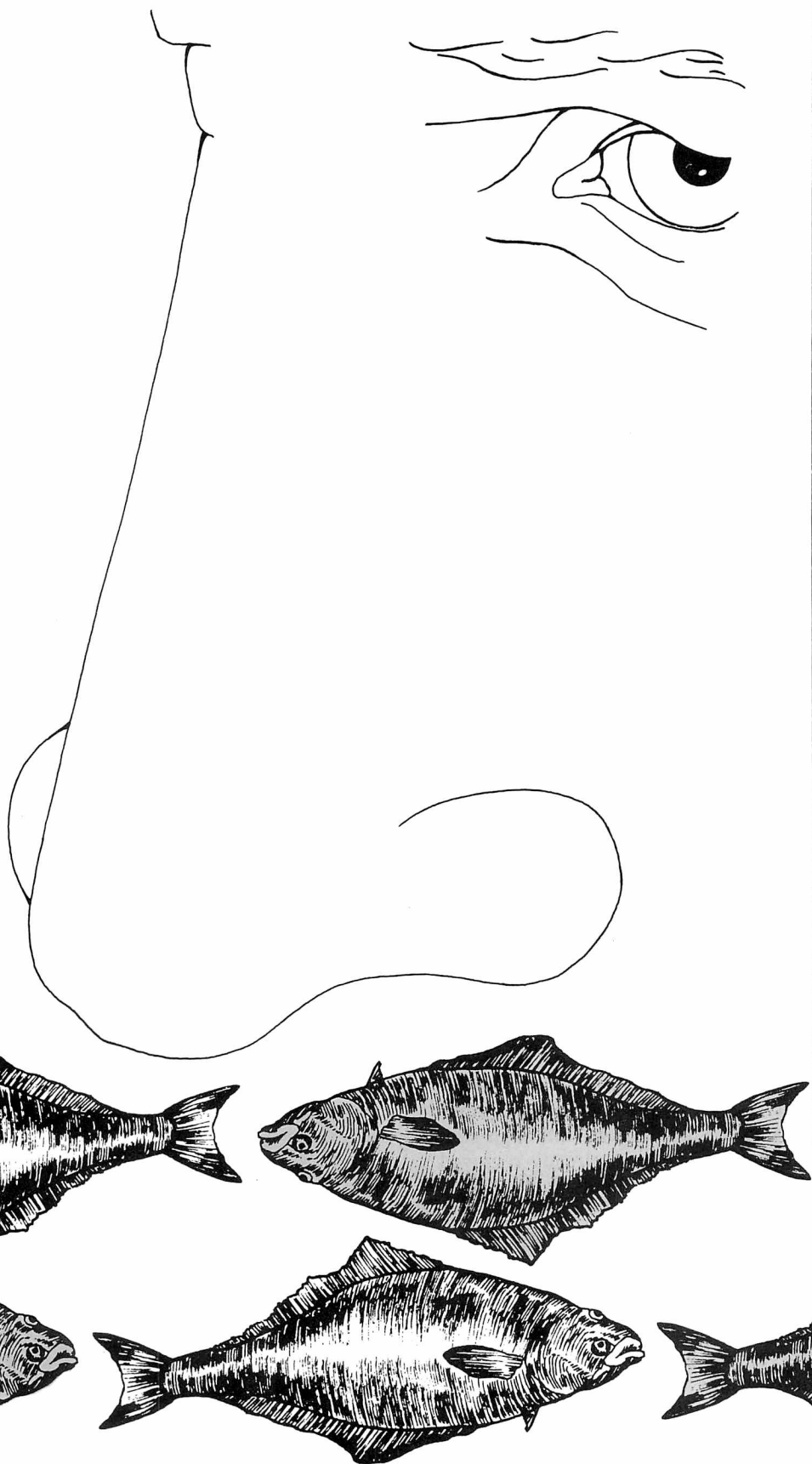
dustrial chemicals and other supplies on the flat concrete surface. But a 55-gallon drum of hide-curing compound (tetrachloroethylene and orthodichlorobenzene) broke open and leaked into the water supply below. The incident happened on the night shift at the plant. It was not noticed until the water, used to process the company's various products, had contaminated some 3,000 animal carcasses and several thousand pounds of animal by-products.

The **U.S. Department of Agriculture** shut down the plant and ordered the beef carcasses held to determine the extent of contamination. FDA's concern was possible contamination of tallow, bone meal and blood meal that the plant normally converts for animal feed.

Samples of these by-products were collected by FDA's **Kansas City district** office and flown to agency laboratories in Washington, D.C. There, Bureau of Foods scientists worked through the weekend doing analyses. The scientists found high levels of the chemicals in the tallow, predictable because the spilled chemicals are defatting agents that would be drawn to fat and tallow. The other by-products were found acceptable.

USDA released the beef carcasses after organs and trimmings that had high chemical levels were removed and buried in a landfill. USDA also required that fat be trimmed from the carcasses. The tallow that FDA found contaminated was diverted to industrial use.





This Nose Knows

The fishing boat off the Alaskan coast may have taken a larger catch than its freezing capacity could handle, or the fish may not have been properly iced when they were dumped into the hold. Whatever the reason, some 24 tons of frozen halibut that FDA found in commercial cold storage in Mount Vernon, Wash., showed signs of decomposition that would keep them from being marketed.

An inspector from the **Seattle district** office was checking the cold storage plant when he came across the suspect halibut. He called in the district organoleptic specialist, Richard Throm, an expert in detecting decomposition in fish by using his trained sense of smell.

Throm drilled into the now hard-frozen halibut, sniffed the area warmed by the drilling action, and found there was decomposition. He did this with 65 fish in the storage plant, and found that 28 were decomposed. His findings were confirmed by later analysis in the district laboratory. The entire lot, valued at \$83,000 wholesale, was seized by a U.S. marshal under court order. With no chance of using the fish for human food, the owners separated the decomposed from the acceptable halibut under FDA supervision. The 30 percent of the lot that was decomposed was destroyed.

Throm was also asked by a district investigator to check some frozen salmon the investigator was suspicious about in the Bellingham Cold Storage Co. at Bellingham, Wash. Again Throm came through: 60 of the 100 fish he examined were decomposed, as confirmed by the FDA laboratory. The salmon was seized and later destroyed by U.S. marshals under court orders.

Whey-out Labeling

FDA doesn't kid around when it comes to recipes for kids.

Coleco Industries Inc., Rochester, N.Y., is routinely inspected by FDA because it repacks the various cake mixes that come with its toy ovens, from a bulk shipment made by a cake mix manufacturer. The company got a letter from the **Buffalo district** office recently when it failed to notice that the manufacturer had changed the ingredients.

During an inspection of the company an FDA investigator noticed that the ingredients list on a 1-ounce packet of pie crust mix failed to declare the presence of the dried whey that was in the bulk supply mix list. The investigator reasoned the error might mislead parents of children with allergies to milk protein, since dried whey is a portion of milk separated during processing, so he collected a sample of the product.

After an FDA laboratory found the product contained 2 percent to 4 percent whey, the district office sent a letter to the company reporting the deviation. As a result, Coleco has changed its labels.

Cough Syrup Embargoed

When two brands of non-prescription cough syrup containing chloroform were manufactured—sometime before 1976—they could be shipped legally in interstate commerce. But in 1981 a shipment of the same products was embargoed by the **New Jersey Department of Health** because interstate shipment of the cough medicine was illegal.

The status of the expectorant products, manufactured by a New York City company, was changed in 1976 as part of FDA's review of non-prescription drug ingredients for safety and effectiveness. This review was initiated by FDA in 1972 and conducted by 17 advisory panels, whose members were chosen by FDA. One of the first panels to conclude its studies was the panel on cough, cold and related products and, although it found many commonly used ingredients to be both

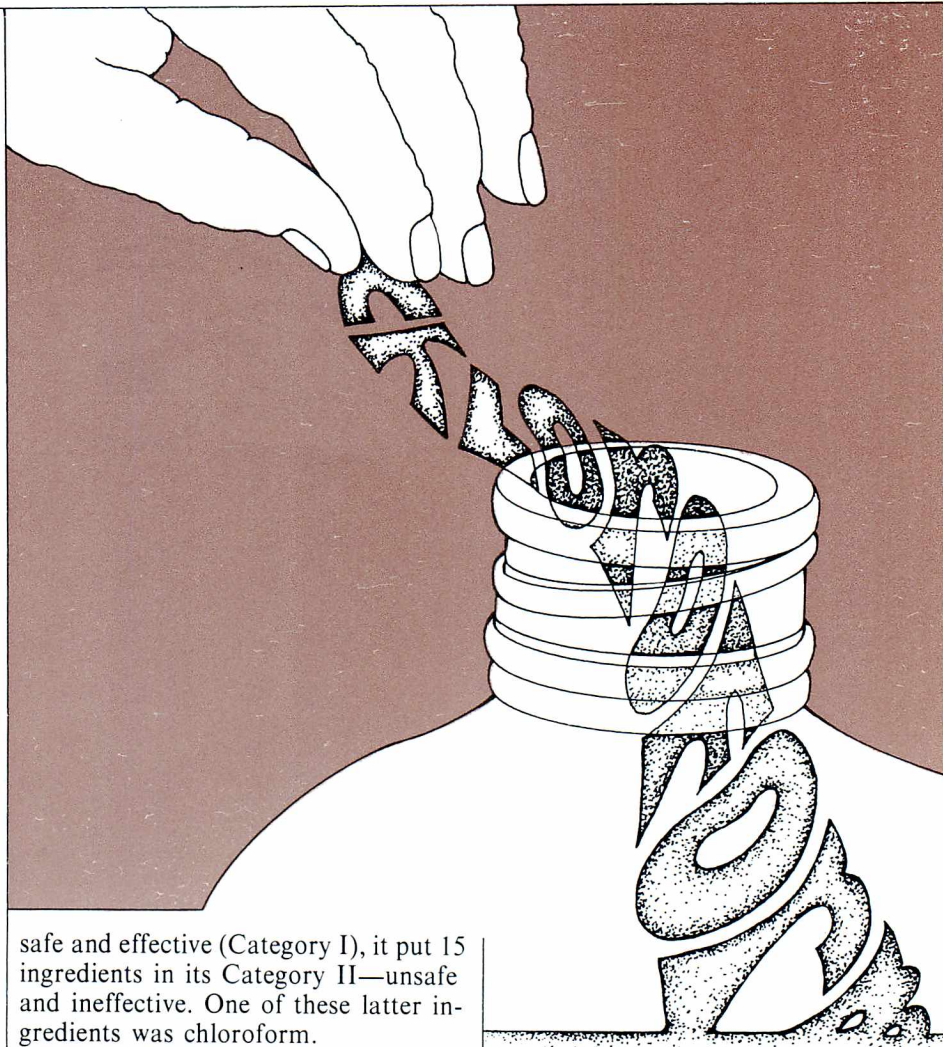
safe and effective (Category I), it put 15 ingredients in its Category II—unsafe and ineffective. One of these latter ingredients was chloroform.

