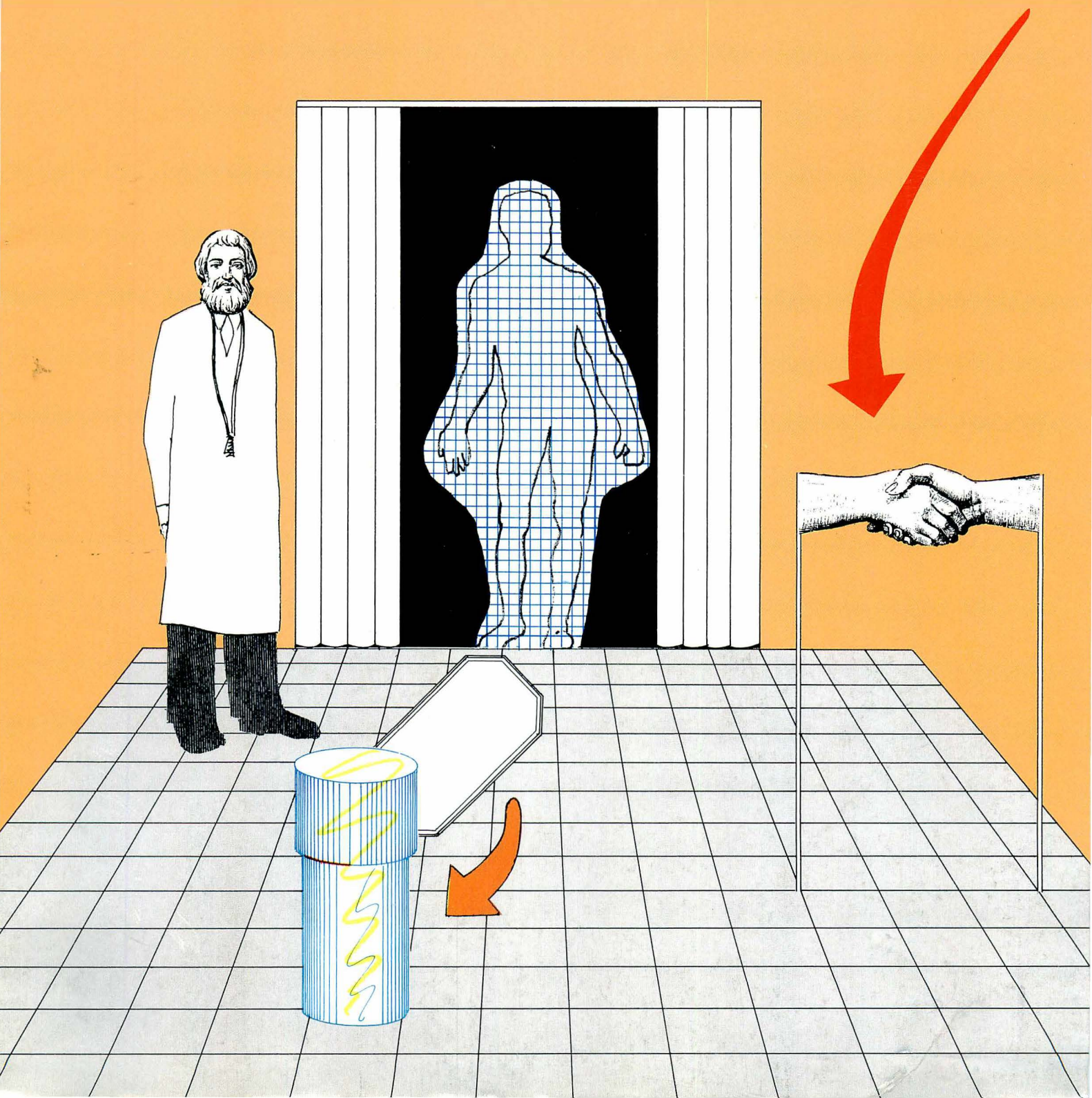


FDA CONSUMER

November 1979

When You And Your Partner The Doctor Talk About Diagnosis



A black and white photograph of a desk. In the foreground, a large, dark book titled "Physicians' Desk Reference" is open. The title is printed in a large, white, serif font. To the right of the title, there is a logo that reads "PDR 333 EDITION 1979". The logo consists of the letters "PDR" in a small font, followed by the number "333" in a large, bold font, and the word "EDITION" in a small font below the number. The year "1979" is printed in a small font at the bottom of the logo. In the background, a desk lamp with a dark, rounded base and a white, circular light fixture is visible. Behind the lamp, a bookshelf filled with various books is visible. The books are arranged in rows, and their spines are visible. The overall scene is dimly lit, with the lamp providing the primary light source.

Physicians' Desk Reference

PDR
333
EDITION
1979

Patricia Roberts Harris
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Health, Education, and Welfare

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FDA CONSUMER was previously known as **FDA PAPERS**.
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.

Cover Design: Thomas Teague

FDA CONSUMER

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NOVEMBER 1979

The Courts, Terminal Patients, and Unapproved Drugs 4

The Supreme Court supports FDA's position, in the Laetrile case, that no patient is ever so near death that the law's protection against quackery is pointless or without compassion.

Listening as a Fetus Becomes a Baby 8

For years, some doctors have been using electronic instruments to check up on baby and mother in the hours before birth. Some think it's a great medical advance and some are skeptical. Here's what they say.

When You and Your Partner the Doctor Talk About Diagnosis 13

With some extra effort and forethought, some common-sense, some perseverance—and perhaps a little pushiness—today's patient can learn more from the doctor and other sources about what ails him, and can often improve the care he's getting.

Look Who's Reading the PDR Now! 16

That doctor's bible, the PHYSICIANS' DESK REFERENCE, was once intended only for the eyes of medical professionals and related audiences. But now it's gone vulgate, and the patient can see for himself what his prescription is capable of.

Advice on Breast-feeding and Drugs 21

Upcoming medical labeling will put into effect FDA requirements that drug labels tell whether they are capable of becoming residues in mother's breast milk and how these could affect the infant.

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Inside Front Cover: *At home in the average home these days is the PHYSICIAN'S DESK REFERENCE, a fat technical publication that tells all about prescription drugs. The PDR, as it is known, was once considered fit only for the eyes of health professionals, but today it is a nonfiction bestseller and a hot public library item.*

Darvon Status Clarified

FDA CONSUMER erred in its description of the restrictions on Schedule IV drugs in an Update item, "Darvon Study Continues," in the July-August issue. Drugs placed in Schedule II of the Controlled Substances Act are limited in production, cannot be prescribed over the telephone, and prescriptions for them cannot be refilled. Schedule IV drugs can be prescribed by telephone, however. No prescription for a Schedule IV drug can be filled or refilled more than 6 months after the date on which such prescription was issued, and no prescription can be refilled more than five times. Darvon currently is a Schedule IV drug.

Daytime Sedatives To Be Banned

Nearly 4 years ago a panel of experts said it was "unable to determine any demonstrable indications for which available OTC daytime sedatives are useful." These comments and others relating to the safety and effectiveness of this class of drugs were reported in an article, Panel Reports on Sleep-Aids, in the February 1976 FDA CONSUMER. Here's an update.

Effective on Christmas Eve of this year, FDA will no longer permit the sale of over-the-counter (OTC) drug products labeled as daytime sedatives. Any nonprescription drug labeled as a daytime sedative introduced in interstate commerce after that date will be subject to FDA regulatory action.

Daytime sedative labels have claimed these products to be effective in relieving "occasional simple nervous tension," "nervous headache," and "simple nervousness due to common everyday overwork and fatigue." These products, as well as nighttime sleep aids, generally contain antihistamines, which make people drowsy. FDA opposes the marketing of nonprescription drugs as daytime sedatives because there is no evidence that drowsiness helps relieve anxiety, and drowsiness is not a desirable side effect during the day when people need to be alert. FDA has not opposed the sale of antihistamines as nighttime sleep aids since drowsiness can help people fall asleep.

A few daytime sedatives contain scopolamine or bromide, ingredients FDA regards as being unsafe or ineffective for daytime sedative use.

FDA had announced in June 1978 its intention to ban daytime sedatives. Since then many manufacturers have relabeled their products to market them as nighttime sleep aids or have removed them from the market.

Review Board Regs Reproposed

On August 8, 1978, FDA proposed standards for institutional review boards, the committees set up by institutions sponsoring clinical research to review and monitor such research. What would be required of these boards, called IRB's, was outlined in an article New Standards for Clinical Research, in the November 1978 FDA CONSUMER. Here's an update.

In a notice in the FEDERAL REGISTER FDA withdrew its proposed standards for Institutional Review Boards and repropose them for compatibility with regulations proposed at the same time by the Department of HEW.

The basic definitions in the repropose standards are the same as in the initial proposal. Sections relating to membership on an IRB are modified to be consistent with HEW proposals through deletion of a requirement that an IRB possesses the competence to comprehend the scientific nature of the investigation.

The new proposals state that a member of the immediate family of persons affiliated with the institution may not serve as the only unaffiliated member of the board. A sponsor would now be allowed to participate in selection of members of a board that will review that sponsor's study. The original requirement that an IRB monitor a clinical investigation has been deleted as beyond the generally accepted scope of IRB responsibilities, i.e., to review and approve clinical investigations. A quorum of an FDA IRB must include at least one licensed physician to help assure the protection of human subjects in clinical investigations.

Procedures for initial review of a clinical investigation have been modified to require the board to give the clinical investigator an opportunity to respond in person or in writing when a proposal is disapproved. Under the new proposal minor changes in the protocol of an approved clinical investigation may be made by a board chairperson or by one or more experienced reviewers. FDA invited comments on what constitutes a "minor change."

The new proposal would authorize IRB's to suspend or terminate approval of a study instead of terminating the study itself. This action would have to be reported to FDA immediately. The Agency would then evaluate the situation and take necessary steps to stop the investigation if warranted.

Records of review boards would be kept for 5 years after completion of a study.

Consumer Forum

Who Saves on Generics?

In response to your article *FDA Drug List: Key to Generic Substitution* (in the February 1979 issue of FDA CONSUMER), I would like to thank you for bringing this matter of therapeutic drug equivalents to the attention of the consumer. It seems as if we might be receiving a break from high medication costs after all. Or will we?

As was mentioned in the article, under the model substitution law the pharmacist has the right to withhold some (if not all) cost savings of the substituted generic drug from the consumer. Personally, I don't feel this is fair. Is not the purpose of the model substitution law to give the consumer a break from high prescription costs? If this is so, then why do pharmacists have this great option? Shouldn't it be left up to the consumer whether or not to use a lower priced medication rather than leave it in the hands of the pharmacist? If this is the way the new law works, maybe we would be better without it.

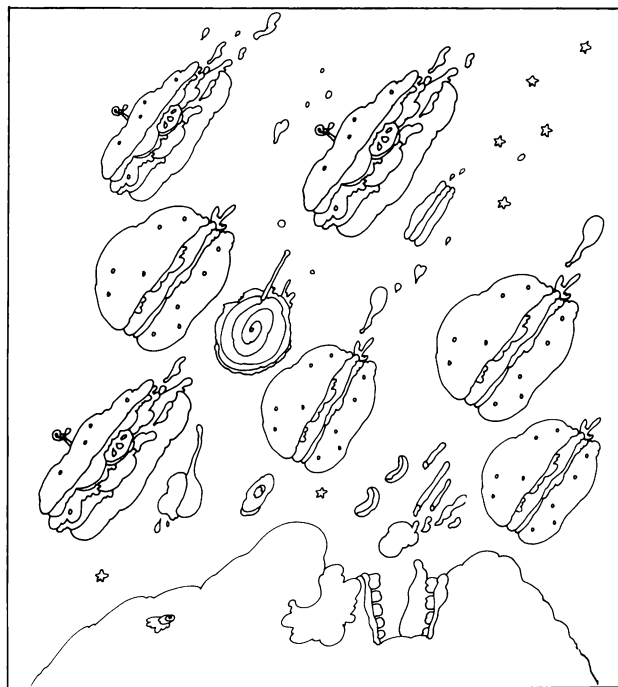
Margaret Hilts
Oakland, California

The FTC Model Drug Substitution Law permits, but does not require, pharmacists to dispense generic drugs for therapeutically equivalent brand name products. If the pharmacist bases his dispensing fees on the cost of the drug, there would be little incentive for him to dispense generic drugs. The model law allows the pharmacist and the consumer to share in the savings. Just how much of the saving should be passed on to the consumer is not specified in the law, but it is expected that competitive forces will provide enough incentive to make the benefit to consumers a considerable one.

'Imitation' Hamburger Clarified?

We respectfully request that you make a correction in a future issue for apparent inaccuracies in your report of State Actions concerning Fitzi's, Inc., San Diego, and the exposure of Imitation Hamburger. (March 1979 issue of FDA CONSUMER, page 33.)

Article 7, Section 26595, of the California Health & Safety Code provides that "hamburger shall not contain more than 30 percent fat" not 21 percent as you reported. Article 7, Section 26596(b) provides: "No restaurant shall use the terms 'hamburger,' 'burger,' or any other cognate thereof in any advertisement, or menu to refer to any imitation hamburger. A restaurant selling or



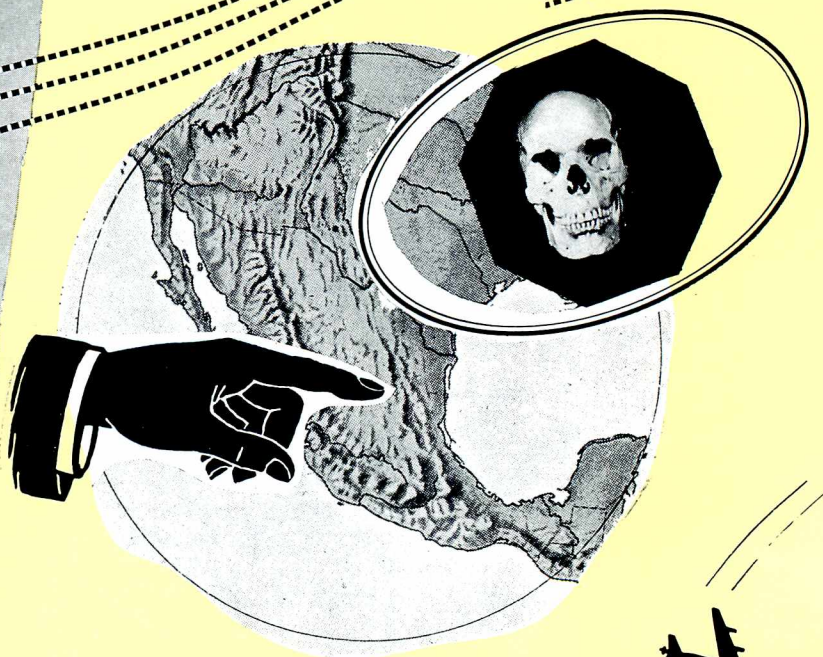
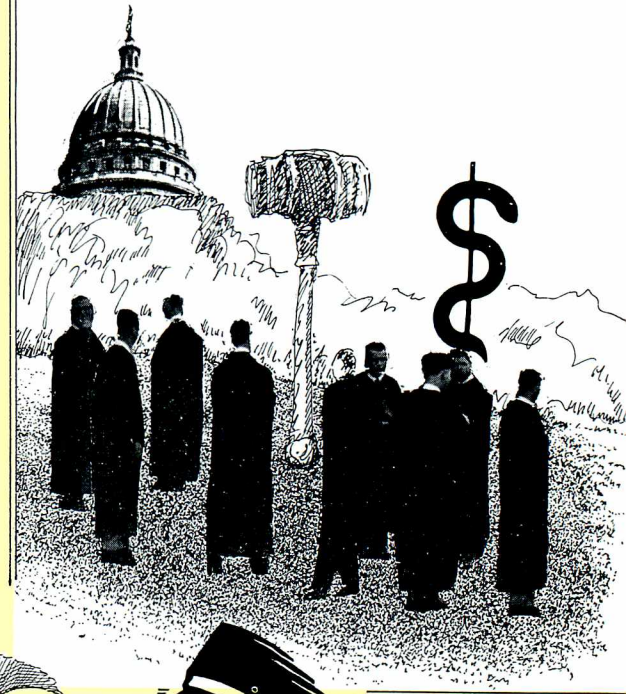
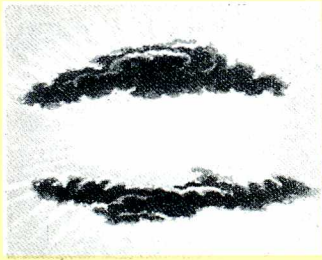
serving imitation hamburger may refer to such product as imitation hamburger or by any other term which accurately informs the customer of the nature of the food product which he is sold or served," and not that if a binder or extender is added to the beef, it must be classified as "imitation hamburger."

You do a gross disservice at taxpayer expense with such sloppy and inaccurate reporting.

Rosemary Mucklow
Executive Director
Pacific Coast Meat Association, Inc.
San Francisco, California

Ms. Mucklow is correct in saying that the maximum level of fat permitted in hamburger is 30%. Our figure was in error.

Ms. Mucklow is also accurate in asserting that a restaurant may call imitation hamburger by any term which "accurately informs the customer of the nature of the food product which he is sold or served." However, the statement in the March issue that the product is classified as imitation hamburger is also accurate, according to Chambers S. Bryson, chief of the Food and Drug Division of the California Health Department. Bryson says that according to the California Health and Safety Code, Section 26595(b), if any amount of binder or extender is added to beef, it is classified as "imitation hamburger" under California law.



The Courts, Terminal Patients, And Unapproved Drugs

In its decision on June 18, 1979, in a Laetrile case, the U.S. Supreme Court, in effect, supported FDA's position banning the drug from interstate commerce. However, the decision was more far-reaching than that. It involved the rights of terminal patients; it raised the question of what is terminal; and it delved into the issue of quackery.

by Wallace Janssen

"There is no substitute for making sure that your patient never once worries about being abandoned. Of course, no true physician would ever really abandon his patient, but I am speaking of a greater commitment: one that makes the patient know that you are there at all times, at the very least in spirit."

—W.P.L. Meyers, M.D. in **TEXTBOOK OF MEDICINE**, Beeson and McDermott.

It is no accident that the introductory pages of the renowned medical textbook quoted above include the care of the patient with terminal illness. Here, medical ethics meet the most difficult challenges, and the ones most controversial. Countless news items and articles deal with death and dying, "death with dignity," euthanasia, and the "right to die," not to mention the right to receive or reject methods of treatment. With increasing frequency, these complex and confusing issues reach the courts—each case a poignant human drama. The U.S. Supreme Court handed down a clarifying opinion in such a case on June 18, 1979.

"Terminal" cancer patients and their spouses had sued the Government to stop law enforcement action against the shipment and sale of Laetrile, a drug not approved as safe and effective under the Federal Food, Drug, and Cosmetic Act.

The background of this drug is significant. Laetrile is one of a number of unproven therapies invented by the late Dr.

Ernst T. Krebs of San Francisco. Krebs's FDA record goes back to the early 1920's when his product Syrup Leptinol was seized on charges that its claims were "false and fraudulent." The syrup—an herbal extract—was put on sale by Krebs when the great 1918 influenza epidemic was still vividly remembered. Its main ingredient was *Leptotoemia*, an herb claimed by Krebs to have protected the little known Washoe Indian Tribe from the ravages of the "flu." According to Krebs's label, it was good not only for "epidemic influenza" but also for bronchial asthma, whooping cough, pulmonary tuberculosis, and pneumonia.

Later, Krebs developed Laetrile, made from apricot pits. For a long time it attracted little attention. The first Federal court seizure of Laetrile occurred in 1960, at the former Hoxsey Clinic in Dallas, Texas.

Both Federal and State authorities have since gone to court repeatedly to prevent the persistent illegal marketing of Laetrile. There have been seizures of Laetrile products and ingredients, an injunction suit to stop its manufacture, and a criminal prosecution for smuggling—all decided in favor of the Government. A civil malpractice suit against a physician/Congressman resulted in a \$15,000 award of expenses to the plaintiffs. Most recent was the suit brought by Laetrile proponents against the Government, decided by the Supreme Court on June 18.

