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A DICHTOMY IN CONSUMER PROTECTION—THE DRUG-DEVICE DEFINITION DILEMMA

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Each year the American public swallows enormous quantities of tablets and capsules containing various drugs, is injected with innumerable gallons of serums and vaccines and applies countless tubes of creams and salves to their bodies to treat and cure a wide variety of ills, both real and imaginary. This quasi-religious reliance on drugs rests upon the premise that drugs are useful in relieving discomfort or disease and are harmless if used as directed despite occasional popular literature to the contrary.¹

Public confidence in drugs is based largely upon the belief that the omniscient government would not permit the marketing of a drug that was harmful or produced under less than the most sanitary conditions. This attitude is encouraged by the existence of the new drug provisions of the Federal Food, Drug and Cosmetic Act which require that every new drug must be proved safe and effective before it can be marketed.² Unfortunately, such provisions did not always exist,³ nor do any equivalent provisions exist for pre-market clearance of medical devices.

PRE-MARKET CLEARANCE OF DRUGS

The Food and Drugs Act of 1906⁴ contained no requirement that

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¹ See, e.g., M. KRETG, BLACK MARKET MEDICINE (1967); M. MINTZ, THE THERAPEUTIC NIGHTMARE (1965). When there was no federal regulation of food and drugs, the most sensational muckraking literature was devoted primarily to unsanitary conditions which prevailed in the preparation of foods, especially meat. E.g., U. SINCLAIR, THE JUNGLE (1906) and Sinclair, IS CHICAGO'S MEAT CLEAN? COLLIER'S, April 22, 1905. Even after the enactment of the Food and Drugs Act of 1906, revolting conditions in the manufacture of food continued to be a popular subject for muckrakers. E.g., W. LIPPMANN, DRIFT AND MASTERY 7 (1914). Cf. the recent controversy over federal meat inspection.


³ See generally Regier, The Struggle for Federal Food and Drugs Legislation, 1 LAW & CONTEMP. PROB. 3 (1933).

⁴ Federal Food and Drugs Act of 1906, 34 Stat. 768.
drugs be tested prior to being marketed. As early as 1917 recommendations were made to Congress to amend the existing law to correct this defect. In its earlier versions even the present Federal Food, Drug and Cosmetic Act did not have a provision dealing with new drugs. Only after the "Elixer Sulfanilamide" disaster during September and October of 1937 was a section proposed for the then pending Federal Food, Drug and Cosmetic Act which would require pre-market clearance of new drugs.

The tragedy which underscored the need for pre-market testing of drugs occurred when a large drug manufacturer in Tennessee, S.E. Massengil Company, decided to market a liquid preparation of sulfanilamide, a valuable drug used to treat infections. Unfortunately, the company chose diethylene glycol as a solvent. Even through diethylene glycol (a common ingredient of antifreeze) may be dangerous when taken internally, the company conducted no tests as to the toxicity of this product when used as a solvent for sulfanilamide. The company's only criterion was that sulfanilamide, which is insoluble in many liquids, would dissolve in diethylene glycol. The preparation was distributed commercially for one and one-half months before the company began recalling the product at the insistence of the Food and Drug Administration (hereinafter FDA). During the short time this preparation was on the market, seventy-three persons died as a direct result of taking the drug. Twenty other persons who took the elixer died, but it was not conclusively established that their deaths were caused by the "elixer."

Public reaction to this calamity became so great that the Senate passed a resolution that the incident be studied by the Department of Agriculture and the cause of the disaster ascertained. In his report to Congress on "Elixer Sulfanilamide," the Secretary of Agriculture emphasized the shortcomings of the Food and Drugs Act of 1906 and pleaded for legislation that would prevent a repetition of the incident. Bills were introduced in both houses of Congress requiring FDA approval before a new drug could be marketed. Although these bills were not enacted, their provisions were incorporated into the Federal Food, Drug and Cosmetic Act.

5. See DEPARTMENT OF AGRICULTURE, REPORT OF THE CHEMIST 16 (1917).
of 1938\textsuperscript{10} as sections 201(p)\textsuperscript{11} and 505.\textsuperscript{12}

Under the present law before a "new drug" may be shipped in interstate commerce, a new drug application must be approved.\textsuperscript{13} A "new drug" is "any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. . . ."\textsuperscript{14} Obviously any drug which has not previously been widely used cannot be "generally recognized as safe and effective." Thus, all newly developed drugs are "new drugs" within the meaning of the Act.\textsuperscript{15} The developer of a "new drug" must submit a new drug application (hereinafter NDA) to the FDA containing reports of investigations which have been made to show the safety and effectiveness of the drug for its intended use, the components and composition of the drug, a description of the methods used in manufacturing the drug, samples of the drug and a specimen of the labeling.\textsuperscript{16}

\begin{itemize}
\item \textsuperscript{10} S. 5, 75th Cong., 1st Sess. (1937).
\item \textsuperscript{13} 21 U.S.C. § 355(a) (1964).
\item \textsuperscript{14} 21 U.S.C. § 321(p) (1) (1964). As originally enacted in 1938, the new drug provisions required only that a new drug manufacturer establish to the FDA's satisfaction that his drug was safe for use; effectiveness was not mentioned. The FDA took the position that if the value of a drug outweighed its danger, a new drug application would have to be approved even though its claims of effectiveness were exaggerated. S. REP. No. 1744, 87th Cong., 2d Sess. (1962) (to accompany S. 1552). As a result a useless remedy or one with exaggerated claims of effectiveness might have been approved if it were safe.
\item The requirement that a new drug be both safe and effective for its intended use was one of several major revisions of the Federal Food, Drug, and Cosmetic Act which were enacted in 1962. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, also known as Kefauver-Harris Drug Amendments Act of 1962. In addition to the changes in the new drug provisions the Drug Amendments of 1962 provides that a drug is adulterated if not manufactured in accordance with current good manufacturing practice (§ 102); allow the F.D.A to designate official names for drugs (§ 111) [See Note, Drug Amendments of 1962—Generic-Name Prescribing: Drug Price Panacea? 16 STAX. L. REV. 649 (1964)]; set standards for prescription drug advertising (§ 131); amend the factory inspection provision (§ 201); and require registration of producers of drugs (§ 301).
\item Just as passage of the 1938 Act with the first pre-market clearance provisions was hastened by the "Elixer Sulfanilamide" disaster, the 1962 amendments were sparked by controversy surrounding the drug Thalidomide in 1961 and early 1962. Use of this sedative by pregnant women in Europe produced an estimated 3,500 to 5,000 malformed babies. S. REP. No. 1744, 87th Cong., 2d Sess. 40 (1962) (to accompany S. 1552) (views of Senators Kefauver, Carroll, Dodd, Hart and Edward W. Long). Despite persistent efforts of the American licensee of the drug to get the new drug application for Thalidomide approved, the medical officer in charge of the new drug application managed to delay any action for over one year, and the firm then withdrew its application after the German experience. S. REP. No. 1744, supra at 41-42. See also R. HARRIS, THE REAL VOICE 184-193 (1964).
\item \textsuperscript{15} See Merritt Corp. v. Folsom, 165 F. Supp. 418 (D.D.C. 1958).
\item \textsuperscript{16} 21 U.S.C. § 355(b) (1964); 21 C.F.R. § 130.4 (1964).
\end{itemize}
After the manufacturer's data have been studied by the New Drug branch of the Bureau of Medicine of FDA, the NDA is either approved, returned to the applicant as insufficient with a request for additional data, or refused. If the application is not accepted, the applicant may request a hearing on the question of whether such application is approvable.

The FDA will not approve a new drug application if: the tests submitted are inadequate; the results of tests show the drug is unsafe; the method of manufacture is inadequate to preserve the identity, strength, quality, and purity of the drug; all of the information available is insuf-

17. All testing of new drugs is done by the manufacturer of the drug. While it might appear that greater public protection would be achieved through independent testing by FDA, several practical considerations mitigate against such a practice. The FDA has neither the personnel nor the facilities to conduct independent tests on each of the hundreds of new drug applications submitted and re-submitted each year, the cost of governmental testing would be prohibitive, and the drug industry would oppose such a plan as an interference with their research and development. One author does suggest pre-market testing by the FDA or private medical institutions. See Rheingold, infra note 18, at 147.

18. 21. U.S.C. § 355(c) (1) (1964). A basic premise of the present new drug procedures is that the data submitted by the manufacturer will be complete, accurate and honest. Consequently, a manufacturer who wants to market a dangerous or ineffective drug can do so if he submits false data which indicate plausible reactions to the drug. A review can only evaluate the NDA in terms of possibilities and probabilities of what a set of ingredients will do. See generally CLINICAL TESTING OF NEW DRUGS (A. Herrick & M. Cattell ed. 1965); Van Winkle, New Drug Applications in Drug Research and Development (A. Smith & A. Herrick ed. 1948); Kleinfeld, New Drug Applications and Suspension Procedure, 18 Food Drug Cosm. L.J. 632 (1963); Smith, New Drug Applications 17 Food Drug Cosm. L.J. 497 (1962). Nevertheless, it is extremely difficult to satisfy the FDA even with accurate data. Only forty new drug applications were approved in 1966. United States Dept. of Health, Educ. and Welfare, Annual Report 198 (1966). However, if the new drug application shows reactions which are neither impossible nor improbable the reviewer, absent independent information, can be fooled.

False toxicity studies were submitted in the new drug application for the anticholesterol drug MER/29, which failed to indicate the eye danger which the tests by the company had revealed. Toole v. Richardson Merrell Inc., 60 Cal. Reprtr. 398 (1967). See generally M. Mintz, The Therapeutic Nightmare (1965). MER/29's application was approved and seven million dollars worth of the drug were sold before the fraud was discovered. Submission of false information to the FDA is a criminal offense [18 U.S.C. § 1001 (1964)] and the corporations involved were convicted and fined a total of eighty thousand dollars, with imposition of sentence suspended following a plea of nolo contendere. Damage suits brought by the over 400 individuals who had sustained injuries from use of MER/29 prayed for approximately 200 million dollars in damages. E. Kefauver, IN A FEW HANDS 60 (1965); see Rheingold, The MER/29. Story—An Instance of Successful Mass Disaster Litigation, 56 Calif. L. Rev. 116, 133 (1968). It has been estimated that at least 5,000 persons were injured by MER/29. In reality, the number could be much higher because many people never attributed an injury to the drug. Rheingold, supra, at 121.

The MER/29 experience, while not unique, is uncommon. See Rheingold, supra, at 144 n.82-83.

19. 21 C.F.R. 130.11 (1968). An applicant may submit an amendment to a pending application, 21 C.F.R. 130.7 (1968), and an approved new drug application may be changed through a supplemental application, 21 C.F.R. 130.9 (1968).


ficient to determine the safety of the drug; the drug is ineffective; or the labeling of the drug is false and misleading in any particular. After a new drug application has been approved, the FDA may withdraw approval, after due notice and opportunity for a hearing, if the agency subsequently finds the drug either unsafe or ineffective. Failure of the manufacturer to maintain records or permit access thereto provides an additional basis for the withdrawal of the new drug application.