Ingredients placed in Category II by this panel undergo review by FDA; and the agency, after considering the panel's recommendations and other information, may issue regulations in the form of a monograph approving ingredients considered safe and effective and prohibiting the use of those not so considered. FDA's final monographs on the dozens of drugs being reviewed by the panels are expected to be published over the next few years after the agency has considered all the information available. Final regulations have not yet been issued on the cough and cold panel's 1976 study report (although some manufacturers have already removed Category II ingredients from their products).

But chloroform was a special case, and the panel had proposed immediate action. Studies had shown that chloroform in cough medicine could cause tumors in mice and rats and therefore might be carcinogenic in humans, as well. For that reason, FDA banned cough products containing chloroform after receiving the panel's

report. However, so as not to cause economic hardship to drug manufacturers, the agency said that products already manufactured and on the market in 1976 could be sold until stocks were depleted—provided that the products were not shipped out of the state where they were located at the time the regulation went into effect.

If the cough medicine manufactured by the New York firm—Pisos brand and Pinex brand—had remained in New York, it would have remained a legal product after 1976. However, when the drugs crossed state lines from New York to New Jersey, FDA regulations were violated. The products' travels were traced by FDA's **New York district** after the district was called by an employee at a salvage distributor who had noticed that chloroform was listed as an ingredient on the recently purchased cough syrup. The major portion of the lot, still located in New Jersey, was embargoed by the New Jersey health department at the request of the district.



Seizures and Postal Service Cases

FILED SEIZURE ACTIONS

charge violations of the Federal Food, Drug, and Cosmetic Act and are initiated based upon FDA recommendations. A seizure action is commenced by the filing in the U.S. district court where the goods are located. A U.S. marshal is then directed by the court to take possession of the goods, removing the product from commerce, until the matter is resolved.

A total of 16 actions to remove from the consumer market products charged to be violative was reported in January. These actions included 15 charges of food concerning contamination, spoilage and insanitary handling, and one charge concerning medical devices.

| PRODUCT, DISTRICT & DATE FILED | FIRM & PLACE OF BUSINESS | CHARGES |
|--|--|---|
| | FOOD/Contamination, Spoilage, Insanitary Handling | |
| Beans, farina, chocolate drink mix, and corn flour/U.S. District Court for the District of Puerto Rico 12/3/81 | Sucrs. de Esmoris & Co. Inc./Mayaguez, Puerto Rico | Products have been held under insanitary conditions. |
| Chili sauce and bean sauces/U.S. District Court for the Northern District of Illinois 11/25/81 | Shipped from San Francisco, Calif. | Products contain mold; contained in leaking jars. |
| Garlic bulbs, dried/U.S. District Court for the District of Puerto Rico 9/22/81 | Shipped from outside Puerto Rico | Product contains insect filth—decomposed garlic bulbs. |
| Halibut, frozen, dressed and headed/U.S. District Court for the Western District of Washington 9/11/81 | Sitka Sound Seafoods/Sitka, Alaska | Product contains decomposed fish. |
| Macaroni products/U.S. District Court for the Western District of New York 1/18/82 | Olindo Imported Foods Inc./Rochester, N.Y. | Products have been held under insanitary conditions. |
| Macaroni products and other foodstocks/U.S. District Court for the Southern District of Texas 12/3/81 | Antone's Imports/Houston, Texas | Some products are contaminated with insect filth; all of the products have been held under insanitary conditions. |
| Pancake mix/U.S. District Court for the District of Puerto Rico 11/30/81 | Shipped from New Orleans, La. | Product contains insect filth. |
| Pancake and waffle mix/U.S. District Court for the District of Puerto Rico 10/20/81 | Shipped from New Orleans, La. | Product contains insect filth. |
| Papaya chunks, canned/U.S. District Court for the District of Puerto Rico 10/23/81 | Shipped from San Paulo, Brazil | Product is contained in swollen and leaking cans. |
| Rice, cheese, macaroni products and other foodstocks/U.S. District Court for the Western District of Washington 10/13/81 | Pacific Food Importers/Seattle, Wash. | Some products contained rodent or insect filth; all products had been held under insanitary conditions. |
| Rice flour/U.S. District Court for the Eastern District of Missouri 1/12/82 | Shipped from Memphis, Tenn. | Product was held under insanitary conditions. |
| Rice and sweet sauce/U.S. District Court for the Western District of Missouri 11/24/81 | King's Trading Inc./Kansas City, Mo. | Rice is contaminated with rodent filth, and both products were held under insanitary conditions. |
| Salmon, dressed, frozen/U.S. District Court for the Western District of Washington 11/17/81 | Can-Inter-Foods Ltd./Delta, Canada | Product contains decomposed salmon. |
| Sesame seeds and sesame seed syrup/U.S. District Court for the District of Puerto Rico 10/16/81 | Tropical Fruit Products Co./San German, Puerto Rico | The sesame seeds contained rodent filth and had been held under insanitary conditions, and the syrup had been prepared under insanitary conditions. |

PRODUCT, DISTRICT & DATE FILED**FIRM & PLACE OF BUSINESS****CHARGES**

Strawberries with sugar, frozen/U.S. District Court for the Western District of Washington 9/25/81

Valley Packers Inc./Puyallup, Wash.

Product contains decomposed strawberries.

MEDICAL DEVICE

DuraSoft 2 (phemfilcon A) hydrophilic bifocal contact lenses/U.S. District Court for the Northern District of Illinois 1/4/82

Wesley-Jessen Inc., Division of Schering Corp./Chicago, Ill.

Products are class III devices and fail to have in effect either an approved application for premarket approval or an exemption for investigational use.

U.S. POSTAL SERVICE actions taken in medical cases as authorized in the Mail Fraud Statute (18 U.S.C. 1341) and/or the False Representation Statute (39 U.S.C. 3005) as reported by the Chief Postal Inspector.

False Representation Orders Issued by Judicial Officer Under 39 U.S.C. 3005

October 6, 1981: Against **Cedar Hills Pharmacal**, RD 1, Box 128, Milroy, Pa. Satisfactory evidence was presented to the Postal Service that Cedar Hills Pharmacal and its agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising "Stimulants." These stimulants are being sold as look-alike narcotics.

October 6, 1981: Against **R&A Distributors**, P.O. Box 493, Springfield, Tenn. Satisfactory evidence was presented to the Postal Service that R&A Distributors and its representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising "Stimulants." These stimulants are being sold as look-alike narcotics.

October 27, 1981: Against **California Medical Research**, P.O. Box 4855, San Diego, Calif. Satisfactory evidence was presented to the Postal Service that California Medical Research and its agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product "CMR Contour Creme," representing the ability to "take off bloaty cellulite and ugly inches without pills, shots, exercise or hunger."

October 28, 1981: Against **The House of Renee**, One Wolfs Lane, Pelham, N.Y. Satisfactory evidence was presented to the Postal Service that the House of Renee and its agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product "Gege Lotion." The ad states, in part, "at last your stretch mark problems gone for good! If you're ashamed of ugly stretch-marks, and really want to do something about them, then it's time you tried Gege Lotion!"

October 30, 1981: Against **The Health Energetic Co.**, 2600 E. Coast Highway, Corona Del Mar, Calif. Satisfactory evidence was presented to the Postal Service that The Health Energetic Co., and its representatives are engaged in conducting a scheme or device to obtain money

by means of false representation. The firm was advertising the product "S-Energetic," representing the ability to "restore your vitality; improve your vigor; reduce breathlessness and fatigue; help combat skin disorders; improve physical appearance, scientifically increase energy levels."

November 4, 1981: Against **Starr Retailers**, P.O. Box 518, Milroy, Pa. Satisfactory evidence was presented to the Postal Service that Starr Retailers and its agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising "Stimulants." These stimulants are being sold as look-alike narcotics.

November 5, 1981: Against **Dalen Labs**, P.O. Box 118, Westmont, Ill. Satisfactory evidence was presented to the Postal Service that Dalen Labs and its representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product "Tropical Tan," representing the ability "to get a deep-dark brown tan."

November 5, 1981: Against **V.V. & L.**, RR 1, Box 312, Milroy, Pa. Satisfactory evidence was presented to the Postal Service that V.V. & L. and its agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising "Stimulants." These stimulants are being sold as look-alike narcotics.