That case got to the high court after the U.S. District Court in Oklahoma issued a decree that enjoined FDA from interfering with importations of Laetrile for Glen L. Rutherford and other cancer patients. Rutherford had testified that he would have died from a cancerous rectal polyp were it not for Laetrile. He had refused surgery in the United States and went to Mexico for Laetrile treatments. These treatments, Rutherford said at an FDA hearing in May 1978, were successful. However, he did not point out, at the district court hearing, that shortly after he began taking Laetrile his polyp was cauterized by Mexican surgeons. Cauterization is a standard medical treatment for rectal polyps.

The district court agreed with the claim of Laetrile advocates that they had a constitutional right to use a "non-toxic substance" for their personal health that takes precedence over the statute's requirement that a drug be withheld from the public until its safety and effectiveness is proven. The court also ruled that Laetrile was exempt

“To the contrary,” the Court said, . . . “Congress expressed concern that individuals with fatal illnesses, such as cancer, should be shielded from fraudulent cures.”

from the requirement of safety and effectiveness because it was being distributed before the 1962 drug effectiveness amendments were passed.

The case was appealed.

The court of appeals upheld the district court's injunction, but on quite different grounds. The appeals court jurists ruled that the “safety” and “effectiveness” requirements of the law have no reasonable application to drugs for terminally ill cancer patients. Since those patients would “die of cancer regardless of what may be done,” the court concluded there were no realistic standards for measuring the safety and effectiveness of drugs for that class of individuals. The court held that such patients could be identified without difficulty by the affidavit of a licensed medical practitioner. FDA's findings that Laetrile is not safe and, in fact, should be regarded as toxic because of its cyanide content, were not mentioned by the court. The Agency was directed to issue regulations for distribution of Laetrile in injectable form (but not its oral form) to terminal cancer patients, as if the drug had been found safe and effective.

In its unanimous decision, the Supreme Court dealt specifically with the legal errors of this appellate decision. The Supreme Court held first that the Federal drug law makes no exception whatever to the safety and effectiveness requirements for drugs intended for the terminally ill. “To the contrary,” the Court said, “in deliberations preceding the 1938 Act, Congress expressed concern that individuals with fatal illnesses, such as cancer, should be shielded from fraudulent cures.”

The Supreme Court emphasized “a special sense in which the relationship between drug safety and effectiveness has meaning in the context of incurable illness. An otherwise harmless drug can be dangerous to any patient if it does not produce its purported therapeutic effect. . . . But if an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible.”

For these reasons, the Supreme Court said, “even before the 1962 Amendments . . . FDA considered effectiveness when reviewing the safety of drugs used to treat terminal illness.”

This practice, the Supreme Court continued, “reflects the recognition, amply suggested by expert medical testimony in this case, that with diseases such as cancer it is often impossible to identify a patient as terminally ill except in retrospect.” The Supreme Court agreed with the FDA Commissioner's conclusion (based on hearings held in 1978) that “to exempt . . . drugs with no proven effectiveness in the treatment of cancer could lead to needless death and

suffering among . . . patients characterized as terminal who could actually be helped by legitimate therapy.”

The Supreme Court pointed out that the court of appeals' reasoning could not be confined to Laetrile. “To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner's authority over all drugs, however toxic or ineffectual, for such individuals. If history is any guide, this new market would not be long overlooked.” The Supreme Court continued:

Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer, including liniments of turpentine, mustard, oil, eggs and ammonia; peatmoss; arrangements of colored floodlamps; pastes made from glycerin and limburger cheese; mineral tablets; and Fountain of Youth mixtures of spices, oil and suet. In citing these examples, we do not, of course, intend to deprecate the sincerity of Laetrile's current proponents, or to imply any opinion on whether that drug may ultimately prove safe and effective for cancer treatment. But this historical experience does suggest why Congress could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise.

Concluding, the Court noted that its interpretation does not foreclose “resort to experimental cancer drugs by patients for whom conventional therapy is unavailing. . . . An application for clinical testing of Laetrile by the National Cancer Institute is now pending before the Commissioner. . . .”

The high court sent the case back to the appeals court “for further proceedings consistent with this opinion.”

By sticking to the question of exempting drugs for “terminal” illness, the Supreme Court left two issues unresolved. A system of affidavits, ordered by the district court, whereby doctors can certify Laetrile-seeking patients as “terminal” and, therefore, eligible to import the drug from Mexico or elsewhere, was not mentioned. Awaiting further interpretation, FDA, therefore, announced that such affidavits would continue to be accepted.

Likewise, the highest court did not rule on the district court's conclusion that FDA, by insisting that Laetrile meet the standards applicable to all other drugs, was restricting cancer patients' “freedom of choice” to obtain Laetrile and, thus, infringing their constitutional rights.

The “freedom of choice” slogan is the most used argument of the Laetrile advocates. The argument is appealing, but it does not consider that freedom of choice means also freedom to sell—including freedom to peddle nostrums that deceive and swindle the sick.

Sympathy makes it difficult for many to see why a “harmless drug”—a placebo—should not be given to a terminal patient if he thinks it will help him. And, of course, the placebo has a recognized role in psychotherapy as well as research. Anything can be effective as a placebo if the patient is led to believe, and has confidence, that the substance he receives will have its desired effect. But the placebo effect has also been a great asset of quackery. It can fool the patient into thinking he is better when his underlying condition has not changed, or has become worse.

Laetrile, however, is not really a placebo because it is not safe. Lacking inspection and manufacturing control, it

"That terminal patients have some special rights is clearly implied by the language of Justice Thurgood Marshall's opinion. First would be the right not to be regarded as 'terminal.' "

lacks uniformity, and lot after lot has been found contaminated. Because Laetrile contains cyanide it can poison and kill. One infant death from cyanide poisoning resulted from swallowing fewer than five Laetrile tablets. At least 16 other deaths have been documented from ingestion of Laetrile or its source materials—apricot and similar fruit pits. Laetrile is especially hazardous if the injectable form is taken by mouth. These and other facts are summarized in a public warning issued by FDA in November 1977—a warning still in effect.

The most significant difference between Laetrile and the long parade of bygone cancer "cures" is the political potency of the organized movement backing it and the threat this presents to the laws that ensure drug safety and effectiveness. To date, some 20 States have enacted legislation withholding enforcement of their drug and medical practice laws as concerns Laetrile. Although these State actions have not "legalized" the distribution of Laetrile in interstate commerce they are, nevertheless, a major threat—not only to the defenses against quackery built up since the turn of the century, but also to the entire system of regulation to insure the reliability of drugs.

In Congress, the Laetrile lobby has succeeded in getting substantial support for Federal legislative proposals to repeal the effectiveness requirements of the 1962 drug amendments. Some 140 House members and four Senators endorsed this legislation in the last Congress.

It may seem that the Supreme Court settled only a single, narrow legal issue—that drugs for terminal patients must meet the same standards as other drugs. Reflection suggests the decision has a wider impact.

That terminal patients have some special rights is clearly implied by the language of Justice Thurgood Marshall's opinion.

First would be the right not to be regarded as "terminal." "It is often impossible to identify a patient as terminally ill except in retrospect." Dr. W. P. L. Meyers, quoted at the beginning of this article, says this determination "can tax all the skills a physician can muster, and yet he may end up defining a patient as terminally ill who would not be so regarded by another doctor."

Closely related is the right to hope for a cure. As Justice Marshall put it: "Even critically ill individuals may have remissions and may respond to conventional treatment."

The citizen's right to have confidence in the safety and efficacy of drugs supported by law is generally accepted. Underlying this right is the fact that it has become possible through modern scientific methods to determine, with a great degree of certainty, whether a drug is safe enough to use and is therapeutically effective. As the Supreme Court

made clear, effectiveness under the law does not mean only the capacity to cure, but also to fulfill "by objective indices, its sponsors' claims of prolonged life, improved physical condition, or reduced pain." As to *safety*, the Supreme Court said: "For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit."

Not to be forgotten is the right to truthful information. This right is meaningless without protection from false and misleading claims. The food and drug law prohibits labeling that is "false or misleading in any particular." Cancer quackery is irresistible and can be fatal to those who have lost confidence.

Even though the Supreme Court remanded the question of a constitutional freedom of choice to the lower courts, it recognized that there is such a freedom—to choose among the many products and methods that have passed the required tests. Over two dozen drugs have been officially approved for use in cancer therapy. The Court, in a footnote, pointed out that some 300 more experimental drugs are available to critically ill cancer patients at authorized institutions, and that in 1977 over 90,000 patients underwent experimental drug therapy, at the National Cancer Institute and the Veterans Administration.

The Food, Drug, and Cosmetic Act requires "patient consent" for use of investigational drugs—a freedom of choice to receive or refuse treatment. Legally, a patient is free to use any treatment he wants, even if the drug or device is illegal to market in the United States. He can go to Mexico, for instance.

But the line must be drawn where freedom for the individual begins to endanger the public health. U.S. law draws this line by prohibiting interstate commerce in drugs for which false and misleading therapeutic claims are made, and requiring scientific proof of safety and effectiveness before new drugs may go on the market. The Supreme Court approved this plan of regulation in its sweeping "drug effectiveness decisions" of 1973.

Medical ethics tell physicians that it is the individual patient who matters, but courts must act on the basis that what matters is the greatest good for the greatest number of people. As the Court said:

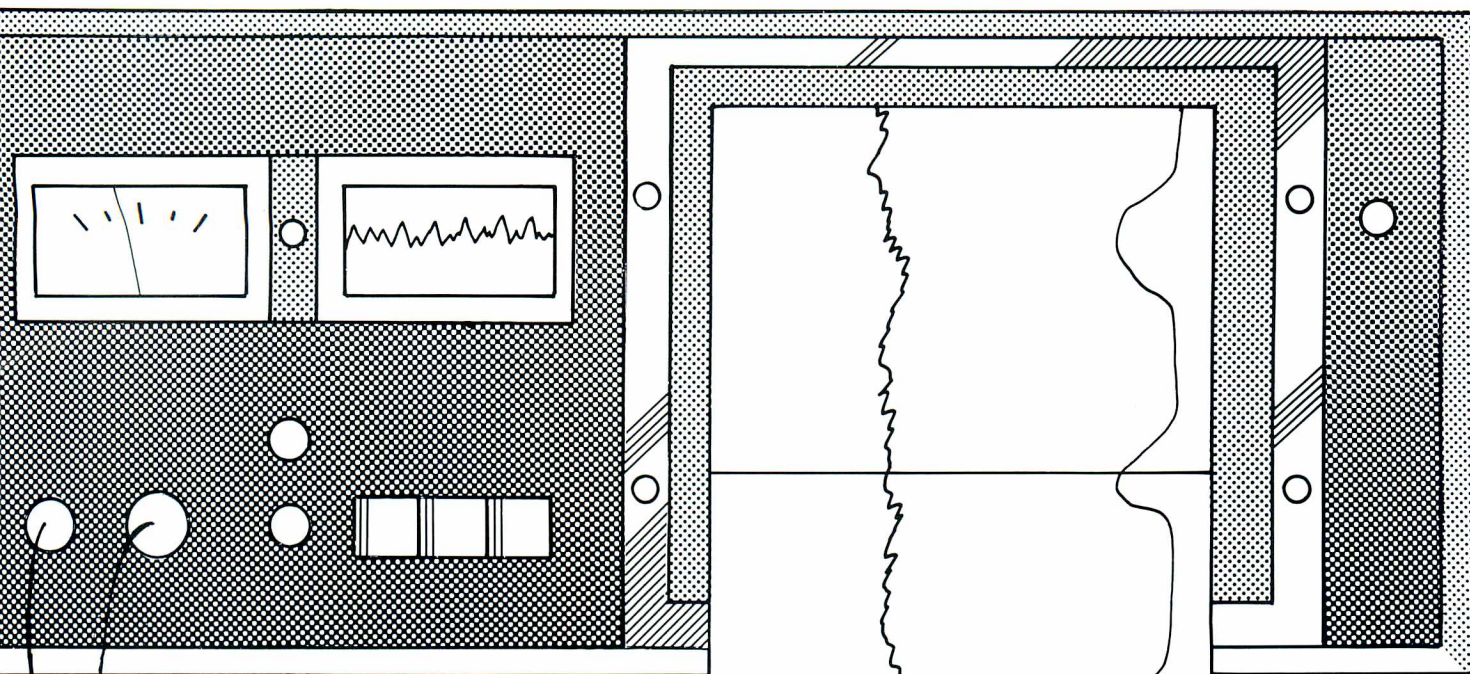
"To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner's authority over all drugs, however toxic or ineffective, for such patients."

In the 73 years since the first Federal food and drug law was passed, FDA has acted against hundreds of worthless and dangerous drugs and devices for the treatment of cancer. All were alike in their appeal to frightened, desperate cancer victims. The famous cancer con man Harry Hoxsey told his secret of success when he wrote: "Cancer victims come to us because they're unwilling to accept as final a death sentence handed them by their own doctors."

Quackery sells false hope—but hope nonetheless. Scientific medicine can provide reasonable hope, and superior care, having much better means to do so. Terminal patients are different, and because they are different they deserve not less care, but the best. There should never be a time when "nothing more can be done."

Wallace Janssen is FDA's Historian.





Listening As A Fetus Becomes A Baby

Electronic fetal monitoring (EFM) is widely used today to monitor the mother and fetus during childbirth. Some experts believe that it is being overused and that it may pose some unnecessary risks. On the other hand, proponents argue that EFM can give early signs of trouble and thus stave off birth complications. This article reviews the controversy.

by Earl B. Abrams

There's a paradox involving childbirth in the United States today. On one hand, more mothers-to-be are opting for old-fashioned "natural" childbirth. On the other, more and more obstetricians are using modern machines to monitor the unborn baby and the mother.

It's estimated that as many as half the 3.3 million births every year in this country are preceded by electronic fetal monitoring (EFM), which employs electronic medical devices for listening in on what's happening to baby in the hours before birth.

This helps nurses and doctors to determine the condition of the unborn infant and the mother during labor and

take whatever action is necessary to make the blessed event as uneventful as possible.

EFM simultaneously monitors the rate of the fetus's heartbeat and the timing and strength of the mother's uterine contractions. Most EFM devices produce a paper copy of the two measurements side by side. Comparing the heart rate with the contractions can help the physician determine how well the baby is reacting to the stresses of labor. Abnormal readings may indicate that some treatment is necessary to help the baby on its journey into the world. Sometimes all that is needed is to change the mother's position to relieve pressure on the fetus. Or she can

be given oxygen that will be carried through her to the baby. Or the physician can use forceps to help in the delivery. If there is a real emergency, the physician can perform a cesarean section, bringing the baby to birth through surgery.

EFM purportedly is more accurate than the traditional stethoscope method of listening to the fetal heartbeat. EFM can detect minute variations that a stethoscope sometimes can't.

There are two types of EFM. The first is indirect or external monitoring, in which two sensors are placed on the outside of the mother's abdomen and held in place with an elastic belt. One of the sensors, called a tocotransducer, records the labor contractions. The fetal heartbeat is monitored by the other sensor, which works either by means of ultrasound, by a microphone, or by an electrocardiogram. Of these three, ultrasound is used most frequently.

Because they must get their "signals" through the mother's abdomen, all these external sensors are subject to problems. If the fetus moves out of the sound pathway, for example, the ultrasound and microphone sensors will not pick up the heartbeat. The electrocardiogram sensor is susceptible to mechanical problems and the tocotransducer, while it can measure the frequency and duration of the mother's contractions, cannot measure their intensity—a factor that could endanger the fetus.

While not as safe and convenient as the external sensors, the second type of EFM—internal or direct monitoring—is generally more reliable and provides a more complete picture of the baby's journey to birth.

Internal EFM monitors the fetal heart rate through a tiny electrode inserted through the mother's vagina and attached to the baby, usually to the scalp. Labor contractions are recorded by using a small, soft plastic tube called a catheter, which is filled with sterile water and inserted through the vagina.

While external EFM can be started any time during labor, the internal method can be used only after the am-

niotic sac (the "water bag") is broken and the mother's cervix has started to dilate. In some cases, a physician may switch from external to internal EFM during labor to obtain more detailed information. In other cases, the amniotic sac may be ruptured artificially and the cervix dilated enough to permit inserting the monitors.

Internal EFM can measure the fetal heart rate and the mother's contractions relatively free of disturbance caused by movement of the mother or child.

On the negative side, the mother may feel highly restricted by all the attachments, and the relative immobility imposed by the monitoring devices can itself lead to complications. Also, the mechanical, depersonalized aspect of the internal devices may cause the mother to become depressed or afraid. In addition, there is a risk of infection. And artificially rupturing the amniotic sac can require additional medical or surgical measures, creating otherwise avoidable complications.

Proponents of internal EFM say such potential adverse effects are outweighed by the benefits that the accurate monitoring provides. This is especially true, they say, for expectant mothers with a known high risk of delivery problems. These problems include diabetes, heart trouble, malnutrition, signs of abnormal fetal development, or difficult previous pregnancies.

But even a healthy fetus may be seriously threatened during labor if the mother's contractions grow too strong or a drop in her blood pressure begins to deprive the baby of necessary oxygen. Also, drugs administered during labor may trigger adverse effects that must be watched carefully.

Medical authorities are not of one mind about the use of EFM. At issue is whether it should be used routinely to monitor mother and child or only in high-risk pregnancies. A task force sponsored by the National Institutes of Health concluded recently that EFM is a valuable and beneficial diagnostic tool in monitoring high-risk labor sit-

uations. A committee of the American College of Obstetricians and Gynecologists supported the use of EFM in high-risk cases, but also says routine EFM may have its place. Other medical authorities urge routine fetal monitoring since physicians cannot predict accurately when risks increase.

The NIH task force agreed that EFM is beneficial where the expectation of a healthy baby is low, where the patient has a medical history of problems that may affect the delivery, or where an abnormal fetal heart rate is noted by stethoscope.

In other than such high-risk cases, the NIH group observed, an acceptable way of determining fetal condition is through periodic stethoscope use—listening to the baby's heart every 15 minutes during early stages of labor and every 5 minutes in the last stages. It conceded, however, that many hospitals do not have enough staff to provide that level of surveillance.

Opposition to the spreading use of EFM was sounded in a study entitled "Premature Delivery of Medical Technology," issued late last year by Drs. H. David Banta and Stephen B. Thacker under the sponsorship of the National Center for Health Services Research, a component of HEW.

The essence of the Banta-Thacker report is the claim that there is no convincing evidence of benefits from the use of internal EFM. The authors report that in four controlled clinical tests, in which the internal EFM technique was used, there was little, if any, evidence that EFM helped prevent death or long-term disability of babies. They estimated EFM adds a \$411 million bill annually to medical care, now running upward of \$180 billion, and termed it "a technology with significant cost and risk and with little evidence of benefit."

They questioned whether an EFM record of fetal heart rate is of any consequence in ensuring safer deliveries, and wondered whether recording of the fetal heart rate makes any difference to the outcome of the infant.

In its EFM report the committee on

An electronic fetal monitoring system is installed for external monitoring of the heartbeat rate of the fetus and the uterine contractions of a patient who has just entered the hospital for childbirth. These are registered on a printed readout sheet coming from the machine in the background.



obstetrics of the American College of Obstetricians and Gynecologists said it supports the use of continuous internal EFM for high-risk patients. The committee conceded that some so-called low-risk patients turn into high-risk patients and that routine EFM thus may have a place. The committee thought physicians and patients should have the right to determine whether they want EFM, and noted that EFM is a diagnostic tool that must be supplemented by "informed clinical judgments."

The practical side of monitoring the pregnant woman during labor was explained more fully by Dr. Allen B. Weingold, chairman of the Department of Obstetrics and Gynecology, George Washington Medical Center, Washington, D.C. He said the same information could be gained if the mother in labor could be continuously attended by a trained obstetrical nurse or house physician. But he felt there is a serious problem in transferring the knowledge into practical terms. "Most hospitals don't have the manpower to assign a medical team one-on-one for hours at a time. Even if this were possible, there still would be the obvious human elements of fatigue and boredom."

"Continuous electronic fetal monitoring obviates the human error and gets more reliable information—as it does in everything else we do in hospitals today, whether it's in the coronary care unit or in the operating room," he said, adding: "I don't think there is any significant information at this point that suggests that monitoring is in any way dangerous."

