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Advertised-Product Liability: Federal Food, Drug, and Cosmetic Act—20 Years of Health Protection

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TWENTY years of major public health protection have been provided since enactment of the Federal Food, Drug, and Cosmetic Act of 1938. The Food and Drug Administration, a constituent of the United States Department of Health, Education, and Welfare, enforces this Act and thereby carries out the purpose of Congress to insure that foods are safe, pure, and wholesome, and made under sanitary conditions; drugs and therapeutic devices are safe and effective for their intended uses; cosmetics are safe and prepared from appropriate ingredients; and that all of these products are honestly and informatively labeled and packaged. Man and animals are provided for in this law.

FDA also enforces the Caustic Poison Act, The Filled Milk Act, the Import Milk Act, and the Tea Act. These several statutes have also been of value in protecting the public.

The Caustic Poison Act requires poison warnings and antidotes on the labeling of twelve caustic and corrosive substances. The Filled Milk Act prohibits the substitution of the butter fat content with other fat except for special dietary products. The Import Milk Act prohibits the importation of milk into the United States except from sources that have been approved either through our inspection facilities or by arrangement with the health authorities of the country of origin. The Tea Act prohibits the importation of tea into the United States except that which has been examined and passed by a Government tea examiner.

The Federal Food and Drugs Act of 1906, popularly referred to as the Wiley "Pure Food Law," was one of the first of a number of statutes designed to regulate interstate commerce. It set forth the rules of conduct producers were to observe in order to enjoy the benefits of interstate commerce in foods and drugs. This pioneer legislation was superseded by the Food, Drug, and Cosmetic law of 1938.

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The importance that the Federal Food, Drug, and Cosmetic Act has in our national life and the character of the legal problems arising under it, received growing recognition in the years following World War II. First, the New York State Bar Association, then the American Bar Association, established a section devoted exclusively to food and drug problems and the promotion of education in this field, for undergraduates, graduates, and practicing attorneys. In 1949 the Food Law Institute was established to implement their educational and research objectives.

Concurrent with the legal developments over the past two decades, medical practice has rapidly improved through the introduction of many new therapeutic agents and procedures. The pharmaceutical industry in its keen awareness of the physician's need has energetically developed new drugs in an unprecedented manner to supply many chemotherapeutic agents to improve the practice of medicine. The Federal Government has actively participated in many ways to encourage these important developments to give this nation an abundant supply of effective and safe drugs. During the same period there have been many new developments in the food and cosmetic industries.

Foods

The public is seeking more and more to have food conveniently prepared, diversified in nature, and in better packages. Industrial scientists must use a wide variety of substances formerly not used in foods in order to meet these demands. In the development of these newer foodstuffs, the chance for error is apparent. Both industry and the Government must be on the alert to prevent the introduction of substances which may be detrimental to the consumer. While no food known to be injurious is being marketed today, authority is needed to insure the safety of products containing new chemical additives. There is presently pending before the Congress proposed legislation that would require the pretesting for safety of chemical additives to food. This is an important piece of legislation which is needed to close a major gap in the present law. At present a manufacturer may use a new additive without first establishing its safety. Of course, if the Government eventually establishes that the substance is unsuitable for such use, there is adequate authority under the law to force discontinuance of its use in foods

shipped in interstate commerce, and for taking action against the careless manufacturer. However, it takes time to develop the data to establish the safety of many additives, and under the present law, this use can go unchecked for considerable periods. Under the proposed legislation, which the Food and Drug Administration strongly favors, it would be illegal to use an additive without first establishing through a procedure provided by law that the substance is in fact safe for its intended use. Avoidance of potential health hazards from our food supply is a grave concern of FDA.

In cooperation with the United States Department of Agriculture and the National Milk Producers Federation an intensive program has been undertaken to eliminate antibiotics and pesticide residues from the milk supply.

On July 22, 1956, The Pesticide Chemicals Amendment became fully effective. This assures that only safe quantities of pesticides can be used on raw agricultural commodities. Since 1954 when the amendment was enacted over 1,450 tolerances or exemptions have been established for 87 pesticide chemicals.