November 30, 1981: Against **Doctor's Capsule Plan**, 1255 Post St., San Francisco, Calif. Satisfactory evidence was presented to the Postal Service that Doctor's Capsule Plan and its representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product "Doctor's Capsules," representing the ability to "lose the fat forever. Lose 10, 20, 30 ... even 60 pounds or more—without time consuming exercise—without one moment of hunger!"

Complaints filed by Law Department Under 39 U.S.C. 3005 (False Representation)

October 14, 1981: **The Mail Order Discount Shopper**, Box CY 373/400 Commonwealth Ave., Boston, Mass. Advertising and sale through the mail of the product "The Boston Hair Life Program," representing the ability to "grow new hair ... the belief that hair follicles are absolutely dead after five years of not growing hair has been disclaimed ... the procedures utilized by the clinics came about as a result of an extensive scientific research project that demonstrated success in developing a method for stopping excessive hair loss and growing new hair."

October 16, 1981: **Maga Research, Ltd.**, P.O. Box 667, Lynbrook, N.Y. Advertising and sale through the mail of the product "Maga Technique Program." The ad states, in part, "new tests prove doctor's wonder enlargement technique can give any woman a dramatic new bustline in just one week! No surgery ... no padding ... no exercisers ... no drugs. Yet many women see up to a 3 inch improvement in 7 days or less."

November 2, 1981: **That Special Look, Inc.**, P.O. Box 1490, Pompano Beach, Fla. Advertising and sale through the mail of the product "Sauna Suit," representing the ability to "turn leisure time into weight

loss time, slims your waist, hips and thighs. No pills. No hunger! Works while you relax ... best, most effective ways to shed unwanted pounds."

November 3, 1981: **Rockwell Scientific Industries**, 210 Fifth Ave., New York, N.Y. Advertising and sale through the mail of the product "Astro Triplex." The ad states, in part, "enlarge your bosom 3 full cup sizes in only 1 week!!!"

November 3, 1981: **Bradford Warner**, 521 Fifth Ave., New York, N.Y. Advertising and sale through the mail of the product "Living Fluids and Living Creme," representing the ability to "enlarge your bosom ... be big busted beautiful in an era of small bosomed women ... gain up to 6 inches and 3 cup sizes now!"

November 3, 1981: **Swedish Extract**, 175 Fifth Ave., New York, N.Y. Advertising and sale through the mail of the product "Big Bosom Creme." The ad states, in part, "increase your bosom ... new Swedish discovery ... adds inches while you sleep. Be the new sexy big size you want to be! Yes, help is finally here for small breasted women."

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions FOOD/Contamination, Spoilage, Insanitary Handling

Cocoa bean sweeps, at Philadelphia, E. Dist. Pa.

Charged 2-14-78: while held by Atlantic & Gulf Stevedores Inc., Philadelphia, Pa., the article contained insect filth and moldy cocoa beans; 402(a)(3) and (4). The article was claimed by the dealer who denied the charges and asserted that the article had been rebagged and prepared for export sale (no intention of selling or offering for sale in domestic commerce).

The parties served written interrogatories on each other. Thereafter, the action came on for trial, on the issue of whether the claimant could be allowed to export the beans, having previously stipulated that the cocoa beans were contaminated. The court ruled in favor of the government, saying:

"First of all, within the meaning of 21 U.S.C., section 334, I find—because it is stipulated—that the article of food consisting of some 200-plus bags of cocoa beans which are at issue in this case are adulterated within the meaning of 21 U.S.C. section 342(a)(3) and that they are being held for sale after shipment in interstate commerce. . . . [A]dulteration and presence in interstate commerce having been stipulated—I have no alternative but to enter a decree of condemnation.

"Under these circumstances I find that the claimant has met neither the requirements of 21 U.S.C. section 334(d), nor 21 U.S.C. section 381(d), which are necessary in order for it to obtain the relief it seeks, i.e., permission to ship the goods to the Netherlands.

"First of all it is plain to me that the statute that applies to this case is 21 U.S.C. section 334(d) which in turn incorporates by reference the requirements of 21 U.S.C. section 381(d). I do not believe that 21 U.S.C. 381(d) can be applied in isolation in this case. Section 381(d) in isolation applies, as I see it, to goods produced here and intended for export, and the reference from the legislative history supplied by Mr. Ewing supports that contention. 21 U.S.C. section 334(d) coupled with section 381, which it incorporates by reference, fits glove-like into this situation, i.e., they deal with goods which were imported by design or accidentally, perhaps here it was accidentally, got into commerce and were adulterated and then you want to ship them back for processing or simply for return. Section 334(d)(1) applies here, I so hold.

"I find that the claimant, A&G [Atlantic & Gulf Stevedore Inc.], who is the person seeking the release of the goods, has not met the requirements of either (a) or (d) of 21 U.S.C. section 334(d)(1).

"First of all, I find that the significant portion of the adulteration occurred after the article was imported, i.e., when the cocoa beans were swept up on the pier, allowed to accumulate and remain on the pier for a considerable period of time. I note in this regard that for quite some period of time the goods were flat on the pier and were not even raised on pallets where they would be free from damage by moisture and water.

"The evidence here supports my finding that the contamination by virtue of contact with dirt and grime on the pier and deterioration of the beans occurred in the year and a half period that they were left on the pier before delivery to Mr. Comly's warehouse.

"Secondly, I find that A&G had cause for believing that the goods were adulterated before they were released from Customs custody simply because in this case, as in every case, a certain number of beans will have mold (the Codex Alimentarius standard demonstrates that) but more to the point because there is a certain amount of sweeps which come out of every vessel which is discharged at A&G and at other terminals in Philadelphia. That is because the longshoreman's hooks will break the bags and some bags will not be tightly secured and there is always a certain amount of cocoa bean material which comes into contact with the pier.

"In any event, the claimant has not met the requirements of section 381(d). Although I am satisfied that the sweeps would accord to the specifications of the foreign purchaser, Mr. Tollig, of the Netherlands, the claimant has not established that shipment would not be in conflict with the laws of the Netherlands. Neither do I find section 381(a) which Mr. Thomas invoked to be applicable.

"I think it would be useful to state in some greater degree of particularity the facts about the cocoa beans themselves.

"I find they were collected over a period of one and a half years over some 16 separate shipments for which claimant Atlantic & Gulf Stevedores acted as consignee.

"I find that the solvent extraction process utilized by H. G. Tollig's company of Rotterdam, which is proposed to be applied to the cocoa bean sweepings in this case, would produce a commercially valuable product from which impurities had essentially been removed.

"I find a pharmaceutical quality product, including cocoa butter which could be applied to a variety of uses would emerge from such process.

"I find that the solvent extraction process is available in the Netherlands and several other companies in Western Europe but is not available in the United States.

"I find that there is no process available in the United States which could result in salvaging of these cocoa beans for any pharmaceutical use or any food use.

"I find that the mechanical processes which have been testified to would be unsatisfactory and would not be commercially applied.

"I further find the end product after the Tollig's refining would not endanger the health and safety of consumers either in the United States or abroad.

"Additionally, I find that the commercial value of the cocoa bean sweeps on the present market is approximately \$25,000.

"For all of these reasons it is most unfortunate that the result in this case must be a decree of condemnation.

"As I read the facts of this case, which represent the result of common practice in the cocoa bean trade, it is almost never possible for cocoa bean sweeps to be shipped to Western Europe for reprocessing. That is because this case obviously represents the pattern in the industry. I think that that result is most unfortunate. When it becomes necessary to destroy products which have commercial value and which can be put to pharmaceutical use because of the cutoff of the law applied to a unique set of facts, economic waste occurs. Economic waste of this kind contributes to world inflation. I therefore urge FDA through the Office of Legal Counsel to consider legislation which might enable FDA under stringent conditions to permit the export of cocoa bean sweeps to plants which have the capacity to reprocess them into a pure and pharmaceutically useful state.

"I find no merit in the claimant's contention that the statute is void for vagueness. Although I have suggested that there might be some substantive due process problems with the unfortunate result which has occurred, a reading of the substantive due process cases suggest to me that it is plainly within the power of Congress to visit this result upon that very low member of the inanimate object order, the class of cocoa bean sweeps which have laid in the nether reaches of docks and wharves and piers for as long as a year and a half.

"Additionally, there is no evidence that the sweeps have a commercial value of zero if not shipped for reprocessing to the Netherlands. The claimant might have introduced evidence to that effect but it did not do so. It therefore may well be that some commercial value, whether for dog food or fertilizer, or something, may be realized from the product at issue.

"I have not made formal findings as to when the beans were imported but I accept the Government's position that they are not imported until



they enter the territorial boundary of the port of entry. Even if I were to accept the claimant's position it would not change my conclusion. I think that it is a fair statement that the goods do not clear Customs custody until they arrive at the port. Nor are they released until formal entry documents are presented, processed and approved. However, even if I were to accept the claimant's view, that would not change my conclusion.

"The foregoing constitutes my findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a)."

The claimant filed an appeal, which was dismissed upon motion of the claimant because the parties had stipulated to sign a consent decree. A consent decree of condemnation authorized release to the dealer for salvaging. However, FDA determined that the article could not be reconditioned for human food use. Subsequently, the government moved for a decree of destruction. The court denied the motion and ordered that FDA permit the claimant to remove the article to a New Jersey reconditioner under FDA supervision for visual inspection and division into one lot containing beans visibly moldy and containing insect filth (which was to be destroyed) and into a second lot determined to be free of visible insect filth or mold. The claimant was to submit proposals and plans for bringing the article into compliance.

The article was removed to the New Jersey reconditioner and the beans were examined and sorted into two lots. FDA objected to the sampling technique used to separate the article into two lots and advised that the article had additionally been contaminated with rodent filth, which (under FDA policy) mandated destruction.