Dr. Weingold believes that patients should have the right to decide whether they are to be monitored electronically. "If they decide not to, that's all right," he said, "as long as there is competent medical surveillance available."

Almost unspoken is another reason for widespread use of EFM in childbirth today: The rise in the practice of

"defensive medicine" by physicians, caused by the increasing frequency of medical malpractice lawsuits. Many obstetricians use EFM, especially ultrasound, almost routinely as a way of "covering all bases," so to speak. This is understandable considering that a dozen lawsuits have been filed against hospitals by patients whose babies were stillborn or born with brain injuries. The suits charge that the institutions were negligent in a number of instances, including failure to use EFM. None had been legally decided by mid-1979, although a few had been settled out of court.

Another concern expressed by some people about EFM is that "false positive" indications of fetal distress from EFM readings have led to an unacceptable increase in cesarean sections. In 1970, according to the National Center for Health Statistics of HEW, 195,000 C-sections were performed among 3.7 million births; last year the number was estimated at well over half-a-million in 3.3 million births.

The NIH task force, however, said several studies indicated that the rise in cesarean deliveries in recent years was independent of EFM.

Yet another worry is that the ultrasound often used in external EFM could damage the cells of the fetus, or the mother, or both.

Because of this concern, FDA—which regulates the equipment used in EFM (though it cannot control where and how physicians use it)—has invited doctors and health specialists to help it assess the potential dangers of ultrasound. In making the request, FDA said its current position is that ultrasound diagnosis should be used only when a clear medical benefit can be expected.

FDA is particularly seeking more information on whether ultrasound affects human cells in any dangerous way. Ultrasound is used therapeutically to relieve arthritic pain or muscular soreness and diagnostically to "paint" images of things within the

body, such as the heart in cardiology, a foreign object in the eye in ophthalmology, a brain blood clot in neurology, or a fetus in obstetrics. Ultrasound is even used in some cancer treatments to bombard cells to destroy or change them. However, the intensity of the ultrasound used in cancer treatment is quite high. Likewise, the levels used in therapy are several times greater than those used in fetal monitoring.

Even so, FDA is looking into the possibility of limiting the amount of energy put out by ultrasound devices used in fetal monitoring.

Dr. Melvyn R. Altman, a scientist at FDA's Bureau of Radiological Health, confirms that so far no clinical problems have been reported from ultrasound in fetal monitoring. But, he explained, there have been indications from laboratory tests on animals that raise possible doubts about ultrasound's safety.

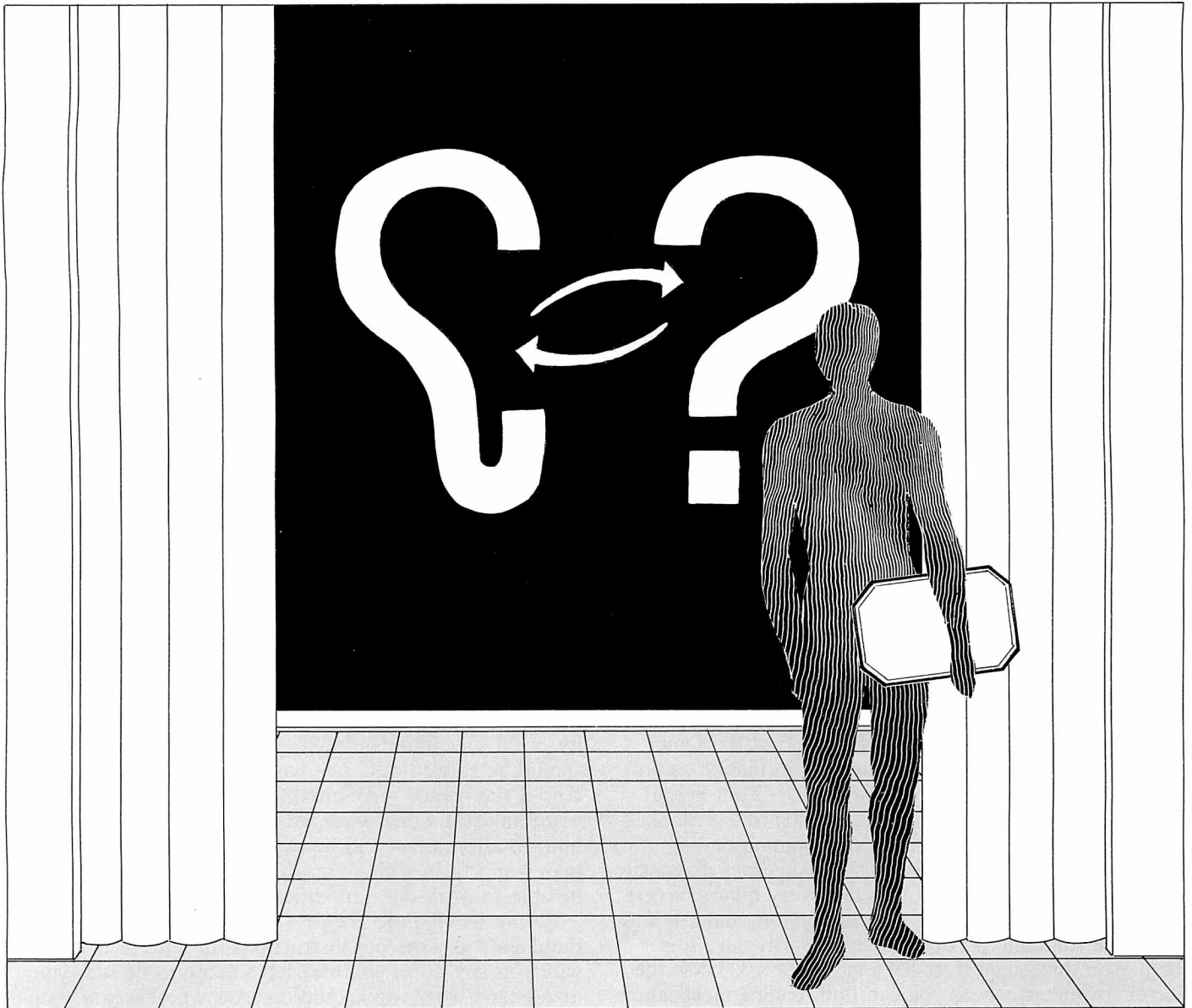
"It's a little tentative," Dr. Altman said. "There's reason for concern. There's reason to look into ultrasound more deeply. But there's no reason to panic, or to take it off the market."

How does he personally feel about ultrasound? Dr. Altman responded: "Would I let my wife be subjected to ultrasound? I would have to ask what the options are, what the risks are. I wouldn't use it so she can hear the baby's heartbeat, just for amusement. But if they say, 'Look, we can find some information that we can't any other way except x rays—and we know the risk in that'—then I probably would go along."

While the verdict is not yet in on the benefits and risks of EFM, there is no doubt that many mothers-to-be will face the decision of whether to use this modern technology. By discussing the pros and cons with their doctors, these women should be better able to decide whether EFM is the right thing for them . . . and for their babies.

Earl Abrams is a freelance writer.

When You And Your Partner The Doctor Talk About Diagnosis



This is the second in a series of articles advising consumers about how to get the most from the doctor-patient relationship in the pursuit of health care. This article tells the patient how to assume a positive role by asking the doctor for all information that will enable the patient to work with the doctor and make his own contribution in treating the illness.

by Flora Taylor

After the doctor has taken your medical history on your first visit to him, you should expect that he will examine you physically. Arthur Levin, M.D., in his book **TALK BACK TO YOUR DOCTOR**, says you should expect a complete physical examination, regardless of your symptoms—especially if it's your first visit. A complete examination may not be necessary for every visit, particularly if you've had one recently; but, if the doctor diagnoses

your condition and prescribes treatment without examining you at all, you may have reason to suspect that you are getting less than optimal care. If your doctor neglects to examine some parts of the body, Dr. Levin suggests that you ask the physician to go back and check the neglected parts. Most doctors will readily comply.

The doctor may order diagnostic tests. In **TALK BACK TO YOUR DOCTOR** Dr. Levin makes these points: You have a right to know the purpose of these tests. Ask what the physician hopes to learn from the tests, and why that information is important in your case. If there are any risks involved, your doctor should tell you what they are and why he or she feels the benefits outweigh the risks. Remember, the decision to have or not have the test is yours, and you have a right to refuse. Find out how much the test will cost, and how long it will take to get a report of the results. If the doctor orders x rays, ask whether they're absolutely necessary and what the

dosage will be. Keep track of how many x rays you've had (including dental x rays) and ask the doctor if your cumulative exposure or dosage is within a safe range.

When test results are in, ask for the exact values, and get the doctor to tell you what the normal range is. If a biopsy is done, ask for the results of the pathologist's report. If any test results are abnormal, expect your doctor to find out why or to follow your progress until the results return to normal or to do both.

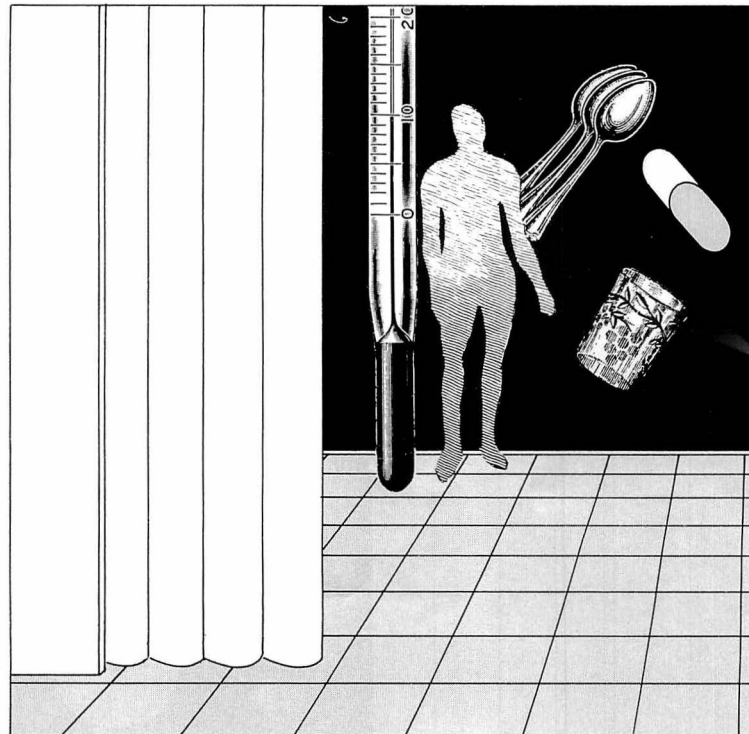
Once the diagnostic workup is completed, you have a right to know what the doctor thinks is wrong with you. Find out what the diagnosis is in medical terms; knowing your "official" medical diagnosis is helpful when checking reference works or consulting other doctors. Then get the doctor to explain what the diagnosis means in terms you can understand. Ask the doctor what findings were used to arrive at the final diagnosis. What body systems are involved? What is the disease process at work? What has caused the illness? Is it catching or will it spread? How could the condition have been prevented? What will the course of the illness be? When can you expect to get better? What signs of worsening should you watch for?

Ask what forms of treatment are available. What are the risks and benefits of each? Which does your doctor recommend and why? If the cause of your problem is unknown, why can this treatment be expected to help? What are the pros and cons of the treatment alternatives in the opinion of experts?

Remember that in many cases there are considerable differences of opinion about what constitutes appropriate therapy. "Don't buy a pig in a poke," warns Arthur Levin of New York's Center for Medical Consumers and Health Care Information (not to be confused with the author of *TALK BACK TO YOUR DOCTOR*, of the same name). It's important to get as much information as possible before making serious decisions. Dr. Tom Ferguson, a physician and editor of the journal *MEDICAL SELF-CARE*, recommends getting a second opinion before agreeing to any costly or potentially dangerous diagnostic procedure, or any surgery other than very minor surgery. Tell the doctor you'd like a second opinion, and ask him to suggest someone. (You don't necessarily have to see the person they suggest, but it's tactful to ask.) Ask the doctor (or nurse) where you can find reading material on your problem. He or she should be able to provide some references. Don't hesitate to seek out information independently. Check with a reference librarian at a health library if possible.

If the doctor prescribes any drugs, you should be sure to get detailed information about the drug. Why is it indicated for your diagnosis? What kind of drug is it? How does it work in the body? Ask about possible side effects or adverse reactions, and be sure to inform your doctor immediately if you notice any unexpected reactions or changes. Are any alternative drugs available? Is there an alternative to drug therapy?

If you do decide to take the drug, make sure you understand what the dosage is (how much should be taken and when), how to administer the drug to yourself, and how long you should take the drug. Find out what to do if you should miss a pill. Ask whether you should avoid any foods, activities, or other medications while taking the drug. And ask the doctor to prescribe the drug by its



generic name, if possible, rather than by a brand name; this can save you money.

If the drug is the only treatment the doctor recommends you might want to ask if there are any other things besides the prescription that will help you get better. Make sure you know how to take care of yourself at home. For any treatment, ask about restrictions on activity, what precautions to take, and how long the treatment should be carried out. Ask what aftereffects to expect. And if the doctor recommends a course of action that you think just won't work for you, don't hesitate to tell him, so alternatives can be explored. If the treatment plan won't fit in with your schedule, the two of you may be able to work out a modification that's more realistic.

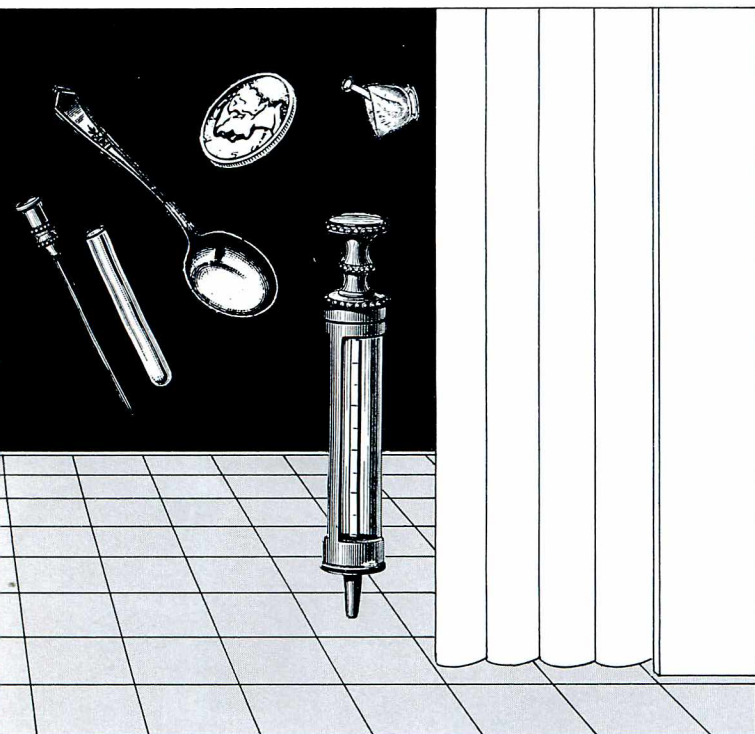
Before leaving the doctor's office, you may want to ask the doctor to write out instructions for you, or to go over with you any notes you may have taken to be sure you understand what you should do. Ask whether you should telephone in for lab reports or report back for any reason. Find out when you should return for further treatment.

A couple of other points: The information in your medical record can be valuable to you in your attempt to educate yourself about your illness. Ask your doctor if you can look over the chart and then ask questions, or ask if the two of you can go over the chart together.

You should feel free to ask about fees. It's a good idea to do it in advance, and to find out what's included for that amount. It's your right to know—don't hesitate to inquire. You're entitled to a full explanation of any charges. Ask for an itemized bill.

You may want to write a summary of your visit when you get home. If anything was unsatisfactory, be sure to talk about that on your next visit.

It's a good idea to establish early in the visit that you want to be considered a partner in your treatment—or the doctor may assume that you want to play a depend-



ent role. "Make it clear that you expect to be treated as an equal—an educated responsible person," advises Dr. Ferguson. "You deserve to be treated with respect; call the provider (doctor) on any violations of that. Make it clear that it's *your* decision whether to have that x ray; don't turn your power over to the provider."

On the other hand, be considerate of your doctor. Dr. Hal Strelnick of the Health Policy Advisory Center, New York, warns that there are two sure ways to turn off your physician: Demanding a particular form of treatment, and asking for a specialist. These requests are seen as hostile if you leave the physician out of the exchange and indicate that you don't expect him to be able to do his job. "Be tactful," Dr. Strelnick advises. "Ask, 'Would a specialist be helpful?' or 'Have you heard of this treatment regimen? What do you think of it?'"

Remember, your doctor is probably doing the best he can to give you good care, though he may not think of everything or remember everything. "Try to help your doctors," Dr. Ferguson suggests. "Talk to them as human beings rather than authority figures. You'll get better results and it will be better for them."

Be aware that it's easy for messages to be misperceived or misinterpreted. Check out what you're hearing. Tell the doctor in your own words what you understood him to say: "This is what I hear you say—is that what you mean?" And ask the doctor for feedback: "What do you think I said?" Language is ambiguous; you and your doctor may not be defining your terms the same way. The only way to be sure you understand one another is to ask.

And if you don't understand, say so. Often doctors use technical language or jargon without realizing it. If the doctor uses unfamiliar terms, stop him immediately and say, "What do you mean?" It's your right to have the doctor explain; continue to ask questions until you do understand.

Expect information. Describe the information you want. Ask the doctor to give you information slowly to allow you time to absorb, reflect, and ask questions. Make sure you ask all the questions you had in mind. During the visit, pressures and anxieties can crowd in and make it hard to remember what you wanted to ask. That's why it's a good idea to write questions down before you come in. Jot them down as they occur to you. Reading up on your illness will help you determine what to ask. It's important to take time to become informed. Ask for textbooks and journal review articles. Talk to nurses and assistants—they can be valuable sources of information. Many have been trained to act as health educators.

It's up to you to let the doctor know if you don't feel you are getting the proper attention. If you feel the doctor has rushed you or if you feel confused, say so. If you feel that your questions aren't being answered or that you're being manipulated, say so.

Not all marriages between patients and physicians are good ones. If you feel you're not being heard, or if you and your doctor have very different points of view, don't assume that it's your own fault, or that you have to just live with the situation. You *can* change physicians. If your doctor won't listen to you, you probably should change. Do be sure to have your records transferred, though. And do let your doctor know if he's not the only physician you're seeing.

Once you do find a physician who seems competent, thorough, and willing to listen, stick with him. There are advantages to having a relationship with your doctor over a long period of time. It takes time for trust to build up, and trust, Dr. Strelnick advises, is ultimately what will let you get what you want out of the relationship.

"When the doctor knows you, it's easier for him to speak to your level—you're not just another anonymous patient in a big fancy clinic where the interest is in the problem, not the patient." Where trust has developed, the doctor doesn't feel threatened, and it's easier for him to admit, "I believe this, but other people believe differently." And it's easier for the patient to ask questions without worrying about seeming simple or naive. If you trust your physician, you won't have to feel that he's going to think you're stupid or uneducated; if you know that he trusts you, you don't have to be afraid that he will think your questions reflect on his prestige or that he will be offended or insulted by them.

Considering the high cost of medical care today, it pays to get the most out of your visits to the doctor. It pays to be an informed patient. Dr. Marvin Belsky, author of *HOW TO CHOOSE AND USE YOUR DOCTOR*, observes: "The informed patient takes a stake in his treatment. He feels confident about monitoring his well-being. He expresses his doubts to his doctor, and he doesn't act until he has been convinced beyond a reasonable doubt that the course he's electing is the right one. He does all this together with his doctor." The informed patient, in other words, is his doctor's partner.

Flora Taylor is a graduate student in English at the University of North Carolina in Chapel Hill. She researched and wrote this article while an intern in FDA's Office of Health Affairs.

Look Who's Reading The PDR Now!

