Drugs and Medical Devices

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The medical program of the Food and Drug Administration is concerned primarily with assuring the safety of drugs and medical devices to protect public health as provided by law. Secondarily, it advises the Commissioner's Office and the other scientific and administrative programs of FDA on medical matters.

The major elements of the medical program may be characterized by the words "Stop, look, and listen." As provided by law and regulation, FDA attempts to stop the violator; it looks at new drug applications and medical investigative data; and it listens to what is going on generally in the drug and device industries so that proper preventive or remedial action can be instituted when necessary.

The objective of the Federal Food, Drug, and Cosmetic Act with respect to drugs is to assure the safety, quality, purity, and identity of all drug products in interstate commerce, thereby fulfilling the ultimate objective of protecting the public health. Drugs imported into this country are subject to the same scrutiny and legal requirements.

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Actually, all aspects of the medical program are geared to one key word—safety. Purity, quality, identity, and labeling, including therapeutic claims, must all measure up to the requirements imposed by the reasonable application of the concept of safety.

It is perhaps of significance that the original Federal food and drug legislation, the Food and Drugs Act of 1906, was conceived and enacted by the Congress at the behest of a physician, Dr. Harvey W. Wiley, who was at the time chief chemist of the Department of Agriculture. The Food and Drug Administration, therefore, has a medical heritage of which it can well be proud and which clearly establishes it, both historically and for the future, as a public health agency of government.

Responsibilities and Functions

The New Drug Branch of the Division of Medicine bears the responsibility for reviewing new drug applications in detail, interpreting the investigative data, and permitting or denying the introduction of a new drug into interstate commerce. Its task is one that requires the exercise of the highest degree of good judgment and medical acumen. It is one thing to assess the investigative results obtained by a few medical experts in carefully selected patients under controlled conditions; it is quite another to extrapolate that data to nationwide use—perhaps indiscriminate use by some physicians or by the public if the drug is one that may legally be sold without a prescription.

The Veterinary Medical Branch has the same purview of new drugs for animal use as does

the New Drug Branch of drugs for human use. In addition, it has a regulatory or enforcement function for all veterinary medicinals, be they old or new drugs.

The Drug and Device Branch works primarily to obtain compliance with, and enforcement of, the law with respect to the safety and adequacy of labeling of drugs and medical devices in interstate commerce. But to apply scientific judgment in a court of law entails peculiar difficulties. Medicine at its best is still far from being an exact science. Biological variation and biological response in the subject, as well as variations of interpretation by the investigator, frequently preclude satisfactory quantitation. The art and the science are not always clearly distinguishable, and opinion and fact are not always readily separable. That this is true becomes evident when FDA resorts to legal measures to achieve enforcement and control. Honest admission of uncertainty by a scientific witness may too often strike a jury as "reasonable doubt" as to the guilt of the defendant. To reach a bona fide medical conclusion is one thing; to prove it beyond reasonable doubt in a court of law is quite another.

One important aspect of assuring the safety of drugs and devices is preventing misbranding. The legal definition of misbranding has many facets. Those readers who are responsible for enforcing parallel State laws know them well; for others, a few basic concepts that illustrate the philosophy of the law may be mentioned here.

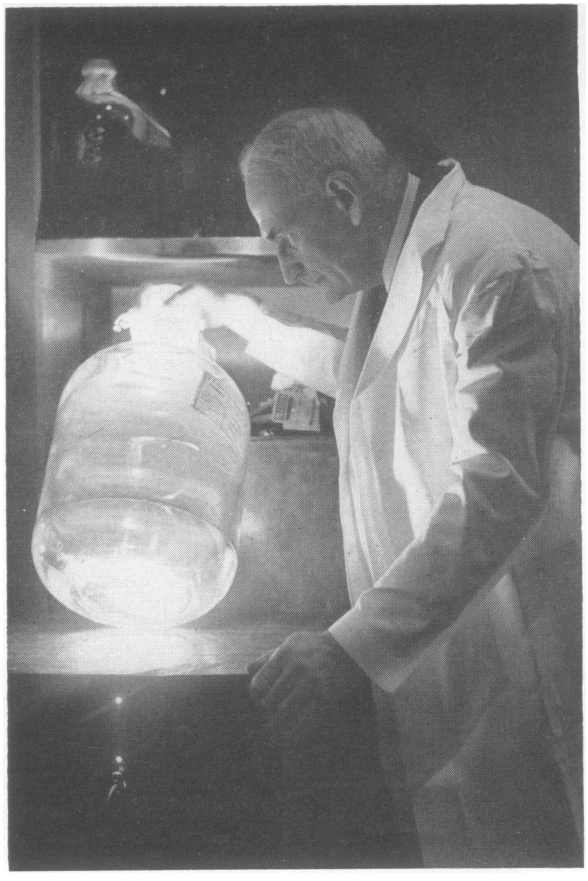
A drug or device is deemed to be misbranded:

1. If its labeling is false or misleading in any particular.

2. If, in finished or bulk package form, it fails to bear a label giving the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of contents.

3. If any word, statement, or other information required under the authority of the act to appear on the label or labeling is not displayed with such conspicuousness and in such terms as to make it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

4. Unless its labeling bears adequate directions for use, adequate warnings against use in pathological conditions or by children when such use may be dangerous to health, and adequate warnings against unsafe dosage or methods or duration of administration or application. This does not, however, apply to household chemicals except those specifically covered in the Federal Caustic Poison Act. Under the Federal Food, Drug, and Cosmetic Act all drugs are subject to this requirement.



FDA inspector in the stock room of a drug factory producing injectables. The bulk solutions are examined for undissolved particles before they are packed and sealed in ampules.

From the foregoing it is apparent that the food and drug legislation is designed to inform and protect the user of drugs or devices whether he be a physician or a patient. While the law is designed to protect, it is well also to recognize its limitations. The Federal Food, Drug, and Cosmetic Act applies only to the content and labeling of products shipped in interstate commerce. The Food and Drug Ad-

ministration, therefore, is not responsible for advertising, which is regulated by the Federal Trade Commission. FDA does, however, cooperate with the Federal Trade Commission, usually by making, at its request, laboratory studies of products in question. In addition, FDA provides the medical support for fraud cases brought by the Post Office Department.

Techniques of Control

To carry out the provisions of the law, the Food and Drug Administration employs many techniques. It maintains a nationwide inspection staff of approximately 250 men who devote their time to food and drug inspections in all channels of distribution from manufacturer to the ultimate distributor. It also maintains a series of field laboratories where samples of drugs are analyzed.

FDA is in continuing contact with all segments of the drug trade and with the medical profession. It is now in the process of enlarging its file of reports on injuries from drugs and household chemicals. The Research and Reference Branch of the Division of Medicine is interested in all types of drug injuries or suspected injuries whether they culminate in death, blood dyscrasias, sensitivity reactions, or other toxic manifestations. Often it is only by slowly and painfully piecing together the puzzle that a significant pattern is found. FDA must and does maintain constant surveillance of the medical literature and medical reports, as well as its incoming mail. Recently, the medical staff has had occasion to work with those interested in the operation of poison control centers throughout the country.

Public health officials can be of great assistance to the Food and Drug Administration in providing the protection which the law intends and which so many people take for granted. For example, health officers often are in a position to supply information about the business of a cancer quack, about medical devices which may not meet the requirements of the law, or about injuries caused by drugs.

About a cancer quack, FDA needs to know such things as how he is operating his racket, the names of his patients, when his patients die, and findings of autopsies.

About medical devices, FDA needs to know: When and where are they sold and used and by whom? What claims are made for them? Is an interstate shipment involved? Is there label copy or descriptive literature available?

An immediate report of a drug injury or a suspected injury containing all the facts available is of utmost importance. What was the drug used? How was it administered? By whom? What dosage was employed? What is the name of the manufacturer? of the patient? of the physician? Too frequently FDA does not hear of adverse experiences with drugs until months after they occur, when the details crucial to intelligent interpretation have been forgotten or are no longer available.

To protect the public against adulterated or misbranded medicines, as provided by law, the Food and Drug Administration needs the assistance of all persons who are concerned with health, whether they be physicians in private practice, officials of government agencies, or members of the drug and device industries. It also needs the understanding and cooperation of an informed public.