A status conference was held to discuss the progress of the claimant's reconditioning attempts. The government set forth reconditioning procedures it deemed necessary to bring the article into compliance. The claimant did not avail itself of such opportunity, and instead the claimant decided that it wished to destroy the article. Accordingly, a supplemental consent decree ordered the article destroyed. (F.D.C. No. 61619; S. No. 78-143-457; N.J. No. 1)

Flour, at Metairie, E. Dist. La.

Charged 4-8-81: while held for sale, the article contained insect filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 63435; S. No. 81-222-196; N.J. No. 2)

Flour, at Yauco, Dist. Puerto Rico.

Charged 9-21-81: while held by Borinquen Macaroni Corp., Yauco, Puerto Rico, the article contained rodent filth and had been held under insanitary conditions; 402(a)(3) and 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 63536; S. No. 81-274-818; N.J. No. 3)

Flours, two lots, at Buffalo, W. Dist. N.Y.

Charged 9-22-81: while held by Barry Food Products Inc., Buffalo, N.Y., the articles had been held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 63563; S. Nos. 81-284-890/1; N.J. No. 4)

Pork and Beans, canned, at Tulsa, N. Dist. Okla.

Charged 7-24-81: while held for sale, the article was held in swollen containers; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 63520; S. No. 81-267-141; N.J. No. 5)

Muffin mix, beans, flour, and other foodstocks, at Baltimore, Dist. Md.

Charged 4-22-81: while held by Andrews Food Co. Inc., Baltimore, Md., some of the articles contained rodent filth; and all of the articles had been held under insanitary conditions; 402(a)(3) and (4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 63450; S. No. 81-240-541 et al.; N.J. 6)

Tarragon leaves, ground jalapeno, and ground fenugreek, at San Antonio, W. Dist. Texas.

Charged 3-29-81: while held for sale (by San Antonio Spice Co., San

Antonio, Texas), the articles contained insects; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 63395; S. No. 81-222-690; N.J. No. 7)

"Maple" syrup, at Raymondville, S. Dist. Texas.

Charged 3-20-81: when shipped by H.W. Pilgrim, DeKalb, Miss., the article, labeled in part "Savage's Maple Syrup . . . Packed For Savage Farms Inc. Raymondville, Texas," had had corn syrup substituted for maple syrup—402(b)(2); the labeling was false and misleading in representing that the food consisted wholly of maple syrup—403(a)(1); and the article failed to conform to the definition and standard of identity for maple syrup because the article was made with syrup from a source other than maple trees—403(g)(1). Consent decree of condemnation ordered constructive destruction by delivery to a suitable charitable institution for use only and not for resale. (F.D.C. No. 63328; S. No. 81-223-160; N.J. No. 8)

Potato-cheese pierogies (dumplings), sauerkraut-potato pierogies, and potato pierogies, at Hellertown, E. Dist. Pa.

Charged 11-1-79: while held by Hanka Foods Inc., Hellertown, Pa., who had manufactured the articles using interstate potato flakes, the articles' labels contained the false and misleading claims "Vitamin Enriched" and "No Preservatives Added," when the articles did not contain a significant amount of vitamin enrichment and did contain the added chemical preservative calcium propionate—403(a)(1); the articles' labeling lacked the common or usual name of each ingredient as required by regulations (e.g., lacked calcium propionate declaration and, for sauerkraut-potato pierogies only, lacked listing of ingredients in descending order of ingredient predominance)—403(i)(2); the articles' label lacked statements declaring the chemical preservative calcium propionate—403(k); and the articles were also in violation of the Fair Packaging and Labeling Act, since the quantity of contents statements were in too small type size and (potato pierogies only) the quantity of contents statement was not within the bottom 30 percent of the principal display panel area—15 U.S.C. 1453(a)(2) and 1453(a)(3)(C).

The articles were claimed by the manufacturer. A consent decree authorized release to the claimant for relabeling. Subsequently a question as to the whereabouts of the goods arose; and since no definitive explanation was provided to the government, the government moved for an order to take inventory of the articles. The court granted the government's motion. Ultimately, after appropriate labels had been designed, the articles were more than two years old and the articles were destroyed. (F.D.C. No. 62462; S. Nos. 79-204-269/71; N.J. No. 9)

FOOD ADDITIVES

Nature's Herbs comfrey, oatstraw, shavegrass (horsetail), & lobelia combination capsules; Nature's Herbs dandelion, golden seal, yellow dock root, & lobelia combination capsules; and Nature's Herbs Desert Herb compound (desert tea), capsicum, & lobelia combination capsules, at Miami, S. Dist. Fla.

Charged 3-6-81: when shipped by Nature's Herbs Inc., Orem, Utah, the articles contained the non-conforming food additive *Lobelia inflata* L., since there was no regulation or exemption prescribing the condition for safe use of such food additive; 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 63338; S. No. 81-239-904; N.J. No. 10)

Popsicle solutions in plastic tubes, at Searcy, E. Dist. Ark.

Charged 6-2-81: when shipped by Marshall Confections Inc., Marshall, Texas, the article, labeled in part "Freeze & Squeeze Popsicle . . . assorted Pops. . . Mfd. By C.D.P. Company . . . Oklahoma City, Okla.," contained the non-conforming food additive saccharin, since the product was not for a valid special dietary use and was not exempted; and saccharin had been substituted for sugar; 402(a)(2)(C), 402(b)(2).



Default decree ordered destruction. (F.D.C. No. 63477; S. No. 81-280-883; N.J. No. 11)

DRUGS/Human Use

Allopurinol tablets, at City of Commerce, C. Dist. Calif.

Charged 6-16-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 63062; S. No. 80-245-421; N.J. No. 12)

Allopurinol tablets, and other specified drug stocks, at Malden, Dist. Mass.

Charged 3-12-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Pursuant to stipulation, the action was transferred to the District of New Jersey for consolidation for trial with a similar action. Subsequently, a consent decree of condemnation ordered the articles destroyed. (F.D.C. No. 62867; S. No. 80-159-291 et al.; N.J. No. 13)

Barbiturate and analgesic combination tablets, at Greensboro, M. Dist. N.C.

Charged 2-17-81: when shipped by D.M. Graham Laboratories Inc., Hobart, N.Y., the article, labeled in part "Sedapap-10 Tablets . . . Mfg. by: Graham Labs., Hobart, N.Y. . . . Analgesic-Antitensive-Antipyretic . . . Mfg. for Mayrand Incorporated Pharmaceuticals, Greensboro, N.C.," was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 63319; S. No. 81-162-996; N.J. No. 14)

Brompheniramine maleate & D-Isoephedrine Sulfate combination tablets, at Little Rock, E. Dist. Ark.

Charged 7-26-81: [when shipped by Pharmadyne Laboratories, Inc., Elmwood Park, N.J.], the article, labeled in part "Nadex sustained-Release Tablets . . . Brompheniramine maleate . . . D-Isoephedrine Sulfate . . . Distributed by Artex Laboratories, Inc.," had been manufactured, processed, packed and held under circumstances that failed to conform with current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 63517; S. No. 81-280-887; N.J. No. 15)

Chlorthalidone tablets, at City of Commerce, C. Dist. Calif.

Charged 6-16-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 63059; S. No. 80-245-421; N.J. No. 16)

Chlorpropamide tablets, at Lincolnwood, N. Dist. Ill.

Charged 4-4-80: when shipped by Darby Drug Co. Inc., Rockville Center, N.Y., the article, labeled in part "Rugby Chlorpropamide Tablets. . . . Manufactured for Rugby Laboratories, Inc., Rockville Center L.I., N.Y. . . . Manufactured by Chelsea Laboratories, Inc. Inwood, N.Y.," was a new drug without an effective approved New Drug Application; 505(a).

The manufacturer claimed the article, denied the charge, and asserted that the article was a generic version of "Diabinese," a brand of chlorpropamide tablets manufactured by another manufacturer who had marketed the Diabinese under an approved New Drug Application since prior to 1962. The claimant (manufacturer) of the article also claimed that even if chlorpropamide was once regarded as a new drug, generic chlorpropamide was not presently a new drug since it had been safely marketed for over 20 years, was safe, effective and generally recognized; that the claimant's article was manufactured according to rigorous quality standards; and that FDA's *Federal Register* statement that chlorpropamide was a "new drug" was not a binding administrative determination because FDA had not followed the requirements of the Administrative Procedures Act. The claimant cited the July 1979 district court finding in *Premo Pharmaceutical Laboratories*

Inc. v. U.S.A., U.S.D.C., S. Dist. N.Y., C.A. No. 78 Cir. 5435; and the claimant also asserted that, without waiving the claim that chlorpropamide was not a new drug, the claimant had filed with the FDA an Abbreviated New Drug Application, but FDA had not acted on such application.

The government served written interrogatories and requests for admissions of the claimant. Ultimately, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 62929; S. No. 80-111-998; N.J. No. 17)

Diethylpropion HCl tablets, at San Francisco, N. Dist. Calif.

Charged 3-8-78: when shipped by Pharmadyne Laboratories Inc., Hackensack, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). The article was claimed by the shipper. Pursuant to stipulation, the action was removed to the Eastern District of New York for consolidation for trial with a similar action. Ultimately, a consent decree ordered the article destroyed. (F.D.C. No. 62176; S. No. 79-179-687; N.J. No. 18)

Diethylpropion HCl tablets, trifluoperazine HCl tablets, doxylamine succinate with pyridoxine tablets, and hydroxyzine HCl tablets, at Bedford, Dist. Mass.