"We tried this drug on you once before," the doctor said. "Did you have any side effects?" The patient looked quizzical. "I don't know," he answered. "What are the side effects?" "Oh, I'm not going to tell you," the doctor replied, "or you'll imagine that you have them." The patient's look was now one of disbelief. "Well," said the one being treated, "then I'll just go look up the drug in the PDR." This is an article about the PDR—the PHYSICIANS' DESK REFERENCE—that tells doctors, nurses, other health professionals, and now the general public all about prescription drugs.

by Egon Weck

It runs for 2,000 pages, weighs 4 pounds, and is full of lequally weighty words. Yet it is the eighth best selling book in one Dayton, Ohio, bookstore despite its \$14.95 price tag, and it frequently "takes a walk," as librarians put it, or mysteriously disappears from the shelves of reference sections of public libraries.

That's the PDR, or PHYSICIANS' DESK REFERENCE, once a book considered fit only for the eyes of physicians and other health professionals, but now increasingly available to an increasingly aware public.

Librarians differ over the precise ranking of the PDR among popular reference works. After all, it competes with auto repair manuals and investor services. But most librarians agree that it is among the hottest volumes kept at their reference desks.

Why the great public interest in this weighty volume? The reason is simple. The PDR contains all anyone needs or wants to know about most prescription drugs.

Many people learn about the PHYSICIANS' DESK REFERENCE from popular medical columns or from a doctor, nurse, or other health care professional and they ask for

it by name. Others come to reference desks seeking a book to check on their prescriptions.

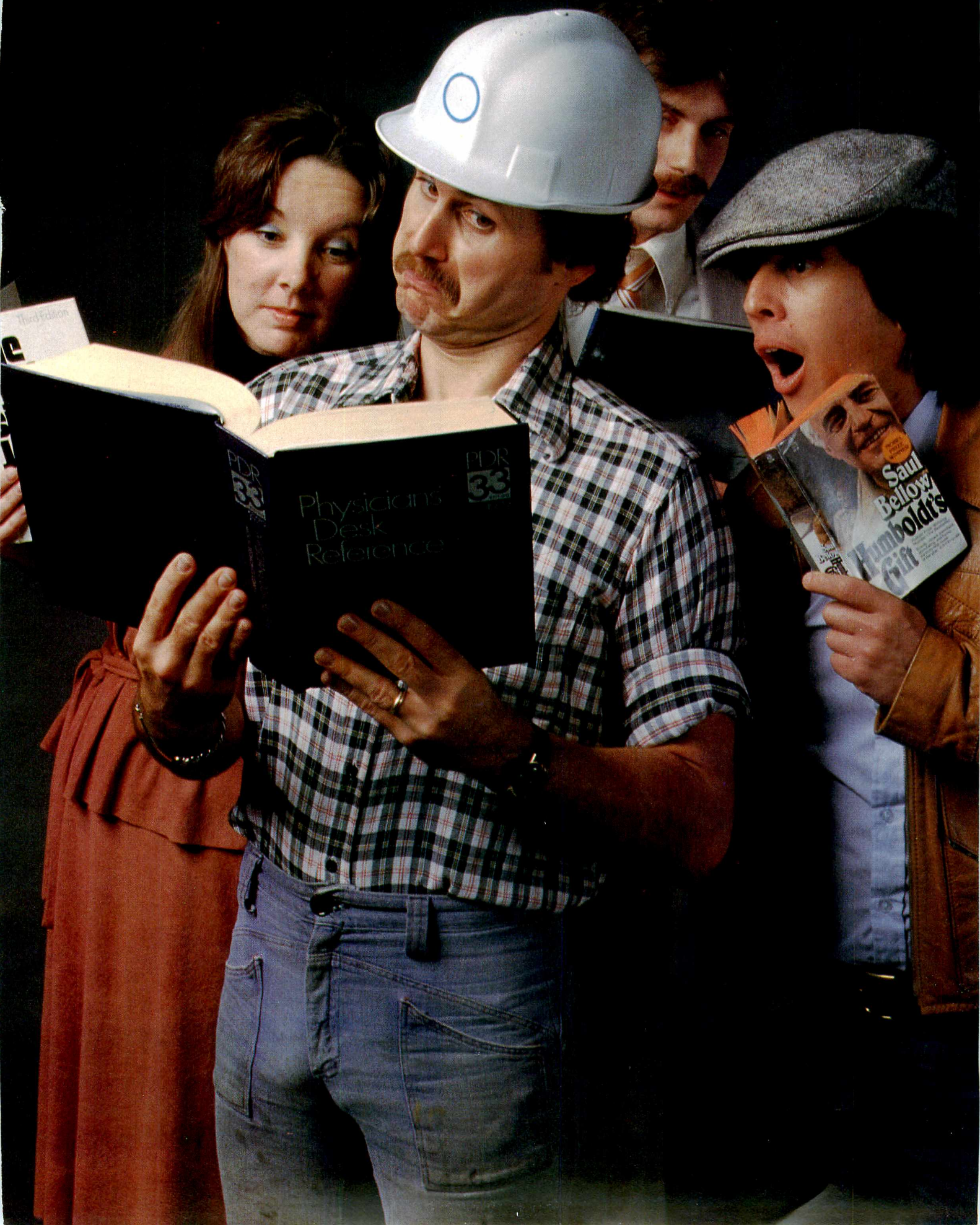
Back when the lay public had no ready access to the PDR, or to other sources of professional medical information, patients learned only what their personal physicians told them; the rest was kept hidden behind an inviolate curtain of professional confidentiality.

Today's busy physician is inclined to shrug off the widespread availability of professional medical information as part of a broader information explosion. And younger physicians, who weren't around in the good old days, are apt to suspect that the physician who still grumps about public access to the PDR may be concerned about his own knowledge of drugs.

According to Dr. John Bellin, who is on the staff of the American Medical Association, organized medicine no longer opposes the public's access to the PDR. In fact, Dr. Bellin points out that AMA's own drug compendium, AMA DRUG EVALUATIONS, is available at some public libraries and can be purchased by anyone directly from AMA in Chicago.

Some doctors have argued that by reading about side effects in the PDR, the patient may be frightened into discontinuing his prescribed medication. Dr. Sidney Wolfe, director of Ralph Nader's health research group, describes this as a theoretical danger and considers such medication dropouts unlikely.

The PDR includes information on about 2,500 drug products. This information is provided to the publisher, Medical Economics of Oradell, N.J., by pharmaceutical manufacturers who decide what drug products go into the book. However, since the idea behind the PDR is to make prescribing information available to physicians in one compendium and the companies are interested in pushing their most important products, the PDR carries



PDR users can find out what some of their medicines will look like by checking the full-color plates in the front of the book. Tablets and capsules are shown in actual size. Pictures of tubes and syringes are reduced, for obvious reasons.

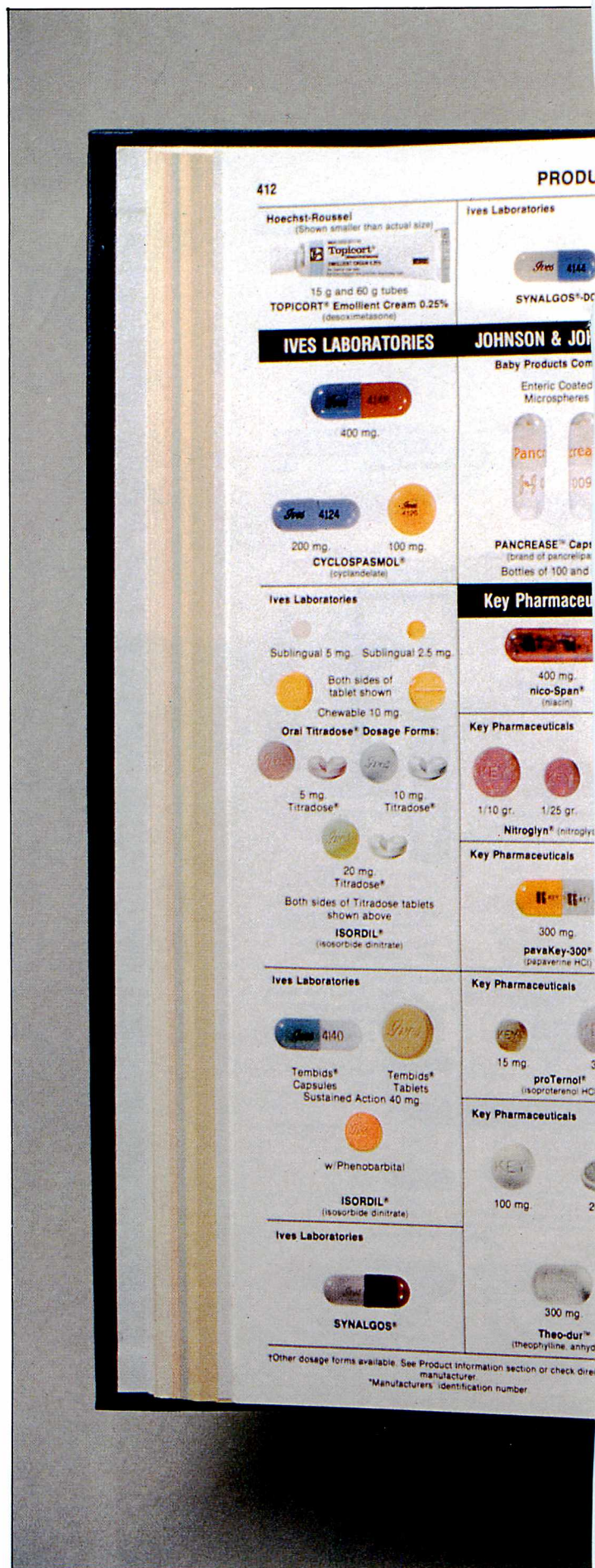
information on 950 of the 1,000 leading prescription drugs.

In 1967, FDA revised its labeling regulations to require all prescription drug packages to include adequate information for professional use of the drug. "Full disclosure" was required in drug file cards, extensive brochures, and publications such as the PDR. Thus, what goes into the PDR must include full disclosure of how the drug works, what it is to be used for, possible adverse reactions or side effects, contraindications and other precautions, and warnings about hazards posed by the drug.





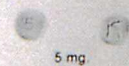



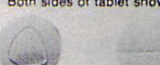



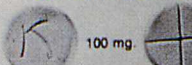

Not all product information is this detailed, however, since drugs that were on the market prior to 1938 have been exempt from the labeling requirements of the 1938 Food, Drug, and Cosmetic Act and its subsequent amendments. Class labeling will be prepared for these products in the coming year.

Despite its formidable appearance there is no real trick to using the PDR. The publisher has provided four convenient indexes in the front of the book. Most useful are Sections Two and Four. Section Two lists all the products included in the book alphabetically by their brand name. The name of the drug on the prescription or on the label of the drug container is usually a brand name. However, if a prescription has been written generically, PDR users can look in Section Four, which lists products under the generic or chemical name. Information provided for the various brands under a generic name will be basically the same.

Section Three provides yet another kind of cross reference—a listing of products according to their classification or type, such as analgesics, diuretics, antihistamines, muscle relaxants, etc. The page numbers given in the three sections will lead the user to the product information in Section Six, the real "guts" of the PDR. Some product listings in the indexes have two numbers. The first refers to the Product Identification Sections, which contains actual size, full-color photographs of certain pills, capsules, and other dosage forms. Not all the prod-



























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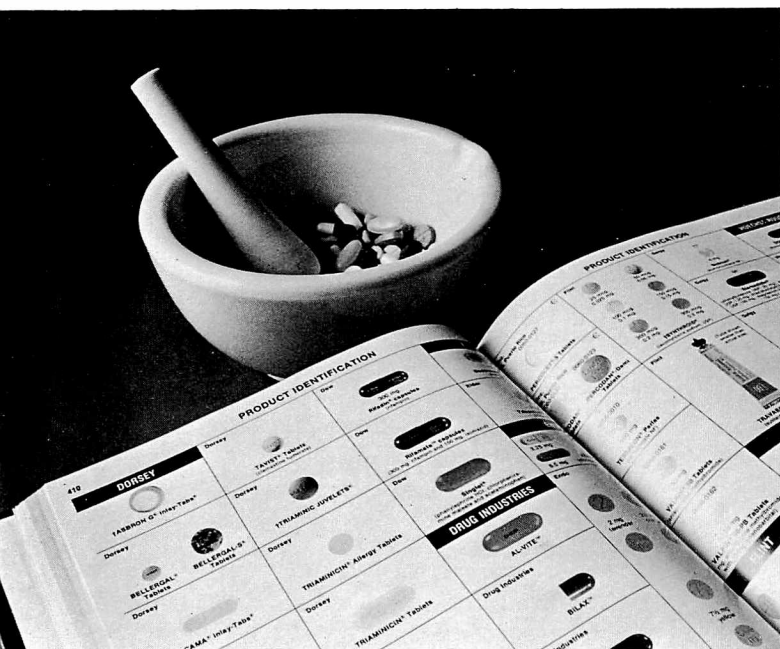
<p>Key Pharmaceuticals</p>  <p>Theo-nar® (theophylline, anhydrous and noscapine)</p> <p>"100" "200"</p>	<p>Knoll</p>  <p>Theophyl® SR (theophylline anhydrous U.S.P.)</p> <p>125 mg. 250 mg.</p>
<p>KNOLL</p>  <p>†Akineton® (biperiden HCl)</p> <p>2 mg.</p>	<p>Knoll</p>  <p>Theophyl®-225 Tablet (theophylline anhydrous U.S.P.)</p>
<p>Knoll</p> <p>Both sides of tablet shown</p>  <p>5 mg. Dicodid® (hydrocodone bitartrate)</p>	<p>Knoll</p>  <p>Vicodin® (hydrocodone bitartrate 5 mg. acetaminophen 500 mg.)</p>
<p>Knoll</p>  <p>1 mg. 2 mg. 3 mg. 4 mg. †Dilaudid® (hydromorphone HCl)</p>	<p>Knoll</p>  <p>LEVSIN® (1-Hyoscyamine sulfate, 0.125 mg.) Oral/Sublingual Tab.</p>
<p>Knoll</p> <p>Both sides of tablet shown</p>  <p>†Quadralin™</p>	<p>Knoll</p>  <p>LEVSINEX® Timecap® (1-Hyoscyamine sulfate, 0.125 mg.) Phenobarbital, 45 mg.</p>
<p>Knoll</p> <p>(Shown smaller than actual size)</p>  <p>Both sides of tube shown</p> <p>Collagenase Ointment</p> <p>Santyl® Ointment (collagenase)</p> <p>250 units per gram. No U.S. standard of potency.</p>	<p>Knoll</p>  <p>KU-ZYME® (Amylase, Lipase, Protease, Cellulase)</p> <p>522*</p> <p>KU-ZYME® HP (Pancrelipase Capsules)</p> <p>525*</p>
<p>Knoll</p> <p>Both sides of tablet shown</p>  <p>100 mg. Theophyl® Chewable Tablet (theophylline anhydrous U.S.P.)</p>	<p>Knoll</p>  <p>CALCIFEROL® (Ergocalciferol U.S.P.)</p> <p>50,000 Units Tab.</p>

PRODUCT IDENTIFICATION

413

<p>Lederle</p>  <p>(Shown smaller than actual size)</p> <p>ARISTO-PAK® (triamcinolone, 4 mg.) Six-Day Therapy Pack</p>	<p>Lederle</p>  <p>(Tubes shown smaller than actual size)</p> <p>Ointment 0.5% 15 Gm. tubes Ointment 0.1% 15 and 75 Gm. tubes ARISTOCORT® A (Triamcinolone Acetonide with Propylene Glycol)</p>	<p>Lederle</p>  <p>FILIBON®</p>  <p>FILIBON® F.A. Supplied in bottles of 100</p>  <p>FILIBON® Forte Prenatal Tablets</p>  <p>FILIBON® OT Tablets</p>
<p>Lederle</p>  <p>1 mg. 2 mg. 4 mg. 8 mg. 16 mg.</p> <p>†ARISTOCORT® Tablets (triamcinolone)</p>	<p>Lederle</p>  <p>2 mg. 5 mg. 5 mg.</p> <p>ARTANE® Tablets (trihexphenidyl hydrochloride)</p> <p>†ARTANE® Sequels®</p>	<p>Lederle</p>  <p>50 mg.</p> <p>HYDROMOX® Tablets (Quinethazone)</p> <p>HYDROMOX® R (Quinethazone 50 mg. with Reserpine 0.125 mg.)</p>
<p>Lederle</p> <p>(Tubes shown smaller than actual size)</p>  <p>Cream 0.5% 15 Gm. Tubes and 240 Gm. Jars</p>  <p>Cream 0.1% 15 and 75 Gm. Tubes and 240 Gm. Jars</p>  <p>Cream 0.025% 15 and 75 Gm. Tubes</p> <p>ARISTOCORT® A (Triamcinolone Acetonide with AQUATAIN™)</p>	<p>Lederle</p>  <p>150 mg.</p> <p>†DECLOMYCIN® Capsules (demeclocycline)</p>  <p>300 mg. 150 mg. 75 mg.</p> <p>†DECLOMYCIN® Tablets (demeclocycline)</p>	<p>Lederle</p>  <p>5 mg. 10 mg.</p>  <p>25 mg. 50 mg.</p> <p>LOXITANE® (Loxapine Succinate)</p>
<p>Lederle</p>  <p>Capsules 150 mg. Tablets 300 mg.</p> <p>†DECLOSTATIN® (demeclocycline and nystatin)</p>	<p>Lederle</p>  <p>MATERNA™ 1-60 Prenatal Tablets Supplied in bottles of 100</p>	<p>Lederle</p>  <p>50 mg. 100 mg.</p> <p>†MINOCIN® (minocycline HCl)</p>
<p>Lederle</p>  <p>125 mg. 250 mg.</p> <p>†DIAMOX® Tablets</p>  <p>500 mg.</p> <p>†DIAMOX® Sequels (acetazolamide)</p>	<p>Lederle</p>  <p>FERRO-SEQUELS® Supplied in bottles of 30 and 100</p>	<p>Lederle</p>  <p>25 mg. 25 mg.</p> <p>Tablets</p> <p>Tablets with Phenobarbital, 15 mg.</p>  <p>75 mg. 75 mg.</p> <p>Sequels®</p> <p>Sequels® with Phenobarbital, 45 mg.</p> <p>†PATHILON® (tridihexethyl chloride)</p>

*Other dosage forms available. See Product Information section or check directly with manufacturer.



ucts listed in the book are pictured in this section.

The PDR has some other handy-dandy information, including names, addresses, and phone numbers of the drug manufacturers in the Section One index, a list of all poison control centers, and a guide to the management of drug overdose in adult patients, best used only by physicians.

Once the reader has found the right page the going might not be so easy. Since the PDR is intended for physicians and other health professionals the language is technical and often difficult for the layman not versed in medicalese. However, a medical dictionary is usually readily available in the public library.

Understanding the PDR is no problem to the 350,000 practicing physicians in the United States who get their copy free, in the mail. Costs for their copies are covered by the pharmaceutical companies whose products are listed. Another 90,000 are bought by drug companies. Other health care professionals buy their copies: 32,000 are sold to pharmacists; 27,000 to dentists; 6,000 to veterinarians; and 95,000 to nurses.

Most hospital nursing stations have a copy of the PDR handy and 125,000 are sold to hospitals; 9,000 to nursing schools; and 17,000 to nursing homes.

Bookstore sales account for 150,000 copies and marketing data indicates most of these are bought by other health care professionals. There is no data to show how many copies are being sold to the general public, but the PDR's publisher is aware that nonprofessionals constitute a growing market. On any given day the prominent New York bookstore Barnes & Noble has several hundred PDR's on hand selling for \$14.95 per copy.

The current annual print run of a whopping one million copies makes the PDR a "bestseller" among professional reference works. When an edition of the PDR is ready to go to press, it takes strings of 70 to 80 boxcars to bring in the 2,600 tons of paper needed.

It wasn't always so. In 1947, the first year of publication, only 135,000 copies were produced.

The idea for the PDR was the brainchild of Jay Morgan Jones, who sold it in the forties to Medical Economics after rejections from four publishers, including McGraw-Hill. The PDR didn't catch hold until the late fifties. Before it did, Jones fell out with the Channing family, then owners of Medical Economics. So he left to start a competitive compendium, the VADEMECUM, which was unsuccessful in the United States because the pharmaceutical industry continued to favor the PDR.

