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Bruce C. Davidson

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# PREVENTIVE "MEDICINE" FOR MEDICAL DEVICES: IS FURTHER REGULATION REQUIRED?

BRUCE C. DAVIDSON*

## INTRODUCTION

One of the major trends in the development of the law of the United States in this century has been an ever-increasing concern for protection of the consumer. This concern has been spotlighted in the past decade by the efforts of "consumer crusaders," who have challenged manufacturers and demanded better and safer products for the public.[1] These efforts have been effective because they focused upon and publicized problems, complaints, and defects which unorganized consumers, as individuals, have little power to protest.

It is unfortunately true that consumer-protection legislation in a particular area has usually not been passed until the need for such legislation was dramatically demonstrated by some event that aroused and united public outrage. The Federal Food, Drug, and Cosmetic Act evolved largely from such events, and its history graphically demonstrates their catalytic effect on the legislative process.

Under the present Federal Food, Drug, and Cosmetic Act there exists an apparently inadvertently created and highly ambiguous dichotomy between "drugs" and "devices" with respect to premarket clearance requirements. This definitional dichotomy has caused much confusion and created significant problems of statutory construction for the courts. Moreover, this dichotomy,

* J.D., Harvard Law School; Associate, Quarles, Herriott, Clemons, Teschner & Noelke, Milwaukee, Wisconsin.

1. *See* R. NADER, UNSAFE AT ANY SPEED (1965). Mr. Nader has also become involved with the problemsof unsafe medical devices. *See, e.g.*, Mintz & Haseltine, *About 1,200 Patients Get Electrocuted Yearly, Hearing Told*, Washington (D.C.) Post, Feb. 20, 1969, at ____, col. ____. This article was reprinted in 115 CONG. REC. 4268 (1969). Even the Food and Drug Administration, itself, has become a target of "Nader's Raiders." In a report based on a two-year study, Nader and his student volunteer investigators "accused the agency of conspiring with the food industry to defraud consumers and even to endanger their health." TIME, April 20, 1970, at 18.

whereby "new drugs" are subject to premarket regulation but new "devices" are not, provides a loophole permitting people to be directly or indirectly injured or otherwise harmed by medical devices which are unsafe or ineffective (or both) for their intended use.

It is ironic that Congress has acted to protect the consumer's pocketbook from "predatory extensions of credit,"[2] while it has failed to act to protect his person (and his pocketbook) from injuries which he is virtually powerless to protect himself against. The present status quo seems even more egregious in that the average person has a false sense of security because he mistakenly believes that the omniscient and omnipresent "Government" is protecting him by setting standards and requiring premarket testing of medical devices—as is the case for articles classified as "new drugs." Added to this is the fact that the "consumer" of a medical device is usually in no position to make an intelligent, independent evaluation of the device to be used upon or implanted within his body. Even if he is not unconscious or so ill that he is incapable of makinguny decision at all, the exigencies of the situation frequently leave no alternative, or the person's state of mind may be so desperate that he will try anything. And, even if he were presented with the opportunity to make a rational choice, the average person does not possess the expertise to make it an intelligent one. Moreover, the "consumer" of a medical device normally does not buy it himself; rather, it is used upon or placed within his body by doctors or medical technicans, so that he is completely dependent upon them for his safety—yet they, in turn, may know little or nothing about the integrity of the device they are using.

Since the ultimate "consumer" of a medical device is normally in no position to peruse before partaking, the existence of the American ideal of a "free market,"without external regulation and dependent on competition and the good-faith cooperation of manufacturers for voluntary standard-setting, is of little value and small comfort to the "consumer" when he becomes the hapless and helpless victim of an unsafe or ineffective medical device, marketed without adequate testing and in disregard of whatever voluntary standards may exist. Therefore, it would seem that there is a need for federal standard-setting and premarket regulation with regard to some types of medical devices.

2. Consumer Credit Protection Act, 15 U.S.C. § 1671(a)(1) (1970).

This article will attempt to review the circumstances leading up to and culminating in the present status quo, analyze the current situation and its implications, and discuss the need and some of the proposed measures for resolving the present dilemma.

## I. THE DEVELOPMENT OF FOOD AND DRUG LEGISLATION

What provisions there are for the federal regulation of medical devices are contained in the Federal Food, Drug, and Cosmetic Act.[3] In order to discuss the present problems with respect to medical devices, however, it is necessary to review the history of food and drug legislation in the United States so as to see the context in and from which these problems have developed.

Although legislation relating to food and drugs dates well back into the nineteenth century,[4] the first comprehensive legislation designed to protect the public from impure and adulterated food and drugs was not enacted until 1906. The Federal Food and Drugs Act of 1906[5] was not easily enacted. The first bill to prevent the adulteration of food was introduced in the House of Representatives in 1879, but died in committee. In the twenty-seven year interim, nearly two hundred related measures were similarly unsuccessful.[6] Passage of the 1906 Act was attributable primarily to the zeal of one man, Dr. Harvey W. Wiley,[7] who continually prodded Congress as to the need for such a measure, urging that only a national law could effectively deal with the problems of fraudulent remedies and impure and adulterated food and drugs. However, even though Dr. Wiley attempted to arouse the public by his speeches and writings, it seems unlikely that this alone would have

3. 21 U.S.C. §§ 301-392 (1970).

4. This early legislation was primarily concerned with the taxation and regulation of imports so as to protect the young American food and drug industries from destructive foreign competition. Most of these laws dealt with foods; however, one law passed in 1848 provided for the examination of all imported drugs, medicines, and medicinal preparations as to their purity and fitness and as to their value and identity as described in the accompanying literature. 1 H. TOULMIN, THE LAW OF FOODS, DRUGS AND COSMETICS § 1.3 (2d ed. 1963).

5. Act of June 30, 1906, ch. 3915, 34 Stat. 768. This Act is popularly referred to as the "Wiley Pure Food and Drugs Act," since it was passed largely due to the efforts of Dr. Harvey W. Wiley, who became chief chemist of the Department of Agriculture in 1883 and had a consuming passion to eliminate impure and adulterated food from the American marketplace. *See* J. YOUNG, *The Medical Messiahs*, in THE LAWLESS CENTURIES (1967). This work also tells of the patent medicine abuses, which were the other primary evil the 1906 Act was intended to curb.

6. 1 H. TOULMIN, *supra* note 4, at § 1.3.

7. See note 5 *supra*. For a good biography of Dr. Wiley, see O. ANDERSON, THE HEALTH OF A NATION: HARVEY W. WILEY AND THE FIGHT FOR PURE FOOD (1958).

been enough to overcome the even then very strong food and drug lobbies; had it not been for the public impact of Upton Sinclair's *The Jungle*, with its description of the horrors of the American meat processing industry at that time, the bill might not have passed. The resulting public outrage was the additional impetus required to make Wiley's goal of a national pure food and drug law become a reality.

Although the 1906 Act was a significant step forward in consumer protection, it soon became evident that it had its shortcomings, which grew more serious as the economy continued to develop and the food and drug industries continued to expand. Amendments were added through the years,[8] but it was apparent that there was needed a new statute which would incorporate the still useful provisions of the 1906 Act, while adding new provisions to deal with problems that were either not regulated at all or were not effectively regulated by it. Also, it was simply not feasible to attempt to adjust to the profound changes in commercial and manufacturing conditions that had occurred in the food and drug industries during the first third of the twentieth century by the method of piecemeal amendments.[9]

Again it was demonstrated that food and drug legislation is not easy to enact. By the 1930's, the food and drug industries had become even more powerful, and they were quick to exercise their lobbying power when any further governmental regulation was suggested. The first bill embodying the proposed new legislation was introduced by Senator Royal S. Copeland on June 6, 1933,[10] but it was not until more than five years later, on June 25, 1938, that the Federal Food, Drug, and Cosmetic Act finally became law.[11]

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8. See 1 H. TOULMIN, *supra* note 4, at § 1.4. These amendments are summarized in U.S. DEP'T OF AGRICULTURE, REPORT OF THE CHIEF OF THE FOOD AND DRUG ADMINISTRATION (1931).

9. See S. REP. No. 493, 73d Cong., 2d Sess. (1934). S. 2800 was one of the earlier unsuccessful versions of what was to become the Federal Food, Drug, and Cosmetic Act of 1938.

10. S. 1944, 73d Cong., 1st & 2d Sess. (1933-34). This bill was prepared in the Department of Agriculture after President Roosevelt had authorized a revision of the Federal Food and Drugs Act of 1906. S. 1944 was prepared in that department because the Department of Agriculture was responsible for the enforcement of the 1906 Act. The Food and Drug Administration (FDA) was first provided for by the Agriculture Appropriation Act of 1931, 46 Stat. 392. The FDA is now part of the Department of Health, Education and Welfare. It was made a part of the Consumer Protection and Environmental Health Service created by the Secretary's reorganization on July 1, 1968. The FDA is responsible for the enforcement of the Federal Food, Drug, and Cosmetic Act, as amended.

11. Five bills, all sponsored by Senator Copeland, were introduced in the Senate during

The Federal Food and Drugs Act of 1906 had not regulated medical devices at all.[12] This was one of the defects sought to be corrected by the new legislation.[13] Also, although the 1906 Act had regulated drugs, in that it was unlawful to manufacture drugs which were adulterated or misbranded, it did not in any way require that new drugs be tested prior to marketing.[14] Moreover, while medical devices were, for the first time, included insofar as adulteration and misbranding were concerned, none of the earlier versions of the 1938 Act[15] required premarket clearance of either new drugs or new devices.

Once again it took a shocking event to enable this glaring gap to be plugged, and unfortunately it was plugged only with respect to new drugs. In 1937, a Tennessee pharmaceutical company marketed a liquid preparation of sulfanilamide, a newly developed "wonder' drug proven valuable in the treatment of infections when

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the course of the legislative battle. The first two—S. 1944, 73d Cong., 1st & 2d Sess. (1933-34), the original bill, and S. 2000, 73d Cong., 2d Sess. (1934), which superseded S. 1944—died in committee. S. 2800, 73d Cong., 2d Sess. (1934), which superseded S. 2000, died on the Senate Calendar. S. 5, 74th Cong., 1st & 2d Sess. (1935-36), which succeeded S. 2800, passed the Senate but was defeated in the House. Finally, S. 5, 75th Cong., 1st & 3d Sess. (1937-38), which succeeded S. 2800, passed the Senate but was defeated in the House. Finally, S. 5, 75th Cong., 1st & 3d Sess. (1937-38), which succeeded the first S. 5, was enacted, as supplemented by the provisions of S. 3073, 75th Cong., 2d & 3d Sess. (1937-38) and H.R. 9341, 75th Cong., 3d Sess. (1938) (companion bill to S. 3073), the so-called "sulfanilamide bills." The lengthy history of the Federal Food, Drug, and Cosmetic Act of 1938 is collected in C. DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT—A STATEMENT OF ITS LEGISLATIVE RECORD 23 (1938).

One of the most hotly contested issues during this long battle was the question of which agency should have control over food, drug, and cosmetic advertising—the FDA or the FTC (Federal Trade Commission). Jurisdiction over this area was eventually given to the FTC.

12. The 1906 Act also did not regulate cosmetics, unless the representations made for the cosmetic brought it within the "drug" definition. For a summary of the chief differences between the Acts of 1906 and 1938, see 1 H. TOULMIN, *supra* note 4, at § 2.3.

13. As the FDA warned:

> Mechanical devices, represented as helpful in the cure of disease, may be harmful. Many of them serve a useful and definite purpose. The weak and ailing furnish a fertile field, however, for mechanical devices represented as potent in the treatment of many conditions for which there is no effective mechanical cure. The need for legal control of devices of this type is self-evident. Products and devices intended to effect changes in the physical structure of the body not necessarily associated with disease are extremely prevalent and, some instances, capable of extreme harm. They are at this time almost wholly beyond the control of any Federal statute. . . . The new statute, if enacted, will bring such products under the jurisdiction of the Law.

U.S. DEP'T OF AGRICULTURE, REPORT OF THE CHIEF OF THE FOOD AND DRUG ADMINISTRATION 13-14 (1933).

14. The Federal Food and Drugs Act of 1906 is reprinted in C. DUNN, *supra* note 11, at 1336-43.

15. See note 11 *supra*.

administered in tablet or powder form. In response to the demand for a liquid preparation, this company developed one using diethylene glycol as a solvent, since sulfanilamide was insoluble in the liquids commonly used in making liquid drug preparations. The resulting "Elixir Sulfanilamide" was put on the market without conducting tests as to its safety. Diethylene glycol proved to be highly toxic when ingested. In the six weeks before the company began recalling the product at the insistence of the Food and Drug Administration (hereinafter FDA), seventy-three persons died as a direct result of taking the drug, and twenty others who took it died, but it was not definitely established that the drug was the exclusive cause of death. The FDA quickly seized or otherwise accounted for virtually the entire amount of "Elixir" that had been manufactured—240 gallons.