Charged 5-5-81: when shipped by Premo Pharmaceutical Laboratories Inc., South Hackensack, N.J., the articles were new drugs without effective approved New Drug Applications—505(a); and, while held for sale, the articles lacked adequate directions for use and were not exempted due to their new drug status—502(f)(1). Default decree ordered destruction. (F.D.C. No. 63461; S. No. 81-254-824 et al.; N.J. No. 19)

Furosemide tablets, at City of Industry, C. Dist. Calif.

Charged 7-14-81: when shipped by Superpharm Corp., Central Islip, N.Y., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 63500; S. No. 81-257-800; N.J. No. 20)

Furosemide tablets, two seizure actions, at Miami, S. Dist. Fla., and Hollywood, S. Dist. Fla.

Charged 10-21-81 and 10-21-81: when shipped by Superpharm Corp., Central Islip, N.Y., the article was a new drug without an effective approved New Drug Application; 505(a). Default decrees ordered destruction. (F.D.C. Nos. 62997, 63221; S. Nos. 80-193-506, 80-239-256; N.J. No. 21)

Furosemide tablets, chlorothiazide with reserpine tablets, and trimethoprim with sulfamethoxazole tablets, at St. Louis, E. Dist. Mo.

Charged 2-1-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Pursuant to stipulation, the action transferred to the Eastern District of New York for consolidation for trial with a similar action. Ultimately a consent decree ordered destruction. (F.D.C. No. 62823; S. No. 80-208-575; N.J. No. 22)

Furosemide tablets, and diethylpropion HCl tablets, at Tifton, M. Dist. Ga.

Charged 3-20-79 and amended 3-23-79: when shipped by Pharmadyne Laboratories Inc., Hackensack, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Pursuant to stipulation, the action was removed to the Eastern District of New York for consolidation for trial with a similar action. Ultimately, a consent decree ordered destruction. (F.D.C. No. 62211; S. No. 79-100-578; N.J. No. 23)

Furosemide tablets, and other specified drug stocks, at Vienna, E. Dist. Va.

Charged 7-21-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). Default decree of condemnation ordered destruction. (F.D.C. No. 62781; S. No. 80-208-543; N.J. No. 24)



Hydroxyzine HCl tablets, allopurinol tablets, and prochlorperazine capsules, at Miami, S. Dist. Fla.

Charged 2-12-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Subsequently, a consent decree of condemnation ordered the articles destroyed. (F.D.C. No. 62828; S. No. 80-166-696; N.J. No. 25)

Hydroxyzine HCl tablets, allopurinol tablets, trimethoprim with sulfamethoxazole tablets, and metronidazole tablets, at Brooklyn, E. Dist. N.Y.

Charged 6-23-80: when shipped by Pharmadyne Laboratories Inc., Hackensack, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). Pursuant to stipulation, the action was consolidated for trial with a similar action in the District of New Jersey. Subsequently, a consent decree of condemnation ordered the articles destroyed. (F.D.C. No. 63009; S. No. 80-200-325; N.J. No. 26)

Hydroxyzine HCl tablets, diethylpropion HCl tablets, furosemide tablets, trimethoprim with sulfamethoxazole tablets, at Plainview, E. Dist. N.Y.

Charged 2-29-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Pursuant to stipulation, the action was transferred to the District of New Jersey for consolidation for trial with a similar action. Subsequently, a consent decree ordered destruction. (F.D.C. No. 62818; S. No. 80-208-578; N.J. No. 27)

Hydroxyzine pamoate capsules, at Tifton, M. Dist. Ga.

Charged 1-31-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). The article was claimed by the shipper. Pursuant to stipulation, the action was transferred to the District of New Jersey for consolidation for trial with a similar action. Ultimately, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 62779; S. No. 800-200-541; N.J. No. 28)

Hydroxyzine pamoate capsules, trimethoprim with sulfamethoxazole tablets, chlorthalidone tablets, hydroxyzine tablets, prochlorperazine tablets, and spironolactone with hydrochlorothiazide tablets, at Ferndale, E. Dist. Mich.

Charged 3-3-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Pursuant to stipulation, the action was transferred to the District of New Jersey for consolidation for trial with a similar action. Ultimately, a consent decree of condemnation ordered the articles destroyed. (F.D.C. No. 62767; S. No. 80-183-483; N.J. No. 29)

Iatric testosterone and estrone combination injectable, at Maryland Heights, E. Dist. Mo.

Charged 5-4-81: when shipped by Carter-Glogau Laboratories Inc., Glendale, Ariz., the article, labeled in part "Iatric I.M. Only . . . O'Neal, Jones & Feldman St. Louis, Missouri," was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 63447; S. No. 81-236-068; N.J. No. 30)

Prochlorperazine capsules, at City of Commerce, C. Dist. Calif.

Charged 6-13-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 63053; S. No. 80-245-421; N.J. No. 31)

Renacidin 10% sterile solution, at Rockford, N. Dist. Ill.

Charged 5-22-81: while held for sale after manufacture by K-N Enterprises Inc., Skokie, Ill., from interstate renacidin powder, the article was a new drug without an effective approved New Drug Application;

and the labeling of the article lacked adequate directions for use and was not exempted due to the article's new drug status; 505(a), 502(f)(1). Default decree ordered destruction. (F.D.C. No. 63472; S. No. 81-248-686; N.J. No. 32)

Trimethoprim with sulfamethoxazole tablets, and other specified drug stocks, at Oklahoma City, W. Dist. Okla.

Charged 2-26-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Pursuant to stipulation, the action was transferred to the District of New Jersey for consolidation for trial with a similar action. Subsequently, a consent decree of condemnation ordered the articles destroyed. (F.D.C. No. 62813; S. No. 80-208-572; N.J. No. 33)

DRUGS/Veterinary

Hexachloroethane suspension drench, at Sanford, M. Dist. Fla.

Charged 9-4-80: when shipped by Chemvet Laboratories Inc., Olathe, Kan., the article, labeled in part "Hexachloroethane Drench. . . . An Aid In The Elimination Of Mature Liver Flukes From Cattle, Sheep and Goats. . . . Manufactured for Veterinarian Specialties, Inc., Cedar Rapids, Iowa," was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to its use or intended use; 501(a)(5).

Joe Baker of Baker Farms, Sanford, Fla., filed an answer on behalf of the article and denied the charge. However, no claim to the article was filed; the answer was not verified, and there was no statement of interest in the article or authorization for counsel to make a claim. Counsel for Baker Farms subsequently notified the government that Baker Farms did not intend to file a verified claim or to intervene in the action. Since no claim to the article was filed, the government moved for a default. A default decree of condemnation ordered the article destroyed. (F.D.C. No. 63139; S. No. 80-165-656; N.J. No. 34)

Neomycin sulfate & methyl violet solution spray, at Odin, S. Dist. Ill.

Charged 7-15-81: when shipped by Chem-Tech Ltd., Des Moines, Iowa, the article, labeled in part "Durvet Pink Eye Spray (Neomycin Sulfate, Methyl Violet). . . . Manufactured for Durvet Inc. Blue Springs, Missouri," was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to its use or intended use; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 63495; S. No. 81-261-921; N.J. No. 35)

Skin Medicine veterinary phenol and camphor combinations for horses and dogs, at Harrisburg, M. Dist. Pa.

Charged 8-14-80: when shipped by Jupiter Veterinary Products and its president, Jupiter, Fla., the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to its intended use—501(a)(5); and the article had been manufactured, prepared, compounded and processed in an unregistered establishment—502(o). Default decree ordered destruction. (F.D.C. No. 63116; S. No. 80-228-127; N.J. No. 36)

MEDICAL DEVICES

X-ray system, Traceray IV, at Poulosbo, W. Dist. Wash.

Charged 10-16-79: the article, which had been manufactured by Western States Supply Ltd., Pueblo, Colo., was dangerous to health when used as directed, because the device would emit radiation beyond the pre-set exposure time—502(j); the accompanying labeling was false and misleading in claiming compliance with the regulation's standards, and in claiming that the device would deliver the radiation exposure stated in the instruction manual—502(a); and the article's quality fell below its purported quality—501(c). Consent decree authorized release to possessor for reconditioning. (F.D.C. No. 62559; S. No. 79-152-951; N.J. No. 37)

X-ray system, Traceray III, at Chaska, Dist. Minn.



Charged 10-2-79: the article, which had been manufactured by Western States Supply Ltd., Pueblo, Colo., was dangerous to health when used as directed, because the device would emit radiation beyond the pre-set exposure time—502(j); and the article's quality fell below its purported quality—501(c). Consent decrees ordered destruction. (F.D.C. No. 62612; S. No. 79-130-185; N.J. No. 38)

X-ray system, Traceray III, at St. Paul, Dist. Minn.

Charged 10-2-79: the article which had been manufactured by Western States Supply Ltd., Pueblo, Colo., was dangerous to health when used as directed, because the device would emit radiation beyond the pre-set exposure time—502(j); and the article's quality fell below its purported quality—501(c). Default decree ordered destruction. (F.D.C. No. 62612; S. No. 79-202-805; N.J. No. 39)

X-ray systems, Traceray III, 12 seizure actions, at Seaside, N. Dist. Calif.; Port Clinton, N. Dist. Ohio; Mountain View, N. Dist. Calif.; Squaw Valley, E. Dist. Calif.; Homestead, W. Dist. Pa.; Charleroi, W. Dist. Pa.; Moorhead, Dist. Minn.; Burnsville, Dist. Minn.; Grand Rapids, Dist. Minn.; North Branch, Dist. Minn.; Lebanon, M. Dist. Pa.; and Lemont, N. Dist. Ill.