The new drug section as originally enacted contained a "grandfather clause" which exempted from the coverage of the new drug requirements any drug, whether or not generally recognized as safe, "if at any time prior to enactment of this chapter the drug was subject to the Food and Drugs Act of 1906" and "if at such time its labeling contained the same representations concerning the conditions of its use . . . ." As a result it was not necessary to submit a new drug application for pre-existing remedies unless the labeling were later revised to recommend a new or different use for the drug or a different duration of administration. The 1962 amendment which required that a drug be effective as well as safe perpetuated the exception verbatim so that a drug approved for sale before 1962, and therefore before the act required that a drug be effective in addi-

23. 21 U.S.C. § 355(e) (1964). Withdrawal of approval may be based upon clinical experience or other scientific data available at the time the application was approved, new evidence not available until after the application was approved, or new information about the drug evaluated together with the evidence available when the application was approved. 21 U.S.C. § 355e(1)-(3) (1964). See Bell v. Goddard, 366 F.2d 177 (6th Cir. 1966). Any untrue statement of a material fact in an application shall also cause approval of such application to be withdrawn. 21 U.S.C. § 355 (e) (4) (1964).
24. 21 U.S.C. § 355(e) (1964). Drugs intended solely for investigational use by qualified experts are exempt from the requirements of the new drug section. 21 U.S.C § 355(i) (1964). Under authority of this section the Secretary has promulgated regulations which spell out in detail elaborate procedures for obtaining an investigational new drug exemption. 21 C.F.R. 130.3 (1968) (new drugs for investigational use in human beings); and 21 C.F.R. 130.3a (1968) (new drugs for investigational use in animals). Whether or not a drug qualifies for an investigational exemption is within the primary jurisdiction of the FDA so that any initial attempt to obtain an investigational exemption must be made through the FDA and not the courts Rutherford v. American Medical Ass'n, 379 F.2d 641 (7th Cir. 1967); Tutoki v. Celebrezze, 375 F.2d 105 (7th Cir. 1967). See Far East Conference v. United States, 342 U.S. 570 (1952). If an application for an investigational exemption is denied or a previously granted exemption is withdrawn, there is no provision for appeal from such an order in the statute. The only recourse available to the unsuccessful applicant is to file a new drug application, demand a hearing if the application is not approved, and if no relief is granted at the hearing appeal from the Secretary's order pursuant to 21 U.S.C. § 355(h) (1964). See Turkel v. Food and Drug Adm'n Dep't of H.E.W., 334 F.2d 844 (6th Cir. 1964).
tion to being safe, would not be deemed to be a new drug if its labeling contained no new representations concerning the conditions of its use.

However, another "grandfather clause" enacted in a different section in 1962 allows the FDA, after the expiration of a two year period beginning with the enactment date, to withdraw approval of a previously approved NDA, if:

On the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, . . . there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the labeling thereof.

Under this provision the FDA may re-examine the hundreds of drugs that were approved for sale to the public during the years 1938 to 1962 without regard to their efficacy. To accomplish this reappraisal an exhaustive review is being conducted by the National Academy of Sciences concerning the usefulness of 2,900 drugs sold in as many as 17,400 different formulations.


28. See note 14 supra.


30. 21 U.S.C. 355(e)(3) (1964). This section is incorporated by reference into § 107(c) (3) (B) of the Drug Amendments of 1962. For a summary of the legislative history of these sections see Goodrich, Legislative Background, in The Washington Briefing on FDA's Efficacy Review, FDA Papers 12 (March, 1968).

31. Wall Street Journal, Jan. 23, 1968, at 4, col. 2. The FDA has neither the personnel nor the facilities to undertake such a massive research task. Instead a contract was let to nongovernment scientists. United States Dept of Health, Educ. and Welfare, Annual Report 197 (1966). In addition to relieving the FDA of the burden of testing thousands of drugs the prestige of the National Academy of Sciences is such that it was able to attract medical experts who would not deign to work directly for the federal bureaucracy. Furthermore the Academy's unmarred scientific reputation will make its conclusions much less susceptible to challenge than judgments of the FDA. Wall Street Journal, May 22, 1968, at 6, col. 2. See generally The Washington Briefing on FDA's Drug Efficacy Review, FDA Papers 7 (March, 1968).

The compounds reviewed by the academy are divided into five categories: 1) "ineffective," 2) "possibly effective," 3) "probably effective," 4) "effective, but," and 5) "effective." The "ineffective" compounds will be taken off the market. Further testing will be necessary in the case of "possibly" and "probably effective" drugs before their new drug applications will be suspended. "Effective, but," drugs are those containing two or more ingredients not all of which are effective, or single ingredient drugs which are effective for some but not all of the uses suggested on their labeling. With respect to these "effective, but" drugs, the FDA will ask manufacturers to remove the ineffective component from the combination drugs and to relabel the single ingredient drugs to delete any exaggerated claims. Of course, nothing additional will be required in the case of drugs categorized "effective." Once the review is completed the FDA has the authority and the personnel to carry out this program expeditiously; however, if the
Device Quackery—The Evil of Unchecked Device Production Examined

Is there any requirement that a device be proved safe and effective prior to interstate shipment? Under the present provisions of the Federal Food, Drug and Cosmetic Act the answer is an unqualified “No.” Thus, a manufacturer who wishes to market a new type of sustained release aspirin must comply with the exacting demands of the new drug regulations while the manufacturer of an X-ray machine may market this product without interference. Medical technology is developing a vast array of medical devices which will not require pre-market clearance; under the present Act even artificial organs may be implanted into human patients without prior proof of their safety and efficacy. The only remedy the government has against dangerous or ineffective devices is the ponderous procedure of seizure after interstate shipment. Then, after a trial, the device may be condemned and eventually destroyed. In a

drug companies demand to exercise their right of a public hearing to contest each suspension of a new drug application, the FDA will be bogged down in a bureaucratic quagmire which will cripple regulatory activities for years.

Where “an imminent hazard to the public health” is found, the FDA is empowered to order suspension of approval of a new drug application immediately and to remove the drug from the market before a hearing is held. 21 U.S.C. § 355(e) (1964). After suspension, the manufacturer is given notice of his opportunity for an “expedited hearing” on the propriety of the agency’s action but in the meantime the public is protected by the withdrawal of the drug from the market.


33. Timed release drugs containing dosages in excess of that considered safe for a single dose are regarded by the FDA as new drugs requiring the submission of a new drug application, 24 Fed. Reg. 3756 (1959).

In the closing days of the 90th Congress the first steps towards control of X-ray devices were taken. The Radiation Control for Health and Safety Act of 1968, was signed by the President on October 18, 1968. The act allows the government to set performance standards for products which emit electronic product radiation. Manufacturers are required to provide the Secretary of Health, Education and Welfare with performance data and other technical data related to safety in order for the Secretary to carry out the purposes of the Act. Section 360A(c). In addition to X-ray machines and color television sets which emit radiation certain medical devices are covered by the act. These include products which emit sonic, infrasonic and ultrasonic waves. Section 355(1)(B).

34. A device which is alleged to be adulterated or misbranded may be seized when introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce. 21 U.S.C. 334(a) (1964). See, e.g., United States v. Diapulse Mfg. Corp., 269 F. Supp. 162 (D. Conn. 1967), aff’d, 389 F.2d 612 (2d Cir. 1969).

35. 21 U.S.C. §334(d) (1964). In lieu of destruction the court may order the article sold and the proceeds paid into the United States Treasury or conditioned upon the payment of costs and the execution of a bond the article may be returned to the owner to be brought into compliance with the Act. 21 U.S.C. § 344(d) (1964). See United States v. Diapulse Mfg. Corp., 269 F. Supp. 162 (D. Conn. 1967), aff’d, 389 F.2d 612 (2d Cir. 1969), and United States v. Allan Drug Corp., 357 F.2d 713 (10th Cir. 1966), cert. denied, 385 U.S. 899 (1968). Reconditioning or relabeling an article
seizure action the government has the burden of proving by a preponderance of the evidence its allegation that the article seized is misbranded or adulterated\textsuperscript{36} in contrast with the pre-market clearance procedure established for new drugs which puts the burden on the manufacturer to submit evidence to the FDA that the drug is safe and effective for its intended use.\textsuperscript{37}

The number of devices available which claim to be panaceas for mankind’s various illnesses is limited only by the ingenuity of those who see pain and suffering as a means to acquire wealth. In the absence of pre-market clearance procedures device quackery has proliferated; a casual glance at the annual reports of the FDA or the reported misbranded device cases reveals a bizarre assortment of gadgets that challenges credulity.

Fantastic devices for which outrageous claims are made are not only historical phenomena but a serious present day “racket.”\textsuperscript{38} In 1966 the government seized and condemned a “Cameron spitler Amblyo-Syntonizer” consisting of a metal tube inside of which were a light bulb, metal discs and colored glass filters, claimed by the owner to be useful in the treatment of eye disease.\textsuperscript{39} Also in 1966 FDA seized an “ionic charger” whose labeling suggested that drinking water charged with “Radon” gas from the device was effective in treating, \textit{inter alia}, gout, rheumatism and liver disease.\textsuperscript{40}

Today’s device quackery cases follow the pattern of earlier cases in that the device typically is described in exotic terminology with claims that the device will cure those diseases for which legitimate medical science does not have a cure, \textit{e.g.}, arthritis or cancer.\textsuperscript{41} The hopeless and incurable are most vulnerable to claims of relief from such questionable


\textsuperscript{37} See United States v. Wood, 226 F.2d 924 (4th Cir. 1955); United States v. 449 cases . . . Tomato Paste, 212 F.2d 567 (2d Cir. 1953); United States v. Five Cases . . . Figlia Mia, 179 F.2d 519 (2d Cir. 1950).

\textsuperscript{38} 21 U.S.C. § 355(b) (1964). Only when the application is approved does the burden of proving a drug unsafe to justify suspension of the application shift to the government. Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966).