The public outrage generated by this tragedy was so great that the Senate requested the Department of Agriculture to conduct a study of the entire affair.[16] The report,[17] submitted to Congress by the Secretary of Agriculture, disclosed the utter inadequacy of the 1906 Act to prevent such a disaster[18] and recommended enactment of at least minimal remedial legislation.[19] In fact, it was only due to a fortuitous technicality that the FDA was able to assume jurisdiction at all.[20] Indeed, the manufacturer—who paid a fine of

16. S. Rep. 194, 75th Cong., 2d Sess., 82 CONG. REC. 25 (1937).

17. REPORT OF THE SECRETARY OF AGRICULTURE ON DEATHS DUE TO ELIXIR SULFANILAMIDE-MASSENGILL, S. DOC. NO. 124, 75th Cong., 2d Sess. 1 (1937).

18. As the report indicated:

> Before the "elixir" was put on the market, it was tested by the firm for flavor but not for its effect on human life! The existing Food and Drugs Act does not require that new drugs be tested before they are placed on sale.
>
> . . . .
>
> The fatal "elixir" was rushed onto the market without adequate tests to determine whether or not diethylene glycol may be safely used as a solvent for sulfanilamide, despite previously published reports in scientific literature showing that diethylene glycol might be dangerous when taken internally. A few simple and inexpensive tests on experimental animals would have quickly demonstrated the toxic properties of both diethylene glycol and the "elixir."

*Id.* 1-2.

19. In the words of the report:

> To protect the public from drugs which, like the "elixir," are dangerous because of their inherent toxicity, it is the Department's recommendation that legislation be enacted to provide at least the following:
>
> 1. License control of new drugs to insure that they will not be generally distributed until experimental and clinical tests have shown them to be safe for use.

*Id.* 9-10.

20. As the report disclosed:

> Since the Federal Food and Drugs Act contains no provision against dangerous drugs,

$26,100, the highest levied under the 1906 Act—denied any wrongdoing or responsibility.[21] However, the chemist who concocted the "Elixir" committed suicide.[22]

As a result of the Secretary's report and the public reaction to the events comprising its subject matter, bills were introduced in both houses of Congress requiring FDA approval before a new drug could be marketed in interstate commerce.[23] The provisions of these bills were incorporated into the then pending Senate Bill 5,[24] which was subsequently enacted, in its supplemented form, as the Federal Food, Drug, and Cosmetic Act of 1938.[25]

A drug was a "new drug" as defined by section 201(p)[26] of the original 1938 Act and, therefore, subject to the premarket clearance requirement in the original section 505(a)[27] only if it was not generally recognized by qualified experts as safe for use as prescribed by its labeling. The Kefauver-Harris Drug Amendments of 1962[28] amended section 201(p) so as to provide that a drug is a "new drug" if it is not generally recognized by qualified experts as safe *and effective* for use under the conditions prescribed in its labeling.[29] The "grandfather clause"—that is, the exemption appl-

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seizures had to be based on a charge that the word "elixir" implies an alcoholic solution, whereas this product was a diethylene glycol solution. Had the product been called a "solution," rather than an "elixir," no charge of violating the law could have been brought. *Id.* 1.

21. *Id.* 9.

22. K. CRAWFORD, THE PRESSURE BOYS 73 (1939).

23. These were the so-called "sulfanilamide bills." See note 11 *supra.*

24. 75th Cong., 1st Sess. (1937). See note 11 *supra.*

25. Act of June 25, 1938, ch. 675, 52 Stat. 1041. For an extensive discussion of the 1938 Act, see *Developments in the Law—The Federal Food, Drug, and Cosmetic Act*, 67 HARV. L. REV. 632 (1954).

26. 52 Stat. 1041-42 (1938).

27. *Id.* at 1052.

28. Act of Oct. 10, 1962, Pub. L. No. 87-781, 76 Stat. 780.

29. As a result of section 102(a)(1) & (2) of the Amendments, section 201(p) of the Act was changed to read:

> The term "new drug" means—
>
> (1) 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, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or
>
> (2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations,

icable to drugs previously subject to the 1906 Act providing no change was made in the representations in their labeling—was continued. Section 505(a) was also amended[30] to make it explicit that it was unlawful to market a "new drug" unless the FDA had first *approved* a new drug application, which was to supply the information and samples required by section 505(b).[31]

The 1962 Amendments once more demonstrated that it required a shocking and well-publicized threat to public health and safety to secure enactment of major food and drug legislation. The Thalidomide tragedy that occurred in Europe in 1961 and early 1962, in which thousands of babies were born with monstrous deformities (phocomelia) caused by their mother's exposure to the drug during pregnancy, aroused world-wide public concern. Fortunately, the new drug application submitted to the FDA by the prospective United States distributor of the drug was never approved, so Thalidomide was never marketed commercially in this country.[32] Even so, the public clamor for additional safeguards

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been used to a material extent or for a material time under such conditions.

21 U.S.C. § 321(p) (1970). The Animal Drug Amendments of 1968 (Pub. L. No. 90-399) amended both subsections by inserting, after the words "Any drug," the parenthetical language, "(except a new animal drug or an animal feed bearing or containing a new animal drug)."

30. As a result of section 104(a) of the Amendments, section 505(a) of the Act was amended to read:

> No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug.

This section remains substantially unchanged in its present official form. 21 U.S.C. § 355(a) (1970).

31. This section now provides:

> Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drugs; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

21 U.S.C. § 355(b) (1970).

32. The FDA physician to whom the new drug application was assigned did not believe that the evidence submitted sufficiently demonstrated that Thalidomide was safe. She was particularly concerned about possible effects on the fetus and, therefore, withheld approval despite vigorous entreaties by the prospective distributor. When the horrible effects of the drug became known, the application was withdrawn. S. REP. No. 1744, 87th Cong., 2d Sess. 40-42 (1962). *See also* R. HARRIS, THE REAL VOICE 184-93 (1964) and J. YOUNG, *supra* note 5, at 415-18.

was so great that Congress quickly responded by passing the 1962 Amendments, which, in addition to adding the "effectiveness" requirement for "new drugs," substantially broadened the FDA's regulatory power over both prescription and over-the-counter drugs in several other significant respects.[33]

## II. ORIGINS OF THE DEFINITIONAL DILEMMA[34]

In the 1906 Act the term "drug" was defined so as to

> include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease in man or other animals.[35]

Medical devices were not included in either this definition or any other provision. This lack of control over medical devices was recognized as one of the major defects in the 1906 Act, indicating the need for more comprehensive legislation.[36]

In Senate Bill 1944,[37] the first of the bills introduced to replace the 1906 Act, the term "drug" was defined so as to include all "devices intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals," and "all devices, intended to affect the structure or any function of the body of man or other animals."[38] The term "cosmetic" was separately de-

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Although Thalidomide was never marketed commercially in the United States, there was a limited distribution for investigational use only. For a discussion of the civil liability of the manufacturer for the birth defects that did result in the United States and in the Commonwealth countries, see Bennett, *The Liability of the Manufacturers of Thalidomide to the Affected Children*, 39 AUSTRALIAN L.J. 256 (1965).

33. S. 1552, 87th Cong., 1st Sess. (1961), the bill which was eventually enacted, originally arose out of the 1959-60 Kefauver hearings on price regulation in the drug industry. Ftr a summary of the ways in which the 1962 Amendments differed from the existing law, see 3 H. TOULMIN, *supra* note 4, at § 53.1, and for a section-by-section summary of the changes effected by them, see this same work at § 53.44.

34. See Styn, *A Dichotomy in Consumer Protection—The Drug-Device Definition Dilemma*, 44 INDIANA L.J. 503 (1969). The author of this article is a former trial attorney in the General Counsel's Office, U.S. Dep't of Health, Education and Welfare, Food and Drug Division. For a good artirle dealing with the present definitional problems of the 1938 Act, see Weitzman, *Drug, Device, Cosmetic?* (pts. 1 & 2), 24 FOOD DRUG COSM. L.J. 226, 320 (1969).

35. C. DUNN, *supra* note 11, at 1338.

36. See note 13 *supra*. *See also* REPORT OF THE CHEMIST, ANNUAL REPORTS OF THE U.S. DEP'T OF AGRICULTURE 210-18 (1917).

37. See notes 10 & 11 *supra*.

38. C. DUNN, *supra* note 11, at 37.

fined.[39] In the Senate hearings on this bill, Walter Campbell, then Chief of the Food and Drug Administration, Department of Agriculture, stated that the word "device" was intended to extend the scope of the law to include not only products like sutures and surgical dressings, but also "trusses or any other mechanical appliance that might be employed for the treatment of disease or intended for the cure or mitigation or prevention of disease."[40] Mr. Campbell also indicated that the definition of "drug"—with devices subsumed thereunder—was "admittedly an inclusive, a wide definition."[41] The purpose of this part of the definition was to reach products that could not be alleged to be treatments for diseased conditions, such as "antifat remedies," "nose straighteners," and "heightening devices."[42]

When Senate Bill 1944 was superseded by Senate Bill 2000, the definition of "drug" was amended to include substances and preparations recognized in the Homeopathic Pharmacopoeia of the United States, but was otherwise unchanged.[43] Similarly, when this latter bill was superseded by Senate Bill 2800, there was no material change in the definition of "drug."[44]

Since it was the use or intended use of a product which determined into which classification it fell—so that if the uses or intended uses fell within two classifications, the product would be subject to the substantive provisions of both—the report of the Committee on Commerce, accompanying the bill, stated that the definitions of "food," "drug," and "cosmetic" should not be construed as mutually exclusive. The report also indicated that the express provision to that effect in the definition of "cosmetic" in Senate Bill 1944 was deleted because it was superfluous in view of the fact that there had never been a court decision holding that the definitions of "food" and "drug" under the 1906 Act were mutually exclusive, despite repeated cases where prosecutions were brought on the basis that a product was both a "food" and a "drug."[45]

Industry opposition caused Senate Bill 2800 to die on the Sen-

39. *Id.*

40. *Id.* at 1053.

41. *Id.* This comment refers to that part of the definition which relates to devices "intended to affect the structure or any function." See note 38 and accompanying text *supra.*

42. *Id.* 1053-54.

43. *Id.* 52.

44. *Id.* 72.

45. S. REP. No. 493, 73d Cong. 2d Sess. (1934).

ate Calendar,[46] but it was reintroduced in the 74th Congress as the first Senate Bill 5.[47] The definitions of "drug" and "cosmetic" were not changed.[48] However, during the course of the Senate hearings, Mr. Campbell was again called to testify, and he submitted a statement in which he again said—apparently in response to criticism—that the definition of "drug" was intentionally very broad, since this was necessary to effect the purpose of reaching therapeutic devices in the absence of a separate definition of the term, "device."[49]

In the Senate debate on this bill, Senator Clark addressed a question to Senator Copeland, inquiring about the incongruity of including purely mechanical devices under the definition of "drug." Senator Clark stated that he had no objection to the inclusion of devices in the proposed legislation, but that to maintain that a purely mechanical device was a drug and should be treated as a drug "in law and in logic and in lexicography is a palpable absurdity." At this time Senator Copeland was actually discussing another matter—an amendment to add the word "diagnosis" to the definition of "drug"[50]—but he digressed to indicate that he would

46. Attempting to pinpoint the cause of its demise, the Chief of the FDA wrote:

> In spite of material public support, this measure, as was to be expected, aroused bitter opposition from certain trade elements, particularly the proprietary-medicine industry and sections of the advertising profession which saw in the passage of such legislation a curb on lucrative practices heretofore indulged in with impunity. A vast amount of misinformation to the effect that the bill if passed would result in destruction of legitimate industries, interfere with the right of self-medication, and deny manufacturers their constitutional rights, was disseminated not only among the industries but among the public. A flood of bills purporting to accomplish the same purposes was introduced with the undoubted result of effectively confusing the issue. While all of them extended somewhat the scope of the present statute, the restrictions of some on regulatory action would have effectually nullified many of the provisions of the present law now potent for public protection. Trade opposition, together with the congested congressional legislative program, was largely responsible for the failure of Congress to take action.

U.S. DEP'T OF AGRICULTURE, REPORT OF THE CHIEF OF THE FOOD AND DRUG ADMINISTRATION 15 (1934).

47. See note 11 *supra*.

48. C. DUNN, *supra* note 11, at 192.

49. On this subject, one author wrote:

> There is a universal recognition that the definition of the term "drug" in the third subdivision is inclusive. This fact was admitted at the hearing on S. 1944. To provide for jurisdiction over the innumerable devices to which therapeutic virtues are ascribed, it will be necessary either to operate under a definition of this character, as incongruous as it is, or to set up, as proposed by one witness, an independent paragraph relating to therapeutic devices.

*Id.* 1223.