Charged 10-5-79, 10-19-79, 10-5-79, 10-10-79, 10-12-79, 10-12-79, 10-10-79, 10-2-79, 10-15-79, 10-2-79, 10-16-79, 11-9-79: the articles, which had been manufactured by Western States Supply Ltd., Pueblo, Colo., were dangerous to health when used as directed, because the devices would emit radiation beyond the pre-set exposure time—502(j); the accompanying labeling was false and misleading in claiming compliance with the regulation's standards, and in that the devices would deliver the radiation exposure stated in the instruction manual—502(a); and the articles' quality fell below their purported quality—501(c). Consent decrees authorized release to the possessors' owners for reconditioning. (F.D.C. Nos. 62458, 62494, 62549, 62572, 62601, 62604, 62607, 62608, 62616, 62619, 62630, 62644; S. Nos. 79-150-776, 79-113-610, 79-150-339, 79-150-563, 79-204-545, 79-204-548, 79-129-256, 79-130-184, 79-218-506, 79-202-983, 79-204-615, 79-109-612; N.J. No. 40)

NOTICES OF JUDGMENT on Contempt Action

Spectro Foods Corp., and Metamail Food Corp. (Ernest O. Moenckmeir, president, Jeanene Moenckmeir, secretary-treasurer) at Summit, Dist. N.J.

Charged 1-24-76 in an order to show cause for contempt of temporary restraining order and preliminary injunction (see N.J. No. 44 of this issue of *FDA Consumer*): that the defendants had failed to comply with the recall order contained in the temporary restraining order and preliminary injunction.

After a hearing, the court found the two corporations in contempt and fined them each \$5,000, plus \$500 per day for each day of continued violation. The defendants appealed such adjudication as well as the issuance of the temporary restraining order and preliminary injunction upon which the contempt was based. Upon appeal, the court upheld the issuance of a preliminary injunction but vacated all of its provisions except Parts I and II (see N.J. No. 44 of this issue of *FDA Consumer*). However, the court ruled in favor of the defendants as far as the contempt action was concerned, saying:

The "Order for Civil Contempt"

"The 'Order for Civil Contempt' recites that it was issued when the defendant corporations disobeyed the recall order embodied in the TRO and the Preliminary Injunction. Since these recall provisions will be vacated, the court must now consider whether the 'Order for Civil Contempt' should continue in effect.

"While a defendant may be punished for criminal contempt for failing to obey an injunction which is later set aside, the same result does not follow in a civil contempt proceeding. The difference in treatment follows from the fact that whereas a criminal contempt order is punitive—to vindicate the authority of the court, the purpose of a civil

contempt order is remedial—to coerce compliance with the injunction or recompense a party for losses caused by non-compliance. The right to remedial relief disappears when it is determined that an injunction was issued erroneously. Therefore, to the extent the contempt order is correctly described as a 'civil contempt,' it falls with the vacation of the recall order on which it was based.

"Although the district court characterized its order as one for civil contempt, appellate courts must look to the substance of the order rather than the form to determine whether the contempt is civil or criminal in light of the nature and purpose of the sanction. The fact that a defendant can purge himself of the contempt and avoid the sanctions indicates that the purpose is coercive and the contempt order is civil. Sanctions which are imposed unconditionally strongly suggest a punitive purpose and a criminal contempt. However, an unconditional fine paid to the opposing party is a compensatory civil contempt.

"In its 'Order for Civil Contempt,' the district court adjudged the two corporations in contempt and fined them each \$5000 plus \$500 for each day they continue to violate the recall provisions of the TRO and the Preliminary Injunction. The continuing \$500 per day fine is unquestionably for civil contempt: It is clearly coercive since it can be avoided by compliance. The flat \$5000 fine, however, seems more in the nature of punishment for past violations of the court's orders, and there is abundant evidence that the court's purpose in imposing it was punitive rather than coercive or remedial. Nevertheless, in light of the considerations discussed below, we vacate the 'Order for Civil Contempt' in its entirety.

"First, it is possible that there was a remedial purpose underlying the \$5000 fine. The fine is payable to plaintiffs, the government, and could be viewed as compensation for their efforts in monitoring defendants' (non)compliance with the TRO and the Preliminary Injunction. Alternatively, the flat fine might have been coercive, to emphasize that the court fully intended to impose the daily fine in the event of further non-compliance, thus increasing the *in terrorem* effect of the daily fine.

"Second, even if the fine were for criminal contempt, it could have been imposed only in a criminal contempt proceeding conducted in accordance with the Criminal Code, 18 U.S.C. §§401, 402 and Rule 42 of the Federal Rules of Criminal Procedure, as well as the constitutional provisions relevant to criminal trials. In the instant matter due process was not satisfied in the form of notice to defendants of a pending criminal contempt charge including describing it as such as required by F.R.Cr.P. 42(b).

"In the matter of criminal contempt, as in all criminal cases, due process also requires that a defendant is presumed innocent and punishment can only be imposed after the government has met its burden of establishing defendants' guilt beyond a reasonable doubt. Yet on several occasions the district judge indicated that defendants' guilt had been established when the first Order to Show Cause was issued and that defendants thereafter had the burden of proving their innocence of the contempt charges. Insofar as defendants were convicted of criminal contempt, adherence to procedural due process requires reversal of the conviction." (Inj. No. 710; S. No. 76-35-128 et al.; N.J. No. 41)

NOTICES OF JUDGMENT on Injunction Actions

Bel-Mar Laboratories Inc., Hannah Schechter, president, and Stephen B. Schechter, secretary-treasurer, Inwood, E. Dist. N.Y.

Charged 12-16-76 in a complaint for injunction: that the defendants, at their Inwood, N.Y., plant, manufactured, processed, packed, labeled, held for sale after shipment of interstate components and distributed in interstate commerce certain drugs (i.e., sterile injectable drugs in the form of solutions, aqueous suspensions and oil preparations; that the circumstances used for the manufacture, processing, packing and holding of the drugs failed to conform with current good manufacturing practices; that FDA inspections disclosed a number of specified deviations from current good manufacturing practices; that, indicative of the



defendants' failure to adequately sterilize drugs, FDA examination found *Corynebacterium equi* (a bacteria found in pregnant mares' urine, the source of estrone) in samples of the defendants' estrone aqueous suspension; that a number of the defendants' drugs were violative as follows: the drugs were U.S.P. or N.F. drugs and their strength differed from and their quality fell below their purported strength or quality; the drugs' labeling contained false and misleading statements with respect to the sterility and quantity of the articles; and the drugs were dangerous to health when used as directed in their labeling; and that the defendants are well aware that their activities are in violation of the law; 501(a)(2)(B), 501(b), 501(c), 502(a) and 502(j).

The action came on for a hearing before the court. The court ruled in favor of the government and authorized a permanent injunction. The defendants litigated the proposed terms of the decree and asserted that an arbitrator should be appointed. Subsequently, the court issued an order of permanent injunction which enjoined the complained of acts and specified which articles on hand could be shipped. (Inj. No. 755; S. No. 76-40-927 et al.; N.J. No. 42)

Barfed Research Laboratories Inc., and Benjamin Z. Friedman, president, Coral Gables, S. Dist. Fla.

Charged 6-2-78 in a complaint for injunction: that the defendants had been, at their Coral Gables, Fla., plant, manufacturing, processing, packing, labeling, holding and distributing various drugs which had had components shipped in interstate commerce; that the circumstances used for the drugs' manufacture, processing, packing and holding failed to conform with current good manufacturing practices; that the strength of a number of the drugs differed from purported strength; that the labels of a number of the drugs failed to bear the name and place of business of the manufacturer; that the labels of a number of the drugs failed to bear an accurate statement of the quantity of contents; that the labels of a number of the drugs lacked the established name of each active ingredient; that the labels of a number of the drugs, which were packaged in bulk form for further processing, packing or manufacturing lacked adequate directions for use and were not exempted, since the labels lacked the required statement "Caution: For manufacturing, processing, or repacking"; that FDA inspections had revealed a number of specified significant deviations from current good manufacturing practices; and that, because of specified written and oral notice and a number of specified recalls, the defendants were well aware that their activities were in violation of the law; 501(a)(2)(B), 501(c), 502(b)(1), 502(b)(2), 502(e)(1)(A)(ii) and 502(f)(1).

A consent decree enjoined the complained of violations, enjoined the distribution of all drug components on hand, and ordered recalls of all drugs shown to be adulterated or misbranded. (Inj. No. 855; S. No. 78-141-013 et al.; N.J. No. 43)

Spectro Foods Corp., Metamail Food Corp., and Ernest O. Moenckmeier, president, and **Jeanine Moenckmeier**, secretary-treasurer, Summit, Dist. N.J.

Charged 1-19-76 in complaint for injunction: that the defendants caused the manufacturing, processing, packing, labeling and holding for sale (after interstate shipment of components) "Bitter Food Tablets" containing amygdalin in strengths of 100 mg and 500 mg per tablet; that the defendants wholesaled the tablets using a Spectro Food Corp. label and retailed the tablets using a Metamail label; that when distributed in interstate commerce, and while held for sale, the article "Bitter Food Tablets" was a non-conforming food additive, was a drug lacking adequate directions for use, since the intended purpose and condition of use (i.e., the treatment and prevention of cancer) were not stated, was a drug lacking adequate warnings against unsafe use, and was lacking the prescription legend; that, as an integral element of their promotion of amygdalin tablets, the defendants employed a pamphlet, reading in part "The Nieper Approach ('Nieper Regimen') to Biological Cancer Treatment . . . based upon: * * * 4) the treatment with nitrilosides (non-toxic

carcinostatic substances)"; that the article "Bitter Food Tablets" was a new drug without an effective approved New Drug Application; that Mr. Moenckmeier had admitted to previous distribution of amygdalin tablets; that the individual defendants had refused to disclose the source of amygdalin, the active ingredient in "Bitter Food Tablets," or where stocks of the tablets were stored; 402(a)(2)(C), 502(f)(1), 503(b)(1), 503(b)(4), 505(a).