\textsuperscript{41} E.g., United States v. Urbreit, 335 U.S. 355 (1948). The claimant, who termed himself a naturopathic physician, used electrical “Sinothermic” devices to treat cancer, diabetes, tuberculosis, arthritis and paralysis. 335 U.S. at 356.
sources. The gullible have spent countless dollars to cure "innumerable diseases and conditions," including leukemia, through use of such devices as orgone energy accumulators.42

Most quack devices are harmless in themselves.43 Use of these devices is hazardous only when the patient foregoes proper medical treatment while undergoing ineffectual therapy from the quack and his miraculous machine. Avoidance of rational medical treatment will frequently allow a curable malady to progress unchecked into an incurable state while the patient thinks he is being cured. In one case, for example, a lump on a woman's breast developed into malignant cancer while being treated by the Drown Radio Therapeutic Instrument.44

42. United States v. Wilhelm Reich Foundation, 17 F.R.D. 96, 98 (D. Maine 1954), aff'd, 221 F.2d 957 (1st Cir. 1955). The devices were also alleged to be beneficial in the treatment of "cancer, anemia, arteriosclerosis, brain tumors, diabetes, gastric ulcers, Burger's disease. . . ." In addition patients have purchased treatments from such things as: (1) a "colortherm" to cure disorders of the liver, eyes, female trouble, etc. United States v. Four Devices . . . "Colortherm," 176 F.2d 652 (10th Cir. 1949). (2) a "Colonic Irrigator" for everything from arthritis to "a host of ills that have heretofore been obscure." The purpose of this device was to flush out the colon by forcing a stream of pulsating water into the intestines. United States v. One Device . . . "Colonic Irrigator," 160 F.2d 194 (10th Cir. 1947). The labeling accompanying the device stressed the need for a clean colon because:

Improper function of the colon is the most frequent contributing cause of intestinal toxemia and the following accompanying symptoms and ailments. They can now be successfully treated by our methods.
(3) The Drown Radio Therapeutic Instrument is among the more outlandish devices seized by the FDA over the years. It was a radio diagnostic and treatment machine represented "as efficacious in treating kidney and bladder complications, tipped uterus, extra kidney, painful urination, streptococcus in the urethra and the pyloric end of the stomach and bladder, cirrhosis and carcinoma of the right kidney, low function of the left supra-renal gland, pancreas, fibrous adhesions in the brain and medulla, heart trouble, head pains and noises, explosions in the right ear while falling asleep, constipation, pains in the lower back, abscesses, loss of speech and memory, worry, fear and nervousness, conditions of the colon and liver." The machine needed only a single drop of the patient's blood for diagnosis and all subsequent treatments. The operator of the machine tuned in on the frequency vibration of the disease no matter where the patient was and the vibrations allegedly would cause the diseased cells to fall away automatically. Drown v. United States, 198 F.2d 999 (9th Cir. 1952).

43. E.g., United States v. Ghadiali, 165 F.2d 957 (3d Cir. 1958). The "Spectrochrome" device "consisted of a cabinet equipped with a 1,000 watt electric light bulb, an electric fan and water container for cooling purposes, two glass condenser lenses to focus the rays from the electric light bulb and five ordinary glass slides, each of a different color." The patient was "irradiated" with harmless "attuned color waves" projected through the colored glass side. See also United States v. Ellis Research Laboratories, 300 F.2d 550 (7th Cir. 1962), cert. denied, 370 U.S. 918 (1962), which involved a highly sensitive galvanometer called "Micro-Dynameter."

44. Drown v. United States, 198 F.2d 999 (9th Cir. 1952).
Occasionally the device itself may be harmful. The Halox Therapeutic Generator was a device for the electrolysis of sodium chloride (salt). Carbon electrodes were extended into a salt solution and, when the generator carried electricity to the electrodes, electrolysis of the solution produced chlorine gas which was blown through a rubber hose by a fan. The patient received "chlorine inhalation therapy" by holding the hose to his nose and inhaling a mixture of air and chlorine gas. Not only was the device ineffective in fulfilling any of the claims made for it, but experts testified at the trial that an effective antiseptic concentration of chlorine gas would be irritating to the average individual, that only very slight concentrations of chlorine gas could be inhaled safely, and that the directions on the device did not indicate which dial settings would provide safe concentrations of the gas.

An X-ray machine is another example of a device which is inherently hazardous; in the hands of an untrained individual untold harm can be done. Yet, one unconscionable manufacturer was selling X-ray machines to beauty shop operators for use in the removal of superfluous hair, even though doses heavy enough to kill hair follicles will cause severe injury to the skin which may develop into skin cancer.

Despite the fact that a device can be as ineffective and dangerous as a drug, the FDA has no statutory authority to establish pre-market conditions for devices—the only means by which the public can be adequately protected. The laxity of device regulation when compared to the severity of drug regulation reveals an unfounded regulatory dichotomy.

The Definitional Dilemma

Since only drugs are subject to pre-market clearance it is essential to answer the question: What is a drug? The Federal Food, Drug and Cosmetic Act states:

The term 'drug' means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention

46. Id. at 915.
47. Id. at 919.
48. See FDA Trade Correspondence No. 163 (Mar. 14, 1940) in V. KLEINFELD & C. DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT, JUDICIAL AND ADMINISTRATIVE RECORD (1938-49) 133 (1949) [hereinafter cited as KLEINFELD & DUNN].
49. FEDERAL SECURITY AGENCY, ANNUAL REPORT 228 (1951).
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of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C); but does not include devices or their components, parts, or accessories.  

Struggling with this definition of drug, courts have determined that the following articles, none of which would be considered drugs by a layman, are drugs because they fit within one of the definitions of drugs included in the Act: mineral water, peppermint tea, water, gauze bandages, insect powder, honey, whole human blood, cigarettes, vaginal suppositories and unrefined petroleum oil.  

The first subsection of the definition of drug, recognition in one of the official pharmocopoeias, accounts for the inclusion of gauze bandages on the list of drugs. Pharmacopoeias were developed in the nineteenth century to provide pharmacists with authoritative definitions of drugs in terms of their chemical components. These "official compendia" set standards for the composition and sterility of drugs. Delegation of the power to standardize drugs to the private agencies which publish the

51. Goodwin v. United States, 2 F.2d 200 (6th Cir. 1924) (Under the definition of drug in the Food and Drugs Act of 1906).
53. Bradley v. United States, 264 F. 79 (5th Cir. 1920) (under the definition of drug in the Food and Drugs Act of 1906).
54. United States v. Forty-eight Dozen Packages... Gauze Bandages, 94 F.2d 641 (2d Cir. 1938).
55. See United States v. Nagase, 11 Ct. Cust. App. 144 (1921). Using the definition of drug in the Food and Drugs Act of 1906 the Customs Court held powder produced from pulverized Japanese camomile flowers and used as an ingredient in insect powders to be a drug dutiable at ten per cent ad valorem under the Tariff Act of 1913.
59. United States v. Grayce, 126 F. Supp. 6 (N.D. Ind. 1954)
60. United States v. Nine Bottles... Colusa Natural Oil, 78 F. Supp. 721 (N.D. Iowa 1947). In addition to the articles listed, some other articles not usually thought of as drugs but which are regarded as such by the FDA are Saccharin in tablet form, FDA Trade Correpondence 388 (July 21, 1942), KLEINFELD & DUNN 726; Corn removers and Corn pads; FDA Trade Correspondence 21 (Feb. 9, 1940), KLEINFELD & DUNN 580.
61. See Urdang, Development of the Pharmacopoeias, 8 Food Drug Cosm. L.J. 69 (1953).
pharmacopoeias relieves the FDA of the duty of doing so although the constitutionality of such delegation is questionable. 63

Many articles not normally thought of as drugs are listed in one of the pharmacopoeias because standards of sterility have been established for that article. For example, because standards of sterility have been recognized for absorbant cottons this particular article is recognized in the official United States Pharmacopoeia. However, courts have reasoned that not only those articles included in the official compendia are drugs but also similar articles. For example, in the gauze bandage case the court said:

[T]he recognition in the Pharmacopeia of absorbant cotton, a substance generally similar in composition and use to a gauze bandage, sufficiently shows that the latter, while not itself recognized, is of a kind with what is...

Honey would normally be classified as food and therefore within the exception to subsection (C); however, it is the intended use as described in the labeling which is determinative of an article's classification. If the labeling states that the honey has medicinal and curative properties for the prevention and treatment of various diseases, such as in a recent case where honey was represented as a cure for conditions ranging from arthritis to weakening of potency, the honey is intended for use in the cure and treatment of disease within the meaning of subsection (B) of the definition of drug; therefore, the honey labeled as a cure is a drug within the meaning of the act. 64

The history of cigarettes further illustrates the ethereal nature of the definition of drug under the Federal Food, Drug and Cosmetic Act. Cigarettes offered as an aid in reducing were held to be drugs under subsection (C) because they were intended to affect the structure and/or function of the human body by reducing the appetite, thereby achieving


64. United States v. Forty-eight Dozen Packages... Gauze Bandages, 94 F.2d 641, 642 (2d Cir. 1938). In United States v. Articles of Drugs... Vit-Ra-Tox, 263 F. Supp. 212, 215 (D. Neb. 1967) the court states: “The principal ingredient of Vit-Ra-Tox 16 Hydrated Aluminum Sulfate, is listed in the Pharmacopoeia of the U.S., therefore ‘# 16’ is a drug as a matter of law.” Vitamin capsules were held to be drugs because vitamins are recognized in the Pharmacopoeias. United States v. Hain, (S.D. Cal. 1943), reported in KLEINFELD & DUNN 265. Cf. United States v. Frank, 189 F. 195, 199 (S.D. Ohio 1911).

a reduction of the body’s weight. Cigarettes represented as useful in relieving respiratory diseases were held to be drugs under subsection (B) because they were intended for use in the cure and treatment of disease.

In addition to the potential malleability of the statutory definition of drugs, the definitions of drugs and devices under the Act are in part identical. Drugs are defined, inter alia, as “articles intended for use in the diagnosis, cure mitigation, treatment or prevention of disease in man or other animals.” Devices are defined as “instruments, apparatus, and contrivances . . . intended for use in the diagnosis, cure mitigation, treatment or prevention of disease in man or other animals.”

For those to whom the difference between an article and an instrument, apparatus, or contrivance is not readily apparent, a perusal of the dictionary definitions of these words unfortunately will only compound the confusion. An article is defined as a “thing” or “commodity.” It is difficult to conceive of any object which is not a thing, yet if there is a difference between drugs and devices there must be a difference between things and devices. Instrument is defined as a “tool” or “implement”; contrivance, a “mechanical device”; apparatus is “machinery” or “mechanism.” Attempting to apply these definitions to actual cases proves to be an entertaining, albeit sometimes futile exercise.