50. By way of amendment, Senator Copeland sought to include in the definition of

not object to the separate definition of the terms "drug" and "device." Senator Clark again interrupted to press his objection while Senator Copeland continued to talk about the other amendment, which was the topic actually under discussion and which was then approved by the Senate.[51]

However, Senator Clark's position as to the definitions eventually prevailed. Devices were removed from the "drug" definition, and a separate definition of "device" was added.[52] The word "diagnosis" was included in the "device" definition, and also remained in the "drug" definition, even though the original purpose for its inclusion was to reach diagnostic devices. Senate Bill 5 was then passed by the Senate in its amended form and referred to the House Committee on Interstate and Foreign Commerce, where hearings were held. During the course of these hearings, Mr. Campbell explained that the reason for the separate definition of device was merely to eliminate the incongruity of classifying certain purely mechanical devices as "drugs."[53] Although the House did not disagree with the Senate definitions, it believed that the Federal Trade Commission, not the FDA, should have jurisdiction over false advertising of drugs, devices, and cosmetics.[54] For this reason, Senate Bill 5 failed to pass the House.

The second Senate Bill 5 having been introduced in the next session, the Senate made some immaterial changes in the definitions of "drug," "device," and "cosmetic."[56] The House, however, revised the bill by adopting the definitions of "drug," "device," and "cosmetic" utilized in its version of Senate Bill 1077,[57] the bill

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"drug" all "substances, preparations, and devices intended for use in the *diagnosis*, cure, mitigation, treatment, or prevention of disease in man or other animals." 79 CONG. REC. 4845 (1935) (emphasis added).

51. For a fuller discussion of this Copeland-Clark dialogue, see Weitzman, *supra* note 34, at 236-38. The complete transcript embodying this interchange is reprinted in C. DUNN, *supra* note 11, at 286-300.

52. C. DUNN, *supra* note 11, at 496.

53. Recognizing this, one author wrote:

> The purpose of the third subdivision is to provide for "devices." Originally this definition of "drugs" also included devices, such as mechanical applicances and contraptions which are to be found without number. But the incongruity of classifying certain devices, such as the electric belt, therapeutic lamps, and so forth, as drugs was pointed out by the Senate in the last consideration of the bill. They felt it proper to provide an independent definition of "devices."

C. DUNN, *supra* note 11, at 1247.

54. See note 11 *supra*.

55. *Id.*

56. C. DUNN, *supra* note 11, at 658 & 696.

57. 75th Cong., 1st Sess. (1937).

which became the Wheeler-Lea Act and which gave the FTC control over the advertising of drugs, devices, and cosmetics.[58] These definitions substituted by the House survived the subsequent events and are the definitions in effect[59] at the present time.

Although the supplementation of Senate Bill 5 by addition of the "new drug" provisions as a result of the "Elixir Sulfanilamide" disaster[61] did not alter the definitions of "drug," "device," or "cosmetic," the addition of these provisions did have a very significant consequence with regard to the respective substantive regulation of "drugs" and "devices."

Since the premarket approval requirement of section 505(a)[62] applied only to a "new drug," and a "new drug" was defined as

58. When S. 1077 was first introduced in the House, it contained the same definitions as the Senate version of S. 5. However, the version of S. 1077 which was enacted changed the definitions by substituting "article" for "substances and preparations" in the definition of "drug;" substituting "instruments, apparatus and contrivances" in place of "devices" in the definition of "device;" and adding a phrase excluding "devices or their components, parts, or accessories" from the definition of "drug." See notes 38, 50, & 52 *supra*. The House Committee on Interstate and Foreign Commerce then revised S. 5 by adopting the definitions of "drug," "device," and "cosmetic" from its version of S. 1077. See Weitzman, *supra* note 34, at 240 & 245, and C. DUNN, *supra* note 11, at 753.

59. The relevant subsections of 21 U.S.C. § 321 (1970) provide:

(g)(1) 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 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 article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories.

. . . .

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(i) The term "cosmetic" means (1) 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, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

60. The only differences in the present definitions from the definitions in the House version of S. 5 are the addition of the word "components" to the definition of "device," and the use of letters in place of numbers to denote the subdivisions of the definition of "drug."

61. See notes 16-31 and accompanying text *supra*.

62. Note 30 *supra*.

"any *drug*,"[63] the separate definition of "device" now took on a significance far beyond that of merely eliminating a semantic incongruity. In fact, the result was a far more serious incongruity in that, although one of the major purposes of the new legislation was to bring devices under federal regulation to the same degree as drugs, the act of removing devices from within the "drug" definition had now created an extreme dichotomy between the substantive regulation of "drugs" and "devices." Because of their separate definition, new "devices" were not subject to the premarket approval requirements thought essential for the protection of the public with respect to "new drugs," even though such devices were originally included within the definition of "drug" because of the similar dangers they presented. Thus, if devices had not been made the subject of a separate definition, they too would have been subject to the premarket clearance requirement, since they would have been "drugs" within the "new drug" definition. Until the addition of the "new drug" provisions, drugs and devices were subject to the same extent of regulation under the proposed legislation, both before and after the separate definition of "device." However, after the addition of the "new drug" provisions, by virtue of the now significant separate definition of "device," the regulaton of devices was vastly less stringent than the regulation of drugs.

There is nothing apparent in the legislative history to indicate Congress was even aware of this anomalous result, much less that it was intended. It seems quite possible that the creation of this dichotomy was inadvertent, the combined effect of the various amendments simply never having been considered. Of course, it is also possible that the present dichotomy is precisely what was intended and that there would have been objections had the final version of the bill explicitly required premarket clearance of devices. However, in view of the closeness in time of the critical amendments, the overwhelming public pressure demanding that some law be enacted immediately, the totally non-substantive reason for the separate definition of "device," and the previously similar modes of proposed regulation, it seems fair to say that the resulting absence of premarket clearance regulation for new devices was probably due to oversight and unfortunate coincidence rather than to a considered decision.

To further compound the confusion—and the irrationality—of

63. Note 29 *supra*.

this situation, the definitions of "drug" and "device" are in part identical, except that "drugs" are "*articles* intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals," or "*articles* (other than food) intended to affect the structure or any function of the body of man or other animals,"[64] while "devices" are

> instruments, apparatus, and contrivances . . . intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.[65]

Thus, an "article" is subject to premarket approval by the FDA, while an "instrument, apparatus, or contrivance" is not.

The question then becomes, what is the difference between an "article" and an "instrument, apparatus, or contrivance?" The answer to this question is not obvious, to say the least!

Since the premarket approval requirement is a significant obstacle to the marketing of a new product in terms of both time and expense, even the most legitimate manufacturer will try to avoid this hurdle if he possibly can. The express exclusion of "devices or their components, parts, or accessories" from the definition of "drug" aids evasion of the premarket approval requirement, since this language literally permits no other construction than that a product which is a "device" cannot also be a "drug."[66] Thus, the categories of "drug" and "device" certainly seem to be mutually exclusive,[67] both because of the express exclusion and because of the fact that classification vis-a-vis the categories of "drug" and

64. 21 U.S.C. § 321(g)(1) (1970). See note 59 *supra*.

65. 21 U.S.C. § 321(h) (1970) (emphasis added). See note 59 *supra*.

66. Compare with text at note 45 *supra*.

67. One writer, in explaining the definition sections of the 1938 Act, originally believed it to be "clear that the categories 'food,' 'drug,' 'device,' and 'cosmetic' should not be denied as mutually exclusive." 1 H. TOULMIN, *supra* note 4, at § 4.15. However, in view of the express exclusion of devices from the definition of the term, "drug," this same writer, by way of supplement, revised his earlier statement, noting that items subject to the device definition "would appear to be excluded totally from drug classification." *Id.* (Supp. 1969).

An argument might be made that the word, "devices," as used in the exclusionary clause, does not mean "devices" as defined in section 201(h), since "device" in section 201(h) is in quotation marks and the word "devices" in the exclusionary clause is not. However, this argument would seem to be foreclosed by the language in parentheses in section 201(h), which says that device means "device" as defined in section 201(h) except when used in certain enumerated sections. Section 201(g)(1), which defines "drug," is not one of the sections enumerated; thus, the word "device" as used therein means "device" as defined by section 201(h).

"device" is no longer determined by intended use.[68] Rather, as between these two categories, classification is determined by the inherent nature of the product, since the respective "intended for use" clauses are identical and are reached only after a determination is made as to whether a product is an "article" or an "instrument, apparatus, or contrivance." Once this elusive determination as to inherent nature is made, the product, if determined to be a "device," is expressly excluded from the "drug" definition and is therefore not subject to premarket clearance. Thu , the manufacturer of a product that could fit under either definition has a very strong incentive to maintain that his product is a "device" and, therefore, not a "drug"—and that it can, thus, be marketed without first having to prove to the FDA's satisfaction that it is safe and effective for the use recommended.

Moreover, while the definitions in the Senate version of the bill had begun, "The term 'drug' *includes*" and "The term 'device' *includes*"[69]—thus permitting the construction that the enumerated classes of items only constituted examples of some of the categories of products which fell within the definitions and that other items could also fall within them—the definitions finally adopted read, "The term 'drug' *means*" and "The term 'device' *means*,"[70] thus implying that only products which fall within the classes enumerated are within the respective definitions, and other items are not.

A further consideration of the legislative history makes this regulatory dichotomy even more perplexing. As has been indicated, the provisions of Senate Bill 3073 and House Bill 9341 were incorporated into the pending Senate Bill 5 to comprise the "new drug" provisions.[71] While the preamble of the House bill paralleled that of the Senate version, the House bill varied from the Senate bill in that it contained a different definition of "drug" for the purpose of the premarket clearance requirement.[72] Under that definition, a "drug" that had to be precleared was defined as an "arti-

68. See text immediately following note 44 *supra*.

69. C. DUNN, *supra* note 11, at 638 (emphasis added).

70. See note 59 *supra* (emphasis added).

71. See note 11 *supra* and note 24 and accompanying text *supra*.

72. H.R. 9341, 75th Cong., 3d Sess. § 8(c) (1938):

> The term "drug" means (1) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (2) articles (other than food) intended to affect the structure or any function of the body of man or other animals.

cle," rather than as "any drug"—which is the language used to define "new drug" in the provisions eventually adopted and still in force.[73] Had the House bill been enacted as a separate measure, its definition might have been construed as broad enough to require preclearance of devices as well.[74] However, when consolidated with the other provisions of Senate Bill 5, even if the House's special definition of "drug" had been used instead of the "new drug" definition actually adopted, it would seem that the preclearance requirement still could not have been construed as reaching devices. The House Bill 9341 "drug" definition was identical with subdivisions (B) and (C) of the amended Senate Bill 5 "drug" definition,[75] so that the only "articles" subject to preclearance would have been those falling within the Senate Bill 5 "drug" definition. The result would have, thus, been that "devices" would still not have been covered. In any event, because the House definition was not used, this speculation is moot.

It is an understatement to say that the final version of Senate Bill 5, which became the Federal Food, Drug, and Cosmetic Act on June 25, 1938, was fraught with complications, implications, and loopholes. Surprisingly, the courts have not had to squarely face these problems until quite recently, although the absence of premarket approval regulation with respect to medical devices has been the subject of as yet unfruitful legislative concern for some time. Before considering the recent judicial decisions and the past and presently pending proposed corrective legislation, it would seem appropriate to explore the magnitude and seriousness of the problems presented by medical devices in the absence of any premarket clearance requirement or federal standards.

## III. Problems in the Absence of Premarket Approval and Federal Standards

Essentially there are two broad classes of "medical" devices from which the present problems emanate. The problems presented by each class are substantially different, which suggests that they might require different solutions or might not be equally amenable to the same solution. Both by virtue of the different essential nature of each class of devices and the different problems each presents, it is appropriate to consider the classes separately.

73. Note 29 *supra*.

74. See Weitzman, *supra* note 34, at 247-48.

75. This is the present 21 U.S.C. § 321(g)(1) (1970). See note 59 *supra*.

The first class is comprised of devices manufactured, used or sold by medical quacks. It is misleading even to call these devices "medical" devices, since they usually have no medical value at all. However, though not normally helpful, these devices are also not usually intrinsically harmful. The dangers they present lie in the fact that they are purported to alleviate or cure conditions for which there is as yet no successful legitimate medical treatment or for which the recognized treatment is drastic (*i.e.* surgery or radiation). Thus, these devices appeal to the victims of such conditions—like cancer and arthritis—who are willing to pursue any alternative in their desperation. Pain, suffering, and an outlook of hopelessness can easily overshadow rationality and cause the sufferer to be vulnerable to representations that he would otherwise deem absurd. Also, the quacks use science to enhance faith in their devices by comparing them to legitimate medical devices.

Where there is a recognized treatment—and assuming the device is not inherently harmful—these quack devices result in harm indirectly by causing their users to delay seeking the recognized treatment, thus allow ng their conditions to worsen, often until it is too late for legitimate medicine to help. In any event, whether these quack devices merely have no effect at all, or are directly or indirectly harmful, they are a source of great profit to the quacks who promote them—a profit which is usually derived from those who can least afford to pay.

The other class is that of the devices made by legitimate manufacturers. These devices have recognized medical value, but often are not as safe or effective as they could be in light of present knowledge. Paradoxically, the harm resulting from these legitimate devices is often direct, in the sense that the resultant damage is due directly to the use of the device. However, it is also possible for these devices to cause indirect harm in that another mode of treatment which otherwise would have been used might have been safer or more effective. Devices within this broad category of legitimate devices are usually manufactured and distributed in large numbers, and are widely used by legitimate hospitals and medical practitioners. The problems presented by these devices—which can truly be called "medical" devices—ordinarily arise not from the fraudulent intent of the manufacturer or distributor, but from a lack of standards as to quality, uniformity, and performance, and a lack of adequate premarket testing under actual conditions of use.