A fundamental program of FDA is the establishment of food standards. The adducing of facts to support food standards and establishing the public hearing record, on which the standards had to be based, developed into a very cumbersome, time-consuming and expensive process for Government and industry alike. In 1954, Congress passed unanimously the "Hale Amendment" sponsored by the Food, Drug, and Cosmetic Law Section of the New York Bar Association and endorsed by food manufacturers and the Secretary of the Department of Health, Education, and Welfare. Under the new program, proposals and orders are published and may become effective without hearing unless some one files objections and requests a public hearing. Only those issues set up by written objection to the proposal must be heard.

The sanitation of our food supply is a long recognized essential to good health. With the development of processed convenience foods, utilizing complex methods, constant vigilance in their preparation is needed to preclude opportunity for contamination.

Debasement or sophistication of foods is prohibited under the Act; substandard and short weight products are also illegal. These are regarded fundamentally as economic violations.

In the instance of special dietary foods, special labeling requirements are required to provide information dealing with vitamin and mineral content and other dietary properties. The minimum daily dietary requirements of vitamins and minerals in human nutrition were established at public hearings and the labeling of products containing certain vitamins and minerals is set forth in the regulations. An important dietary food group recently covered by regulations consists of items of low sodium content. They must be labeled with the amount of sodium in 100 grams of the food and in an average serving. This is a public health protection for those whose sodium intake must be restricted.

The representations made for foods must be truthful. The blatant representations made for simple nutritional adjuncts, both written and oral, for the prevention and cure of serious diseases have served as the bases for numerous court cases. In June 1957 the Supreme Court denied certiorari in two important cases involving health claims made for "health foods." FDA charged that such claims made these articles drugs and resulted in their being misbranded since they failed to bear adequate directions for use for the conditions described by their promoters. Both claimants argued that the legal issue involved was false advertising which is not controlled by the Act. Having lost their appeals, both were sent to the penitentiary, amidst lengthy protests of their followers. The problem of quackery and its eradication in the field of nutrition is a major public health matter, just as it is in the general field of medicine. There is need for an extensive public education program to expose the health quacks as well as to combat ignorance of what constitutes food nutrition.

Drugs and Devices

The Act regulates the labeling of drugs and devices with respect to adulteration and misbranding in a manner parallel to foods. Drugs and devices must conform with the strength, purity or quality which they purport or are required through official compendia (such as the U. S. Pharmacopeia and National Formulary) to possess. Their labeling must be truthful. False or misleading therapeutic claims made for a drug or device are violative and constitute a major problem frequently necessitating regulatory action under Section 502 (a) of the Act. All

written, printed and graphic matter used to promote the sale of the drug or device, whether in the retail package or distributed separately, must avoid any false or misleading statement regarding the composition of the article or the effects produced.

Required Labeling Information

The labeling must state the name and address of the manufacturer, packer or distributor, and also a statement of quantity of contents.

The label of non-official drugs must list each active ingredient by its common or usual name, and if alcohol is present, it must be declared as to the quantity, kind and proportion contained. Whether present as an active ingredient or not, a declaration must be made of the name and quantity or proportion of any bromide, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, atropine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivatives of these drugs.

If the article contains any of a list of narcotic or hypnotic substances, or any derivative of such substance which has been found to be and by regulations designated as habit-forming, the label must carry the statement: "WARNING—May be habit-forming." The declaration must be in juxtaposition to the quantitative declaration of the drug. Section 502(d) of the Act names in this group alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulfonmethane.

Adequate directions for use are required to be provided in the labeling of drugs and devices. In the case of articles sold for lay use, proper indications for administration must appear and adequate directions for such uses must be supplied. Drugs which can be safely used only under the supervision of physicians or dentists must bear the statement: "CAUTION: Federal law prohibits dispensing without prescription." When this exemption is used, the drug label must also provide the recommended or usual dosage, the route of administration, if not for oral use, and the quantity and proportion of each active ingredient. If not for oral use, the names of all other ingredients must also be given to inform the professional user fully. With prescription

drugs, informative medical brochures are made available setting forth detailed technical and clinical information relating to the use of the article. For new drugs descriptive circulars are required to be submitted for critical review before the drug can be released. This requirement serves to insure that the physician will have accurate information to enable his safe and effective use of the drug.

Potent drugs which may not be sold legally without prescription may not be refilled without authorization from the prescriber. It should be emphasized that this restriction to sell only on prescription applies not only to those drugs which are toxic or habit-forming, per se, but also to any drug, even though it may be comparatively innocuous, if the only rational use of the drug is in a condition which a layman could not reasonably be expected to diagnose and treat for himself.