67. United States v. Forty-six Cartons . . . Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953). The FDA’s success in classifying two types of cigarettes within two of the definitions of drug was not equalled by the Federal Trade Commission when that agency unsuccessfully attempted to characterize regular Chesterfield cigarettes as drugs because tobacco is included in the Homeopathic Pharmacopoeia. Mere inclusion of “tincture of tobacco” in the Homeopathic Pharmacopoeia was insufficient to persuade the court that all forms of tobacco were drugs. The court conceded that it was not necessary for cigarettes, as such, to be listed in the Pharmacopoeia in order to invoke the imprimatur of the compendium because “[s]urely, if smoking tobacco is a drug, the manner in which it is packaged, and what it is called after packaging is, in this instance, of no greater significance than the difference between other drug preparation in pill or powder form.” Nevertheless tincture of tobacco, a liquid preparation of “Tabacum,” distilled water and “strong alcohol” was held to be a preparation “far removed in form and purpose from the ordinary cigarette.” FTC v. Liggett & Myers Tobacco Co., 108 F. Supp. 573 (S.D.N.Y. 1952) [under an identical definition in the Federal Trade Commission Act, 52 Stat. 116 (1938), 15 U.S.C. § 55(c) (1964)]. Although the court did not cite nor distinguish the gauze bandage case (note 54, supra) it apparently decided that non-recognized cigarette tobacco was not “of a kind with what is.” See 108 F. Supp. at 575. Likewise the court was unpersuaded that claims in advertisements that Chesterfields would prevent irritation were claims that the cigarette had a beneficial effect on the body and was a drug. Claims of nonadverseness are not such claims as cause an article to be given the status of a drug. See id. at 575-77.
68. See text at note 50 supra.
70. WEBSTER’S NEW INTERNATIONAL DICTIONARY (3d ed. 1966).
71. Id.
72. Id.
73. Id.
Whether a given instrument, apparatus or contrivance will be classified as a device within the meaning of the Federal Food, Drug and Cosmetic Act and therefore within the jurisdiction of the FDA and subject to the provisions of the Act, is contingent upon the claim of therapeutic value made for the product. Just as not all cigarettes are drugs, not all combs, for example, are devices. But a comb labeled "for dandruff and scalp infection" is a device. An ordinary toothbrush is not a therapeutic device; the same is not true of a toothbrush represented as useful in treating pyorrhoea. If the definitions of drug and device overlap, why not classify every product as a drug within the broader category of article? Unfortunately, such an effortless exit would blatantly ignore the congressional mandate in the language at the end of the definition of drug

74. See text at notes 66 & 67 supra.
75. FDA Trade Correspondence 111 (Feb. 29, 1940), Kleinfeld & Dunn 613.
76. United States v. 2000 . . . Cases . . . Toothbrushes, 231 F. Supp. 236 (M.D. Pa. 1964) ; FDA Trade Correspondence 109 (Feb. 29, 1940), Kleinfeld & Dunn 612. Similarly the FDA regards surgical rubber gloves as devices whereas ordinary rubber gloves for household use are not so regarded. FDA Trade Correspondence 41 (Feb. 12, 1940), Kleinfeld & Dunn 585-86. The following list illustrates a few of the products the FDA considers to be devices within the meaning of the Act: ankle supports, FDA Trade Correspondence 105 (Feb. 29, 1940), Kleinfeld & Dunn 611; clinical heat pads, FEDERAL SECURITY AGENCY, ANNUAL REPORT 228 (1951) ; clinical thermometers, FDA Trade Correspondence 316 (Aug. 20, 1940), Kleinfeld & Dunn 693; dental plates, FDA Trade Correspondence 260 (Apr. 25, 1940), Kleinfeld & Dunn 671; elastic and leather wrist bands and athletic supporters, FDA Trade Correspondence 104 (Feb. 29, 1940), Kleinfeld & Dunn 611; hot water bottles, FDA Trade Correspondence (Feb. 29, 1940), Kleinfeld & Dunn 613; prophylactics, see, e.g., United States v. 43½ Gross . . . Rubber Prophylactics, 65 F. Supp. 534 (D. Minn. 1946), aff'd sub. nom., Gellman v. United States 159 F.2d 881 (8th Cir. 1947) ; surgical instruments, such as knives, scissors, forceps, saws, mallets, chisels, needles, nails, drills, and screwdrivers, FDA Trade Correspondence 160 (Mar. 14, 1940), Kleinfeld & Dunn 631; sutures, FDA Trade Correspondence 128 (Mar. 7, 1940), Kleinfeld & Dunn 619; syringes, FDA Trade Correspondence 110 (Feb. 29, 1940), Kleinfeld & Dunn 613; tongue depressors, FDA Trade Correspondence 100 (Feb. 21, 1940), Kleinfeld & Dunn 609; x-ray machines, FDA Trade Correspondence 163 (Mar. 14, 1940) and FDA Trade Correspondence 333 (Sept. 5, 1940), Kleinfeld & Dunn 633, 670; and sleep inducing phonograph records, United States v. Twenty-three, More or Less, Articles, 192 F.2d 308 (2d Cir. 1951) (recording intended to induce sleep by suggestion). Cf. the medical devices mentioned in A. Leff, Medical Devices and Paramedical Personnel: A Preliminary Context for Emerging Problems, 1967 WASH. U.L.Q. 332, 344-45 (1967). In a private damage action, Orthopedic Equipment Co. v. Eutsler, 276 F.2d 455 (4th Cir. 1960), a surgical nail was held to be a device within the meaning of the Federal Food Drug and Cosmetic Act.

The following articles have been ruled to be outside the provisions of the act, if not medicated, and if not intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or if not used to affect the structure or any function of the body of man or other animals: 1) materials used in taking dental impressions, FDA Trade Correspondence 260 (Apr. 25, 1940), Kleinfeld & Dunn 671. The FDA regards materials used in filling teeth and in making dentures as "either devices, accessories to devices, or drugs, depending upon the representations for the specific article,..." Id. Dental plates are devices. Id. Razors and manicuring implements, FDA Trade Correspondence 112 (Feb. 29, 1940), Kleinfeld & Dunn 613; rubber nipples, FDA Trade Correspondence 114 (Feb. 29, 1940), Kleinfeld & Dunn 614; and shaving brushes, FDA Trade Correspondence 109 (Feb. 29, 1940), Kleinfeld & Dunn 612.
which bluntly states that the term drug "does not include devices or their components, parts, or accessories." 77

OTHER DEFINITIONS AND OTHER DICHOtOMIES

The Act's glossary contains other definitions which may overlap with those already discussed. Cosmetics are "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance . . . except that such term shall not include soap." 78 Since there is no exemption of cosmetics from the definition of drug such as there is for device, any indication that the article is intended to affect the structure of the body or intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease may bring it within the drug provisions. 79

Toothpaste offered for the purpose of keeping teeth clean and breath fresh is a cosmetic, but if claims are made that use of the product will prevent tooth decay then it is intended for use in the prevention of disease—ergo, it is a drug. 80 Similar transubstantiations will occur if claims are made that a deodorant stops perspiration instead of merely absorbing it or masking its odor 81 or if a suntan lotion is represented as not only an aid in obtaining an even tan but useful in preventing sunburn. 82 Surprisingly the FDA regards some articles which clearly affect the structure of the body, such as cuticle removers 83 and depilatories 84 as cosmetics.

Soap is not a cosmetic. The Act is unequivocal about this. 85 What, however, is the appropriate category for a medicinal soap represented to be beneficial in the treatment and prevention of skin disease? The FDA has said that representations of therapeutic benefit might transform a soap, although exempted from the definition of cosmetic, into a drug. 86

77. See text at note 50 supra.
80. Cf. FDA Trade Correspondence No. 229 (April 11, 1940), KLEINFELD & DUNN 657. The word "healthful" on the label of tooth powder causes it to be classified as a drug.
81. FDA Trade Correspondence No. 26 (Feb. 9, 1940), KLEINFELD & DUNN 581.
82. FDA Trade Correspondence No. 61 (Feb. 15, 1940), KLEINFELD & DUNN 593. Baby oil is a cosmetic unless claims are made for the article which changes it to a drug.
83. FDA Trade Correspondence No. 40 (Feb. 9, 1940), KLEINFELD & DUNN 585.
84. FDA Trade Correspondence No. 245 (April 25, 1940), KLEINFELD & DUNN 655.
86. FDA Trade Correspondence No. 146 (Mar. 7, 1940), KLEINFELD & DUNN 625, 626. The exemption of soap from the definition of cosmetic does not apply to shampoos and shaving creams. Id. See United States v. 45 2/3 Dozen Packages . . . "U-X Improved Shaving Medium," 46 F. Supp. 112 (S.D.N.Y. 1942).
If the soap were not generally recognized as safe and effective by qualified experts, it would be a "new drug" which could not be marketed until the manufacturer persuaded the FDA that the product was safe and efficacious for its intended use. Under the FDA's construction of the statute, soap is an all or nothing proposition. If the soap manufacturer is careful about the claims he makes for his soap, he may avoid totally the restrictions of the Act and the jurisdiction of the FDA. However, by a few incautious words in an advertisement which could be construed by the FDA as claims that the soap is intended for use in the cure, mitigation or treatment of a disease, the soap manufacturer may find himself confronting the most formidable pre-market barrier that any businessman has to hurdle—the approval of a new drug application.

Face creams, represented as effective in removing wrinkles from the skin caused by advanced age, inhabit the never-never land between cosmetics and drugs. Smoothing out wrinkles would appear to be "promoting attractiveness or altering the appearance," yet at the same time within the penumbra of drug's "affect the structure."

Two recent district court decisions involving virtually identical wrinkle-removers illustrate the problem faced by FDA in attempting to regulate uniformly products that are traditionally thought of as cosmetics but which affect the structure of the body. "Line Away" by Coty was held to be a drug because: "Obviously, by intending to smooth, firm and tighten the skin, Line Away has as its objective affecting the structure of the skin. Hence it falls within the literal definition of a drug in section 321(b)(1)(c)." A few months later "Sudden Change" by Hazel Bishop was held to be a cosmetic because the judge thought the buyer should be sufficiently skeptical to realize the claims that the product gives a "face lift without surgery" and "smoothes out wrinkles" do not mean a "structural change of the kind available through plastic surgery." Thus the effect on the structure of the body was insufficient to place the article in the class of drugs.

While the term drug does not include device, there is no exclusion

88. 21 U.S.C. § 321 (g) (3) (1964). In a recent case, United States v. Thirty-six Boxes ... "Line Away, Temporary Wrinkle Smoother, Coty," 284 F. Supp. 107 (D. Del. 1968), the court held the wrinkle smoother to be a drug because its intended use is to affect the structure of the body. Contra, United States v. 216 Individually Cartoned Bottles ... Sudden Change, 288 F. Supp. 29 (E.D.N.Y. 1968), rev'd, —F.2d— (2d Cir. 1969). Cf. FDA Trade Correspondence No. 9 (May 13, 1939), KLEINFELD & DUNN 565 (bleaching creams are both cosmetics and drugs).
of foods or cosmetics.\textsuperscript{91} Chewing gum and any article used for food or drink for man or other animals are foods.\textsuperscript{92} Representations that a food is intended for use in the diagnosis, cure, etc. of disease will cause the article to be classified as a drug.\textsuperscript{93} Foods, however, are specifically exempted from being treated as drugs if they are intended to affect the structure or any function of the body of man or other animals.\textsuperscript{94} All foods, with the possible exception of chewing gum, are intended to affect the structure of man in some fashion or another. Without this exemption all foods would be drugs making them subject to the new drug pre-market clearance requirements. Nevertheless, since it is possible for an article to be both a food and a drug, many foods, particularly products advertised as diet supplements or as nutritional supports, have been held to be drugs because of therapeutic claims.\textsuperscript{95}

The definitional dichotomy in practice: The AMP and Bacto-Unidisk cases

Recently AMP Incorporated developed a new method of tying off severed blood vessels during surgery. The FDA regarded the products used in this method as new drugs requiring the submission of a new drug application. AMP took the position that the products were devices, and under the threat of regulatory proceedings if it did not comply with the pre-market clearance requirements for new drugs, filed suit against FDA seeking a declaratory judgment that its products were devices and not subject to the new drug provisions of the Federal Food, Drug and Cosmetic Act.\textsuperscript{96}

The articles involved appear to be devices in the normal sense of that word, and without reference to the definitions of "drug" in the Federal

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\textsuperscript{91} 21 U.S.C. § 321(g) (1964).
\textsuperscript{94} 21 U.S.C. § 321(g) (3) (1964).
\textsuperscript{96} AMP Inc. v. Gardner, 275 F. Supp. 410 (S.D.N.Y. 1967), aff'd, 389 F.2d 825 (2d Cir. 1968), cert. denied, 393 U.S. 825 (1968). The trial court held that the article involved was a drug and the Second Circuit affirmed. However, the courts used different reasoning to reach this result. Therefore to understand fully the issues involved in determining whether this article is a drug or a device, it is necessary to analyze in detail both opinions.
Food, Drug and Cosmetic Act characterization of the products involved as drugs would be unlikely.