As has already been indicated, there is no requirement under

present federal law that a "device" be proved safe and effective for its intended use before it may be marketed in interstate commerce.[76] Putting aside temporarily the definitional difficulties previously discussed, and before considering recent judicial decisions, a brief review of some of the past and present problems involving medical devices of both the quack and legitimate varieties will help in analyzing the present situation and the need for and wisdom of the proposed solutions.

### *A. Device Quackery*

It is unfortunate, but true, that advances in science and technology have been and still are capitalized on by charlatans who promote fantastic devices purportedly operating upon accepted scientific principles. Thus, while the early quack devices in this country were represented to be based on theories of magnetism and electromagnetism, the development of the utility of electricity was paralleled by a proliferation of diagnostic and therapeutic devices which were alleged to apply the emerging body of electrical and electronic knowledge to the field of medicine. Because these new devices were advertised as being highly scientific and technical, it was natural that self-healing was replaced by a norm in which supposedly learned practitioners operated these various devices, often in their own "clinic," where patients would come for treatment. These quack practitioners analogized their fantastic machines to such legitimate devices as the X-ray instrument and the electrocardiograph, and purported to be able to diagnose and treat virtually any and all ills. After World War II, there was an increase in device quackery due to the cheap availability of war surplus electrical and electronic equipment.

Because many of these devices were being used by licensed practitioners—such as chiropractors, osteopaths, and medical doctors—it was difficult to deal with the problems presented by such devices once they were on the market. The traditional right of a doctor to be free to exercise his judgment as to the best treatment for his patients was not to be transgressed lightly. Unfortunately, this "right" of the legitimate practitioner was being effectively used as a shield by many licensed quacks.[77]

76. The scope of this article does not include a consideration of state laws dealing with the regulation of medical devices. Due to the national character of the market, it would seem that only federal regulation could effectively cope with the interstate problems presented.

77. See J. YOUNG, *supra* note 5, at 242-45.

The general nature of the problems presented by quack devices is dramatically illustrated by the case of the "Drown Radio Therapeutic Instrument." This device was simply a little black box with several dials on it which did absolutely nothing. The only operative part was a simple galvanometric circuit which the "patient" completed by placing his or her feet on one dissimilar metal and holding another to the skin of his or her abdomen. This device was manufactured and promoted by a "self-taught" woman chiropractor and was reputed to be able to diagnose and treat virtually any disease merely from analysis of a single drop of the "patient's" blood. It was not even necessary that the "patient" have direct access to the machine, since the treatment could just as well be conducted from afar via "radio waves."

The incident which finally brought Mrs. Drown to trial involved a woman with breast cancer who delayed surgery in reliance on the healing powers of Mrs. Drown's fraudulent machine until her condition was inoperable and death inevitable. Proceeding on the ground that the device was "misbranded,"[78] the FDA succeeded in winning a verdict against Mrs. Drown, which was sustained on appeal.[79] However, the resulting $1,000 fine was little more than a slap on the wrist to Mrs. Drown, and she continued to ply her trade, merely being careful to avoid interstate distribution of her devices so as to evade federal jurisdiction.[80] The cost of the case to the government was conservatively estimated at $50,000, and it was brought and won only with very great difficulty. Mrs. Drown had been under surveillance for some time before the opportunity arose for the FDA to successfully seize one of her devices, file a libel of information against it, and have it condemned by the court.[81]

By making minor changes in models, a seizure action can be frustrated. Further, in such an action, the burden of proof is on the

78. 21 U.S.C. § 331(a) (1970) prohibits "[t]he introduction or delivery for introduction into interstate commerce of any . . . device . . . that is adulterated or misbranded." Under 21 U.S.C. § 331(c) (1970), the receipt in interstate commerce and the delivery of such a device are prohibited. Further, 21 U.S.C. § 331(b) (1970) prohibits the adulteration or misbrading of any device in interstate commerce. The circumstances under which a drug or device will be deemed misbranded are defined in 21 U.S.C. § 352 (1970).

79. Drwon v. United States, 198 F.2d 999 (9th Cir. 1952), *cert. denied*, 344 U.S. 920 (1953).

80. For a fuller discussion of the *Drown* case and a brief history of device quackery in general, see J. YOUNG, *supra* note 5, at ch. 11.

81. The procedure to be followed for purposes of obtaining such a remedy is set forth in 21 U.S.C. § 334 (1970).

government to prove, by a preponderance of the evidence, that the article seized is misbranded or adulterated.[82] In contrast, under the "new drug" provisions, the burden is on the manufacturer to submit evidence to the FDA proving that his "new drug" is safe and effective for its intended use before he can legally market the drug in interstate commerce.[83] Thus, where the government's only remedy is seizure and there is no premarket approval requirement—as is the current law with respect to "devices"—any device can be distributed in interstate commerce with virtual impunity, and the burden is on the government when it tries to get the device off the market.

The list of quack devices is seemingly endless,[84] and new ones continue to be marketed because of the relative ease and impunity with which this can be done under present federal law. A significant victory was won by the FDA in 1962 in that the protective shield which a medical license had given a quack was pierced when the Court of Appeals for the Seventh Circuit held that the "Ellis Micro-Dynameter" was so misbranded and so worthless as to be unsafe for use even in the hands of a licensed practitioner.[85]

However, although the FDA is certainly continually aware of the problems presented by quack devices[86] and is constantly attempting to halt their spread by obtaining injunctions against their interstate distribution, it is severely handicapped by the fact that this remedy can only be commenced by seizure after interstate shipment.[87] The undesirability of this *ex post facto* proceeding is

82. *See, e.g.*, United States v. Wood, 226 F.2d 924 (4th Cir. 1955).

83. 21 U.S.C. § 355(b) (1970). If a new drug application has been approved and the government then widhdraws the approval, pursuant to 21 U.S.C. § 355(e) (1970), the burden of proof is then shifted to the government, should the manufacturer challenge the withdrawal of approval. Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966).

84. For a sample, and a survey of the FDA's efforts to regulate quack medical devices by seizure and injunction, see Milstead, *Quackery in the Medical Device Field*, PROCEEDINGS OF THE SECOND NATIONAL CONGRESS ON MEDICAL QUACKERY (1963). For an example of the quack devices that continue to be marketed, see United States v. Diapulse Mfg. Corp., 389 F.2d 612 (2d Cir.), *cert. denied*, 392 U.S. 907 (1968), wherein the court condemned for misbranding a device which was represented as adequate and effective for 121 diseases and related conditions.

85. United States v. Ellis Research Laboratories, Inc.,300 F.2d 550 (7th Cir.), *cert. denied*, 370 U.S. 918 (1962). This "Micro-Dynameter," which was reputed to be able to diagnose some 55 diseases or conditions, was in fact merely a highly sensitive galvanometer, and the only thing it measured was the relative amount of perspiration on the skin.

86. See Goddard, *Drug and Device Quackery*, PROCEEDINGS OF THE THIRD NATIONAL CONGRESS ON MEDICAL QUACKERY (1966). This is a report by the Commissioner of the FDA as to the then-current efforts of the FDA to cope with the problems of medical device quackery and drug abuse.

87. 21 U.S.C. § 334 (1970).

manifest in that it allows unimpeded initial distribution of the objectionable device, is difficult to commence, puts the burden of proof on the government, and is tremendously costly to the government and ultimately to the taxpayers, who are in effect "paying" for these devices twice and still not getting anything for their money. Moreover this remedy is impractical and inefficient even if the government overcomes all the obstacles in its path. It is very costly and virtually impossible to locate all the devices which have been distributed and are in use, and the manufacturer can start all over again by changing the name and making an insignificant modification in his device.

Therefore, whether directly harmful,[88] or directly harmless[89] and harmful only indirectly as a result of causing delay in obtaining legitimate medical treatment, quack medical devices are still very much a detriment to public health and account for millions of wasted dollars. The fight goes on to eliminate them, but the odds are still heavily weighted in favor of the quack.

### *B. Legitimate Medical Devices*

Although the problems presented by quack devices have been receiving substantial attention,[90] the problems pertaining to legitimate medical devices are perhaps greater, more pervasive, and more serious. That an ill person is defrauded and has his health endangered by a quack device is, of course, a deplorable matter; however, that a person who seeks the recognized, legitimate medical treatment for his injury or condition is subjected to unnecessary and preventable hazards is even more appalling and egregious. Although the problems extant in the context of this latter situation are beginning to receive some limited general publicity,[91] for the most part the public remains unaware of the needless risks it is

88. *See, e.g.*, United States v. 22 Devices, More or Less, Halox Therapeutic Generator, 98 F. Supp. 914 (S.D. Cal. 1951), wherein the device electrolyzed sodium chloride so as to produce chlorine gas for "chlorine inhalation therapy" with regard to safe levels of concentration.

89. *See, e.g.*, United States v. Chadiali, 165 F.2d 957 (3d Cir. 1948), wherein the "Spectro-Chrome" device under attack merely focused harmless colored light on the patient.

90. This attention is witnessed in part by the sponsorship of the National Congresses on Medical Quackery by the AMA and FDA in 1961, 1963, and 1966. See notes 84 & 86 *supra*.

91. *See, e.g.*, *Medical Devices: An Unhealthy Situation*, 35 CONSUMER REPORTS 256 (1970). This short article provides an excellent and very readable concise summary of the situation in the absence of effective regulation.

subjected to in the course of diagnosis and treatment by means of legitimate medical devices.

While quack devices have received considerable attention from the FDA—ineffective as the present regulatory mechanisms may be—the problems presented by legitimate medical devices have been virtually ignored, simply because the present law affords no real basis for their regulation. If it is difficult to successfully proceed against a device that is easily demonstrated to be utterly worthless and pure quackery, it is virtually impossible (as well as quite inappropriate) to try to regulate, by means of the present inadequate procedures, legitimate medical devices which are recognized as having significant medical value, but are not as safe, reliable, or effective as they could be in light of present knowledge.

As examples, a few types of legitimate medical devices and the problems they present are discussed below.

1. Orthopedic Internal Fixation Devices and Internal Prostheses

Orthopedic internal fixation devices and internal prostheses comprise one of the categories of legitimate medical devices with which there are significant problems. Internal fixation devices consist of the various screws, staples, plates, bands, wires, pins, and intramedullary nails[92] employed in the reduction of bone fractures and for joint fusion.[93] Internal prostheses are used in the construction of new movable joints and are used primarily in the reconstruction of hip joints destroyed by arthritis, bone diseases, or severe fractures.

There are three basic problems that must be met in implanting metals in living tissue.[94] The first of these is electrolytic inflammation, in which the corroding metal causes a tissue reaction. Then there is the problem of stress tolerance. The metal must be able to meet the stresses which will be imposed upon it without succumbing to metal fatigue and breaking. Because these stresses can be quite great, other presently available materials besides metals (and

92. *See* G. KUNTSCHER, PRACTISE OF INTRAMEDULLARY NAILING (1967). Intramedullary nails are used in the internal fixation of fractures of the long bones. The medullary canal in the center of the bone is reamed to size and the intramedullary nail is then driven in to hold the fractured pieces of the cortex in rigid juxtaposition.

93. *See generally* J. ADAMS, OUTLINE OF FRACTURES (INCLUDING JOINT INJURIES) (5th ed. 1968), J. ADAMS, OUTLINE OF ORTHOPAEDICS (6th ed. 1967), and A. SHANDS & R. RANEY, HANDBOOK OF ORTHOPAEDIC SURGERY (7th ed. 1967).

94. C. BECHTOL, A. FERGUSON & P. LAING, METALS AND ENGINEERING IN BONE AND JOINT SURGERY 19-20 (1959).

bone) are just not strong enough to be used in internal fixation. Also, the stress factor must be considered in conjunction with corrosion, since the combined effects of repeated stress and corrosion may cause a metal to fall well below its calculated safe limit. The third problem is that of insuring that the device is uncontaminated when implanted. This means not only uncontaminated by infection-causing organisms, but also uncontaminated by other metals or surface defects, and with no new stresses or structural changes since its manufacture.

Although new alloys are constantly being developed, most surgical implants manufactured in the United States are made of one or the other of two kinds of stainless steel or of a cobalt-based alloy called Vitallium. Of all the available metals, these best meet the exacting comprehensive requirements for a surgical implant. However, a manufacturer could decide to use some wholly untried metal. There is presently no federal law which would require him to test the resulting devices for safety, reliability, or effectiveness before he markets them in interstate commerce. Thus, there could well be another "Elixir Sulfanilamide" disaster, only this time because of an unsafe surgical implant.

Moreover, there are significant problems with respect to the devices now on the market made out of the commonly used metals. While such devices can probably be said to have been proven fairly safe, reliable, and effective when used under optimum conditions, problems may arise because the implantation of internal fixation devices and prostheses is too often done in ignorance or in disregard of the knowledge that has been accumulated about the causes of adverse metal reactions in surgical implant cases.