Nevertheless, Jones made money by putting out foreign editions of the VADEMECUM from a Florida island. Eventually, Jones had a VADEMECUM in each of 26 countries. But as nationals in these countries began publishing competing compendiums, the VADEMECUMS were gradually forced out of business. At the time of his death, Jones had only one left.

With the growth of the consumer movement there has been an ever increasing public demand for information about prescription drugs; and, thus, it comes as no surprise that Charles E. Baker, Jr., the PDR's publisher, expects sales to the general public to increase. He, too, feels that medical objections to such sales have all but vanished. Last February, when the '79 edition began to appear for sale in bookstores, he received less than 100 complaining letters from physicians and he found it was mostly older physicians who raised a fuss. Their letters said that patients have no right to the information in the PDR. Or they complained that patients aren't smart enough to know what the side effects mean.

Medical Economics is readying a second pharmaceutical directory for publication that will cover nonprescription or proprietary drugs—sometimes called "patent medicines"—which are sold over the counter. Every month the average physician makes 114 recommendations to patients for nonprescription drugs.

The PDR FOR NON-PRESCRIPTION DRUGS will share the older PDR's cover color and general format. Similarly, it will be indexed by brand name, manufacturer, active ingredient, and product category.

The Proprietary PDR, which has been under discussion or in preparation since 1975, will be distributed free to physicians and pharmacies. The first edition is expected to be ready by March 1980.

Anyone getting medicine from a pharmacy can save a trip to the library by asking the pharmacist for a copy of the official package insert. Materials prepared specifically for patients are required by FDA for a few drugs, including contraceptives, estrogens and progestins, and for hearing aids. These brochures, called Patient Package Inserts (PPI's), provide consumers with essential information about these drugs in easy-to-understand language. At the present time, FDA is developing a program to provide PPI's for many more drugs.

The PPI's will add to the knowledge explosion and aid the consumer/patient, just as he was aided when the cover was blown on the PHYSICIANS' DESK REFERENCE.

Egon Weck is a freelance writer who has worked in the pharmaceutical industry.

Advice On Breast-feeding And Drugs



Mother's milk is the perfect food for newborn infants, but sometimes it can become contaminated by the drugs the mother may be taking. FDA soon will require that the labeling for all new drugs include information for physicians on whether the product is excreted in breast milk and its effects on the nursing infant.

by Annabel Hecht

Mother's milk, it is said, is something that cannot be improved. It is the perfect food, meeting all the nutritional needs of the growing infant. In fact, the only way it can become less than perfect is through contamination with some substance the mother gets into her system. One form of such contamination can be the drugs the mother takes.

Just as the unborn baby may be exposed to the effects of drugs an expectant mother takes when she is pregnant, so the newborn infant may be the unintended recipient of some medication excreted through the mother's milk. Because many drugs can reach the infant via this route, FDA is requiring that information concerning nursing mothers be provided in the "Precautions" section of prescription drug labeling, that is, in the informational material prepared by drug manufacturers for physicians, pharmacists, and other health personnel.

As of December 26 of this year, all new drugs that are absorbed through the system (as contrasted to those applied to the skin) will have labeling for physicians that will include all that is known about excretion of the drug in human milk and the effects on the nursing infant. If it is not known whether the drug is excreted in human milk, the labeling will so indicate and urge that caution be used when the drug is given to a nursing woman. Drugs already on the market will have similar information in their labeling by June of 1980.

Current labeling for many prescription drugs already carries warnings against use of the product in nursing mothers when the potential for harm to the infant is known. Some labeling simply advises against use on the basis of the fact that nothing is known about this potential. This gap in knowledge about drugs and breast milk is understandable. Few clinical studies are done in this area for ethical and practical reasons, including the difficulty of finding nursing mothers to be research subjects.

Although many, if not most, drugs will be detectable in the mother's milk, not all, by any means, will cause harm to the nursing infant. Some drugs will be present in such small amounts as to be insignificant. However, it should be kept in mind that a little bit of a drug will go a long way in a small child. Thus, even

though only a small amount of medicine may be present in the milk, the amount consumed in the course of several feedings, during a 24-hour period, could add up to a full therapeutic dose for the infant. Because a newborn's enzyme system is immature and its kidney function not fully developed, it is easy for toxic levels of drugs to accumulate in little bodies.

How high the concentration of the drug will be in the milk depends on the amount of the drug present in the mother's blood. This, in turn, depends on a number of factors, such as when she took the drug, the dosage form of the drug, and the food she ate. Drugs also may be present in higher concentrations if the mother has kidney problems.

Whether a drug dissolves readily in fat is another factor. Milk is basically an emulsion of fat in water. The relative proportion of each of these milk components varies with the time of day and even changes during the course of a feeding. Drugs that are soluble in fat tend to transfer into the mother's milk as the fat content rises.

Among the drugs that are known, through case reports, to affect the offspring of nursing mothers are chloral hydrate, diazepam (better known as Valium), phenobarbital, and bromide. These drugs can do to babies what they do to the mothers,

that is, make them drowsy. One infant exposed to diazepam through its mother's milk became lethargic and lost weight. It also has been suggested that this drug could produce jaundice in infants.

Chlorpromazine (Thorazine) is reported to cause infant drowsiness. High doses of barbiturates appear to have a greater potential for producing this effect than many small doses. The manufacturer of primidone (Mysoline), an anticonvulsant drug, recommends that women taking the drug stop nursing if their infants exhibit "undue somnolence and drowsiness."

Caffeine, as one might suspect, has the opposite effect. This drug can reach detectable levels in the blood of nursing infants, and in one recorded case the child showed signs of the jitters.

Some drugs excreted in mother's milk may be relatively harmless to the average infant, but can cause serious problems in infants with the inherited enzyme deficiency glucose-6-phosphate dehydrogenase (G6PD) deficiency. Sulfonamides can cause hemolytic anemia in such infants. Another drug to be avoided where G6PD-deficient infants are concerned is nitrofurantoin, an antimicrobial agent used to treat certain infections.

Women taking such drugs as chloramphenicol, metronidazole, lithium, reserpine, and antithyroid drugs probably should not breast feed their babies, according to some experts. Chloramphenicol (Chloromycetin and others) has been associated with such adverse reactions in infants as refusal to nurse, falling asleep during the feeding, and vomiting. Metronidazole (Flagyl) would be an unwelcome addition to an infant's diet since it is known to cause cancer in laboratory animals. Lithium can be present in breast milk at high enough concentrations to cause loss of muscle tone, reduction in body temperature, and blueness of the infant's skin.

Reserpine, a widely used antihy-

pertensive drug, is reported to cause increased respiratory tract secretions, nasal congestion, blueness of the skin, and weight loss in breast-fed infants whose mothers are being treated with this drug. Antithyroid drugs pose a particularly serious hazard to nursing infants. Radioactive iodine, taken in therapeutic doses by the mother, can destroy the infant's thyroid gland. Even small amounts, used in diagnostic studies in the mother, may increase the infant's risk of developing thyroid cancer later in life.

The effect of drugs secreted in mother's milk may be more subtle than the foregoing. Penicillin may not occur in milk in sufficient concentration to do immediate good or harm to the infant, but trace amounts absorbed by the child could lead to the development of an allergic reaction to the drug at a later time.

An infant can become addicted to heroin if the mother is taking large doses of that drug while she is nursing. But, at the same time, nursing can help the baby break the habit if the mother is using methadone. Used in the treatment of drug addiction, methadone is excreted in the mother's milk and in high enough amounts to prevent withdrawal symptoms in the infant. This means of treatment probably is not to be recommended, since there have been case reports of infant deaths from methadone in mother's milk. Another narcotic-type drug that could pose problems for nursing infants is propoxyphene (Darvon and others). If the mother is taking the maximum dose of this popular prescription painkiller the infant could receive a substantial dose as well.

The list of drugs known to be excreted in mother's milk is not limited to the more powerful prescription drugs. Products that can be obtained "over the counter" without a prescription also may cause reactions in nursing infants. For example, certain

ingredients found in laxatives, such as aloe, calomel, cascara, and danthron, are believed to have an effect on the baby's bowels.

The subject of drugs in breast milk is of concern to FDA for another reason: namely, the effect on those who are participating in tests of drugs still being developed. In the general guidelines for clinical evaluation of drugs, the Agency advises that a determination should be made whether a drug is excreted in breast milk before it is used experimentally in nursing mothers. And, in its guidelines relating to tests of drugs for infants and children, FDA also advises that the possibility of interaction from chemicals, hormones, and drugs in breast milk be considered when suckling infants participate in drug evaluation.

In addition, the American Academy of Pediatrics, in its "General Guidelines for the Evaluation of Drugs to be Approved for Use During Pregnancy and for Treatment of Infants and Children," notes that most drugs given to the mother are excreted in breast milk and suggests the various factors that should be considered in evaluating the potential effect on the infant.

Because of the possibility that her baby might be affected, it is a good idea for the nursing mother to ask her doctor about all the medications she is taking—both the prescription and the over-the-counter varieties. It may be that some drugs she is taking aren't really necessary, or that a substitute can be prescribed for a product that is known to affect the nursing infant. Whether she should stop nursing will depend on the importance of the drug to the mother's health.

Annabel Hecht is a member of FDA's Public Affairs staff. (Contributing research for this article was Carolyn Khan, an FDA intern from Houston, Texas.)

News Highlights

Mercury Lamp Standards Set

Under a safety standard established by FDA, automatic shut-off devices are to be used in some public places on mercury vapor lamps to protect the public from ultraviolet radiation from damaged lamps.

The self-extinguishing lamps are to be used in areas where people could be exposed for extended periods. They are to shut off within 15 minutes of the outer globe breaking. It is when the outer globe or envelope breaks that the potentially harmful ultraviolet radiation is released.

Mercury vapor lamps, which usually emit a bluish-white light, are widely used to light large indoor areas such as gyms, sports arenas, factories, and department stores. They also are used to light streets, parking areas, sports fields, and driveways. More than 25 million of them are used in the United States.

The lamp consists of an inner tube containing mercury gas and an outer glass globe that absorbs most of the ultraviolet radiation given off by the gas. When the outer glass is broken and the lamp continues to glow, the escaping ultraviolet radiation can cause eye injuries or skin burns when people are exposed for extended periods.

The new standard permits continued manufacture of lamps that do not shut off automatically, but they are intended for use where people are not likely to remain for more than a few minutes, such as parking lots or streets.

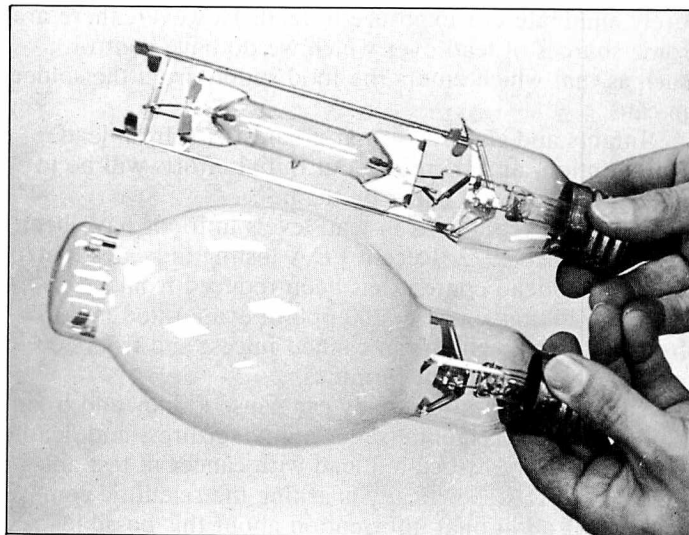
The safety standard applies to lamps manufactured after March 6, 1980. Some manufacturers already make vapor lamps that self-extinguish after the outer globe is broken.

Sherwin Gardner, Deputy Commissioner of Food and Drugs, said: "Because they are economical to operate and have a long life, mercury vapor lamps represent a valuable technology. But FDA has received reports of more than 460 injuries associated with broken lamps. This new standard is designed to permit the continued use of vapor lamps while providing adequate protection to the public if they break."

Of the injuries reported to FDA, most have required medical attention. The severity of injury depends on the person's length of exposure and distance from the lamp.

The standard also requires manufacturers to provide adequate information to users of mercury vapor lamps, and clear warnings on the labels of lamps that do not shut off automatically. The labeling for a lamp that shuts off automatically is to state: "This lamp should self-extinguish within 15 minutes after the outer envelope is broken or punctured. If such damage occurs, TURN OFF AND REMOVE LAMP to avoid possible injury from hazardous shortwave ultraviolet radiation."

For a lamp that does not shut off automatically, the labeling will state: "WARNING: This lamp can cause seri-



ous skin burn and eye inflammation from shortwave ultraviolet radiation if outer envelope of the lamp is broken or punctured. Do not use where people will remain for more than a few minutes unless adequate shielding or other safety precautions are used. Lamps that will automatically extinguish when the outer envelope is broken or punctured are commercially available."

FDA had proposed the standard April 21, 1978. The new standard was published in the September 7, 1979 FEDERAL REGISTER.

Getting the Lead Out of Food

With an initial goal of reducing the lead intake from cans by at least 50 percent within 5 years, FDA has announced a stepped up program to get the lead out of the food supply.

In announcing the program, the Agency noted that its efforts, and those of other Federal agencies over the past few years, have reduced consumer exposure to lead, but FDA added that it believed that further reductions can be realized.

The goal of a 50 percent reduction in lead from cans is the most significant part of FDA's program. Lead is used to solder the seams and closures on food cans. The intention to establish the program was announced in the FEDERAL REGISTER of August 31. After receiving comments on the REGISTER notice, the Agency will propose a more specific program, with likely first targets noted as reductions in canned evaporated milk, canned infant formulas, canned infant fruit and vegetable juices, and glass-packed infant foods (lead is used in glassmaking and can leach from the glass).

The new program would be coordinated with work by

other Federal agencies, especially the Environmental Protection Agency, which has jurisdiction over lead in air and water.

Sherwin Gardner, Deputy Commissioner of Food and Drugs, said: "Because of its natural or unavoidable presence in food, air and water, there is no way we can entirely eliminate our exposure to lead. However, there are some sources of lead over which we do have control, such as that which enters the food supply from the solder in cans.

"Infants and children are at greatest risk from lead consumption, and therefore our initial efforts will be to reduce lead in food eaten by them."

Significant reductions in lead levels in foods have been achieved since 1972. Recent FDA testing indicates that the average lead content has been reduced from 520 parts per billion (ppb) to 100 ppb in evaporated milk; from 300 ppb to 50 ppb in canned juices; and from 100 ppb to 60 ppb in infant formulas.

Too much lead in the body can cause kidney and brain damage, anemia, mental retardation, seizures, and death. Some data have associated lead with cancer in test animals, and FDA specifically is asking the scientific community for additional information about this possible link.

Lead-soldered cans are used to package 10 to 15 percent of all foods. They contribute about 14 percent of the total lead ingested by people and are the most important source of lead that becomes added to foods.

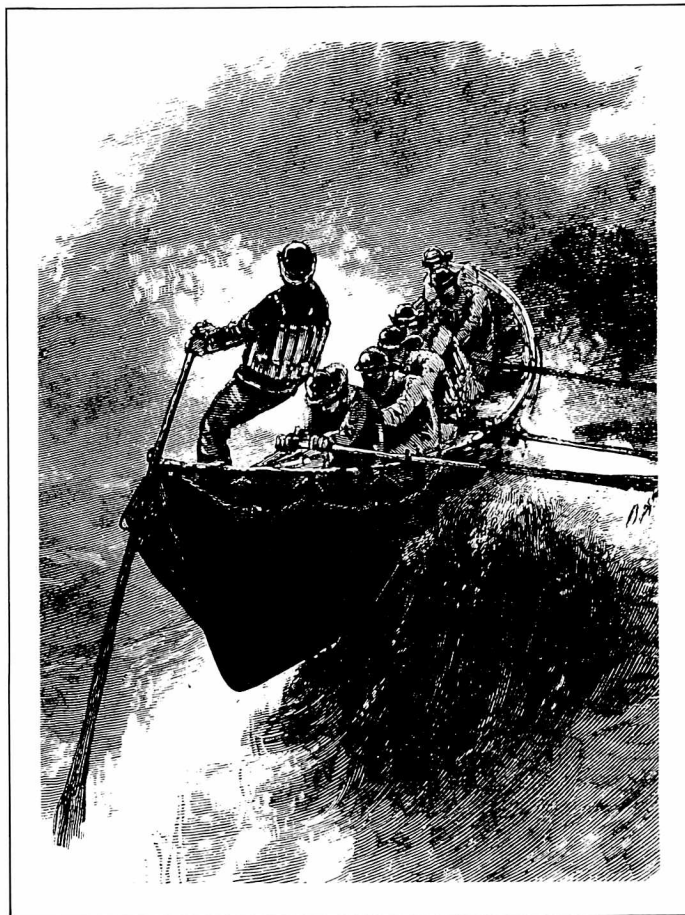
Approximately 33 billion cans per year are used to package foods in this country. Lead contamination can come from the solder used in making the can's side seam. Composition of the solder is 2 percent tin and 98 percent lead.

Motion Sickness Drugs OK'd

Three drug ingredients are safe and effective for use in nonprescription drugs to prevent or treat motion sickness, according to the Food and Drug Administration. In a "tentative final order" published in the *FEDERAL REGISTER*, the Agency identified the three as cyclizine hydrochloride and meclizine hydrochloride (both benzhydryl piperazine antihistamines), and dimenhydrinate. These drugs are known as antiemetics.

FDA's classification of the three ingredients as safe and effective was based on a review of the recommendations of a panel of non-Government experts and of public comments on those recommendations. The panel, one of 17 set up by the Agency to evaluate all nonprescription, or over-the-counter (OTC), drugs was assigned to study laxatives, antidiarrheals, emetics, and antiemetics. The panel's initial report was published in March 1975.

Although FDA agreed for the most part with the panel's recommendations, the tentative final monograph contains a number of changes. Two ingredients not reviewed by the panel were studied by the Agency in response to some of the public comments. Diphenhydramine hydrochloride, at present available only on prescription, could be switched to an OTC antiemetic if



clinical studies show that it is as safe as its chemical relative, dimenhydrinate, FDA said. In addition, the Agency said scopolamine hydrobromide might be classed as safe and effective if double-blind clinical studies are conducted to establish its effectiveness at the proposed dosage of 0.25 mg every 4 to 6 hours. The Agency agreed with the panel's recommendation that further testing would be required for bismuth subsalicylate and phosphorylated carbohydrate to establish their effectiveness in treating or preventing nausea caused by motion sickness.

There is no evidence that aminoacetic acid, phenyl salicylate, and zinc phenolsulfonate are effective as antiemetics, FDA said. These ingredients should be removed from the market. In its initial report, the panel of experts had recommended further testing for the last two of these ingredients. No combination products were classed as safe and effective antiemetics.

The only claim that can be made on the labels of antiemetic products is for the "prevention and treatment of nausea and vomiting associated with motion sickness," FDA said in the order. Claims that these drugs are effective in treating nausea associated with other causes must be proven by well-controlled clinical studies.

FDA also will require that labels on antiemetic products containing antihistamines include warnings that these products may cause drowsiness and that patients should

not drive or operate machinery. Alcohol should be avoided.

Labeling for physicians may include, as an additional indication, the claim that antiemetics may be used "for treatment of vertigo or motion sickness."

A tentative final order is the next to last step in the process by which FDA establishes standards for over-the-counter drugs. If there are no further objections or requests for oral hearings, the Agency will publish a final monograph. A tentative final order for emetics, drugs to induce vomiting, was published in September 1978. FDA's conclusions on tentative final monographs for laxative and antidiarrheal products will be published later.

Salt Guidelines Urged

A select committee has told FDA that guidelines should be developed restricting the amount of salt in processed food.

The recommendation came in a final report—on the health aspects of using salt (sodium chloride) and potassium chloride as food ingredients—from the Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology (FASEB). The evaluators are an independent group of scientists that have scrutinized nearly 300 GRAS (generally recognized as safe) substances to date for FDA.

In its final evaluation, the committee said that sodium chloride is an essential constituent of the body and is present in many foods. For many, the daily requirement is less than one gram (28 grams equals 1 ounce), but most diets contain a larger amount as a naturally occurring ingredient.