Both of the products are intended to be used in a new method of tying off, or ligating, severed blood vessels during surgery. The conventional ligating method is to hand-tie ligatures around severed vessels by means of a surgeon's knot (which is a reef knot). AMP's products both consist of a disposable applicator, a nylon ligature loop, and a nylon locking disk. In one product the applicator is a hemostat [clamp]; in the other, it is a long slender tube. The ligature is applied by inserting the hemostat or tube into the body and placing the loop around the severed vessels then tightening the loop and locking it in place with the disk. The excess nylon thread is cut off, and the disk and the rest of the thread remain in the patient's body.97

AMP argued that because the nylon ligature loop and the locking device are merely components, parts or accessories of the hemostat or the tube, the whole product should be classified a device. The trial judge rejected this argument and adopted the FDA's position that "the hemostat or the tube is no more than a container for the method of applying the suture."98 The court analogized the product to a drug administered by a disposable syringe. "The syringe alone is a device when used separately . . . But a drug in a syringe will not become a component of a device or a device for purposes of the act simply because it is packed for use in such a syringe."99 Having accepted the Government's position that the essential element of AMP's product is the suture, the court was urged to classify the suture as a drug.

Narrowing the product involved to a suture enabled the Government to point to the first subsection of the definition of drug which states: "The term 'drug' means (A) articles recognized in the official United States Pharmacopeia. . . ."100 "Suture" is listed in the official USP.101 To complete the syllogism, argued the Government, logic demands the conclusion that sutures are drugs.102 The court rejected such an easy

97. 389 F.2d at 826.
98. 275 F. Supp. at 413.
99. The FDA regards syringes by themselves as devices. FDA Trade Correspondence No. 110 (Feb. 29, 1940), KLEINFELD & DUNN 613.
100. 21 U.S.C. § 321(g) (1) (1964).
102. The Government's argument is fallacious in that it fails to consider the last phrase in 21 U.S.C. § 321(g) (1964), "but does not include devices or their components, parts, or accessories." If this phrase means what it says, then not all articles listed in a pharmacopoeia are drugs because a device listed in one of the compendia is not a drug.
solution to its dilemma, taking a middle position. The court stated that "the listing of an item in an official compendium should be some evidence that such item is a drug,"103 and looked at the definitions of "article" (drug) and "instruments, apparatus and contrivances," (device). The court quickly realized the futility of such an approach because the products "are arguably either articles, or instruments, apparatus and contrivances."104

After exhausting all of the technical legal arguments offered by counsel the court found the products to be drugs because:

The public will be better protected by classifying plaintiff's products as drugs rather than devices so that proper testing, controlled by the Government, can be pursued. It would seem that where an item is capable of coming within two definitions, that definition according the public the greatest protection should be accepted.105

On appeal the Second Circuit Court of Appeals affirmed the ruling that the products were new drugs and could not be shipped in interstate commerce without an approved new drug application.106 The court conceded arguendo "that the hemostat and the tube taken alone are 'instruments' and thus 'devices' within the meaning of the Act."107 But, relying on the trial court's analogy to a drug packed in a disposable syringe, Judge Smith rejected AMP's argument that the nylon thread and disk are also devices because they are "components, parts, or accessories" of the hemostat and the tube.108 After pointing out that if it were not for the provision in 21 U.S.C. § 201(g) (1964) which provides that the term drug "does not include devices," . . . "the Act's definition of 'drug' [would be] so broad as to cover AMP's disk and thread,"109 the court traces the legislative history of the 1938 Act, noting that in the early drafts of the bill there was no separate definition of "device." These early versions defined the term drug as "all substances, preparations and devices intended for use in the cure, mitigation, treatment or prevention of disease. . . ."110 In the course of debate in the Senate this definition was subjected to the criticism that ". . . to maintain that a purely mechanical device is a drug and to be treated as a drug in law and in logic and in

103. 275 F. Supp. at 414.
104. Id. at 414.
105. Id.
106. AMP Inc. v. Gardner, 389 F.2d 825 (2d Cir. 1968); cert. denied, 393 U.S. 825 (1968).
107. 389 F.2d at 827.
108. Id.
109. Id.
110. Id. at 828, citing 79 CONG. REC. 4841-45 (1935).
lexicography is a palpable absurdity. . . ."\textsuperscript{111} In response to this criticism a parallel, separate definition of device was inserted to insure that devices would be subject to precisely the same requirements as drugs. The court could find nothing in the legislative history indicating "that the Congressional purpose in providing a separate definition of 'devices' was anything other than to avoid the incongruity of classifying such things as electric belts as 'drugs.'"\textsuperscript{112}

When in 1937 the "Elixer Sulfanilamide" tragedy sparked Congress to require pre-market clearance for new drugs,\textsuperscript{113} no thought was given to the distinction between drugs and devices; yet, since only new "drugs" were covered, the distinction between drugs and devices became important for the first time. Giving the broadest possible construction to the word "drug" for new drug purposes and the narrowest possible construction to the word "devices" the court held that:

Since the only significance in classifying AMP's products as either 'drugs' or 'devices' is that if they are 'drugs' they may be subject to the new drug provisions of the Act, we must classify them with reference to the purpose for which Congress enacted those provisions. That purpose was, very clearly to keep inadequately tested medical and related products which might cause widespread danger to human life out of interstate commerce. The product which immediately precipitated Congressional concern—"Elixer Sulfanilamide"—was a drug within the everyday, narrow sense of the word, but we would hardly suppose that when Congress incorporated the 'new drug' bills resulting from the 'Elixer Sulfanilamide' tragedy into an Act which contained an extremely broad definition of the word 'drug,' it intended that the operation of those provisions should be restricted to products commonly called 'drugs,' and that products such as ligatures, which might present the very dangers the provisions were designed to meet, should be excluded. . . . The exclusionary classification 'devices' should, we think, be limited to such things as Congress expressly intended it to cover. The language of section 201 (g) plainly permits calling AMP's nylon thread and disk, in their intended use, 'drugs,' and we hold that that is their appropriate classification.\textsuperscript{114}

\textsuperscript{111} Id. at 828, citing remarks of Senator Clark of Missouri, 79 Cong. Rec. 4841 (1935).
\textsuperscript{112} Id. at 829.
\textsuperscript{113} See text accompanying note 7 supra.
\textsuperscript{114} 389 F.2d at 829-30.
THE DRUG-DEVICE DEFINITION

THE DEFINITION DICHOTOMY IN ANTIBIOTIC
DRUG CERTIFICATION

Whether an article is classified as a "drug" or a "device" has significance in other areas of drug regulation. When antibiotics, the so-called wonder drugs, were developed the need arose for government certification of batches of antibiotics. The certification regulations are applicable only to drugs; if one were thus able to conceptualize a product containing an antibiotic as a device, such an article, not being a drug, would not have to be certified prior to being shipped in interstate commerce.

The history of antibiotic certification begins with the first antibiotic, penicillin. Initially large scale production of penicillin was undertaken to supply the armed forces with adequate supplies for the enormous number of battle casualties suffered during World War II. The vagaries of penicillin production, the instability of the product and the military's purchasing specifications made it imperative that the FDA examine all batches of penicillin.

Toward the end of the war when penicillin became available for civilian use, Congress amended the Act to provide for certification of products containing penicillin. In 1949, when the certification section was enlarged to include Aureomycin, Chloramphenicol and Bacitracin, the FDA urged passage of the amendment because the unusual difficulties inherent in the manufacture of these antibiotics and the manufacturers' unsatisfactory methods of testing finished lots created an unusual likelihood that lots would be marketed which were not of the appropriate strength, quality and purity and created a need for a check of each batch by a disinterested authority. Later, as they came into use, other types of antibiotics were added to the statute and in 1962 the Act was amended to require certification for "any antibiotic drug."

115. Antibiotics did not come into general use until several years after the enactment of the 1938 Federal Food, Drug and Cosmetic Act.
116. "The Secretary of Health, Education, and Welfare, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin, streptomycin, chlorotetracycline, chloramphenical, bacitracin, or any other antibiotic drug or any derivative thereof." 21 U.S.C. § 357 (a) (1964) (emphasis added).
118. 59 Stat. 463 (1945).
119. See letter from Oscar Ewing, Administrator of the Federal Security Agency in S. Rep. 600 (to accompany H.R. 3151), 81st Cong., 1st Sess. 2-3 (1949). In 1949 the FDA was a part of the Federal Security Agency Under the Reorganization Plan No. 1 of 1933, the Federal Security Agency was abolished and all functions of that Agency were transferred to the Department of Health, Education and Welfare.
At its inception the certification program had industry support, and later some industry officials complained that certification was no longer necessary on a batch-by-batch basis. In response to this, the 1962 amendment provided that antibiotic drugs may be exempted from the batch certification rules if the manufacturer produces fifty or more consecutive satisfactory batches within eighteen months or otherwise demonstrates satisfactory consistency in production. The procedure for obtaining exemption from certification is explained in the regulations.

Antibiotic drug certification proceeds pursuant to regulations promulgated by the Secretary of Health, Education and Welfare, as authorized by the Act. Among the antibiotic drugs required to be certified are antibiotic sensitivity discs, i.e., cardboard discs impregnated with various antibiotics used in laboratory tests to determine which of several antibiotics will be most useful in treating a particular infection. One regulation sets out the tests and methods of assay used to determine the potency of these discs, the standards of potency, and the methods for calculating potency. Another regulation fixes the certification procedure for antibiotic sensitivity discs, and establishes approved standards of identity, strength, quality and purity as well as packaging requirements and procedures to be followed to obtain certification by the FDA. In order to obtain certification, the person requesting certification must submit tests and assays made by him on a (accurately) representative sample and must submit samples of the drug for re-testing in the Government's laboratory.