Even though the devices manufactured by a particular manufacturer may be inherently safe, reliable, and effective when implanted only with other devices manufactured by that same manufacturer, these same devices may be neither safe, reliable, nor effective if combined with components made by another manufacturer who uses a different metal or different manufacturing processes.[95] It may seem that this type of mishap is the fault of the surgeon or the hospital that implanted or allowed to be implanted devices

95. This is due to the fact that the juxtaposition of dissimilar metals or of components of the same metal in dissimilar conditions in a suitable electrolyte will result in electrolysis, which in turn results in corrosion. The wet chloride environment of the tissues in the human body constitutes a very good electrolyte. It was established in 1936 that "except for infections, all unfavorable reactions about metals in bone were due to electrolysis." C. VENABLE & W. STUCK, THE INTERNAL FIXATION OF FRACTURES 36 (1947).

made by different manufacturers, rather than the fault of the individual manufacturers, who have no control over what the hospitals and surgeons do with their devices after they are purchased. It is certainly true that some hospitals and surgeons could do much with respect to improving their respective procedures so as to reduce the risks of corrosion and metal failure with internal fixation devices and prostheses.[96] However, since it is much easier to regulate the practices of a relatively few manufacturers than it is to reform the procedures of all the hospitals and surgeons in the United States, it only makes sense to deal at the manufacturing level with as many problems as can possibly be prevented there. Thus, simply stated, although problems such as those resulting from the implantation of mixed metals and metals in different metallurgical states may not be the fault of the individual manufacturers, the manufacturers are in the best position, from a pragmatic standpoint, to do the most to prevent them.

Certainly, many manufacturers realize that they have a great responsibility to the public and, in recognition of this, have set up voluntary standards. However, because of the fact that most internal fixation devices and prostheses consist of more than one part (*i.e.* a plate must be secured by several screws), and components made by different manufacturers of different metals and by different methods are frequently used together in the same fixation, corrosion and metal failure due to electrolysis is still a frequent occurrence.

Thus, by virtue of the unique nature of the problem—no matter how excellent the standards of a particular manufacturer—if his device is used with another device made by another manufacturer, who may have equally good standards but use a different metal or different manufacturing processes, so that there is an electrolytic potential difference between the devices when implanted within the body, the patient will be exposed to needless harm, from which each manufacturer's individual standards afford little or no protection. This does not mean that manufacturing standards cannot solve this problem. Rather, it means that such standards must be extremely uniform on an industry-wide basis, since the slightest difference in metallurgical condition, not merely the extreme case of the combination of mixed metals, can give rise to electrolysis and corrosion. The alternative solutions of either trying to educate all hospitals and surgeons as to the complexities of the process of

96. *See* C. BECHTOL, *supra* note 94, at ch. 2.

corrosion or of requiring hospitals to buy all of their internal fixation devices from one manufacturer seem clearly unsatisfactory, if not impossible. As long as devices made by different manufacturers are incompatible and hospitals continue to purchase different devices from different manufacturers, the combination of such devices is virtually inevitable.

It might be argued that the threat of civil actions for malpractice against hospitals and surgeons is sufficient to prevent the implantation of incompatible internal fixation devices. However, this is an unsatisfactory solution for several reasons. First, the patient may never discover the cause of his difficulty, since the hospital and surgeon are unlikely to tell him and expose themselves to liability, and he has almost no other means of discovering the truth. It is probable that many of the internal fixations that fail because of adverse metal reactions are never reported. Secondly, this remedy is undesirable because it merely attempts to compensate for harm for which there really is no compensation, and which could probably have been prevented by adherence to now known principles of metal behavior. If the patient had his choice he would probably much prefer prevention to *ex post facto* compensation. Also, litigation is costly and time consuming to both the parties and the courts, and unnecessary litigation should be avoided whenever possible. Finally, a case-by-case remedial approach is a poor solution when the problem involved can be prevented at the point of its inception.

Obviously, there are difficult problems involved in arriving at any satisfactory solution to a situation which has so many variables. However, with respect to the metals which have been proven by experience to be acceptably suitable for the manufacture of internal fixation devices and prostheses, one way to reduce the incidence of adverse metal reactions due to electrolysis would be to require that all devices and components of devices designed for a particular type of fixation or prosthesis be made of the same metal and by the same manufacturing processes, by whomever made. Then it would be impossible to mix metals in different metallurgical conditions in effecting a fixation or other implantation. Standards of composition as to variation between different melts of that metal should also then be prescribed.

Although this may seem to be a significant impingement on free enterprise, it must be remembered that the implantation of devices in the body is about as intimate an invasion of the person as can be made. And when it is also considered that the person

affected is so little able to protect himself in this situation, such a measure might well be warranted and justified. Under the circumstances which such regulation would bring about, a surgeon, under the trying conditions of the operating room, would be unable to inadvertently secure a bone plate of one metal with bone screws of another, since all such devices to be used together would be made of the same metal in the same metallurgical condition, no matter by whom made. As things are now, when hospitals commonly purchase different devices from different manufacturers who use different metals and different manufacturing methods, and the hospitals do not carefully separate the different devices in the operating room, such metal mixing is quite likely to occur. It is emphasized that it is neither necessary nor desirable that all internal fixation devices and prostheses be made of the same metal, since different metals may be best for different types of jobs. It would only be necessary that all devices and components designed for the same type of procedure be standardized, so as to minimize the risks of corrosion and failure as much as possible.

Standardization of sizes and tolerances within sizes would also seem desirable. In many cases these standards would be quite similar to the standards voluntarily established by device manufacturers; however, the federal standards would insure complete uniformity and would be enforceable. There is sometimes significant deviation not only between the same size devices manufactured by different manufacturers, but also between the same size devices manufactured by the same manufacturer.[97] Also, there is sometimes a significant discrepancy between the actual dimensions of an internal fixation device and its labelled dimensions.[98]

Although these are only some of the problems that exist with respect to metal implants, they are problems which could be significantly reduced by uniform regulation of medical device manufacture and the establishment of a premarket clearance requirement. Unfortunately, despite recognition of the problems in this and other medical device areas by several legislators in recent years,[99]

97. *Id.* at 95-96.

98. *See, e.g.*, Orthopedic Equip. Co. v. Eutsler, 276 F.2d 455 (4th Cir. 1960), wherein an intramedullary nail which varied by more than ten percent from its labelled diameter became impacted in plaintiff's femur, with resultant incurable osteomyelitis and loss of the use of his leg. In this case, it was held that an intramedullary nail was a "device" within the Federal Food, Drug, and Cosmetic Act, that it was "misbranded" in violation of the Act, and that this violation constituted negligence *per se* (under Virginia law).

99. *See, e.g.*, 115 CONG. REC. 11814-15 (1969) (remarks of Sen. Nelson upon introduc-

no legislation has been passed, or even gotten out of committee.

Aside from the common problems they share with internal fixation devices, internal prostheses present some unique problems in that they are intended to remain in the body for the life of the patient.[100] Thus they must be both extremely resistant to corrosion and strong enough to withstand repeated severe stresses in a corrosive environment over a long period of time.[101] In addition, there are special problems of lubrication and wear.[102] These problems, unique to internal prosthetic devices, have also been recognized by legislators, but, as of yet, to no avail.[103]

2. Electrical and Electronic Medical Devices

Another problem which has received some limited publicity is the high incidence of accidental electrocutions among hospital patients in the course of "routine diagnostc tests" or "routine treatment." The number of such accidental electrocutions has been estimated at 1,200 per year.[104] Among the causes enumerated for these electrocutions are high leakage current and poor circuit design.[105] Because more and more electronic equipment is being used, this problem is an increasing one. The director of scientific and

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tion of S. 2107—"The Medical Device Safety Act of 1969"); 115 CONG. REC. 4264 (1969) (letter from Morton M. Schneider, Office of Legislative & Governmental Services, HEW, FDA, to Rep. Foley, included as an exhibit upon introduction of H.R. 7315—"The Medical Device Safety Act of 1969").

100. In contrast, devices employed for internal fixation of fractures are usually removed after union is effected, since the continued presence of the metal is then unnecessary, may retard complete healing, and presents the dangers of acute inflammation, osteomyelitis, and so forth. The only usual exception is with elderly persons where, in view of their age, it is considered that the operation for removal of the metal presents greater dangers than its continued presence in the body. *See* M. MULLER, M. ALLGOWER & H. WILLENEGGER, TECHNIQUE OF INTERNAL FIXATION OF FRACTURES (1965), and C. BECHTOL, *supra* note 94, at 44-45.

101. ENGINEERING IN THE PRACTICE OF MEDICINE 152 (B. SEGAL & P. KILPATRICK ed. 1967).

102. *See* INSTITUTE OF MECHANICAL ENGINEERS, LUBRICATION AND WEAR IN LIVING AND ARTIFICIAL HUMAN JOINTS (1967).

103. 111 CONG. REC. 19067 (1965) (remarks of Sen. Williams upon introduction of S. 2350, 89th Cong., 1st Sess. (1965), a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of therapeutic, diagnostic and prosthetic devices).

104. *Accidental Electrocutions Claim 1,200 Patients a Year*, ELECTRONIC NEWS, Jan. 27, 1969, at ____, reprinted in 115 CONG. REC. 4265 (1969). The FDA's own estimates are more conservative; 656 deaths and in escess of 10,000 injuries were attributed by it to all types of medical device malfunctions between 1963 and 1969. *The Law Moves In On Medical Hardware*, BUSINESS WEEK, March 18, 1972, at 51.

105. *Accidental Electrocutions Claim 1,200 Patients a Year, supra* noe 104.

medical instrumentation at Downstate Medical Center, State University of New York, estimated that 40 percent of incoming equipment is defective with respect to safety requirements.[106] At least one manufacturer of electronic monitoring equipment, which is connected directly to the patient, voluntarily undertook to have all such equipment approved by Underwriter's Laboratory.[107] However, there is no requirement that such approval be sought, and many manufacturers do not submit their products for testing. The establishment of a uniform requirement for such approval would be one way of reducing the number of accidental electrocutions caused by electrically unsafe medical equipment.

The chief defects in these electrical and electronic devices which can cause accidental electrocution are faulty wiring, so as to result in direct application of the line current to the patient,[108] and leakage current caused by inadequate grounding.[109] The first results in gross shock, which usually kills by causing fibrillation of the heart, but may also kill by attacking the brain's respiratory control center or paralyzing the muscles used in breathing. Leakage current is a problem with such diagnostic devices as cardiac cathethers, which can introduce current directly into the body, by-passing the greater resistance of the skin. When current is introduced directly into the heart, as little as 20 microamperes can induce fatal ventricular fibrillation.[110] Also, it is quite possible that the figure of 1,200 electrocutions per year is conservative. Hospitals are obviously not going out of their way to publicize such deaths, and death caused by fibrillation accidentally induced by leakage current leaves no evidence that shows up at autopsy and is indistinguishable from death due to natural causes.[111]

Although some of the problems in this area may be due to deficiencies in the electrical system of the hospital or in the connection of one machine to another, a large percentage of these accidental electrocutions could probably be avoided by better equipment design and mandatory premarket testing. The fact that these

106. *Id.*

107. *Id.*

108. *See, e.g.*, Letter from Morton M. Schneider, *supra* note 99.

109. Doyle, *Designers of Medical Instruments Face Serious Qestions on Safety*, ELECTRONICS, Feb. 17, 1969, at ____. This article was reprinted in 115 CONG. REC. 4264-65 (1969).

110. *Id.*

111. *Id.*

instruments are usually quite complex and are often used by technicians having little or no knowledge of or training in electronics or electricity is all the more reason to require manufacturers to make these machines as inherently safe and foolproof as possible.

Experts have said that electrical hazards are exceeded only by misadministration of drugs and falling out of bed as the leading cause of hospital accidents, and that the risk keeps rising with the ever-increasing use of electronic equipment for diagnosis, monitoring, and treatment.[112] Having noted that "hospitals tend to be apathetic about the problem and equipment manufacturers indifferent,"[113] these same experts[114] indicated a need for "stiff quality standards and the machinery for enforcement."[115] It has been suggested that each hospital should attempt writing the necessary standards into its purchase orders;[116] however, this seems like a very unsatisfactory and unworkable solution. Uniform federal standards would seem to be beneficial to all parties concerned, since the public would benefit by the increased safety of such devices, the hospitals would have certifications that the equipment they are using is safe, and the manufacturers would have a defense, in the event of litigation, afforded by the fact that their product complied with the applicable standards.[117]

3. Other Medical Devices

Orthopedic internal fixation devices and prostheses, and electrical and electronic diagnostic, monitoring, and therapeutic instruments are certainly not the only classes of medical devices which present problems in the absence of standards and a premarket clearance requirement.

Another class of devices which present actual and potential problems with respect to safety are intauterine contraceptive devices (IUDs). These devices are being marketed in many different forms by many different manufacturers and are being used by

112. Randal, *Electrical Risk in Hospitals Is Held Rising*, Washington (D.C.) Evening Star, Feb. 17, 1969, § ____, at ____, col. ____. This article was reprinted in 115 CONG. REC. 4267 (1969).