This section of the law deserves the particular attention of the physician because of its intimate connection with the physician-pharmacist-patient relationship. The public generally is not yet adequately informed about the public health reasons for restricting many of these drugs to prescription sale, and the cooperation of the physician and pharmacist is needed to prevent misunderstanding and ill will.

It should be clearly understood that the physician can authorize refilling of his prescription as many times or for as long a time as he feels necessary or desirable. He can do that by noting on the original prescription or by subsequent written or telephoned authorization to the pharmacist. A word of caution is in order regarding the "ad lib" type of refill authorization which makes a prescription refillable at the request of the patient for an unlimited time. The practical reason for objecting to such a refill authorization is that it is subject to abuse, and in our experience, is too often abused.

Another major health safeguard achieved through labeling is the requirement that adequate warnings against unsafe use to protect users be set forth in the labeling under section 502 (f) (2) of the Act. Upon request, FDA will supply information concerning suggested warning statements required for certain articles.

The article must not be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended or suggested in its labeling.

Illegal Sales of Drugs

In 1957, of 114 drug prosecution cases filed, 100 were based on violative sales of prescription drugs. FDA investigations began after complaints were received from law-enforcement officials, physicians, social workers, and families of persons being injured by the drugs.

In the 105 cases terminated in 1957, 145 individuals were convicted on their own pleas or by the courts. In about 10 percent of the cases the defendants were persons with no professional training who sold the drugs at truck stops, general stores, or through peddling. Seven individuals, some of them previous offenders, were sentenced to serve jail sentences ranging from 2 months to a year. On others, suspended jail sentences, probation periods, and fines were imposed.

The determination of the legality of the dispensing of a drug by a physician depends in full measure on whether or not there is a bona fide doctor-patient relationship. A recent case decided in favor of the Government involved a physician who dispensed potent drugs without prescription and without an established doctor-patient relationship; his conviction was upheld by the Court of Appeals for the Fifth Circuit.

Drug Adulteration

FDA's attention to drugs which become adulterated is of major public health importance, in view of the dangerous effects which arise from administration of a potent drug which may be contaminated or substituted in whole or in part by another potent substance. An error in drug compounding may result in a fatality.

Certification Services

FDA conducts several pre-distribution certification services. Coal-tar dyes used in foods, drugs, and cosmetics for interstate distribution must be from batches which have been certified as harmless and suitable for intended use. In recent years advanced pharmacological methods have shown that some of the colors which were being certified were not free of toxicity. Accordingly, steps were taken to remove them from the list of certifiable colors. This resulted in litigation over the question of whether the Secretary of Health, Education, and Welfare had the authority under the law to establish safe tolerances for those colors which were not safe in unlimited amounts. The

Government contended that no such authority exists. The opposition argued to the contrary. Two conflicting circuit court opinions resulted. The matter is presently before The Supreme Court of the United States.

Insulin and drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, and bacitracin or any of their derivatives are also subject to certification procedures through laboratory testing and labeling review before distribution. Each batch must be certified as complying with the fixed standards.

New Drugs

From a public health standpoint, the new drug provisions of the Act are constructive and an important contribution to the safe use of drugs. Legally no new drug may be introduced into interstate commerce except for investigational use by qualified researchers unless an application giving full reports of all investigations, both experimental and clinical, the composition, methods and controls of manufacture and proposed labeling for the drug are submitted in a formal application to FDA to establish its safety.

Since 1938, over 11,000 new drug applications have been submitted to FDA. In addition many thousands of supplements to original applications have been cleared. Pharmacologists and physicians play major roles in the development of new drugs since they perform the necessary animal and clinical studies to determine the safety of the drug. Their reports are submitted by the manufacturer. It is essential that such reports be complete and detail the full investigational experience.

The new drug regulations were rewritten and became effective August 24, 1956. Subsequently a portion of the regulations dealing with investigational drugs was revised to remove the requirements that shippers of new radioactive drugs obtain signed statements from investigators when the consignee has been licensed by the Atomic Energy Commission.