The committee said it is not possible to recommend an optimal intake level of sodium chloride because the daily requirement is subject to fluctuation from such conditions as excessive sweating and diarrhea.

Ten to thirty percent of the U.S. population is genetically predisposed to hypertension, the committee said, and reduction of sodium chloride consumption by the population would reduce the occurrences of hypertension. Adequate labeling of sodium content of foods could help cut down on consumption, the committee said.

Apart from those considerations, the committee concluded that salt has not been demonstrated to be harmful for at least 70 percent of the population at present levels of use.

Potassium chloride is used as a nutrient and dietary supplement and as a drug for potassium depletion conditions. It also may have a protective effect against the hypertensive action of high salt intake. The committee concluded that there is no available evidence that potassium chloride poses a hazard to the public when used at levels that are current or that might reasonably be expected in the future.

FDA will evaluate the final report and decide what, if any, regulatory actions are needed. The report is available at \$5.25 a copy at the National Technical Information Service, 5255 Port Royal Rd., Springfield, Va. 22152. The order number is PB 298-139/AS.

Worry About Food Additives

Food colorings and preservatives are still considered moderate to high risks by a majority of Americans, according to a survey by a leading polling firm.

The Roper Organization, Inc., found that 52 percent of the public rated eating foods with artificial coloring either a moderate or a high risk, while 57 percent of the people polled thought the same about eating foods with preservatives. By comparison, smoking cigarettes was considered a high risk by 61 percent, and 28 percent more considered it a moderate risk.

Only 15 percent gave the high risk rating to eating foods with preservatives and only 14 percent gave this rating to dining on foods with artificial coloring. Both of those percentages were up a point from a similar survey taken 6 months earlier in 1978.

As might be expected, there was a sizable jump in the number of people who think that living near a nuclear powerplant constitutes a high risk. In the survey, taken after the Three Mile Island incident, 45 percent called it a high risk. By comparison, the 1978 survey found just 37 percent in that category.

The quiz on risks was in 12 parts ranging from flying in a plane to living in an area subject to frequent hurricanes or tornadoes. Actually, the food preservative and food coloring sections brought the lowest high risk response, and flying in an airplane was next to lowest at 16 percent. Another question concerned food crops sprayed with pesticides. Thirty-four percent called that a high risk and another 39 percent thought it a moderate risk.

FDA was among the supporting organizations that contributed to the survey.

New Milk Ordinance Printed

Some four and a half decades ago, milkborne illness in the United States accounted for 25 percent of all disease outbreaks due to infected food and contaminated water. Today, disease borne in milk accounts for less than 1 percent of that category.

One reason for the change is the Public Health Service model milk ordinance, now a responsibility of FDA. The latest version of that model law, entitled "Grade A Pasteurized Milk Ordinance," and four related documents, were recently printed by the Agency. The publications are used by State and local governments to assure uniformity and a higher level of safety in milk sanitation practices.

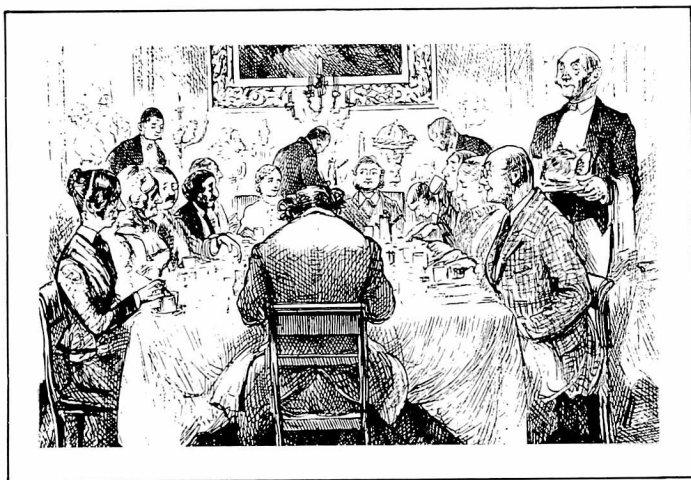
The newest version is the 14th revision since the original model ordinance was published as the "Standard Milk Ordinance" by the Public Health Service in 1924. At that time, it was aimed at helping States initiate milk sanitation programs.

Now the ordinance is part of the Federal-State Milk Sanitation Program, administered by FDA through the Interstate Milk Shippers Agreements. The current publication takes into consideration "new products, new processes, new chemicals, new materials and new marketing patterns" and suggests how to use this new knowledge in

practical public health practice.

Copies of the milk ordinance and the four supplements are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

More Iron Data Sought



A great deal more needs to be known about the absorption of iron by the body, according to the Select Committee of the Federation of American Societies for Experimental Biology (FASEB), which has made a tentative report to FDA in the latter's comprehensive review of food ingredients classified as GRAS (generally recognized as safe). The committee of scientific experts, whose studies and reports on various GRAS substances are being done under contract to FDA, said there is a serious lack of reliable information about the amount of iron absorbed by the body, the amount being ingested from all sources, and the nature and prevalence of a disease resulting from a metabolic defect known as hemochromatosis—in which iron is deposited in excessive, harmful amounts in various body organs and tissues.

The committee noted the importance of fortifying food with iron to combat serious dietary iron deficiency among some segments of the population, and said that if iron is added to food it should be in a form that is highly bioavailable (is absorbed by the body)—at least 50 percent as bioavailable as ferrous sulfate, a form which has a relatively high bioavailability. Food processors have been adding one of mainly four forms of iron and iron salts to food over the years, the choice being determined by technological factors, cost, and bioavailability. In recent years they have become more aware of bioavailability problems and the trend has been to use iron forms of higher bioavailability.

The FASEB group reported specifically on 20 forms of iron or iron salts that are either considered GRAS by

FDA or about which the Agency has asked for more information on safety when added to foods. Because of unknowns about various aspects of iron use and absorption by the body, the committee was unable to recommend either the use or prohibition of use of the substances under study. It did say that for the following substances there is no information available that would suggest they would be hazardous when used at the present levels in foods:

Elemental or metallic iron in one of three forms—reduced iron, electrolytic iron, and carbonyl iron; ferrous fumarate, ferrous carbonate; ferrous sulfate, ferric citrate, ferric phosphate, and ferric pyrophosphate.

The committee was less certain about the following list, for which it said there are serious deficiencies in experimental data or clinical experience:

Ferrous ascorbate; ferrous citrate; ferrous gluconate; ferrous lactate; ferric ammonium citrate; ferric oxide; iron peptonate; iron polyvinylpyrrolidone; sodium ferric EDTA; sodium ferricitropyrophosphate; and sodium ferric pyrophosphate.

The committee wasn't worried about several forms of iron that become indirect additives when used in paper and paperboard food packaging or in treating the film surface of food can linings because their migration to the food is believed to be minimal. But the committee said it feels not enough is known about one of these—iron naphthenate.

The concern about hemochromatosis and "iron overload" in some persons resulted several months ago in FDA's abandonment of its efforts of several years to increase the amounts of iron added to enriched bread, rolls, and some other cereal-based products. The many unknowns about iron metabolism and bioavailability were emphasized in this agency proceeding too and FDA said it intended to develop specifications on iron bioavailability to help resolve these public health concerns.

The iron and iron salts substances studied by the committee are classified as GRAS, but iron is added to other processed foods under FDA's food additive regulations and, of course, iron is marketed in dietary supplements.

In its conclusions the committee said that avoidance of "iron overload" from fortified foods might be accomplished by limiting both the amount of iron added to foods and the number of foods to which iron is added, but emphasized that the basic questions about iron overload were not considered in its reports and that these deserve separate study, with due consideration for iron intake from all sources, including vitamin and mineral supplements. Regular monitoring of the iron nutritional status of the population is essential for such a comprehensive study, the group said.

The committee is considering comments from the public and industry before making a final recommendation to FDA.

Regional Reports

A Fire That Spread Insidiously

Around Jacksonville, Florida, water is just about everywhere. To the east there's an ocean of it, on the other sides there are rivers and creeks and lakes full of it, and quite often there's a lot of it coming down from above. People swim, fish, sail, ski, and surf in it, and bathe and shave in it, and still have more water than they need. At times they've even cussed it when its arrival was accompanied by high winds. In Jacksonville, there's enough surplus water to disperse and dispose of many environmental contaminants before they become major threats to health. They simply get carried out to sea.

But some contaminants won't wash, and this can spell trouble under certain conditions, as a recent episode in that city made evident.

The primary active ingredient in the cockroach poison *Rid-a-Bug*, formulated by Kenco Chemical & Manufacturing, Inc., Jacksonville, is a chemical called *Dursban* (chlorpyrifos). It's an organophosphate compound manufactured by Dow Chemical and is incorporated into insecticide formulations used in the home, on such crops as cotton, corn, rice, and vegetables, and sometimes for mosquito control. *Dursban* is not the most toxic pesticide chemical around, but it has one characteristic not common to all pesticides: in water, it remains stable—that is, it refuses to dissolve, or break down.

On Thursday, June 7, at 9 a.m., a fire broke out in the Kenco plant in the floor area where aerosol cans are filled with *Rid-a-Bug*. The smoke activated a fire alarm, the building was quickly evacuated, and the Jacksonville Fire Department arrived to fight the blaze for what turned out to be 4 hours. During this time, millions of gallons of water were poured on the fire, but firemen were unable to save the plant and it was destroyed. In the storage area the intensifying heat caused some 20 fifty-gallon drums of undiluted

Dursban to explode one by one and burn, whereupon billows of insecticide-laden smoke fumes belched into the air to be carried downwind toward the north.

As the fire raged, city police squad cars equipped with public address systems were sent to the scene of the emergency. They fanned out for three miles downwind in the industrial and residential area to the north, including an elementary school, and for a half mile upwind in the industrial area to the south, ordering people in these areas to leave immediately to keep from being exposed to the poisonous fumes.

Upon its investigation, the Jacksonville Fire Department identified the contents of the stored drums as *Dursban* and reported that Kenco had neglected to inform the department of the identity and peculiarities of the chemicals being kept in the plant, as the company is required to do under a city ordinance.

This discovery pointed to another unhappy consequence: The water used on the fire was draining into nearby Cedar Creek, which would carry the insecticide chemical *Dursban* downstream in an undissolved and highly potent concentration. The poisoned water could threaten marine life and contaminate fish and crabs caught by commercial and private fishermen at the mouth of Cedar Creek where it empties into the St. Johns River 2 miles away from the Kenco plant. There was a heavy kill of fish and other marine life in Cedar Creek, especially for the first mile past the Kenco plant.

This potential threat prompted the fire department to notify the U.S. Coast Guard's Strike Team, which is assigned to cope with oil spills and other chemical mishaps in the general area, along with the Environmental Protection Agency (EPA). These groups combined resources to dam Cedar Creek and begin treating the water in the stream with an aerating

device to break down the chemical through oxidation. EPA teams from Atlanta and New York, assisted by the city of Jacksonville, set up a laboratory to test monitoring samples of water from the creek to determine when it would be free of unsafe levels of the pesticide. Unhappily, heavy rains caused the dam to break, slowing the aerating operation, and it was not until the end of the following week, on June 16, that EPA's monitoring showed the water to be safe once again.

FDA investigators Dave Aken and Phillip Waldron and imports inspector Arthur Copedge, all of the Jacksonville Resident Post, learned about the fire in progress from television and radio broadcasts, and the next day, June 8, moved into the general area to check out establishments processing or storing products regulated by the Agency.

They collected samples of fresh vegetables from a Winn-Dixie food store cooler warehouse; green coffee beans at Astor Products, a coffee roasting house; and feed from the Paramount Poultry Feed Mill—all within a quarter of a mile from the fire. Laboratory assays found no contamination with *Dursban*.

The FDA men recorded one complaint, from a woman truckdriver who was hauling a load of frozen chickens from the Paramount Poultry processing plant, an affiliate of the feed plant in the same area. She told them the toxic fumes entered her truck through its air conditioning system and she became ill. Her complaint was referred to the U.S. Department of Agriculture because of the latter's regulatory jurisdiction over processed poultry. USDA took samples of the chickens and, when they were found to be contaminated with *Dursban*, embargoed the load of chickens on the truck's arrival at its destination in Miami.

The Jacksonville Fire Department has not yet announced any findings about how the fire started.

Regional Reports consists of information on inspections, product seizures, court proceedings, and other regulatory and administrative actions initiated by FDA's regional and district field offices across the country to provide protection to consumers under Federal laws.

REGION I

Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

FDA's **Boston District** witnessed the destruction of more than \$18,000 worth of decomposed fruit salad by a Boston dealer. The destruction resulted after the U.S. Department of Agriculture notified FDA that a truck contained 3,400 8-ounce jars of potentially adulterated fruit salad from Mexico. Laboratory analysis of samples collected by District investigators revealed fermentation to the point of decomposition.

More than \$400,000 worth of seafood was detained by the Boston District, at the Port of Boston, after routine import inspections revealed that the products were in violation of FDA regulations. The major detentions: approximately \$300,000 worth of frozen shrimp from India and Indonesia for insect contamination, and \$72,000 worth of red snapper from Thailand for decomposition.

REGION II

New Jersey, New York, Puerto Rico, Virgin Islands

Pharmadyne Laboratories, a drug manufacturer in Hackensack, New Jersey, attempted unsuccessfully to restrict FDA's efforts to regulate "me too" drugs. The dispute was over two products—prochlorperazine T.D. (time disintegration) capsules and allopurinol tablets—that were, according to FDA, unapproved new drugs. Pharmadyne contended that the products were not "new" because they were equivalent to two already approved drugs. The firm filed an injunction in the U.S. District Court for the Eastern District of New York in an attempt to prevent seizure of the products. However, the court

supported FDA's position and ruled that the public health is threatened when unapproved drugs—even those "equivalent" to others—are marketed. A **New York District** investigator accompanied a U.S. marshal to the New York City warehouse where approximately \$6,500 worth of the drugs were seized.

Violations of FDA Good Manufacturing Practice Regulations (GMP's) led to seizure of \$28,000 worth of drug products and raw materials at Brown Manufacturing Co., a drug manufacturer and repacker in Leroy, New York. The seizure was initiated by FDA's **Buffalo District** after an inspection at the firm revealed GMP violations, such as the company's haphazard identification of raw materials, inadequate recordkeeping, and failure to test the stability of finished drugs. The firm manufactures several ointments and a cough syrup and repacks a variety of products, including Ramon's Brownie pills, Pink pills, and laxatives with bile salts.

A host of Federal and State investigators descended on Huguenot, New York, after a malfunctioning air compressor released over 5,000 pounds of aluminum chlorhydrate powder, an ingredient used in antiperspirants, into the air. Samples of food and water were collected by investigators from the Buffalo District, the Environmental Protection Agency (EPA), and the New York departments of Environmental Conservation and of Health. Although the chemical was discharged over an area of approximately 2 square miles around the plant of the manufacturer, Wickhens Products, Inc., levels of the substance in the samples were not toxic and presented no danger to health.

A U.S. marshal seized over \$3,000 worth of Beta-VAL, a brand of beta-methason valerate cream, at Premo Pharmaceutical Laboratories, Inc., South Hackensack, New Jersey, because the product was being marketed without an approved New Drug Application. FDA's **Newark District** initiated seizure action when the firm continued to market the drug after receiving a regulatory letter warning that the drug was unapproved. The product is a topical

steroid used in the treatment of inflammation associated with skin disease.

Failure to correct deficiencies in drug manufacturing practices led to seizure of approximately \$40,000 worth of finished drugs, in-process materials, and raw materials at Francisco L. Anselmi, Inc., Coamo, Puerto Rico. The firm, also doing business as Flar Medicine Co., manufactures both over-the-counter and prescription drugs, including sedatives, cough syrups, and decongestants. A series of inspections by FDA's **San Juan District** revealed numerous violations of Good Manufacturing Practice regulations. When the firm failed to heed the District's warning to correct the violations, the District filed for seizure.

A U.S. marshal seized 7,534 cans of guava purée, valued at over \$92,000, at Toa Baja, Puerto Rico, because of bacterial contamination. The seizure was initiated by FDA's San Juan District after investigators noticed, during an inspection of the firm, that some of the cans were swollen. Swelling is caused by gases produced as a by-product of bacterial growth. Laboratory analysis subsequently confirmed that the purée was decomposed and contained carbon dioxide.

REGION VI

Arkansas, Louisiana, New Mexico, Oklahoma, Texas

Over 8 million pounds of cottonseed meal was seized at the Helena Cotton Oil Co., Inc., Helena, Arkansas, because of aflatoxin contamination. Aflatoxin is a naturally occurring cancer-causing contaminant produced by mold that, under certain conditions, grows on cottonseed, peanuts, corn, wheat, rice, and other foods. Investigators from FDA's **New Orleans District** collected samples of the meal after learning from the Mississippi Department of Agriculture that it might be contaminated. When laboratory analysis revealed that it was indeed contaminated, the District initiated seizure of all cottonseed meal stored on the firm's premises. In addition, the firm recalled all of the product that had been distributed.

REGION VII

Iowa, Kansas, Missouri, Nebraska

Two cases of food poisoning last summer demonstrated the hazards consumers face when they eat food without taking proper precautions for safety. A Culbertson, Nebraska, woman became ill with botulism after eating some of her own home-canned mixture of tomato juice and green peppers. Laboratory analysis of samples collected by FDA's **Kansas City District** found botulinal toxin in the juice, which had been processed by the open kettle boiling bath method—a technique inadequate to kill spores of *Clostridium botulinum*.

The second case of food poisoning resulted in the hospitalization of a family of four in Joplin, Missouri, after they collected and ate wild mushrooms. Joplin city officials quickly alerted local consumers to the hazards of eating this particular

type of mushroom, which laboratory analysis showed to be a member of the genus *Amanita*. *Amanita* toxins attack the liver and the parasympathetic and central nervous systems, causing severe illness and, often, death. City health officials notified the Kansas City District that they had collected and destroyed all the *Amanitas* they could find. Both the Missouri and Nebraska victims recovered.

Three lots of peanuts and mixed nuts were destroyed at Hiland Potato Chip Co., Des Moines, Iowa, following a routine inspection by the Kansas City District that revealed rodent contamination. One lot of peanuts was destroyed by the company. The two remaining lots of nuts, one peanuts and one mixed, were seized by a U.S. marshal and subsequently ordered destroyed by the U.S. District Court for the Southern District of Iowa.

REGION IX

Arizona, California, Guam, Hawaii, Nevada

Shipments of ginseng drink and frozen Australian shrimp were denied entry through the Port of Los Angeles as a result of routine import inspections by FDA's **Los Angeles District**. The shrimp, valued at \$30,-000 was detained because of contamination by maggots, flies, and other insects. The ginseng drink, valued at \$6,100 and imported by Sisco Boeki Co., Los Angeles, was detained because it was derived from ginseng, a plant that is an illegal food additive whose use is permitted only as a tea. The U.S. Customs Service at Los Angeles subsequently fined the importer \$7,514 for failing to re-export or destroy the tea.



Oxygen Embargoed

The relabeling of five cylinders of oxygen could have proved disastrous. They were embargoed at Morristown Airport, near Morristown, New Jersey, by an investigator from the

State Actions

New Jersey Department of Health after he noticed that the cylinders, which contained medical oxygen USP, had been relabeled to identify the contents as aviation breathing air. The moisture limit for aviation breathing air is 0.005 percent, whereas medical oxygen USP may contain up to 1 percent moisture. The difference is critical because almost any moisture in aviation breathing oxygen could freeze at high altitudes and cause a blockage in the equipment. This would pose a serious hazard to people in the aircraft. The airport emptied the containers and found a new supplier of aviation breathing air.