All of these regulations are based on the premise that antibiotic sensitivity discs are "drugs" within the meaning of the Act and are therefore subject to the antibiotic certification requirements of the Act. Recently, however, the courts have had to deal with the question: Are antibiotic sensitivity discs drugs or devices? As a result of two conflicting

121. See 2 H. TOULMIN, THE LAW OF FOODS, DRUGS AND COSMETICS § 29.2 (2d ed. 1963). Manufacturers of high quality antibiotics support certification because it protects them from illegitimate competition and producers who are improperly equipped, inadequately staffed, or who make irresponsible representations for their products. W. Van Winkle, Drug Certification in DRUG RESEARCH AND DEVELOPMENT 415 (A. Smith & A. Herrick ed. 1948); The FDA ruled recently that generic manufacturers of chloramphenical must conduct tests to prove that their versions of the drug are as effective as the brand name version. Wall Street Journal, Dec. 26, 1967 at 3, col. 1.
123. 21 C.F.R. § 144 (1968).
125. 21 C.F.R. § 147.1 (1968).
126. 21 C.F.R. § 147.2 (1968).
127. 21 C.F.R. § 147.2(d) (1968).
decisions the discs were drugs in Chicago and devices in Detroit.\textsuperscript{128}

The first of these cases was a suit to enjoin the shipment in interstate commerce of a product labeled a "Multidisk," a circular piece of paper around the circumference of which are individual discs each impregnated with a different antibiotic. The "Multidisk" is used in laboratories to test the sensitivity or reaction of a specimen, such as sputum, urine or throat swab, drawn from a patient, to each of the antibacterial agents contained on the small discs. The function of the disc is to indicate which of the several antibiotics is to be preferred in treating the patient's infection.\textsuperscript{129} The sensitivity disc provides a means for eliminating much of the trial and error approach to antibacterial therapy by identifying the drug most likely to be effective without experimenting on the patient himself.

After a hearing on a motion for summary judgment, the trial judge filed findings of fact and conclusions of law holding the "Multidisk" to be "an article that is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man within the meaning of 21 U.S.C. 321(g).\textsuperscript{130} Thus "Multidisks" are drugs and subject to the antibiotic certification requirements of the Act. A permanent injunction enjoined the manufacturer from introducing into interstate commerce any uncertified "Multidisk." Nowhere in the court’s findings is there a hint that the "Multidisk" might be something other than a drug. Neither does the court mention that its definition of a "Multidisk" as an article intended for use in the diagnosis, cure, etc. does not exclude it from being defined as a device.

In 1962, at approximately the same time the FDA was seeking to enjoin Consolidated Laboratories from shipping uncertified "Multidisks" in interstate commerce, a libel of condemnation\textsuperscript{131} was filed against another


\textsuperscript{129} United States v. Consolidated Laboratories, CCH F.D. Cosm. L. Rep. \textsuperscript{\textcopyright} 80,030 (N.D. Ill. 1963).

\textsuperscript{130} Id. at 80,106.

\textsuperscript{131} An ordinary libel "in rem" brought by the United States to condemn food in interstate commerce as adulterated, is a "civil action." United States v. 935 Cases . . . Tomato Puree, 136 F.2d 523 (6th Cir. 1943); cert. denied, 320 U.S. 778 (1943). An actual seizure is not a necessary prerequisite to a libel for condemnation. United States v. Capon Water Co., 30 F.2d 300 (E.D. Pa. 1929).

The procedure in a libel for condemnation must conform as nearly as possible to the admiralty rules. United States v. 74 Cases . . . Cobbs Pure Tropical Fruit Delicacies Plum Jelly, 73 F. Supp. 1009 (D. Minn. 1947). Otherwise, all rights are determined as in any other action at law. United States v. 397 cases . . . Salad Oil, 16 F. Supp. 387 (D. N. J. 1936). Admiralty rules apply only to the seizure of the property by process in rem. After the seizure pursuant to libel, the proceedings take on the character of a law action. United States v. Arizona Canning Co., 212 F.2d 532 (10th Cir. 1954); United
brand of uncertified antibiotic sensitivity discs. Several cases of “Bacto-Unidisks” were seized and alleged to be misbranded because they were drugs composed partly of antibiotic drugs and not certified. A “Bacto-Unidisk” is similar to a “Multidisk” in that it is a circular piece of cardboard in the form of a ring. Extending inwardly from the ring are eight circular paper units, seven of which are impregnated with different antibiotic drugs and the eighth with sulfadiazine, a chemical antibacterial agent. Like “Multidisks,” “Bacto-Unidisks” are used to determine which antibiotic or sulfadiazine will be most effective in treating an infection.

At the trial both sides presented the expert testimony of doctors who testified as to the medical definition of a drug. The doctors thought of drugs as those articles applied to the body or taken internally either orally or by injection. Of course, the definition in the Act, not the opinion of doctors, controls the definition of a drug for purposes of the Act. Nevertheless, counsel for the Government and the claimant examined and cross-examined medical experts for three days to produce a transcript of over 300 pages of irrelevant testimony.

The parade of medical witnesses did accomplish one thing; it enabled the trial judge to render an opinion inconsistent with the statute by substituting the medical definition of drug for the statutory definition of drug. The judge cited the testimony of a doctor who was unable to think of a drug which was neither taken into nor applied to the body. A layman, when asked whether he thinks a piece of cardboard with antibiotics on it is a drug or a device will probably answer “device.” A piece of cardboard is not what one thinks of as a drug. After the trial the judge was able to say that the “Bacto-Unidisk” is not a drug because it is not “administered to man or other animals either internally or externally.”

States v. 216 Bottles ... Sudden Change, 36 F.R.D. 695 (E. D. N. Y. 1965).


132. United States v. An Article of Drug ... Bacto-Unidisk, Trial Court's finding's of fact 1 and 4, Joint Appendix on Appeal 145a.


134. See the excerpts from the transcript reproduced in the joint appendix prepared for the appeal to the Sixth Circuit Court of Appeals. Joint Appendix at 52a (Testimony of Dr. C. K. Wolfe, Jr.) ; 92a-93a (Testimony of Dr. C. S. Keefer) ; 124a (Testimony of Dr. L. C. Miller).

135. Memorandum Opinion, Joint Appendix at 153a.

This conclusion was no longer a layman’s intuitive judgment but a conclusion based on “expert testimony.”

The trial court conceded that a literal reading of the definition of drug contained in the act clearly applied to the “Bacto-Unidisk” but he could not accept the idea that a piece of cardboard not taken into or applied to the body is a drug. The court concludes its opinion by stating frankly, if indelicately:

When it comes right down to the determination which we must make, a literal reading of (g)(2) [21 U.S.C 321(g)(2)] which defines ‘drug’ as ‘articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals’ clearly has application to the article libeled herein. Our reluctance to make this finding and conclusion our holding is due to the fact that it appears to us to be ridiculous and contrary to common sense. . . .

We are not here called upon to decide if the disk is a device, but it appears to us that consideration of it in this category under (h) [21 U.S.C. 321(h)] is far more appropriate than consideration of it as a drug within the purview of (g) [21 U.S.C. 321 (g)].

The Court of Appeals for the Sixth Circuit affirmed the trial court’s decision in an opinion which is noteworthy for its brevity, if for no other reason. The court attempts to rationalize its decision by co-mingling the medical and legal definitions of drug with considerations of legislative intent. In this way the court hedges the issues so that it does not have a clear question to decide. Rather than accept the trial judge’s candid statement of his dilemma that a literal reading of the section which defines drug as an article intended for use in the diagnosis, etc. of disease clearly has application, the court qualifies the trial court’s application of the definition by explaining:

This [literal reading and application of the definition] is only true in an indirect sense. Certainly it [“Bacto-Unidisk’] has nothing to do with diagnosis or prevention of disease. In itself it is not intended for use either internally or externally to cure, mitigate or treat disease. It could only aid the physician in determining what antibiotics to use for the cure, mitigation or treatment of the patient’s disease. We agree with the trial judge that it was not the legislative intent to apply the phrase

137. Memorandum Opinion, Joint Appendix at 153a-154a.
Careful scrutiny of the court’s reasoning reveals that the opinion violates not only the spirit and purpose of the Act but the letter of the law as well.

Drug is defined disjunctively in the act; an article fits within the definition if it is used in diagnosis, etc. or prevention of disease. Therefore, an article is a drug if it is intended for use in any aspect of disease therapy or prophylaxis. Furthermore the act does not require that the article be used either internally or externally but only that it be intended for use in contravention of disease; the manner of utilization is immaterial. It may be conceded that an antibiotic sensitivity disc is not intended for use in the diagnosis or prevention of disease. With respect to the other parts of the definition, however, the disc clearly is intended for use in the “cure, mitigation or treatment of disease.” Realizing the definition is sufficiently broad to encompass the libelled article, the court amended the statutory definition by adding the requirement that the article be used internally or externally. Nowhere in the Federal Food, Drug and Cosmetic Act is there any mention of the requirement that a drug be applied either internally or externally. Consequently, the external or internal condition that the court imposes can only have come from the medical understanding of the word drug. Again, in protestation, it must be pointed out that the Federal Food, Drug and Cosmetic Act does not include any reference to the medical definition of drug or any standard other than the definition contained in 21 U.S.C. 321(g) (1964). The court’s confusion can be forgiven because the transcript is filled with the testimony of medical experts who attempted to articulate their definition (a medical definition) of drug.

It is far more difficult, however, to forgive the court’s lack of candor in imposing an additional test—direct versus indirect manner of use. Once more the absence of any prerequisite of directness in the statute must be pointed out. With respect to the court’s off-hand comment that it was not the legislative intent to apply the phrase in such an indirect manner, there is no indication that the court referred to the legislative history. If the court had perused the Congressional debates and reports, it would have found that thirty years before, when Congress debated the Act, Congress had not anticipated this problem and there was no discussion of a directness test.

139. 392 F.2d 21 at 22.
140. 21 U.S.C. § 321(g) (1) (B) (1964).
141. See note 133 supra.
142. See generally C. Dunn, supra note 6.
If one purpose of the definition of drug is to delineate the jurisdiction of the Food and Drug Administration and if the FDA is supposed to regulate those products used in the diagnosis, etc. of disease to insure that such articles are safe for use, what possible legislative purpose could be served by excluding those articles which are used in an indirect manner? If it is important that antibiotics maintain proper potency and sterility, then it must be equally important that all precautions are used to insure the use of the most appropriate antibiotic. If the Congressional intent in enacting antibiotic drug certification was to guarantee more effective use of the so-called “wonder drugs,” it is a perversion of the purpose to deny FDA regulation of the article used to select the drug—an essential step in antibacterial therapy.

The Sixth Circuit states that the “evidence affords no basis for the conclusion that the definition of 'drug' in [21 U.S.C. 321(g)(1964)] was intended by Congress to extend beyond the meaning of that term in medical science. . . .” If Congress had intended the definition of drug in the Act to be co-extensive with the medical definition of drug, there would have been no need to specify a definition of drug in the Act. It seems far more reasonable to conclude that Congress took the trouble of spelling out a definition of drug in the Act because it intended the definition of drug to mean something other than the medical definition of drug.

The court distinguishes those cases which held such substances as honey, mineral water, cigarettes, peppermint tea leaves and human blood to be drugs by first quoting the statutory definition of drug with emphasis on the phrase “intended for use.” It then reasoned:

In holding honey, mineral water, cigarettes and peppermint tea leaves to be drugs, the courts based their opinions on the fact that by advertising these products as possessing therapeutic and medicinal powers, such products were ‘intended for use’ as drugs and hence within the statutory definition. Whole human blood which may be used in human blood transfusions clearly comes within the meaning of the statute. [Footnotes omitted.]