The court entered a Temporary Restraining Order which restrained the manufacture and distribution of Bitter Food Tablets. The court further ordered Spectro Foods Corp. to recall all previously distributed tablets within the next five days. After an *ex parte* hearing, the court issued an order to show cause why the defendants should not be held in contempt for failure to comply with the recall order. Shortly thereafter, after a hearing on the alleged contempt and on the motion for preliminary injunction, the court issued a preliminary injunction, set up a compliance schedule and held the contempt matters in abeyance. The government moved for a second order to show cause why a contempt order should not issue (See N.J. No. 41 of this issue of *FDA Consumer*.) The defendants appealed the temporary restraining order, the preliminary injunction and the contempt order.

Upon appeal, the court of appeals found that the parts of the Temporary Restraining Order and Preliminary Injunction which granted FDA supervisory power over the conduct of the defendant's business were unwarranted; and except for parts I and II of the Preliminary Injunction, the court vacated the injunction and remanded the matter for further proceedings. The court said:

"Presently before the court is an appeal from a Preliminary Injunction secured by the government pursuant to the Federal Food, Drug, and Cosmetic Act ('the Act'), 28 U.S.C. §332(a), and from an Order for Civil Contempt arising out of alleged violations of a Temporary Restraining Order and the Preliminary Injunction. The appellants are Spectro Foods Corporation ('Spectro') and Metamail Food Corporation ('Metamail'), both New Jersey corporations, Ernest O. Moenckmeier, president, and Jeanine Moenckmeier, secretary-treasurer of the two corporations. They manufacture and distribute a product known as 'Bitter Food Tablets' which they allegedly market for use in the treatment of cancer. The complaint alleged that Bitter Food Tablets contain amygdalin which is an 'unsafe' 'food additive,' that the tablets themselves are a 'food,' a 'drug' and a 'new drug,' and consequently that the defendants were in violation of section 331(a), (d) and (k) by virtue of their manufacture, distribution and holding for sale of an 'adulterated food,' a 'misbranded drug' and an unapproved 'new drug.'

"At the time the complaint was filed on January 19, 1975, the district judge entered a Temporary Restraining Order ('TRO') which restrained the manufacture and distribution of Bitter Food Tablets. At the government's urging that the public safety was jeopardized by the current availability of these tablets, the court further ordered Spectro to recall all previously distributed tablets by January 23. The next procedural development was an *ex parte* hearing held on Saturday, January 24. The result of the January 24 hearing was the issuance of an order to show cause why defendants should not be held in contempt for failure to comply with the recall order.

"A hearing was held on January 28 to determine whether a preliminary injunction should issue and whether defendants should be held in contempt for violation of the TRO. At that time, a compliance schedule was set up and the contempt matter held in abeyance. The district judge also made findings of fact and conclusions of law and on January 29, he issued a preliminary injunction, the scope of which is contested in this appeal. The Preliminary Injunction not only incorporated the restraints on manufacture and distribution and the recall order of the TRO, but also restrained the distribution of any food additive or drug in violation of the Federal Food, Drug, and Cosmetic



Act. The court added further provisions which, in effect, ordered the FDA to supervise and control the conduct of defendants' business.

"On February 9, the government, having concluded that the defendants had defaulted on the agreed upon compliance schedule, moved for a second order to show cause why a contempt order should not issue. At a hearing on February 17, the corporate defendants, Spectro and Metamail, were found in contempt for noncompliance with the recall order contained in the TRO and the Preliminary Injunction, and on the following day the district judge issued an 'Order for Civil Contempt.'

"The defendants responded on February 20 by filing notice of this appeal from the TRO, the Preliminary Injunction and the Order for Civil Contempt. On February 27, a judge of this court denied a stay of these three orders.

I. Jurisdiction of the Reviewing Court

"The Preliminary Injunction is a reviewable interlocutory order under the jurisdiction conferred by 28 U.S.C. §1292(a)(1). Although an order of civil contempt is not ordinarily appealable, one who is a party may appeal from a civil contempt order in connection with some other appealable order, including a preliminary injunction. Consequently, the court has jurisdiction over the appeal from the Order for Civil Contempt.

"A TRO is not an injunction and consequently is not an appealable order. Further, any purported notice of appeal from the TRO was not timely filed and the TRO had, by its terms, expired prior to the appeal. The court therefore need not consider whether the provisions of the TRO which did more than merely temporarily restrain defendants converted it into a form of an interlocutory injunction independently reviewable under 28 U.S.C. §1292(a)(1). The contempt order, however, does purport to be based in part on defendants' non-compliance with the TRO. Although this court has no jurisdiction to entertain an appeal from the TRO, the validity of the TRO must nonetheless be examined for the limited purpose of our review of the Order for Civil Contempt which the district court issued because of the defendants' failure to comply with the recall provisions of the TRO and Preliminary Injunction.

II. Validity and Scope of the Preliminary Injunction

"Defendants have alleged a plethora of procedural defects in the district court proceedings. Most of these are wholly without merit, and the remainder, though in some respects disturbing, do not warrant reversal of the entire order granting the Preliminary Injunction. However, because several provisions of the Preliminary Injunction are far broader than the record justifies and others exceed the permissible scope of interlocutory relief, some portions of the Preliminary Injunction are invalid.

"The prohibition of the manufacture and distribution of the Bitter Food Tablets or other amygdalin-containing articles in parts I and II of the Preliminary Injunction (and parts I and II of the TRO) are unobjectionable. The FDA affidavits indicated that amygdalin is a food additive not on the list of additives generally recognized as safe ('GRAS') and is a new drug for which no New Drug Application is on file. Other affidavits concerning defendants' manufacture and distribution of the Bitter Food Tablets provided a sufficient basis for the district court's preliminary conclusions that defendants violated 21 U.S.C. §331(a), (d) and (k) by virtue of their manufacture, distribution and holding for sale of Bitter Food Tablets. Parts I and II of the TRO and the Preliminary Injunction are properly tailored to enjoin these particular violations of the act.

"The restraints in parts III and IV of the Preliminary Injunction are far broader than those in parts I and II. While parts I and II are limited to restraints on the manufacture and distribution of Bitter Food Tablets and other amygdalin-containing articles, parts III and IV prohibit the distribution of *any* article of food containing a food additive not recognized as safe or any new drug for which no new drug approval application has been filed. This broad injunctive restraint was issued

notwithstanding that the court had no evidence concerning distribution by defendants of any unsafe food additive or unapproved new drug other than the Bitter Food Tablets.

"The district courts are invested with discretion to model their orders to fit the exigencies of the particular case, and have the power to enjoin related unlawful acts which may fairly be anticipated from the defendants' conduct in the past, but a decree cannot enjoin conduct about which there has been no complaint. All the alleged violations here stemmed from the manufacture and distribution of a single item. There was no evidence of record from which the district court could fairly have anticipated that defendants would distribute other substances in violation of the act, nor did the court make any such findings. The use of the broad injunctive language on so scant a record constitutes error. Parts III and IV of the Preliminary Injunction will be vacated.

"The primary controversy and that which led to issuance of the contempt order centers upon part V of the Preliminary Injunction and part III of the TRO. Those provisions employ identical language and encompass the recall order directing defendants to: (a) notify an FDA representative of the location and amount of all stocks of Bitter Food Tablets, amygdalin and associated labeling; (b) notify all recipients of the Bitter Food Tablets to return them to defendants; (c) provide an FDA representative with a copy of said notice and a list of all persons to whom the Bitter Food Tablets had been distributed; (d) obtain statements from each recipient of the Bitter Food Tablets as to amount of the article received, the amount returned, and disposition of that which was not returned; and (e) make copies of the customer statements available to an FDA representative.

"Those aspects of the recall order which culminated in the Order for Civil Contempt did not merely operate to restrain further violations of the act by defendants for, according to the record, they involved items no longer in defendants' possession. Neither did the recall order operate *pendente lite* to preserve the status quo, i.e., 'the last actual uncontested status which preceded the pending controversy.' Rather, the recall provision functioned as though it were 'actually a discovery provision,' as the district court characterized it, enabling the government to locate various quantities of the tablets for seizure pursuant to 21 U.S.C. §334.

"The power to issue a preliminary injunction, especially a mandatory one, should be sparingly exercised. Parts I and II of the Preliminary Injunction are based on the alleged violation of 21 U.S.C. §331(a)(d)(k), and therefore do not require a showing of immediate and irreparable injury. On the other hand, the recall order does not address a particular violation of the act from which injury may be presumed and thus there must be an independent showing of irreparable harm to warrant its issuance.

"The district court made no finding that the public would be irreparably harmed absent a recall order. In fact, the court made no specific findings of irreparable injury other than that resulting from defendants' violation of the act itself. In this circumstance it was error for the court to issue an interlocutory mandatory injunction unsupported by specific findings of irreparable injury *Cf. A. O. Smith Corp. v. FTC*, 530 F.2d 515, 525 (3d Cir. 1976).

"From this discussion of part V of the Preliminary Injunction and part III of the TRO, it is equally apparent that the order granting the FDA supervisory power over the conduct of defendants' business was wholly unwarranted. The order forbids defendants from distributing or holding for sale any article of food or drug without the FDA approval, requires the FDA to sequester defendants' inventory and their entire stock of raw materials and to destroy all items which it does not 'approve.' Further, the decree orders defendants to abide by the decisions of the FDA representative, to compensate the government for the cost of this supervision, and generally enjoins defendants from selling or disposing of any article of food or drug in violation of the act or the laws of any state or territory.