113. the experts who have made these statements include Dr. Carl Walters, Surgeon at Peter Bent Brigham Hospital, Boston, Mass.; David Lubin, Administrative Engineer of Sinai Hospital, Baltimore, Md.; and Paul E. Stanely of Purdue University School of Engineering.

114. *Id.*

115. *Id.*

116. *Engineering in the Practice of Medicine, supra* note 101, at 72.

117. *Id.* 73.

women in ever-increasing numbers. Although IUDs were found to be highly effective (although not quite as reliable as oral contraceptives) and generally safe, a 1968 FDA report stated:

> The safety of the material used, the quality control in its manufacture, and the labeling and packaging of intrauterine devices are at present the sole concern of each manufacturer. Furthermore, new devices can be introduced practically at will.[118]

The most common short-term adverse reactions reported with respect to IUDs were infection and uterine perforation during insertion. Although serious adverse reactions were relatively rare, this may have been due, in part, to underreporting. It was suggested that suitable standards of sterility in packaging could reduce the incidence of infection, and that the number of cases of uterine perforation followed by intestinal obstruction might be reduced by avoiding the use of closed type devices which open upon insertion.[119] For these reasons and because these devices are intended to remain in the body for long periods of time, and in light of the fact that it is too early to tell whether such devices or certain kinds of such devices may have long-term harmful effects, it was recommended that IUD's be included within the proposed medical device legislation requiring premarket clearance, although legislation directed specifically at contraceptive devices was opposed.[120]

A rapidly expanding frontier in medicine is the development of artificial internal organs and extracorporeal machines.[121] These also are not now subject to federal standards or premarket clearance requirements. The problems presented by these kinds of medical devices are legion, and no attempt will be made todiscuss them here other than to say that reasonable federal standards for and premarket regulation of such devices, with adequate exemptions for investigational and experimental uses, is probably in the best interest of the public for much the same reasons as with other medical devices. Namely, the harm to the public in the form of needless dangers prevented by such regulation will be greater than the harm to the public (in the sense of discouragement of research and development of new beneficial devices) caused by such regulation.

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118. FDA ADVISORY COMMITTEE ON OBSTETRICS & GYNECOLOGY, REPORT ON INTRAUTERINE CONTRACEPTIVE DEVICES 39 (1968).

119. *Id.* 8

120. *Id.* 40. See note 202 *infra.*

121. *See* D. LONGMORE, SPARE-PART SURGERY (1968).

New types of devices are constantly being developed and existing devices are continually being modified.[122] This innovation and evolution should certainly not be discouraged. But, at the same time, it is paradoxical and unnecessary that the public should be subjected to needless dangers by the very devices designed to promote, preserve, and protect public health. Undoubtedly, a compromise approach which balances the public's current need for greater protection with the realities of business would be most desirable. Some medical device manufacturers maintain that stringent government regulation will stifle the development of new products and may even put small manufacturers out of business. However, others would welcome reasonable regulaion because it would clear up the present confusion resulting from the "drug-device" dichotomy and because federal standards would upgrade the industry and prevent the unfair competition to which safety-conscious manufacturers are now subjected by other manufacturers who are less concerned.[123]

There seems to be little real doubt that reasonable standards for and premarket regulation of some types of medical devices is necessary and desirable. It also appears likely that some legislation of this kind (which has been introduced in Congress continually since 1954) will actually be passed. Congress must now determine precisely what type of requirements and standards to impose and what scope and application they should have. The medical device industry could seemingly best protect both its own interests and the best interests of the public by cooperating in the development of reasonable regulatory measures. Continued resistance against any further regulation may only result in the hurried passage of unduly restrictive and ill-considered legislation should there occur another well-publicized tragedy, this time involving a medical device.

## IV. THE RECENT JUDICIAL DECISIONS[124]

In view of the fact that the dichotomy between the regulation

122. Soft contact lenses present a good example of this. Hard lenses were established as "devices," and therefore it was assumed that a soft variant thereof would likewise be a "device." However, because soft lenses can be used to treat eye diseases as well as correct vision, and because they may harbor infections, the FDA classified them as "drugs" in 1968, thus making them subject to the "new-drug" premarket clearance requirements. *When a Medical Device May Be a Drug*, BUSINESS WEEK, March 18, 1972, at 52.

123. *See, e.g., The Law Moves In On Medical Hardware*, *supra* note 104.

124. For other discussions of the recent cases dealing with the definitional problems presented by the 1938 Act, as amended, see Styn, *supra* note 34, at 518-32, and Weitzman, *supra* note 34, at 321-40.

of "drugs" and "devices" with respect to premarket clearance has existed since 1938, it is somewhat remarkable that the courts have not had to construe the definitions of "drug" and "device" in light of this dichotomy until quite recently. As already pointed out, since the definitions of "drug" and "device" are in part identical,[125] but only "new drugs" are subject to premarket approval,[126] the manufacturer of a new product which could arguably fall under either definition has a powerful incentive to maintain that his product is a "device." What is also surprising is that cases did not arise earlier presenting the situation of a manufacturer claiming his new product is a "device" and therefore not subject to the premarket clearance requirement, while the FDA contends it is a "drug" not generally recognized by qualified experts as safe and effective for its intended use, so as to be a "new drug" subject to premarket approval. Finally, however, such cases have been presented and decided.

### *A. AMP Inc. v. Gardner*[127]

In this case, the plaintiff manufacturer sought a declaratory judgment declaring its products to be "devices" and an injunction against application and enforcement of the "new drug" provisions with respect to the products concerned. Both plaintiff and defendants—nominally the Secretary of Health, Education, and Welfare and the Commission of Food and Drugs—moved for summary judgment, the defendants contending that the items in question were "drugs," not "devices." The products involved were intended for use by surgeons in ligating blood vessels severed during surgery. They consisted of a disposable applicator in the form of either a hemostat or a long slender tube, the nylon ligature itself, and a nylon locking disc which maintained the ligature loop in a tightened position after it was pulled tight around a blood vessel. The excess ligature was then cut off, the applicator removed, and the ligature loop and locking disc remained in the body. (Ordinarily, severed blood vessels are hand-tied by the surgeon with a reef knot.)

Plaintiff had initially written to the FDA asking whether these products would be classified as "drugs," "new drugs," or "de-

125. See notes 64 & 65 and accompanying text *supra*.

126. See notes 29 & 30 *supra* and notes 62 & 63 and accompanying ext *supra*.

127. 275 F. Supp. 410 (S.D.N.Y. 1967), *aff'd*, 389 F.2d 825 (2d Cir.), *cert. denied*, 393 U.S. 825 (1968), *rehearing denied, sub nom.* AMP Inc. v. Cohen, 395 U.S. 917 (1969).

vices," and was advised that they would be considered "new drugs." Six months after filing for an investigational exemption,[128] AMP was advised by the FDA of various deficiencies with respect to the investigational exemption and was told that long-term studies would be required concerning the possible carcinogenic effects of the nylon ligature and locking disc remaining in the body. Subsequently, plaintiff took the position that its products were "devices," and after threat of regulatory action by the FDA for failure to comply with the investigational drug regulations, removed its products from interstate commerce and commenced an action for a declaratory judgment.

AMP contended that its products were principally mechanical instruments, with the nylon ligaure and locking disc being merely "components, parts, or accessories" thereof, so that the products as a whole were "devices" under section 201(h).[129] The FDA maintained that the hemostat and long selnder tube merely constituted unique applicators for administering a nylon suture, that a suture is a "drug," and that the products constitued "new drugs," since this new method of application was not generally recognized by qualified experts as safe and effective for use under the conditions recommended.[130]

The district court granted summary judgment for the FDA[131] concluding that the essential element of AMP's products was the suture. Analogizing the products to drugs administered by means of disposable syringes, such syringes alone being "devices," the court said that the mere packaging of a drug in a syringe did not make it a component of a device. Thus, if the suture were a "drug," the use of such a "device" as an applicator did not convert the suture into a mere component of the "device."[132]

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128. 21 U.S.C. § 355(i) (1970).

129. 21 U.S.C. § 321(h) (1970). See note 59 *supra*.

130. See note 29 *supra*.

131. 275 F. Supp. at 416.

132. However, the court did not agree with defendants' contention that he fact that sutures were listed in the official United States Pharmacopeia was conclusive to classify the products as "drugs." This, said the court, would make meaningless the express exclusion of "devices" from the "drug" definition, and, therefore, the listing of an item in an official compendium is merely "some evidence" that such item is a "drug."

Both parties had argued that he terms "drug" and "device" were mutually exclusive. Without further comment, the court quoted Toulmin to the effect that these terms should not be defined as mutually exclusive. As indicated in note 67 *supra*, Toulmin has now reversed his position on this point. The definition of "drug" expressly excludes "devices," so a "device" cannot also be a "drug;" for the same reason, a "drug" cannot also be a "device," because if it is a "device," it is not a "drug."

After discussing the ambiguity of the "drug" and "device" definitions,[133] and assuming that AMP's products could arguably fit within either, the court concluded that the remedial nature of the Act warranted a liberal construction for the protection of the public health, and thus held them to be "drugs."

> The public will be better protected by classifying plaintiff's products as drugs rather than as 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.[134]

The court also agreed with defendants that plaintiff's products were "new drugs," since the unique method of administration of a suture gave rise to a genuine difference of medical opinion as to their safety and efficacy for use in ligating blood vessels severed during surgery.[135]

AMP then appealed, and the judgment below was affirmed.[136] The court of appeals agreed with AMP that the applicators taken along were "instruments," and therefore "devices." However, it also agreed with the district court's syringe analogy, concluding that the ligature and locking disc were the essential elements of the new products. Thus, the applicators were considered to be "components" of the ligature and disc, not vice versa.[137]

More disturbed about the express exclusion of "devices" from the "drug" definition than the district court had been, the court of appeals undertook a review of the legislative history[138] to ascertain the purpose of the separate definition of "device," so as to determine the kind of things Congress meant to distinguish from the "articles" that are "drugs." Absent this exclusion there would have been no hesitancy to classify AMP's new products as "drugs." The court concluded that there was nothing in the legislative history to indicate that the separate definition of device was for any purpose other than to avoid the semantic incongruity of classifying mechanical applicances, such as electric belts, as "drugs." It was also concluded that the "new drug" provisions were incorporated into

133. See notes 64 & 65 and accompanying text *supra*.
134. 275 F. Supp. at 414.
135. *Id.* at 415.
136. AMP Inc. v. Gardner, 389 F.2d 825 (2d Cir. 1968).
137. *Id.* at 827.
138. See notes 23-75 and accompanying text *supra*.

the Act without awareness of the fact that the "drug"-"device" distinction had for the first time become significant.[139]

The opinion then reasons that since the only difference between classifying the new products as "drugs" instead of "devices" is that they might be subject to the "new drug" provisions if "drugs," they must be classified in light of the purpose of the "new drug" provisions. The court found this purpose "very clearly" to be, "to keep inadequately tested medical and related products which might cause widespread danger to human life out of interstate commerce."[140] It was then held that AMP's new products had been correctly declared to be "drugs," because ligatures[141] might present the same dangers as products commonly called "drugs," and thus were intended to be covered,[142] and also because a statute touching the public health is usually not narrowly construed. The court also cited the fact that nylon suture material of the type from which plaintiff's ligatures were made was included in the United States Pharmacopeia,[143] and concluded: "The exclusionary classification 'devices' should, we think, be limited to such things as Congress expressly intended it to cover."[144]

The court of appeals also agreed with the district court that AMP's products were "new drugs." The Supreme Court refused to grant certiorari.[145]

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139. 389 F.2d at 829.

140. *Id.*

141. The court rejected the distinction *AMP* attempted to make between a suture, which sews tissue, and a ligature, which ties it. *Id.* at 830 n.12.

142. As the court noted:

> The product which immediately precipated Congressional concern—"Elixir 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 "Elixir 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.

*Id.* at 829-30.

143. The accuracy of the court's additional statement that nylon suture material has always been regarded as "drugs" by the FDA depends on when "always" begins. Apparently there was doubt as to whether sutures were within the "drug" definition of the 1906 Act, and this is one of the reasons why the word "device" was added to the "drug" definition in the earlier versions of the 1938 Act. See note 40 and accompanying text *supra*.

144. 389 F.2d at 830.

145. 393 U.S. 825 (1968), *rehearing denied*, 395 U.S. 917 (1969).

### B. *United States v. An Article of Drug * ** Bacto Unidisk*[146]

In 1945, Congress added section 507[147] to the Federal Food, Drug, and Cosmetic Act, which required premarket certification of "antibiotic drugs" pursuant to regulations promulgated by the Secretary of Health, Education, and Welfare, establishing such standards as were necessary to adequately ensure that each batch of these substances is safe and effective. Section 502(l)[148] then provides that such antibiotics are "misbranded" unless batch-certified or exempted. As with the "new drug" provisions, since the term "antibiotic drug" is defined as "any drug,"[149] a product must first be classified as a "drug" within the meaning of the Act[150] before it can be determined to be an "antibiotic drug" and therefore subject to the premarket batch-certification requirement.