Funny Honey

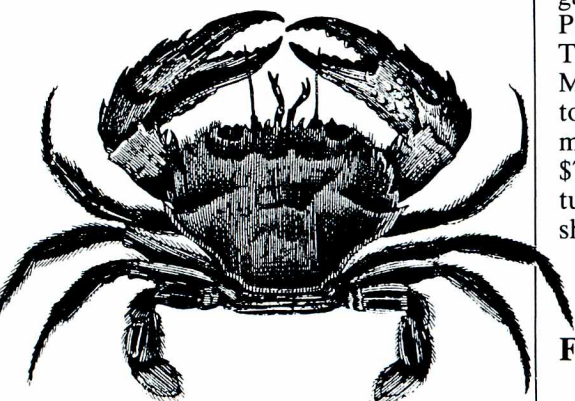
The "honey" stored at Interstate Food Products, New York City, would never have fooled a bee, nor did it fool the analysts at Geochron Laboratories, Cambridge, Massachusetts. Samples were collected by investigators from the New York Department of Agriculture and Markets and sent to the private Massa-



chusetts laboratory. After analysis revealed the honey was adulterated with approximately 25 percent corn and cane sugar, the Department embargoed and destroyed 1,608 pounds of the sweet stuff. The State is seeking criminal indictments against both the New York distributor and the Philips Honey Co., the manufacturer in Lake Wales, Florida.

In Chancery

The Chancery Court of Lawrence County, Tennessee, ordered MGH Wholesale Grocery Co., Inc., Lawrenceburg, Tennessee, to stop selling food that is adulterated or held under insanitary conditions. The Tennessee Department of Agriculture requested the injunction after a series of State inspections revealed continued widespread rodent infestation in the firm's warehouse.



Crabs for the Picking

Virginia crab lovers got a break last June when Virginia Governor John Dalton agreed to permit harvesting of male crabs from the Lynnhaven Estuary on the Chesapeake Bay. The pickings for crabs have been slim since the end of 1975, when State officials discovered that large amounts of Kepone, a toxic chemical used in ant control, had been dumped into the James River. Virginia Health Department officials prohibited the harvesting of certain fish from the James River, the Hampton Roads (Virginia) area, and portions of the Chesapeake Bay. Included in the prohibition was the harvesting of male crabs. The Department began monitoring both crabs and oysters for Kepone contamination and in the spring of this year determined that it was safe to consume male crabs from the Lynnhaven-Broad Bay-Linkhorn Bay estuary, located along the mouth of the James River.

Shortweight Shrimp

A fishy situation prompted a large Michigan restaurant to get in touch with the Michigan Department of Agriculture. The restaurant owner complained that boxes labeled as containing 12.5 pounds of shrimp in fact had only 10 pounds. Although the shrimp were glazed in ice for shipping purposes, the labeled weight should have equaled the weight of the shrimp when deglazed. When a State examination confirmed that the shrimp packages were shortweight, the Department brought legal action against the product's broker, Superior Seafoods, Grand Rapids, Michi-

gan, and the packer, Singleton Packaging Corp., Tampa, Florida. The broker pleaded guilty, in the Michigan District Court of Lansing, to violating State labeling requirements and was assessed court costs of \$75 and was required to make restitution to the restaurant of \$910. The shipper was fined \$300 plus \$55 court costs in the Michigan District Court of Kentwood.

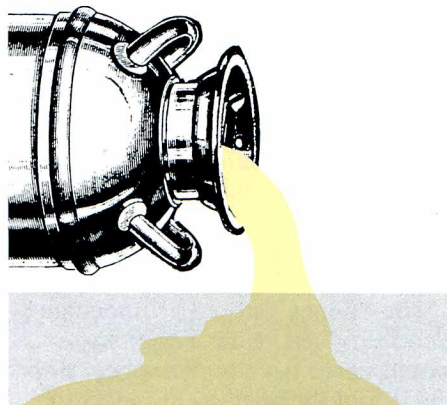
Flood Damage

Flash flooding along the Walnut River in Butler County, Kansas, wreaked havoc on county merchants last June. Salvaging efforts, following an 8-inch-plus rainfall on June 8, were shared by the Kansas bureaus of Food and Drugs, Food Service and Lodging, Water Supply, and Water Quality. State investigators inspected all flood-damaged grocery stores, pharmacies, and warehouses and eventually witnessed the destruction of approximately \$150,000 worth of foods and drugs.

Milk Contaminates Creek

Officials of the New York Department of Environmental Conservation (DEC) approved a new wastewater treatment system proposed by Queens Farms Dairy, Inc., Pierrepont Manor, New York. The system, which will cost \$300,000 to implement, should be more effective than the current system in removing pollutants from the dairy's milk wastes, which are emptied into Bear Creek.

The proposal follows a legal action taken by DEC after the dairy ille-



gally discharged about 250,000 gallons of only partially treated milk wastes into the creek. DEC investigators found that the discharge discolored Bear Creek for about 3

miles below the plant; and Sandy Creek, which Bear Creek empties into, was discolored for another 3 miles below that. Such discoloration violates State water quality standards for turbidity. The dairy admitted the violation and paid a \$2,500 fine.

Shrimp Spoils After Wreck

At daybreak in the Texas Panhandle a cargo of food in a truck, whose driver had been killed in a head-on collision on Highway 54 near Amarillo, was beginning to thaw. The truck, left on the highway



after the accident, was owned by Southwest Truck Services, Oklahoma City. It had been transporting 24,610 cases of frozen shrimp and a quantity of red meat. FDA's Dallas District learned of the accident from Liberty Mutual Insurance Co., Amarillo, Texas, and notified the Texas Health Department and the U.S. Department of Agriculture (USDA). Both agencies sent investigators to see if the products could be salvaged. State officials embargoed the shrimp, which had thawed and was unsafe to eat, and later witnessed the product's burial in an Amarillo sanitary landfill. USDA assumed control of the meat.

State Actions reports on regulatory and administrative actions conducted by State and local government agencies to provide health and economic protection to consumers of foods, drugs, cosmetics, and medical devices.

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 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 21 actions to remove from the consumer market products charged to be violative was reported in September. These actions included 14 of foods: 1 involved a charge concerning a poisonous and deleterious substance, and 13 involved charges concerning contamination. Others included 7 of drugs.

PRODUCT, DISTRICT & DATE FILED	FIRM & PLACE OF BUSINESS	CHARGES
FOOD/Poisonous and Deleterious Substances		
Cottonseed hulls/U.S. District Court for the Eastern District of Arkansas 7/5/79	Prepared from cottonseed shipped from Gila Bend, Ariz.	Contains the added poisonous and deleterious substance aflatoxin.
FOOD/Contamination, Spoilage, Insanitary Handling		
Cat food, and cocoa beans/U.S. District Court for the Western District of New York 6/28/79	Specialized Warehouse Enterprises Corp./Rochester, N.Y.	Held under insanitary conditions; rodent contaminated.
Cheese, chopped, for pizza/U.S. District Court for the Western District of Pennsylvania 6/1/79	Cheese Corp. of America, Inc./Amsterdam, N.Y.	Contaminated with metal fragments, paint chips, and plastic-like particles.
Coffee beans/U.S. District Court for the Northern District of California 7/13/79	Prieto, S.A./San Salvador	Contains extraneous material and poor quality beans.
Coffee beans/U.S. District Court for the Eastern District of Louisiana 7/5/79	Roberts Steamship Agency, Inc./New Orleans, La.	Held under insanitary conditions; rodent contaminated.
Flour, dried milk, rolled wheat, and other foodstocks/U.S. District Court for the Eastern District of Arkansas 6/21/79	Arkansas Food Distribution Division, Arkansas Social Services/North Little Rock, Ark.	"
Guava pulp, canned, and canned guava/U.S. District Court for the District of Puerto Rico 6/25/79	Shipped from Sao Paulo and Santos, Brazil.	Contained in swollen and leaking cans.
Mahi-Mahi fish fillets, frozen/U.S. District Court for the Western District of Washington 7/10/79	Washington Fish & Oyster Co./San Francisco, Calif.	Decomposed.
Raisins/U.S. District Court for the District of the Virgin Islands 5/23/79	Angelitos Bakery/Christiansted, St. Croix, V.I.	Held under insanitary conditions; insect infested.
Rice, sweet rice, sesame seed, and kidney beans/U.S. District Court for the District of Hawaii 6/4/79	Shimaya Shoten, Ltd./Honolulu, Hawaii	Held under insanitary conditions; all articles are rodent contaminated.
Salt/U.S. District Court for the District of Idaho 6/18/79	Idaho Fresh-Pak, Inc./Lewistown, Idaho	Held under insanitary conditions.
Salt, dog food, and other foodstocks/U.S. District Court for the Middle District of North Carolina 6/22/79	Robert J. Tucker Co., Inc./Albermarle, N.C.	Held under insanitary conditions; the dog food contained rodent filth.
Soup mix with oriental noodles, gelatin dessert, and canned papaya slices/U.S. District Court for the District of Puerto Rico 5/16/79	Puerto Rico Supplies, Inc./Puerto Nuevo, P.R.	Soup mix and gelatin dessert mix are rodent and insect contaminated. Papaya is contained in swollen, leaking, and damaged cans; and all goods held under insanitary conditions.
Wheat starch/U.S. District Court for the Northern District of California 7/11/79	Returned from Seattle, Wash., to San Francisco, Calif.	Held under insanitary conditions; rodent contaminated. Label of one lot lacks name and place of business of manufacturer, packer, or distributor.

PRODUCT, DISTRICT & DATE FILED	FIRM & PLACE OF BUSINESS	CHARGES
DRUGS/Human Use		
Hydroxyzine hydrochloride tablets, and hydroxyzine pamoate capsules/U.S. District Court for the Eastern District of New York 5/18/79	Premo Pharmaceutical Laboratories, Inc./ South Hackensack, N.J.	New drugs without effective approved New Drug Applications.
Hydroxyzine pamoate capsules, hydroxyzine HCl tablets, dihydroergocorinne combination sublingual tablets, doxylamine succinate combination tablets, and other drugs/U.S. District Court for the District of New Jersey 5/18/79	"	"
Magnesium sulfate injection/U.S. District Court for the Northern District of California 7/13/79	Pasadena Research Laboratories, Inc./ Pasadena, Calif.	Quality falls below the standard for pH set forth in the U.S. PHARMACOPEIA.
Nitrous oxide liquid/U.S. District Court for the Western District of New York 6/27/79	Liquid Carbonic Corp./West Seneca, N.Y.	Circumstances used for article's processing, packing, and holding not in conformity with current good manufacturing practice.
Scopolamine hydrobromide tablets/U.S. District Court for the Western District of Oklahoma 6/26/79	Buddy Heaton/Texhoma, Okla.	Labeling fails to bear adequate directions for use, and was not exempted.
Spirolactone with hydrochlorothiazide tablets/U.S. District Court for the Eastern District of Pennsylvania 6/29/79	Pharmadyne Laboratories, Inc./Hackensack, N.J.	New drug without an effective approved New Drug Application.
Spirolactone with hydrochlorothiazide tablets/U.S. District Court for the Eastern District of Pennsylvania 6/29/79	Premo Pharmaceutical Laboratories, Inc./ South Hackensack, N.J.	"

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions FOOD/Poisonous and Deleterious Substances

Cottonseed, at Texico, Dist. N. Mex.

Charged 10-20-78: when shipped by Monty Corbin, Gila Bend (Theba), Ariz., the article contained the added poisonous and deleterious substance aflatoxin; 402(a)(1). The article was claimed by Texico Feedlot, Inc., Texico, N. Mex., who denied the charge. The Government served written interrogatories on the claimant. Subsequently, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 61910; S. No. 78-116-394; N.J. No. 1)

Eggs, extra large, at Norfolk, E. Dist. Va.

Charged 8-12-71: when shipped from Durham, N.C., the article contained the added poisonous and deleterious substance polychlorinated biphenyls (approximately 1.42 ppm); 402(a)(1). Default decree ordered destruction. (F.D.C. No. 57368; S. No. 60-627 E; N.J. No. 2)

Feed corn, shelled, at Loxley, S. Dist. Ala.

Charged 8-31-78: when returned from Jacksonville, Fla., to Lapeyrouse Grain Corp., Loxley, Ala., the article contained the poisonous and deleterious substance aflatoxin; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 61879; S. Nos. 78-141-612/3; N.J. No. 3)

Feed for catfish, at Guntersville, N. Dist. Ala.

Charged 8-17-71: when shipped from Memphis, Tenn., the article contained the added poisonous or deleterious substance polychlorinated biphenyls; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 57386; S. No. 16-747 E; N.J. No. 4)

FOOD/Contamination, Spoilage, Insanitary Handling

Beans, canned, at Catano, Dist. P.R.

Charged 12-1-78: while held by the Department of Instruction (School Lunch Division), Catano, P.R., the article was unfit for food, since some cans (2 of 18 examined cans) contained plastic objects; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61977; S. No. 78-147-579; N.J. No. 5)

Chamomile flowers, at Boulder, Dist. Colo.

Charged 3-9-77: while held for sale, the article contained insect, bird, and other filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61106; S. No. 77-79-831; N.J. No. 6)

Chilies, cassia, and coriander, at Brooklyn, E. Dist. N.Y.

Charged 12-15-77: while held by Pittston Warehouse Corp., Brooklyn, N.Y., all of the articles were held under insanitary conditions, and all of the articles (except the coriander) contained mold and insect and/or rodent filth; 402(a)(3), 402(a)(4). Default decree ordered destruction of the lot of cassia, the lot of coriander, and one of the lots of chilies. Consent decree authorized release to various claimants of the remaining lots of chilies. (F.D.C. No. 61489; S. No. 77-140-223 et al.; N.J. No. 7)

Cocoa beans, at Philadelphia, E. Dist. Pa.

Charged 12-14-78: while held by Independent Pier Co., Philadelphia, Pa., the article contained bird filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61992; S. No. 79-169-522; N.J. No. 8)

Cornhusks, Tampico Brand, at Los Angeles, C. Dist. Calif.

Charged 8-4-71: while held for sale, the article contained insect filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 57357; S. No. 90-226 E; N.J. No. 9)

Cumin seed, and celery seed, at Brooklyn, E. Dist. N.Y.

Charged 5-31-78: while held by Held Warehouse & Transport Corp., Brooklyn, N.Y., the articles had been held under insanitary conditions; 402(a)(4). Consent decree authorized release of the cumin seed to B. C. Ireland, Inc., San Francisco, Calif., for salvaging. Consent decree authorized release of the celery seed to Otto Gerdau Co., New York, N.Y., for salvaging. (F.D.C. No. 61765; S. No. 78-146-884; N.J. No. 10)

Dates, pitted, at Chicago, N. Dist. Ill.

Charged 4-2-75: while held by Action Warehouse, Inc., Chicago, Ill., the article contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). At about the time a default decree was entered, Edward F. Devitt, Chicago, Ill., claimed the article. However, the claimant made no appearance or answer; and, subse-

quently, an amended default decree was filed that ordered the condemnation and delivery of the article to FDA for further examination and analysis and for ultimate destruction. (F.D.C. No. 60310; S. No. 98-726 H; N.J. No. 11)

Eggs, frozen, at Brooklyn, E. Dist. N.Y.

Charged 7-30-71: when shipped from Toms River, N.J., the article contained decomposed eggs; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 57346; S. No. 45-131 E; N.J. No. 12)

Flour, at Greenville, N. Dist. Miss.

Charged on or about 6-18-71: while held for sale, the article contained filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 57263; S. No. 23-164 E; N.J. No. 13)

Fruit mixture, dried, at Bayshore, E. Dist. N.Y.

Charged 2-7-79: while held for sale, the article contained mites and human hair; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 62137; S. No. 79-139-788; N.J. No. 14)

Peanuts, at Detroit, E. Dist. Mich.

Charged 8-11-71: while held for sale, the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents statement was not within the bottom 30 percent of the principal display panel area, and the quantity of contents statement was expressed as "2 Pounds," instead of "Net Wt. 32 Ounces (2 Pounds)"; 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i). Default decree authorized donation to a charitable institution. (F.D.C. No. 57361; S. No. 81-614 E; N.J. No. 15)

Pecans, peanuts, and other foodstocks, at Longmont, Dist. Colo.

Charged 4-13-79: while held by Weaver Potato Chip Co., Longmont, Colo., some of the articles contained rodent filth, and all the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 62259; S. No. 79-196-087 et al.; N.J. No. 16)

Peppers, hot, ground, at Bellingham, W. Dist. Wash.

Charged 3-29-79: while held for sale, the article was unfit for food because of being contained in swollen containers; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 62199; S. No. 79-153-030; N.J. No. 17)

Popcorn kernels, at Worcester, Dist. Mass.

Charged 10-30-78: while held for sale, the article contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered constructive destruction by donation to a public zoo for use only as animal feed. (F.D.C. No. 61946; S. No. 79-160-869; N.J. No. 18)

Rice, sugar, flour, and other foodstocks, at Fort Wayne, N. Dist. Ind.

Charged 3-1-79: while held by Quality Foods, Inc., Fort Wayne, Ind., some of the articles contained rodent filth, and all of the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 62163; S. No. 79-198-822; N.J. No. 19)

Rice sticks, and shelled peanuts, at San Francisco, N. Dist. Calif.

Charged 2-5-79: while held by Art's Trading Co., San Francisco, Calif., the articles contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 62140; S. No. 79-150-710; N.J. No. 20)

Salmon, frozen, at Duluth, Dist. Minn.

Charged 2-6-79: while held for sale, the article contained decomposed fish; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 62148; S. No. 79-202-706; N.J. No. 21)

Wheat, durum, at Minneapolis, Dist. Minn.

Charged 7-26-78: when shipped by Bradley Grain Co., Bradley, S. Dak., the articles contained rodent filth; 402(a)(3). Consent decree authorized release to the shipper for salvaging. (F.D.C. No. 61841; S. No. 78-130-215; N.J. No. 22)

FOOD/Economic and Labeling Violations

Cookies, at Midland Park, Dist. N.J.

Charged on or about 10-4-71: when shipped from San Fernando, Calif., the article was in violation of the Fair Packaging and Labeling Act, since the article's labeling lacked a statement of the identity of the commodity on the principal display panel of the article, and the



quantity of contents declaration did not appear on the article's principal display panel; 15 U.S.C. 1453(a)(1), 1453(a)(2). Consent decree authorized release to the claimant for relabeling. (F.D.C. No. 57529; S. No. 83-215 E; N.J. No. 23)

Corn, cream-style, canned, and canned fruit juice, at Fargo, Dist. N. Dak. Charged 9-13-71 and amended 9-24-71: when shipped from St. Paul, Minn., the articles were in violation of the Fair Packaging and Labeling Act, since the quantity of contents declarations were not placed within the bottom 30 percent of the principal display panels in lines generally parallel to the articles' bases; 15 U.S.C. 1453(a)(2). Consent decree authorized release to the shipper for relabeling. (F.D.C. No. 57490; S. Nos. 76-395/6 E; N.J. No. 24)

Margarine, at Buffalo, W. Dist. N.Y. Charged 8-5-77: while held by Wylie Distribution & Warehousing, Inc., Buffalo, N.Y., without refrigeration and with apparent leakage of the article from the packages, the article was short weight; 403(e)(2). The article was claimed by Niagara Frontier Services, Inc., Buffalo, N.Y. A consent decree of condemnation ordered release for salvaging. (F.D.C. No. 61371; S. Nos. 77-96-070/2; N.J. No. 25)

Potato salad, pasteurized, Seidner, at Roxbury, Dist. Mass. Charged 5-11-78: when shipped by Seidner Dressings, Inc., Westerly, R.I., the article was short weight (approximately 5.2 percent); 403(e)(2). Default decree ordered destruction. (F.D.C. No. 61766; S. No. 78-107-193; N.J. No. 26)

Shrimp pieces, breaded, frozen, at Livonia, E. Dist. Mich. Charged 6-16-71: when shipped from St. Simons Island, Ga., the article's labeling was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not within the bottom 30 percent of the principal display area, and since the quantity of contents declaration was expressed as "Net Wt. 1½ lbs." instead of "Net Wt. 24 oz. (1½ lbs.)"; 15 U.S.C. 1453(a)(2), 15 U.S.C. 1453(a)(3)(A)(i). Default decree ordered destruction. (F.D.C. No. 57262; S. No. 13-018 E; N.J. No. 27)

Yogurt, Swiss-style, lemon and strawberry flavors, at Houston, S. Dist. Tex. Charged 7-16-71: when shipped from Springfield, Mo., the articles were in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration on the lids of both articles was not duplicated on the alternate principal display panels on the sides of the packages of the articles—15 U.S.C. 1453(a)(2); and the quantity of contents declaration on the lemon yogurt's package lid was not separated from other printed label information appearing above and below the declaration—15 U.S.C. 1453(a)(2). Default decree ordered destruction. (F.D.C. No. 57236; S. Nos. 70-567/8 E; N.J. No. 28)

DRUGS/Human Use

Androgen combination tablets, two lots, at Hialeah, S. Dist. Fla.