"This far-reaching order *might* appropriately be included in a perma-



nent injunction issued after a full evidentiary hearing disclosed a history of repetitive, flagrant violations, suggesting a real danger of recurrent evasions of a more carefully drawn order. However, in the context of this interlocutory order, based on a narrow showing by affidavit, the government's request for such a broad order can only be characterized as gross over-reaching. In the absence of any relevant findings of irreparable injury, the court's acquiescence evidenced by the grant of the order constitutes both an abuse of its discretion and 'a serious mistake in considering the proof.' *Cf. A.O. Smith Corp. v. F.T.C., supra*, at 525."

Subsequently, a hearing was held on a permanent injunction. The defendants indicated their desire to enter into a consent decree. A consent decree permanently enjoining the complained of violations was filed. (Inj. No. 710; S. No. 44-986H et al.; N.J. No. 44)

NOTICES OF JUDGMENT on Miscellaneous Actions

Menstrual tampon Rely, its classification by FDA as a device, and alleged hazards and injuries, San Francisco, N. Dist. Calif.

Charged 9-23-80 by Carol A. Thompson and Barbara Lee, against Procter & Gamble Co., H.H.S. Secretary Patricia Roberts Harris, FDA Commissioner Jere Goyan, and Bureau of Medical Devices Director Victor M. Zafra, in a class action complaint for judicial review, mandamus, injunction and other relief (e.g., restitution and damages): that Procter & Gamble Co., Cincinnati, Ohio, had manufactured and marketed Rely tampons; that Rely tampons were promoted as a revolutionary new kind of tampon consisting of tiny sponges and super absorbent synthetic fibers; that Rely tampons achieved their primary purpose through chemical action; that FDA had failed to classify the tampons as a new drug, had improperly classified the tampons as a medical device, and had improperly delegated authority over the tampons to the Bureau of Medical Devices who had improperly classified the tampons, first as class I devices and subsequently as class II devices; that, even after reports indicated that the tampons posed a serious threat to all women using them, FDA had failed to require affirmative proof of safety and effectiveness, and had allowed continued marketing; that FDA had a plain, clear and non-discretionary duty to classify the tampons as a class III device; that, in February, March, April and May of 1980, plaintiff Thompson had experienced adverse symptoms while using the tampons and had to be taken to the hospital in June of 1980; that plaintiff Lee had experienced adverse symptoms while using the tampons for approximately one year and in March 1980 had been hospitalized for eight days and confined to an intensive care unit for approximately three days; that the defendant Procter & Gamble Co. had been unjustly enriched; that the plaintiffs sought restitution, compensatory and punitive damages, judicial review and declaratory judgment, injunctive relief, mandamus, and award of attorneys' and experts' fees and costs of the suit.

The plaintiffs served written interrogatories and a request for the production of documents in the possession of the government. The government moved to dismiss, asserting that FDA had already negotiated a consent agreement with Procter & Gamble Co. under which: (1) Rely had been withdrawn from the market; (2) Rely may not be reintroduced without FDA's prior written permission; (3) a warning to cease using Rely was extensively advertised; and (4) unused Rely was retrieved and the purchase price was refunded; that, because Rely was no longer on the market, the plaintiffs' claims against the government were moot; that the action should also be dismissed because: (1) The

classification of medical devices and drugs was within FDA's discretion and thus not subject to mandamus; (2) there was no jurisdiction under the Administrative Procedures Act; and (3) the plaintiffs had failed to exhaust their administrative remedies.

The court dismissed the actions against the federal officials saying:

"This case concerns Procter and Gamble's Rely brand tampons, which plaintiffs allege are unsafe. In addition to Procter and Gamble, plaintiffs have sued several federal officials. The federal officials have moved to dismiss the action as against them for failure to state a claim on which relief can be granted.

"The two counts against the federal defendants seek relief in the nature of mandamus directing the Food and Drug Administration to reclassify Rely tampons. However, the existence of alternate remedies precludes such an action. *Kennecott Copper Corp., Nevada Mines Division v. Costle*, 572 F.2d 1349, 1356 (9th Cir. 1978). Here, plaintiffs have not alleged that they have exhausted their administrative remedies or that it would be futile to do so. They may be able to obtain the relief they seek by petitioning the Food and Drug Administration pursuant to 21 U.S.C. §360c(e) or 21 C.F.R. §10.25. Accordingly, it is hereby ordered that counts XV and XVI of the complaint are dismissed.

"It is hereby further ordered that the federal defendants' motion to dismiss is granted and that the action is dismissed against defendants Patricia Roberts Harris, Secretary of the Department of Health & Human Services, Jere Goyan, Commissioner of the Food & Drug Administration, and Victor M. Zafra, Director of the Bureau of Medical Devices." (Misc. No. 616; N.J. No. 45)

NOTICE OF JUDGMENT on Criminal Action

Francois Savery, clinical investigator, Long Beach, C. Dist. Calif.

Charged 7-9-81 by grand jury: that, in a matter within FDA's jurisdiction, the defendant, knowingly and willfully, submitted a false writing and document containing false and fraudulent material statements, i.e., an SMA 12/60 chart dated June 17, 1976, representing the results of blood tests; 18 U.S.C. 1001. Guilty plea; \$5,000 fine and five years probation with special conditions, including not practicing medicine unless lawfully licensed and taking no part in the conduct of any medical research investigation in connection with the New Drug Applications. (F.D.C. No. 61861; S. No. 78-25-604 et al.; N.J. No. 46)

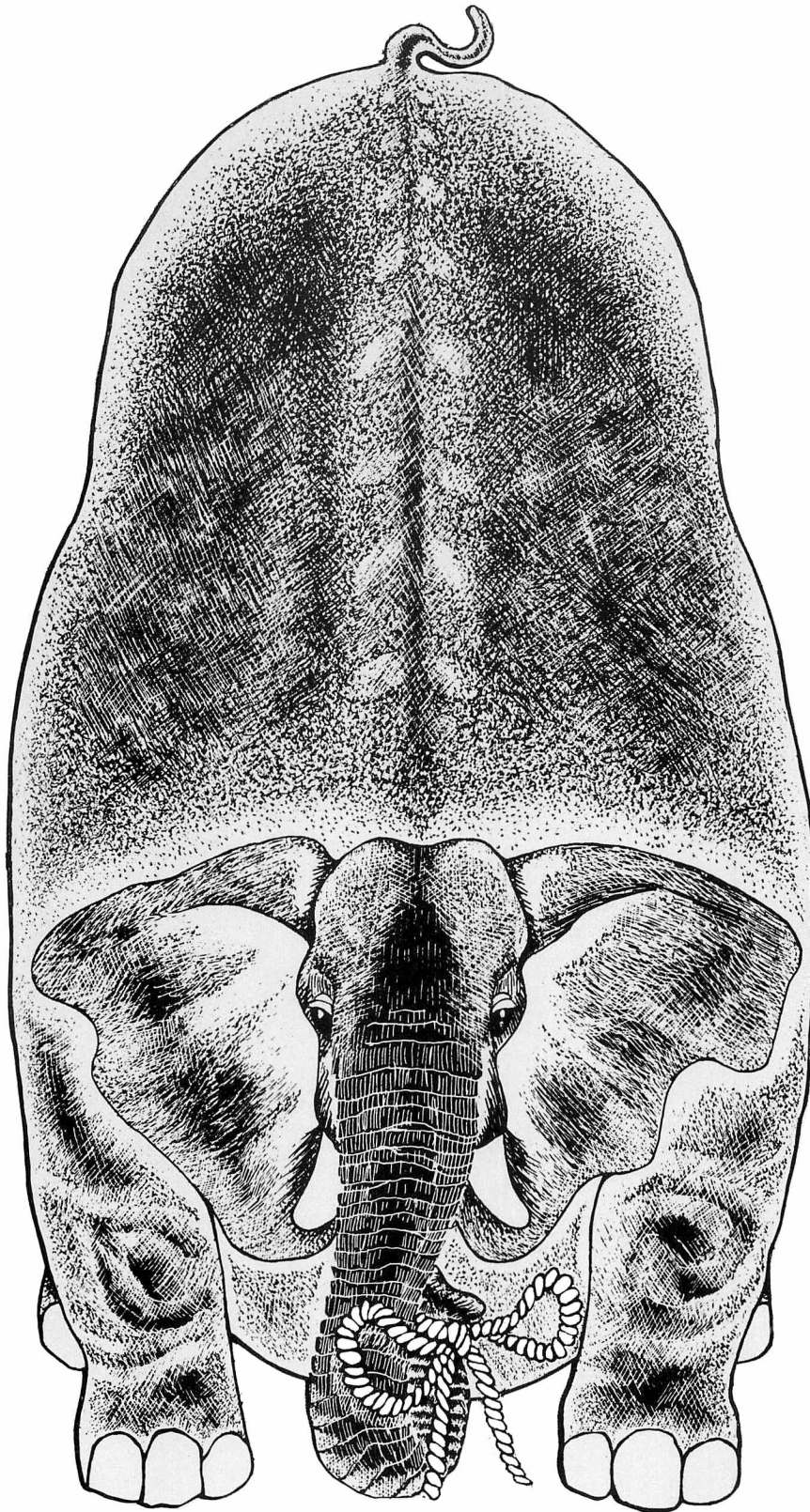
Notices of Judgment are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act. Notices of Judgment report cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizure proceedings are civil actions taken against *goods* alleged to be in violation, 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.

Notices of Judgment are prepared by Food and Drug Division, Office of the General Counsel, HHS.

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

Arthur Hull Hayes Jr., M.D., *Commissioner of Food and Drugs*
Washington, D.C., April 1, 1982

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