In response to the need for a way of determining which of the many available antibiotics would be most effective in treating a particular infection in a particular patient, products called antibiotic sensitivity discs were developed. In 1960, the FDA undertook to regulate these discs under section 507, and regulations requiring preclearance, batch-testing, and certification were promulgated. Since section 507 only applied to "antibiotic drugs," the validity of these regulations was dependent on whether or not these antibiotic sensitivity discs were "drugs" within the meaning of the Act. If they were not, they were not subject to premarket regulation under section 507 or elsewhere, and these regulations would therefore be unauthorized and invalid.[151]

In the first case that presented this issue, it was held that the particular antibiotic sensitivity discs involved were "drugs." Thus, the regulations were found to be valid, and the manufacturer was enjoined from introducing his "MULTIDISKS" into interstate commerce without certification.[152] However, another district court

146. 392 F.2d 21 (6th Cir. 1968), *rev'd*, 394 U.S. 784, *rehearing denied*, 395 U.S. 954 (1969).

147. 21 U.S.C. § 357 (1970).

148. 21 U.S.C. § 352(l) (1970).

149. 21 U.S.C. § 357(a) (1970).

150. 21 U.S.C. § 321 (1970), the general definitions section of the Act, begins merely with, "For the purposes of this Act . . . ." There is no phrase—such as, "unless the context otherwise requires"—which might provide some leeway. Also, as has been indicated, the fact that he individual definitions begin, "The term . . . *means*," rather than *includes*, further restricts their flexibility. See notes 69 & 70 and accompanying text *supra*.

151. This history of the premarket antibiotic batch-certification requirement is drawn from Chief Justice Warren's opinion in *Bacto-Unidisk*, 394 U.S. at 784-89.

152. United States v. Consolidated Laboratories, Inc.,

thereafter held that a similar type of antibiotic sensitivity disc was not a "drug."[153]

In a very brief opinion, the Sixth Circuit Court of Appeals affirmed the judgment in the latter case.[154] The product involved, "Bacto-Unidisk," consists of a small cardboard ring with eight circular paper units, seven impregnated with different antibiotics and the eighth impregnated with sulfadiazine, extending inwardly from the ring.[155] The purpose of the "Unidisk" is to determine the antibiotic which would be most effective in treating an infection, without experimenting directly on the patient. Instead, samples of virus grown from a specimen (blood, urine, sputum, and the like) taken from the patient are placed on the various circular units impregnanted with different antibiotics and the most effective antiobiotic is thereby determined as being the one which most retards growth of the virus.[156]

This case originated when the government filed a libel of condemnation against a quantity of the product, alleging that the "Unidisks" were "misbranded" under section 502(1), since they contained "antiobiotic drugs" which had neither been certified nor exempted from certification. In affirming the judgment for the manufacturer, based on the finding that the product was not a "drug" under the Act, the Sixth Circuit Court of Appeals did little more than reiterate the district court's opinion.

Somehow, the chief issue at the trial in the district court was thought by both parties and the judge to be whether this product fitted within the generally recognized medical definition of drugs—that is, substances which are either applied to or taken into the body for treatment of injury or disease. Indeed, one of the judge's conclusions of law was that there was no basis for concluding that Congress intended the definition of "drug" to extend beyond the medical definition of that term.[157] In the words of Senator

153. United States v. An Article of Drug * ** Bacto-Unidisk, Case No. ____, (E.D. Mich., July 21, 1966).

154. 393 F.2d 21 (6th Cir. 1968).

155. *Id.* at 21.

156. 394 U.S. at 787.

157. The court of appeals quoted this finding:

> In medical science the concept of "drugs" is limited to articles administered to man or other animals, either internally or externally. This is the general accepted view among physicians. The evidence affords no basis for the conclusion that the definition of "drug" in the Federal Food, Drug and Cosmetic Act—21 U.S.C. 321(g)—was intended by Congress to extend beyond the meaning of that erm in medical science, to encompass these sensitivity disks.

392 F.2d at 23.

Clark,[158] this conclusion is virtually a "palpable absurdity," since the legislative history indicates nothing if not that the term "drug" is a term of art and was intended to be construed very broadly.[159] Moreover, since the term "drug" is defined in the statute, the proper question was whether a "Bacto-Unidisk" fell within the provisions of the statutory definition. It was irrelevant whether or not it met the medical definition of a drug.

Even more amazingly, although the district judge admitted that on a literal reading the language of the section 201(g)(1)(B) definition of "drug,"[160] "clearly has application to the article libeled herein,"[161] the Sixth Circuit Court of Appeals said that this was true only in an indirect sense, since the sensitivity disc itself was not intended for use "either internally or externally to cure, mitigate or treat disease."[162] Concluding, again in agreement with the trial judge, that "it was not the legislative intent to apply the phrase 'intended for use in the . . . cure, mitigation, treatment' . . . in such an indirect manner,"[163] the court held that a "Bacto-Unidisk" was not a "drug" within the meaning of the Act and was therefore not required to be certified or exempted pursuant to section 507 before it could be legally marketed in interstate commerce.

The government then appealed, and the Supreme Court reversed the decision below.[164] Chief Justice Warren, writing the opinion of the Court, stated that the courts below were correct in determining that the issue was whether the antibiotic sensitivity disc regulations were authorized by the Act's definition of "drug" and not whether premarket certification of these discs was really necessary to protect the public health.[165] However, this was about the only point on which the Supreme Court did not find the lower courts in error.

First, Chief Justice Warren, reviewing the legislative history,[166] demonstrated that the term "drug" was a term of art and was clearly intended to encompass "far more than the strict medical

158. See notes 50-51 and accompanying text *supra*.
159. See notes 40-42 and accompanying text *supra*.
160. See note 59 *supra*.
161. 392 F.2d at 22.
162. *Id.*
163. *Id.*
164. 394 U.S. 784 (1964).
165. *Id.* at 791.
166. See notes 23-75 and accompanying text *supra*.

definition of that word."[167] He then pointed out that "devices" were removed from the "drug" definition and separately defined for semantic reasons only, the separate definitions having had no substantive significance until the "new drug" provisions were added.[168] Thus, the lower courts erred in refusing to apply the language of the "drug" definition literally—the broad coverage which the district court characterized as "ridiculous and contrary to common sense"[169] being precisely what Congress had intended.[170] Furthermore, it was stated that this congressional intent must be given effect

> in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health, and specifically, § 507's purpose to ensure that antibiotic products marketed serve the public with "efficacy" and "safety."[171]

In summary, the Court concluded that:

> Viewing the structure, the legislative history and the remedial nature of the remedial nature of the Act, we think it plain that Congress intended to define "drug" far more broadly than does the medical profession.[172]

Thus, the lower courts' restriction of the "drug" definition to items conceived of as drugs in the medical sense of the term, so as to limit it to articles directly administered either internally or externally, was resoundingly rejected by the Supreme Court.

Having disposed of the respondent's primary contention that none of the provisions of the Act applied to antibiotic sensivitity discs "because Congress did not intend the Act to cover articles used so *indirectly* in the 'cure, mitigation, [and] treatment' of disease,"[173] the Court went on to consider and reject the alternative contention that even if the discs did fall within the Act, they were "devices" and thus by definition could not be "drugs."

Since the discs could be arguably either "drugs" or "devices," the classification, said the Court, should be made in light of statu-

167. 394 U.S. at 793.
168. *Id.* at 797-98.
169. *Id.* at 790.
170. *Id.* at 798.
171. *Id.*
172. *Id.* at 793.
173. *Id.* at 792.

tory purposes, and since the purpose of section 507 to provide for safe and effective antibiotics would be subverted if the wrong antibiotic were administered because of a deficiency in the sensitivity disc, it was reasonable for the Secretary to determine that the discs were also "drugs" and thus also subject to premarket certification.[174]

Moreover, Chief Justice Warren stated:

> "[T]he legislative history, read in the light of the statute's remedial purpose, directs us to read the classification 'drug' broadly, and to confine the device exception as nearly as is 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. In upholding the Secretary's determination here, without deciding the precise contours of the 'device' classification, we need only point out that the exception was created primarily for the purpose of avoiding the semantic incongruity of classifying as drugs (1) certain quack contraptions and (2) basic aids used in the routine operation of a hospital—items characterized more by their purely mechanical nature than by the fact that they are composed of complex chemical compounds or biological substances."[175]

Justice Douglas was the sole dissenter from the majority opinion. He would have affirmed the judgment because he felt that "it would indeed be difficult to write a clearer description of an antibiotic sensitivity disc"[176] than that provided by the language of the "device" definition in section 201(h).

The ambiguity and difficulty in application of the present provisions is well demonstrated by the gyrations the courts in these cases found necessary in order to decide the matters before them. Even though the "right" result was probably reached, excursions into legislative history and resort to public policy as the final basis of decision should not be necessary in applying a statute which

174. *Id.* at 798-99. It has been pointed out by one commentator that the antibiotic sensitivity discs could have held to be "drugs" merely by applying the language of part (D) of the "drug" definition, and thus it would not have been necessary to resort to any strained construction in light of statutory purpose. The reasoning would be that the essential parts of the discs are the impregnated antibiotics, and these are certainly "drugs," so that the disc would merely be "an article intended for use as a component" of an article specified in clause (B), and therefore also a "drug." Styn, *supra* note 34, at 531. See note 59 *supra* for the definition of "drug."

175. *Id.* at 799-800.

176. *Id.* at 801.

affects such a broad and vital public interest. Instead of facilitating predictability and certainty, the present definitions and statutory framework only cause confusion and encourage attempts at avoidance.

### C. *The "Drug"—"Cosmetic" Cases*

There are also recent cases dealing with the issue of whether a new product is a "cosmetic" or a "drug" within the Act.[177] Like "devices," "cosmetics" are not now subject to any premarket clearance requirement. Thus, the situation again is one where the manufacturer contends his product is a "cosmetic" while the FDA contends it is a "drug" and a "new drug."[178] In two cases reaching United States Court of Appeals, the new products, which were "wrinkle removers," were determined to be "drugs."[179] However, a more recent district court decision involving another "wrinkle remover" held that the product was not a "drug."[180]

Since the definitions of "drug" and "cosmetic," unlike the definitions of "drug" and "device," are not mutually exclusive, it is possible for a product to be subject to simultaneous regulation as a "cosmetic," a "drug," and a "new drug." Therefore, the issue in these cases is not whether the product is a "drug" instead of a "cosmetic," but whether it is a "drug" as well as a "cosmetic."

Since 1953, numerous bills have been introduced in Congress that would have required premarket testing of new cosmetics,[181] but as with the similar, and in some cases the same, bills dealing with devices, none has yet been passed.

## V. Is Additional Legislation Really Required?

It has been suggested that there may be no need for Congress to enact legislation requiring premarket clearance of medical de-

177. *See* DiPrima, *Which Cosmetics Are Also Drugs?—The Wrinkle Lotion Cases*, 27 THE BUSINESS LAWYER 49 (1971).

178. See note 59 *supra* for the definitions of "drug" and "cosmetic." See note 29 *supra* for the definition of "new drug."

179. United States v. Article Consisting of 36 Boxes . . . Line Away, Temporary Wrinkle Smoother, Coty, 415 F.2d 369 (3d Cir. 1969), *aff'g* 284 F. Supp. 107 (D. Del. 1968); United States v. An Article . . . Consisting of 216 Cartoned Bottles . . . Sudden Change, 409 F.2d 734 (2d Cir. 1969), *rev'g* 288 F. Supp. 29 (E.D.N.Y. 1968).

180. United States v. An Article . . . 47 Shipping Cartons, Magic Secret, 331 F. Supp. 912 (D. Md. 1971).

181. For a list of such bills through the 90th Congress see United Statesv. An Article . . . Consisting of 216 Cartoned Bottles . . . Sudden Change, 288 F. Supp. 29, 37-38 (E.D.N.Y. 1968).

vices because the recent "judicial legislation" engaged in by the courts has made such legislation unnecessary.[182] It is true that the Supreme Court's broad construction of "drug" in *Bacto-Unidisk* should allow the FDA to successfully maintain that products which could be arguably either "drugs" or "devices" are to be classified as "drugs."[183] However, the fact that the FDA can probably prevail in a court contest over the proper classification of a new product is still not a satisfactory solution to the problem of the "drug-device" dichotomy.