143. 392 F.2d at 23.
149. 382 F.2d at 23.
All of these cases are distinguishable, but not on the intended use rationale used by the court. Sensitivity discs are advertised and intended for use as laboratory reagents. Their intended use is to determine which of several antibiotics is the proper one to use in the cure, mitigation and treatment of certain diseases. The labeling of the disc states that it has certain powers though not powers to aid in therapeutic treatment.\textsuperscript{150}

By sticking to its medical definition of drug, the court could have distinguished the "Bacto-Unidisk" from the other articles because it is not eaten, drunk, smoked or transfused into or onto the human body. While such a distinction is not suggested by the statute, at least it would have been consistent with the earlier portion of the opinion.

At this point, it should be noted that the Act does not define a drug to be the treatment or cure; it need only be an article used in the treatment or cure of disease.\textsuperscript{151} Many items commonly thought of as drugs (and which are drugs within the definition of drug contained in the Act) are not in and of themselves a treatment but are used in the treatment of disease. Some everyday examples are: aspirin, which does not treat any disease but is used in the treatment of arthritis because it relieves pain so that stiffened joints may be moved more freely; anesthetics, which do not cure anything but are used in surgical treatment of disease; and tranquilizers, which are not a cure or treatment but are used in the treatment of psychiatric disorders. By the same reasoning an antibiotic sensitivity disc, which is not a cure or treatment of disease, is used in the treatment of infection by indicating the relative susceptibility or resistance of organisms to antibiotics and in this manner enables the physician to make a rational choice of the appropriate antibiotic for use in treating the disease.

The Sixth Circuit would have been well advised to follow the \textit{AMP} case\textsuperscript{152} because the Second Circuit's reasoning in that case applies with equal validity to antibiotic certification. In enacting the certification

\begin{itemize}
\item \textsuperscript{150} The labeling states that "Bacto sensitivity discs are especially valuable in selecting the drug effective against chronic or persistent infections refractory to primary therapy," and that they "are recommended as a rapid, practical, clinically accurate and inexpensive means of determining the relative sensitivity of microorganisms to these therapeutic agents." Label of Bacto-Unidisk, Joint Appendix at 143a.
\item \textsuperscript{151} 21 U.S.C. § 321(g) (1) (B) (1964).
\item \textsuperscript{152} AMP Inc. v. Gardner, 389 F.2d 825 (2d Cir. 1968), \textit{cert. denied}, 395 U.S. 825 (1968). The AMP case was decided by the Second Circuit on Feb. 13, 1968 and appeared in the Federal Reporter dated April 29, 1968. The Bacto-Unidisk decision, handed down on March 29, 1966, does not mention the decision. Perhaps this oversight resulted from the neglect of counsel to provide the court with a pre-publication copy of the Second Circuit's opinion. However, failure to cite and to distinguish the trial court opinion in the AMP case which was decided September 29, 1967, and which appeared in the Federal Supplement dated January 13, 1968 (275 F. Supp. 410 (1968)) must be attributed to inexcusable neglect on someone's part.
\end{itemize}
requirements for antibiotic drugs, Congress did not intend to exclude those antibiotic drugs impregnated into a piece of cardboard because they might be deemed devices. Because Congress did not foresee the development of antibiotic sensitivity discs, it did not contemplate their status. However, to further the congressional purpose of insuring safe and uniform antibiotics, sensitivity discs should be included in the certification program. To include otherwise would be to put the physician in the anomalous position of knowing that those antibiotic drugs he prescribes for treatment come from a batch which has been tested for purity and potency without being certain that the drug he prescribed is the proper one.

Even if the Sixth Circuit were unwilling to adopt the policy-oriented approach of the Second Circuit, there was a technical alternative available to the court which would have allowed it to further the Act's health protection aims without flatly stating that the trial judge erred. Reliance upon the forgotten fourth part of the definition of "drug" might have provided the solution to the court's dilemma. "Articles intended for use as a component of any articles specified in [the first three definitions] are drugs." From this definition the court could reason as follows: There is no question that each of the articles impregnated into the disc is a drug. No one would question that penicillin, sulfadiazine, tetracycline or any of the other articles, are by themselves drugs. Furthermore, it is the drugs that do the work of providing information as to which drug is the proper therapy. Therefore, rather than consider the drugs as components of the disc, it is the cardboard disc which should be characterized as a component of the drugs. Certainly it is a more appropriate and a more logical interpretation of the statute to conclude that the active ingredients, the drugs, are the "article" and the inert cardboard is merely a component of the drugs.


The FDA has taken the position that the entire antibiotic sensitivity disc is a drug; therefore, the disc must be certified. While this reasoning makes sense, it is unnecessary to the FDA's certification program. The FDA could have relieved its attorneys of having to create arguments for the proposition that antibiotic sensitivity discs are drugs within the meaning of the Act merely by taking the position that each of the antibiotics impregnated into the disc is a drug and each of the antibiotics must be certified. No one could argue persuasively that penicillin is not a drug. Nor could a manufacturer argue convincingly that penicillin ceases to be a drug merely because it is impregnated into some cardboard. The FDA would then certify each of the antibiotics separately and if one of them failed to meet the requirements for certification, it could not be shipped in interstate commerce. An effective certification program could be accomplished by certification of individual component antibiotics because failure of one antibiotic drug to pass the potency tests would stop the interstate shipment of the entire disc. In order for the disc to be shipped, each antibiotic drug would have to meet the certification requirements. Thus, individual certification would have avoided the semantical problems and accomplished FDA's health protection goals.
As this article was going to press, the Supreme Court in an eight to one decision reversed the decision of the Sixth Circuit and upheld the Secretary's construction that antibiotic sensitivity discs are drugs.\textsuperscript{154} Writing for the Court, Chief Justice Warren characterized the case as a "definitional controversy" and without criticizing the opinion of the court below, the court made it clear that this was a legal, not a medical question:

Viewing the structure, the legislative history, and the remedial nature of the Act, we think it plain that Congress intended to define 'drug' far more broadly than does the medical profession. Furthermore, the legislative history, read in light of the statute's remedial purpose, directs us to read the classification 'drug' broadly, and to confine the device exception as nearly as possible to the types of items Congress suggested in the debates, such as electric belts, quack diagnostic scales, and therapeutic lamps, as well as bathroom weight scales, shoulder braces, air-conditioning units, and crutches.\textsuperscript{155}

The court throughout the opinion restated the Congressional intent to protect public health. In its concluding paragraph, the court stated:

In upholding the Secretary's construction of the Act, we are not unmindful of our warning that 'In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.' 62 Cases of Jam v. United States, 340 U.S. 593, 600 (1951). Our holding here simply involves an obvious corollary to that principle, that we must take care not to narrow the coverage of a statute short of the point where Congress indicated it should extend.\textsuperscript{156}

This decision allows the continued governmental certification of antibiotic sensitivity disks which is so important to insure uniformity of potency. By basing its decision on policy grounds, the court avoided both semantical difficulties and the confusion of the medical debate which ensued at the trial. This method, like that of the Second Circuit in the AMP case, is by far the most appropriate judicial approach to the drug-device dilemma.

\textsuperscript{155} Id.
\textsuperscript{156} Id.
THE DRUG-DEVICE DEFINITION

THE DILEMMA RESOLVED — PROPOSED LEGISLATIVE DESTRUCTION OF THE PRE-MARKET CLEARANCE DICHOTOMY

The broad construction of the Act by the Supreme Court should enable the FDA to classify any borderline objects as drugs rather than devices; nevertheless, the solution to the entire drug-device definition dichotomy is legislation. The FDA cannot, by its own action, require a new device application from the manufacturer of medical devices. An administration bill which would have required pre-clearance of certain medical devices and set standards for others was introduced into the House of Representatives during 1967. H.R. 10726, the Medical Device Safety Act of 1967, would have given the Food and Drug Administration the authority to promulgate regulations establishing standards for the composition, properties or performance of any device other than a device intended solely for diagnostic use. More importantly this bill would have required pre-market clearance by the FDA of medical devices intended to be placed in whole or in part within the human body, or intended to be used for subjecting the human body to ionizing radiation or other types of energy. The bill would have allowed the Secretary by special order to require pre-market clearance for other devices if probable cause existed to believe that the device was neither effective for its intended use nor safe for use nor reliable under the conditions prescribed, recommended or suggested in its labeling. Obviously, antibiotic sensitivity discs would not fall within the purview of the bill, thus not resolving the disc dilemma.

In addition to the Administration bill, the Ninetieth Congress had

158. H.R. 10726 § 513(a). An example of the type of device which would have to meet the FDA's standards of safety, reliability and effectiveness under the proposed legislation is an intrauterine birth control device. Even though this method of contraception is now used by about one million women in the United States, it is doubtful if a manufacturer could establish that intrauterine devices are generally recognized among experts qualified by scientific training and experience to evaluate the safety, reliability, and effectiveness of such device, to be safe, reliable, and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof.

Recently, a government advisory committee studied intrauterine devices for a year concluding that while the devices are highly effective and generally safe, there should be greater governmental regulation of their production, Wall Street Journal, Jan. 22, 1968, at 7, col. 1. One of the dangers inherent in intrauterine devices is infection caused by insertion of a non-sterile device into the uterus. Contamination may occur when the coil, loop or bow is straightened out and placed into a tube-like inserter prior to implantation. The committee suggested sterilization by the manufacturer and pre-packaging so that physicians need only make minor adjustments to put the device into the inserter as a method of procuring major public health protection. Absent new legislation, the FDA is powerless to impose manufacturing or packaging requirements upon device manufacturers. The usual remedies used by the FDA if an article is misbranded or adulterated are unavailable if the FDA's only complaint is that there might be a better way to manufacture or package the articles.
before it a bill which would have emasculated the Medical Device Safety Act of 1967. The National Medical Devices Standards Commission Act would have established a presidentially appointed commission of twenty members, consisting of four each from private industry, university or private laboratories, the private practice of medicine, government agencies and Congress. The commission would have (1) reviewed minimum standards and quality controls used in the manufacturing of medical devices to determine the need for federal regulation; (2) advised on manufacturing practices and standards; (3) established methods for determining minimum performance standards for the manufacture of medical devices; (4) established methods for determining the medical value of devices manufactured; and (5) recommended to the President and to the Congress feasible methods for federal regulation.\(^\text{159}\) The commission would have operated as a federal agency for no longer than five years with the authority to hold hearings, employ staff personnel and enter into contracts or agreements to make grants for studies and surveys with public and private organizations and institutions.

The most obvious objection to the proposal was that it called for studies, surveys, reviews and recommendations for five years during which action could not be taken. But even assuming, \textit{arguendo}, that it would be useful to have a commission study medical device standards, the proposed composition of the Commission is such as to guarantee inaction and a paucity of constructive suggestions. Only four of the twenty members would be chosen from government agencies concerned with the protection of public health, whereas twelve of the members would be chosen from the private sector of the medical device industry, an industry which has inherent antipathy to and distrust of government regulation. Presumably the four members of Congress would have no definite bias one way or the other. However, even if the four Congressional members were pro-regulation, they would have neither the time nor the expertise to offset the overwhelming anti-regulation character of the majority of the Commission.