Charged 9-28-78: when shipped by Milkart, Inc., Atlanta, Ga., the articles, labeled in part "Grageas Tonosex . . . Tarmac Products, Inc., Hialeah, Fla.," and "Grageas Sex-Potentia . . . Stuttgart Drug Corp., Hialeah, Fla.," were new drugs without effective approved New Drug Applications—505(a). Default decree ordered destruction. (F.D.C. No. 61828; S. Nos. 78-141-733/4; N.J. No. 29)

Aspirin tablets, buffered analgesic tablets, and other drugstocks, at Jamaica, E. Dist. N.Y.

Charged 12-23-76: when shipped by Davis Manufacturing Co., Inc., Knoxville, Tenn., the circumstances used for the articles' manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; 501(a)(2)(B). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61034; S. No. 77-42-676 et al.; N.J. No. 30)

Aspirin tablets, calamine lotion, isopropyl rubbing alcohol, and other drugstocks, at Linden, Dist. N.J.

Charged 12-14-76: when shipped by Davis Manufacturing Co., Inc., Knoxville, Tenn., the circumstances used for the articles' manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; 501(a)(2)(B). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61033; S. No. 77-36-928 et al.; N.J. No. 31)

Benlyn cough syrup, at Minneapolis, Dist. Minn.

Charged 11-30-76: when shipped by Parke, Davis & Co., Minneap-

olis, Minn., the article was a new drug without an effective approved New Drug Application—505(a); and the article's labeling lacked adequate warnings against unsafe use (e.g., Do not use in patients with: hypersensitivity to components, stenosing peptic ulcer, pyloroduodenal obstruction; do not use in patients receiving monoamine oxidase inhibitors; avoid use with hypnotics, sedatives, and tranquilizers; may inhibit lactation; may, in large quantities, produce convulsions or death or side effects such as confusion, nausea, vomiting, photosensitivity, diarrhea, hemolytic anemia, diplopia, vertigo, insomnia, etc.)—502(f)(2). The shipper appeared specially for the purpose of holding the case in abeyance pending a decision in the U.S. Court of Appeals for the Sixth Circuit in *Parke, Davis & Co. v. Califano*. In accordance with the shipper's motion, the case was held in abeyance. Subsequently, without waiving any defenses or making any admissions, the claimant consented to an order of condemnation that authorized release of the articles to the shipper for relabeling in accordance with the shipper's recall agreement with FDA. (F.D.C. No. 61022; S. No. 77-98-305; N.J. No. 32)

Epsom salt (magnesium sulfate), castor oil, aspirin tablets, and other drugstocks, at Hickory, W. Dist. N.C.

Charged 12-15-76: when shipped by Davis Manufacturing Co., Inc., Knoxville, Tenn., the circumstances of the articles' manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; 501(a)(2)(B). Consent decree authorized release to the shipper for salvaging. (F.D.C. No. 61037; S. No. 77-61-498 et al.; N.J. No. 33)

Mineral oil, isopropyl rubbing alcohol, aspirin, and other drugstocks, at York, M. Dist. Pa.

Charged 12-22-76: when shipped by Davis Manufacturing Co., Inc., Knoxville, Tenn., the circumstances of the articles' manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; 501(a)(2)(B). Consent decree authorized release to the shipper for salvaging. (F.D.C. No. 61035; S. No. 77-44-991 et al.; N.J. No. 34)

Spirolactone with hydrochlorothiazide tablets, at New Britain, Dist. Conn.

Charged 1-3-79: when shipped by Premo Pharmaceutical Laboratories, Inc., South Hackensack, 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. 62076; S. No. 79-188-984; N.J. No. 35)

DRUGS/Veterinary

Super Speed Anemiaban liver & iron vitamin solution, Codesine Gel for horses, Iron Cacodylate for horses, and Pepto-Liv iron and copper injectable, at Charlestown, N. Dist. W. Va.

Charged 6-17-71: when shipped from El Monte, Calif., the articles were new animal drugs, and no approval of a New Animal Drug Application was in effect with respect to the use and intended use of such drugs—501(a)(5); the labeling of the Anemiaban solution, the Iron Cacodylate, and the Pepto-Liv contained false and misleading claims as follows: false and misleading claims for Anemiaban, for use in horses, for vitamin B complex deficiencies and iron deficiency anemia, and for acting at super speed; and false and misleading claims for Iron Cacodylate for anemia in horses due to iron deficiency—502(a). Consent decree ordered destruction. (F.D.C. No. 57256; S. Nos. 6-986/9; N.J. No. 36)

MEDICAL DEVICE

Inhalator, steam-vapor, Respirizer, inhalator components, inhalator menthol-camphor- & -petrolatum medicament, and medicament components, at Gettysburg, M. Dist. Pa.

Charged 7-11-78: while held by Campillary Systems, Inc., Gettysburg, Pa., who was assembling the inhalator devices and the inhalator medicament using interstate components, the device carton label and accompanying brochures entitled "New Discovery - Sub-micron H₂O/ particles Respirizer . . . Relief and Therapy" and "Respirizer . . . Instructions For Use" contained false and misleading claims for emphysema, asthma, allergies, sinusitis, bronchitis, colds, flu, migraine and sinusitis headaches; for instant relief; for relief to thousands who do not respond to other medical therapeutic devices or drugs and those affected by environmental air pollution; for protecting health;



for promptly relieving airway resistance due to respiratory congestion by producing an atmosphere of 100 percent humidity for direct inhalation; for doing away with sinusitis headaches within 10 minutes; for liquifying mucus so that it can be expelled; for providing a specially formulated antibacterial decongestant which converts into a gas resulting in dilation and mucociliary clearance of heavily congested passages; for providing the only known means of humidifying sinuses, respiratory tract, and lungs; that breathing the steam at a comfortable temperature resulted in the complete saturation of tissues; that 5 to 15 minutes of treatment diluted irritants due to air pollution and cleared congestion; that smokers and sufferers of respiratory ailments such as bronchitis, sinusitis, asthma, allergies, emphysema, and colds benefited from use of the device; that the Respirizer was the first and only product of its kind producing distilled steam vapor of submicron particles which remained airborne and could moisten tissues throughout the pulmonary system; that the design was unique because it washed out air impurities; that the device delivered a premeasured dosage of medicament; and that the device had been approved by the Food and Drug Administration—502(a); the device labeling lacked adequate directions for use for its intended purposes and lacked adequate information for use by licensed practitioners for its intended purposes—502(f)(1); and the circumstances used for the drugs' manufacture, processing, and packing failed to conform with current good manufacturing practice—501(a)(2)(B). Consent decree authorized release to the dealer for relabeling. (F.D.C. No. 61825; S. Nos. 78-142-874/5; N.J. No. 37)

COSMETIC/BEAUTY PRODUCT

Toothpicks, cinnamon-flavored, at Hattiesburg, S. Dist. Miss.

Charged 8-3-71: when shipped from McCook, Nebr., the article contained the added poisonous or deleterious substance cinnamaldehyde (approximately 20 percent), which might render the article injurious to users under customary or usual conditions of use; 601(a). Default decree ordered destruction. (F.D.C. No. 57355; S. No. 753 E; N.J. No. 38)

NOTICE OF JUDGMENT on Injunction Action

Torigian Laboratories, Inc., Puzant C. Torigian, president, and **Navin S. Dave**, quality control director, Queens Village, E. Dist. N.Y.

Charged 12-27-76 in complaint for injunction: that the defendants had been engaged—at their Queens Village, N.Y., plant—in manufacturing, processing, packing, labeling, holding, and distributing in interstate commerce various parenteral drugs which purported to be sterile and which were intended for injection into the body; that the defendants similarly processed, packed, labeled, and distributed in interstate commerce intraocular lenses, which purported to be sterile and which were intended for implantation into the eye to replace cataract-damaged human lenses; that the parenteral drugs had been manufactured, processed, packed, and held under circumstances that failed to conform with current good manufacturing practice; that the intraocular lenses had been prepared, packed, and held under insanitary conditions whereby they might have been rendered injurious to health; that the quality and purity of some of the intraocular lenses fell below their purported quality and purity, their label statement "sterile" was false and misleading since the devices were not sterile, and the devices were dangerous to health when used as directed in their labeling; that FDA inspections revealed a number of inadequacies relating to sterility procedures, recordkeeping, the building, equipment, and the handling of components; that the defendants were well aware that their drug operations were in violation of the law; that their processing of intraocular lenses resulted in injuries to patients; and that, accordingly, the defendants should be enjoined; 501(a)(2)(A), 501(a)(2)(B), 501(c), 502(a), 502(j).

A consent decree of permanent injunction enjoined the complained of violations, and enjoined the defendants' interstate operations unless and until a number of specified conditions were met. (Inj. No. 760; S. No. 77-88-979 et al.; N.J. No. 39)

NOTICE OF JUDGMENT on Miscellaneous Action

Turtle eggs and small turtles, ban on their commercial distribution, and suit for declaratory judgment and pre-enforcement injunction, Baton Rouge, E. Dist. La.

Charged 6-24-75 by the State of Louisiana, through the Department of Commerce & Industry, for and on behalf of the National Turtle Farmers & Shippers Association, Inc., Schriver, La., the association president John L. Haydel and two turtle farmers and shippers, Ralph Boudreaux, Ponchatoula, La., and Edward Alleman, Pierre Part, La., against HEW Secretary Caspar W. Weinberger and FDA Commissioner Alexander M. Schmidt: that FDA regulations had previously required that pet turtles shipped in interstate commerce be tested for and certified free of *Salmonella* and *Arizona* organisms; that the FDA Commissioner had realized that such certification program was not preventing contaminated turtles from reaching the market; that FDA published two proposals as possible solutions: first, a complete ban on the sale and distribution of small turtles; and, second, improvement of the certification scheme with the imposition of additional requirements on the sale and shipment of turtles; that the National Turtle Farmers & Shippers Association, Inc., and others had an informal hearing with FDA opposing the ban, had informally met with FDA concerning the status of the proposed ban, had submitted a proposal to FDA for a new and improved scheme to keep contaminated small turtles off the market, and had petitioned for a stay; that plaintiffs sought a pre-enforcement injunction against FDA prohibiting enforcement of the ban and a declaratory judgment that it was null and void, because it was an unconstitutional deprivation of property, because farming and shipping small turtles was a million dollar industry primarily located in Louisiana and the FDA regulation would cause the turtle farmers to discontinue their calling and livelihood, and because the FDA order was arbitrary and capricious, was a denial of equal protection of the laws, and was contrary to the evidence.

The Government admitted the existence of the ban but denied the other allegations. The Government also moved to dismiss the State of Louisiana, for lack of standing.

The court denied that motion, saying:

"The State of Louisiana, for and on behalf of the National Turtle Farmers and Shippers Association, Inc., John L. Haydel, president of the association, and two individual turtle farmers have brought suit against the Secretary of HEW and the Commissioner of Food and Drugs Administration. The plaintiffs are seeking a declaratory judgment as to the validity of a regulation promulgated by the Commissioner and published in 40 FEDERAL REGISTER 22545. This rule became effective on June 23, 1975. This regulation amended Section 1240.64 of Title 21 of the CODE OF FEDERAL REGULATIONS and it effectively bans the sale and distribution of small turtles.

"Plaintiffs allege that the farming and shipping of turtles is a million dollar industry located mainly in Louisiana. They allege that the above regulations will force the farmers and shippers of small turtles to discontinue their livelihood. Louisiana contends that the regulation will deprive the State of a viable revenue generating industry. The Association maintains that it will cease to exist if the regulation is upheld.

"This matter is currently before the court on defendant's motion to dismiss the State of Louisiana, through the Department of Commerce and Industry, for and on behalf of the National Turtle Farmers and Shippers Association, Inc., for lack of standing.

"The question of standing must be considered in light of Article III of the Constitution which restricts the judicial power to actual 'cases' and 'controversies.' . . . 'The gist of the question of standing is whether the party seeking relief has alleged such a personal stake in the outcome of the controversy as to assure that concrete adverseness which sharpens the presentation of issues upon which the court so largely depends for illumination of difficult . . . questions.'

"Standing under 5 U.S.C. § 702 only exists in those who allege that the Secretary's regulation will cause them injury in fact and that this injury will be to an interest arguably within the zone of interests to be protected or regulated by the regulation in question. . . . The interest alleged to have been injured includes economic values. . . . It is sufficient if this interest is no more than an 'identifiable trifle.' . . . Moreover, an organization whose members are injured is entitled to represent them in an action seeking judicial review. . . .

"The plaintiffs have alleged that they will at least suffer economic injury if they follow these regulations. A failure to abide by them could lead to the imposition of strong sanctions. Upon application of the above principles it seems clear that the plaintiffs have the requisite standing to pursue the matter. They have sufficiently alleged that they were 'adversely affected' or 'aggrieved' within the meaning of 5 U.S.C. § 702 to withstand defendant's motion to dismiss. Accordingly, de-



fendant's motion to dismiss for lack of standing to sue should be, and it is, denied."

Subsequently, the Government moved to dismiss the action or, in the alternative, moved for summary judgment. After a hearing before the court, the court found in favor of the Government and dismissed the action, saying:

"This matter came on for hearing on a former day on motion of the defendants to dismiss the complaint for failure to state a claim upon which relief can be granted or for summary judgment, at which time the Court took the matter under advisement. After due consideration of the argument and memoranda of counsel, the record, and the law, the Court finds as follows:

"This is an action for review of the final regulation of the Food and Drug Administration [42 CFR § 1240.62] banning the sale and distribution of small turtles pursuant to authority conferred by Section 361 of the Public Health Service Act, 42 U.S.C. § 264. Plaintiffs, the State of Louisiana, for and on behalf of the National Turtle Farmers and Shippers Association, Inc., the president of the association and two turtle farmers, seek a declaratory judgment and injunctive relief with respect to the regulation.

"Plaintiffs contend that the regulation in question exceeds the authority granted to defendants by Section 361 of the Public Health Service Act; that it was arbitrary and capricious; that it was issued in violation of the provisions of the Administrative Procedures Act; and that it denies plaintiffs equal protection of the laws. Each of these contentions will be discussed in turn.

"Judicial review of this action is made pursuant to Section 10 of the Administrative Procedure Act, 5 U.S.C. §§ 701-706. Under that statute, the scope of judicial review is limited to whether the defendants have acted arbitrarily, capriciously, in abuse of their discretion or otherwise unlawfully. In applying this standard, it is the function of the Court to look only at the administrative record upon which the defendants made their decision. . . . As stated by the Court in *Bradley v. Weinberger*, 483 F.2d 410, 415 (1st Cir. 1973): ' . . . it is a re-view, a second look at the same material, not a re-doing.' Moreover, it is clear that the questioned regulation 'is ripe for summary disposition, for whether the order is supported by sufficient evidence . . . or is otherwise legally assailable, involves matter[s] of law.' . . .

I.

"Plaintiffs have contended that the ban on the commercial sale of small turtles exceeds the defendants' authority under 42 U.S.C. § 264. Particularly plaintiffs argue that only those individual lots of small turtles infected with *Salmonella* and *Arizona* organisms and which have been shown to be health hazards may be banned; that the questioned regulation exceeds the authority granted because it authorizes the apprehension and detention, by penal sanctions, of individuals; and that defendants are authorized to prohibit only the interstate shipment of turtles which may spread communicable disease.

"Congress has granted broad, flexible powers to Federal health authorities who must use their judgment in attempting to protect the public against the spread of communicable disease. Studies show that a large percentage of turtles certified as organism-free are eventually recontaminated. One survey showed a 54 percent recontamination rate; other figures suggest incidence of recontamination which is higher. . . . Under these circumstances, it is clear that the law does not require the adoption of an onerous testing scheme under which every turtle, or lot of turtles, is to be tested every week so as to find that percent which becomes reinfected. Such a testing alternative is patently unreasonable, and a total ban is permissible as necessary to prevent the spread of communicable disease.

"Plaintiffs' contention that the provisions of the questioned regulation violate 42 U.S.C. § 264(b) because it authorizes the apprehension and detention of individuals is incorrect. The regulation does not authorize the apprehension and detention of individuals; neither does it set criminal penalties for those who violate the provisions of the regulation. Section 368(a) of the Public Health Service Act, 42 U.S.C. § 271(a), makes any violation of a regulation issued under 42 U.S.C. § 264 a crime. The regulation's provisions discussing penal sanctions are not substantive, but are designed only to give those affected by the regulation notice that sanctions may be imposed in the case of violation.

"Plaintiffs also contend that defendants exceeded their authority under 42 U.S.C. § 264 by restricting commercial activity with respect to small turtles and turtle eggs. It has long been established that businesses which affect interstate commerce may have their intrastate activities regulated. . . . Reference to subsection (d) of 42 U.S.C. § 264 confirms the defendants' authority to regulate intrastate activity. . . . Thus, the intrastate ban is not only authorized by the law, but,

under modern conditions of transportation and commerce, is clearly reasonable to prevent the interstate spread of disease.

II.

"Plaintiffs contend that the questioned regulation is arbitrary, capricious, and lacking a rational basis because, in their view, there is evidence in the administrative record that organism-free turtles can be produced. Plaintiffs also contend that a new certification scheme would prevent contaminated turtles from reaching the public. To support this contention, plaintiffs point to studies made by Dr. R. J. Siebeling, Associate Professor of Microbiology at Louisiana State University. Dr. Siebeling himself admits in the final two paragraphs of his paper, 'Evaluation of Methods for the Isolation of *Salmonella* and *Arizona* organisms from Pet Turtles Treated with Antimicrobial Agents,' that treated turtles may still be carrying organisms, that the treatment could result in the production of antibiotic resistant organisms, a serious health hazard in itself, and that laboratory findings may have no commercial application. It should also be noted that the paper does not purport to address the problem of recontamination after certification. Considering the administrative record as a whole, defendants properly found that this research was not adequate to permit a finding that certification would prevent the interstate transmission of disease.

"The Court appreciates the progressive nature of science, and realizes that Dr. Siebeling's research has resulted in considerable advancement in this field. The FEDERAL REGISTER order promulgating the regulation recognizes that Dr. Siebeling's work may one day result in a method by which disease-free turtles can be marketed, and evidences a willingness to reconsider the ban on turtles at that time. . . . However, until such time as that evidence is developed, the defendants' finding that there is a lack of evidence which 'demonstrates that an improved certification scheme would result in a *Salmonella*- and *Arizona*-free turtle that will remain free of these organisms in commerce' is not arbitrary and capricious.

III.

"Plaintiffs attack the regulation on the ground that defendants prejudged the issues involved and failed to properly consider and comment upon material submitted by plaintiffs. Section 4 of the Administrative Procedure Act specifically provides that in rulemaking proceedings of this type, an opportunity for the submission of written comments is sufficient and no opportunity for oral presentation is required. . . . Here plaintiffs availed themselves of the opportunity to participate and their written comments were given ample consideration. No more is required under the Act. The record does not reflect that defendants had already decided to ban turtles at the time they published their proposal for comment. . . . The defendants' response to the comments received shows that the questioned regulation was not promulgated in an arbitrary or capricious manner. . . .

IV.

"Plaintiffs contend that the regulation banning turtles is discriminatory because other regulations ban only certain lather brushes . . . and Psittacine birds . . . which have been found to be disease carriers. This argument fails to take into account the particular facts and circumstances underlying the ban on turtles. The regulations applicable to lather brushes and Psittacine birds and similar regulations are based upon a judgment that a total ban is not necessary to insure that the articles sold are free of disease. As the administrative record reflects, such a judgment is not possible in this case at this time.

"Considering the foregoing, the motion of defendants to dismiss and in the alternative for summary judgment is hereby granted, and plaintiffs' suit is hereby dismissed, with prejudice, each party to bear its own costs." (Misc. No. 354; N.J. No. 40)

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, HEW.

Published by direction of the Secretary of Health, Education, and Welfare.

Jere E. Goyan, *Commissioner of Food and Drugs*
Washington, D.C., November 1, 1979



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