Enforcement Procedures

Under the Act, misbranded or adulterated goods may be seized, the responsible persons may be prosecuted, or enjoined from further interstate shipment. FDA has no embargo powers, or other authority for summary action, such as those of State and local jurisdictions, or cease and desist procedures, such as

those employed by the Federal Trade Commission, which is responsible for enforcing advertising restrictions for foods, drugs, devices, and cosmetics. The cases brought under the statutes FDA enforces are heard in district courts and the adjudicating processes are those of the courts and not of an administrative body.

Before FDA recommends a case to the Department of Justice, it must be prepared to produce convincing evidence that the law has been violated. This may involve inspectional evidence of interstate shipment; analytical evidence by chemist, microanalyst, physicist, nutritionist, pharmacologist, physician, or experts of other scientific disciplines that the product is not what it purports to be; trade testimony that the practice is not condoned; or establishment of a preponderance of medical opinion as to the value of the product.

Actions under the Food, Drug, and Cosmetic Act follow the procedures of admiralty law, insofar as possible, as directed by the statute, except that jury trials may be had on request of either party. Our search may be of two kinds—factory inspection and sampling of goods in interstate commerce. The first is really a guide to the second and provides an orderly method of conducting our operations. After a determination is made as to where coverage is most needed to protect the public welfare, we apportion our limited staff by geographic area and commodity so that there will be uniform coverage throughout the Country.

When the U. S. marshal seizes products following the filing of a libel, the claimant has the choice of abandoning the goods, consenting to the seizure but salvaging fit portions under bond and FDA supervision, or contesting the action in a Federal District Court. Seizure is usually our first recourse when we find that violative articles are in channels of distribution.

Criminal Prosecution

The Act does not condone irresponsibility nor does it make consciousness of wrongdoing an element of the offense. The Act does, however, distinguish between conscious and unknowing violations by establishing for misdemeanors of the mala prohibita type, maximum one year prison and/or \$1,000 fine penalties, and for violations "with intent to defraud or mislead" or for repeat violations, maximum penalties of 3 years imprisonment, a \$10,000 fine or both.

Injunction

The sanction of a statutory injunction was added in the 1938 law. Primarily, this provision of the law has been employed to prevent the interstate shipment of violative products while still in the producer's possession. Injunction is a ready approach when it becomes an undue burden to keep the goods under surveillance and apprehend them before they reach the ultimate consumer. For example, in a number of instances we have found warehouses full of filth-contaminated foods. After we petitioned the Federal Courts to prohibit their shipment for food use, they were diverted into nonfood channels or reprocessed so that they would meet the decencies the public expects of foods.

Injunction orders have also been effective against promoters of nostrums, some knaves and others pathetically misguided, but determined to cure mankind of all ills. Such persons have no business encouraging diabetics to abandon insulin for their weed concoctions, or others to risk their lives or health in seeking cures for cancer and other serious diseases through worthless drugs or mechanical contraptions.

Medical Quackery

Medical quackery is a great national health problem. There is a strange contrast between the way society reacts to crimes such as robbery, kidnapping or murder, and its comparative indifference to quackery. Since there is no physical violence on the part of the quack, society regards his chicanery benignly, yet quackery has the same consequences to the individual as those of the criminal who commits manslaughter. Organized health groups are moving forward vigorously to eliminate this great risk to the health of the people of our Nation. Beyond taking legal actions against the responsible individuals, FDA has also been actively engaged in public health education programs to alert the Nation of this serious health problem.

Drug Reactions Study

Drug adverse reaction reporting is currently the basis of a pilot study to provide methodology for collecting such essential data in order to protect the physician, the patient and the pharmacist through accurate and revealing labeling of drugs. This is jointly participated in by the American Association of Medical Record Librarians in cooperation with the American

Society of Hospital Pharmacists, American Medical Association and American Hospital Association. Physicians who encounter unusual or severe reactions are encouraged to report such experiences promptly. FDA can be reached easily through its Washington office or any of its District offices in 16 major cities.

FDA through its specialized staff maintains vigilance over the national supply of foods, drugs, devices, cosmetics, caustics and corrosives to assure the protection provided in the several statutes it administers. Since the laws to be enforced are dynamic legal instruments, frequent congressional revisions are necessary in order to keep them up to date as the needs arise. Only with the public-spirited cooperation of physicians, attorneys, and other professional persons can the public health be fully protected.