The National Medical Devices Standards Commission would be a do-nothing Commission providing an obstacle in the path of any attempts at effective medical device legislation for five years. Furthermore, the bill discounted completely the ability of the FDA to establish regulations in this field as it has previously done in numerous other fields of equal complexity. It likewise ignores the procedural statutory safeguards followed by the FDA in promulgating regulations. Under the existing law a regulation is first proposed and published after which interested parties

may comment orally or in writing. After all comments have been received, the Secretary acts upon the proposal by publishing an order which is the regulation. At that time any person who will be adversely affected by the order may file objections specifying with particularity the objectionable provisions, stating grounds and requesting a public hearing on the objections. The objections operate to stay the effectiveness of the provisions of the order objected to. As soon as possible after such request for a public hearing, and after due notice, the hearing is held. At the hearing any interested person may present evidence relevant and material to the issues raised by the objections. After the hearing the Secretary publishes an order based on substantial evidence in the record of such hearing. In case of actual controversy, any person who will be adversely affected by an order may file a petition for judicial review of the order with a United States Court of Appeals for the circuit

160. 21 U.S.C. § 371(e)(1) (1964). Such a proposal may be made by either the Secretary of Health, Education, and Welfare or by any interested person.


162. 21 U.S.C. § 371(e)(2) (1964). A complaint must allege that a person may be adversely affected by the regulation. Such an allegation was held sufficient where the petitioner and his family were consumers and it was claimed that allowing the vitamin content of oleomargarine to be supplied by synthetic sources, under an order by the Federal Security Administrator, would adversely affect him and members of his family. Read v. Ewing, 205 F. 2d 630 (2d Cir. 1953). See also Washington State Apple Advertising Comm’n v. Federal Sec. Adm’r, 156 F.2d 589 (9th Cir. 1946) (apple grower failed to show that he would be harmed by a harmful residue left on fruit since he failed to state there was any residue on his fruit).

163. 21 U.S.C. § 371(e)(2) (1964). The Secretary then publishes notice of any provisions which have been stayed.

164. 21 U.S.C. § 371(e)(3) (1964). Notice of the public hearing must be sufficient. See Federal Security Administrator v. Quaker Oats Co., 318 U.S. 218 (1943); Willapoint Oysters v. Ewing, 174 F.2d 676 (9th Cir. 1949); United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint, 61 F. Supp. 847 (W.D. La. 1945). A party is entitled to a public hearing only after filing of objections, stating grounds therefor, and requesting a public hearing. In order to be effective to necessitate a hearing, the objections must be legally adequate so that, if true, the order complained of could not prevail. Dyestuffs & Chemicals, Inc. v. Fleming, 271 F.2d 281 (8th Cir. 1959); cert. denied, 362 U.S. 911 (1960).

165. 21 U.S.C. § 371(e)(3) (1964), although relevant and material evidence is required in a hearing it is not reversible error to receive immaterial, irrelevant, or hearsay evidence as long as the order is not based solely on this evidence. Willapoint Oysters v. Ewing, 174 F.2d 676 (9th Cir. 1949).

166. 21 U.S.C. § 371(e)(3) (1964). The order of the Secretary must set forth detailed findings of fact. The findings must be based on evidence with sufficient "rational probative force" to support the Secretary's judgment. Federal Sec. Adm'r v. Quaker Oats Co., 318 U.S. 218 (1943). The findings cannot be based on hearsay evidence or mere guess, conjecture, or chance, Willapoint Oysters v. Ewing, 174 F.2d 676 (9th Cir. 1949), but substantiality of the evidence is to be determined in the light of all that the record relevantly presents. Cream Wipt Food Prod. Co. v. Federal Sec. Adm'r, 187 F.2d 789 (3d Cir. 1951). An order cannot become effective for at least ninety days after the hearing.
wherein the adversely affected party lives or has his principle place of business. The court of appeals has jurisdiction to affirm the order or set it aside in whole or in part, temporarily or permanently, or the court may order the Secretary to hear additional evidence if there are reasonable grounds for failure to adduce such additional evidence at the hearing.

Thus, there is little danger that the FDA would arbitrarily or capriciously set up standards which could, as feared by the bill's author, Congressman Reineke, "seriously limit and hinder advanced research somewhere in the country."

Beyond the usual safeguards against administrative abuse of discretion was the explicit command of the Medical Device Safety Act of 1967 to the Secretary of Health, Education and Welfare in the Development and consideration of proposals for the issuance of standards for therapeutic devices: to invite appropriate participation by "informed persons representative of scientific, professional, industry, and consumer organizations that in his judgment can make a significant contribution to such development."

The proposed Medical Device Safety Act would also have established an Advisory Council on Devices consisting of "persons chosen with a view to their special knowledge of the problems involved in the regulation of various kinds of devices . . . members of the professions using such devices, scientists expert in the investigational

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167. 21 U.S.C. § 371(f)(1) (1964). To be an adversely affected person, a party must show some direct adverse effect traceable with reasonable certainty to the regulation. The adverse effect must be a result that is not only reasonably sure to follow the enforcement of the regulation but will be "something more than nominal or highly speculative." United States Cane Sugar Refiner's Ass'n v. McNutt, 138 F.2d 116, 120 (2d Cir. 1943).

A regulation of the Commissioner of Food and Drugs is considered a final agency action which is reviewable by the courts. Abbott Laboratories v. Gardner, 387 U.S. 136 (1967). However, there must be an "actual controversy" over the lawfulness of the order before it will be reviewed by the court of appeal. Land O'Lakes Creameries v. McNutt, 132 F.2d 653 (8th Cir. 1943).

168. 21 U.S.C. § 371(f)(3) (1964). It should be noted that the findings of the Secretary as to the facts, if supported by substantial evidence, are conclusive. Therefore, when supported by substantial evidence, the findings of the Secretary based on the record cannot be reversed by the reviewing court even if the court would have reached a different conclusion as long as the findings are within statutory and constitutional limitations. Federal Sec. Adm'r v. Quaker Oats Co., 318 U.S. 218 (1943); Reade v. Ewing, 205 F.2d 630 (9th Cir. 1953); Byrd v. United States, 154 F.2d 62 (5th Cir. 1946).

169. 21 U.S.C. § 371(f)(2) (1964). In addition, the petitioner who applies to the court for leave to adduce additional evidence must show it is material. In Reade v. Ewing, 205 F.2d 630 (2d Cir. 1953), the court would not stay the operation of an order or require the Secretary to reopen hearing new evidence, because the Secretary had notified petitioner that the new evidence would not change his decision and because the court considered the case as if the record contained such evidence and a formal ruling on the evidence.


171. H.R. 10726 § 512(b).
use of devices and members of the general public.\footnote{172} The precise composition of the advisory council was unspecified; however, it would have been similar to the National Medical Devices Standards Commission with the significant addition of representatives for consumer organizations, who, although they might not have impressive credentials, would give the consuming public a well-deserved voice in decisions affecting public health.

The real difference between the two bills was not a disagreement as to whether private industry should have a voice in setting standards. That was provided by both bills. The significant, albeit unarticulated, difference concerned vesting control of setting standards. Should the government agency charged with protecting the public from potentially dangerous devices or the representatives of private industry who develop, manufacture and market medical devices set standards? Self-interest in the greater profits to be made in the absence of meaningful pre-market clearance requirements or in the absence of potentially costly manufacturing controls seems to disqualify from consideration the representatives of private industry. While they have superior knowledge about manufacturing techniques, their conflict of interest is too substantial to allow them to wield the ultimate authority over medical device standards.

Admittedly the manufacturers who exercise above average care in the production and distribution of medical devices welcome additional regulation because it protects them from what they deem to be the unfair competition of the producers who cut every possible corner to increase profits.\footnote{173} Nevertheless, when the time came to consider the extent of standards or pre-market clearance to be required, the duty to consumers and the duty to stockholders would be in hopeless conflict. Far more appropriate was the Administration bill's device of the federal agency which has no built-in conflict of interest and which can utilize the expertise of the manufacturers through consultation either formally or informally.\footnote{174}

One other bill introduced during the past Congress is worthy of note. It classified devices not generally recognized among qualified experts

\footnote{172}{H.R. 10726 § 707(a).}

\footnote{173}{See A. Smith, \textit{A View from the Top—The Pharmaceutical Manufacturer's Multi-responsibilities}, 23 Food Drug Cosm. L.J. 203, 208 (1968); see also Louisville Courier Journal, May 31, 1968, at A7, col. 1 (article by D. Pearson).}

\footnote{174}{Whenever decision making is transferred from a government agency to a panel of experts or any extracurricular advisory committee, the objection is frequently raised that the panel is subject to "backstairs influence," D. Cavers, \textit{Administering that Ounce Of Prevention: New Drugs and Nuclear Reactors}, 68 W. Va. L. Rev. 109, 129 (1966); and "every type of direct and indirect lobbying," Austern, \textit{Sanctions in Silhouette: An Inquiry Into the Enforcement of the Federal Food, Drugs and Cosmetic Act}, 51 Calif. L. Rev. 38, 45 (1963).}
as safe and effective as new devices and through the simple expedient of inserting "or device" after drug every time the term drug appears in the new drug section of the present act, subjected "new devices" to the identical pre-market clearance requirements as new drugs. For clarity, simplicity and lack of ambiguity the proposal is praiseworthy. It has the additional advantage of incorporating standards of pre-market clearance which have proved workable and with which both the FDA and pharmaceutical industry are familiar.

Despite its obvious advantages the simple solution is not the optimum resolution of the drug-device dichotomy. The vast number of devices which would be encompassed within the definition of new device would be a substantial administrative burden. Since the greatest danger to public health is from devices left in the body, devices which give off rays or energy, or those devices for which there is probable cause to believe they are not safe, reliable or effective for their intended use, it would be a waste of time and money to require pre-market clearance procedures for devices outside these categories. Also the new drug requirements are more stringent than those proposed for devices, and some of the requirements, such as clinical testing, are inappropriate for many types of devices. For these reasons the more thoughtful procedures contained in the Administration bill are better suited to effective pre-market clearance for devices.

Even though the FDA desperately needs some authority to keep quacks from marketing their worthless devices as well as standards for the many new and sometimes frightening advances made by scientists in the medical device field, enactment of device pre-market clearance legislation was not forthcoming during the ninetieth Congress. It may take a tragedy like "Elixer Sulfanilamide" or Thalidomide to arouse sufficient interest for enactment of medical device legislation; but someday lawyers will no longer be able to spend innumerable hours exercising their ingenuity by conjuring up differences between articles and contrivances and otherwise dissecting the definitions of drugs and device. In this case the lawyer's loss is the public's gain—for the first time since devices were placed within the Federal Food, Drug and Cosmetic Act thirty years ago they will be subject to much the same rigid scrutiny as drugs.

175. H.R. 2135, Sec. 4, 90th Cong. 1st Sess. (1967).