Under the present law, the FDA must first make a seizure of the device it alleges is "adulterated"[184] or "misbranded"[185] in order to commence a prosecution. The purpose of such seizure, pursuant to section 304,[186] is merely to secure *in rem* jurisdiction. The seizure procedure is not designed to remove all devices of the type in question from the market; in fact, multiple seizures for misbranding are prohibited except when the alleged misbranding has already been adjudicated in favor of the United States in a prior proceeding under the Act, or when the Secretary finds probable cause to believe the product is "dangerous to public health" or the labeling is fraudulent or would be materially misleading to the injury or dam-

182. Kleinfeld, *Surgical Implants: Drugs or Devices, and New Device Legislation*, 23 FOOD DRUG COSM. L.J. 510, 516-18 (1968). This suggestion was made in view only of *AMP Inc. v. Gardner*, since *Bacto-Unidisk* had not yet been decided by the Supreme Court at the time this article was written. In a more recent article, which briefly discusses the current state of confusion as to the regulation of medical devices, Mr. Kleinfeld predicts that legislation providing for some form of preclearance and standardization will be enacted in the near future. Kleinfeld, *Sterile Disposable and Other Therapeutic Devices and the Law*, 27 FOOD DRUG COSM. L.J. 19 (1972). The pro-legislation viewpoint is set forth in two other recent articles: Cooper, *Device Legislation*, 26 FOOD DRUG COSM. L.J. 165 (1971) and Pilot, *Remarks on Medical Devices*, 25 FOOD DRUG COSM. L.J. 466 (1970). Dr. Cooper was chairman of the committee which studied the standards and pre-clearance aspects of medical device regulation pursuant to President Nixon's October 30, 1969, message to Congress to the effect that minimum standards should be established for certain medical devices and authority should be granted to require premarket clearance in some circumstances. The general recommendations resulting from this study are set forth in Dr. Cooper's article. Basically, it was recommended that (1) a panel of experts be organized to review existing devices and advise in the categorization of medical devices; (2) the Secretary of HEW be given authority to certify acceptable existing standards, establish or encourage the development of new standards, and audit manufacturers for compliance; and (3) legislation providing for premarket evaluation be enacted to avoid the dangers of marketing inadequately tested medical devices and to promote needed new device development. 26 FOOD DRUG COSM. L.J. at 170-71.

183. See Styn, *supra* note 34, at 533.

184. 21 U.S.C. § 351 (1970). As a practical matter, "devices" will seldom be subject to this section.

185. 21 U.S.C. § 352 (1970).

186. 21 U.S.C. § 334 (1970).

age of the consumer.[187] Obviously this libel for condemnation procedure is very cumbersome. It is also very ineffective in that devicds which may be dangerous are already in distribution before proceedings can be commenced against them.[188] In the event of an extremely dangerous device, this could be too late.

Even of multiple seizures were permitted without limitation, this is a very impractical and expensive procedure, since it is very difficult to trace the devices to their ultimate location and virtually impossible to recover them all. Moreover, by making insignificant changes in the product and changing the name, the manufacturer can evade the initial seizure and force the FDA to institute a separate proceedings against each variation of the device. Finally, there is the fundamental inconsistency that the burden of proof is on the Government to prove that a new "device" is misbranded in order to get it off the market, while with "new drugs" the burden is on the manufacturer to prove that the product is safe and effective before it can legally be put on the market.[189]

Present law also provides for injunction[190] and criminal penalties.[191] However, these sanctions are insufficient for purposes of affording protection from inadequately tested unsafe or ineffective medical devices for the same reasons that the libel for condemnation procedure is inadequate. At best, all three of these sanctions may prevent continuing harm if the Government is completely successful in court. However, even in this event, the damage resulting from the initial distribution will have already been done.

It appears that the public would be better protected if the law were such that unsafe, unreliable, and ineffective devices could never get on the market, as opposed to the present law, which seems to heavily favor the manufacturers of quack devices and the manufactures of legitimate medical devices who do not conduct adequate premarket testing. The present law seems detrimental both to the public and to the conscientious manufacturer who does conduct adequate premarket testing of his devices, because he is put at a competitive disadvantage with respect to the other manufacturers who do not spend the money to do this.

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187. 21 U.S.C. § 334(a)(1)(A) & (B) (1970).

188. Adulterated or misbranded devices are only liable to be proceeded against "while in interstate commerce, or at any time thereafter." 21 U.S.C. § 334(a)(1) (1970).

189. See noes 82 & 83 and accompanying text *supra*.

190. 21 U.S.C. § 332 (1970).

191. 21 U.S.C. § 333 (1970).

Moreover, it is questionable just how far the Supreme Court's broad construction of "drug" in *Bacto-Unidisk* can be stretched. In both *AMP* and *Bacto* the products involved were border-line; they arguably could have been classified as either "drugs" or "devices." In *AMP*, although the decision was grounded primarily on public policy, the Second Circuit did note that sutures (equating ligatures and sutures)[192] are listed in the United States Pharmacopeia,[193] which puts them within the "drug" definition of the Act under part (A) of the definition.[194] And, in *Bacto-Unidisk*, the antibiotics with which the units comprising the sensitivity disc were impregnated were certainly "drugs."[195] Thus, this broad construction of the definition of "drug" may not be so broud at all, since the decided cases have dealt only with products of which one component was squarely within the "drug" definition. In these cases, as already indicated, the products as a whole could more easily have been classified as "drugs" merely by employing the seemingly forgotten part (D) of the "drug" definition.[196]

There are many medical devices which would not fit within the judicially broadened definition of "drug." Chief Justice Warren's guidelines in *Bacto-Unidisk* as to the "contours" of the "device" classificatin, even though dicta, are sure to be seized upon by device manufacturers who seek to avoid premarket clearance.[197] In fact, it would seem that most of ty devices which currently present problems would fall within the suggested limits of the "device" classification, as either "quack contraptions" or "basic aids used in the routine operation of a hospital"—both such classes being "characterized more by their purely mechanical nature than by the fact that they are composed of complex chemical compounds or biological substances."[198]

According to these guidelines, quack devices are expressly within the "device" classification, and therefore are not subject to premarket clearance; and, by virtue of the "basic-aids-used-in-the-routine-operation-of-a-hospital" and "purely-mechanical-nature" language, orthopedic internal fixation devices and electrical and electronic diagnostic, monitoring, and therapeutic devices are

192. See note 141 *supra.*
193. 389 F.2d at 830.
194. 21 U.S.C. § 321(g)(1)(A) (1970). See note 59 *supra.*
195. See note 174 *supra.*
196. See note 174 and accompanying text *supra.*
197. See note 175 and accompanying text *supra*, where these guidelines are quoted.
198. *Id.*

"devices" not subject to premarket clearance. Of the examples discussed in this paper, only some intrauterine contraceptive devices (IUDs) and artificial internal organs would seem to stand a chance of not being classified as "devices," since these may fit within the class of items "composed of complex chemical compounds or biological substances" which are characterized as being not intended to be classified as "devices." Also, these could not really be characterized as "basic aids used in the routine operation of a hospital."[199]

Indeed, it would seem that the Supreme Court's decision in *Bacto-Unidisk* cut back on the breadth of the construction of the term "drug" as construed by the policy-oriented Second Circuit in *AMP Inc. v. Gardner*. Thus, the optimism of the FDA after the Supreme Court refused to grant certiorari in the *AMP* case to the effect that this decision "revolutionizes the situation for a great number of products, ranging from nails used in bone repair to artificial eyes," and gives the FDA power to require preclearance of all these products[200] seems rather overexuberant in light of the subsequent decision in *Bacto-Unidisk*. The position of the FDA that it would be able to subject IUDs to premarket regulation[201] seems more plausible, not because of the *AMP* case, but, rather, because of the decision in *Bacto-Unidisk*.[202]

Thus, it seems fair to say that the recent judicial decisions have really not changed the overall situation with respect to medical

199. *Id.*

200. statement by counsel for the FDA, printed in the Washington (D.C.) Post, June 8, 1968, § ____, at ____, col. ____. This statement is quoted in Kleinfeld, *Surgical Implants: Drugs or Devices, and New Device Legislation*, 23 FOOD DRUG COSM. L.J. 510, 517-18.

201. *Id.* 518.

202. The FDA has undertaken further regulation of IUDs and in vitro diagnostic products. A policy statement proposing to classify as "new drugs" intrauterine devices containing heavy metals, drugs, or other added substances has been released. 36 Fed. Reg. 10983 (1971). Notice has been given to manufacturers of in vitro diagnostic products for human use (used solely to provide information on specimens taken from the body) that they must conduct adequate premarket tests to demonstrate that their products are safe and effective under the conditions described in their labeling. 37 Fed. Reg. 819 (1972). This notice states that the Act provides "clear authority to exercise appropriate regulatory controls over these producgs as *devices and/or drugs*" (emphasis added). The failure to conduct adequate premarket tests may cause the product to be misbranded, the notice concludes. This appears to be a novel way of attempting to impose a premarket clearance requirement without specifically invoking the premarket clearance requirement for "new drugs" and without taking a position that the products are "drugs" and "new drugs," rather than "devices."

devices. They may still be marketed without prior proof of safety, reliability, and effectiveness, and the burden is still on the Government in actions to remove unsafe, unreliable, or ineffective devices from the market. Furthermore, such devices are not within the jurisdiction of the FDA at all unless "misbranded" or "adulterated;" thus, as a practical matter, if the manufacturer avoids labeling which is "false and misleading in any particular,"[203] and does not use any "filthy, putrid, or decomposed substance," or manufacture under "unsanitary conditions,"[204] he is free to market his device no matter how unsafe, unreliable, or ineffective it may be, without being subjected to any regulation whatsoever.

Even if the recent decisions do give the FDA more leeway in classifying new products as "drugs," it is still a poor compromise in that it calls for a case-by-case determination, since manufacturers will undoubtedly continue to maintain that their products are "devices" so long as new "devices" are not subject to the same regulation as "new drugs." Elimination of the dichotomy between the regulation of drugs and devices as to premarket approval appears to be the most logical and practical way to prevent these attempts at avoidance.[205]

The argument that subjecting medical devices to preclearance of federal standards, or both, will discourage research and inhibit the development of new beneficial devices is not necessarily true. Drug manufacturers have been functioning under the "new drug" provisions for many years, and new products are constantly being introduced. Such regulation could benefit the legitimate device manufacturer who now voluntarily attempts to adequately premarket test his products and make them as safe, reliable, and effective as possible. Requiring such action from all manufacturers prior to

203. 21 U.S.C. § 352(a) (1970).

204. 21 U.S.C. § 351(a)(1) & (2)(A) (1970).

205. A recent decision from the Fourth Circuit creates a new problem under the present statutory framework of regulation. In a case presenting the issue of whether a product was within the grandfather clause of the Drug Amendments of 1962 (note 28 *supra*) and therefore did not have to be generally recognized as effective (as well as safe), it was held that the FDA has neither primary nor concurrent jurisdiction to adjudicate whether a product is a "drug" or a "new drug." Bentex Pharmaceuticals, Inc. v. Richardson, F.2d (4th Cir. 1972). Thus, this classification must be determined in court. The same result would seem to follow from this decisions with respect to the issue of whether a product is a "drug" and therefore perhaps a "new drug," rather than a "device." However, the Court of Appeals for the Third Circuit has reached the opposite result in an even more recent case, holding that the FDA does have jurisdiction, subject to judicial review, to decide whether a product is a "new drug." Ciba Corp. v. Richardson, F.2d (3d Cir. 1972).

marketing would tend to put them all on an equal footing and protect the legitimate device manufacturer from those who are not so legitimate and cut costs by minimizing or eliminating premarket testing and by taking other manufacturing shortcuts. A set of uniform standards and a premarket clearance requirement would thus both give increased protection to the public and benefit the manufacturer who is now engaging in the kinds of activity in which it would be desirable for all manufacturrs to engage. Naturally, this will probably increase the cost of the various medical devices; but at least users of such devices will be getting the protection from dangerous, worthless or inferior devices they now erroneously believe to be afforded by government regulation.

There should also be a great saving in cost and manpower to the FDA, since the long, tedious, and frequently fruitless eizure actions would be replaced by a procedure similar to that under the "new drug" provisions, whereby the manufacturer would have to submit data to the FDA proving that his device is safe, reliable, and effective for its intended use before it could be legally marketed. Thus, the amount of largely ineffective and inefficient remedial enforcement would be reduced, and the amount of preventive regulation would be increased. The FDA is now apparently badly overburdened, but it is possible that this is largely due to the inefficient system under which it must operate—at least with respect to medical devices. Lack of funds is also undoubtedly a problem. But, in any event, whatever obstacles exist in this very vital area of consumer protection should be overcome.

Proper legislation would not unnecessarily burden the manufacturers of legitimate medical devices, because it will presumably require nothing more than that which most reputable manufacturers are doing now. Also, only certain types of medical devices need be subject to additional regulation; devices which do not present significant possible dangers should not be needlessly encumbered. Under this type of approach, research and development would not be stifled and manufacturers and distributors of medical devices would not be needlessly burdened, but the present unworkable legal dilemma and the presently existing gap in consumer protection would be remedied.

Since 1954, introduced into Congress were numerous bills which would have required premarket approval of new devices by the FDA.[206] House Bill 1235,[207] which has been introduced in each

206. For a list of the bills introduced up through the 90th Congress which would have

Congress since the 87th, would subject new devices to premarket clearance simply by inserting "or device" after the term "drug" each time it appears in the "new drug" provisions. However, this bill has been criticized as being too broad, since it would needlessly subject all kinds of devices to premarket clearance, thereby imposing an unnecessarily great administrative burden on the FDA[208] and an unjustifiable economic burden on manufacturers.

As has become the pattern, pending before the present Congress are a number of other bills which would subject medical devices to varying further regulation. These proposals range from a measure which merely calls for further study and recommendations[209] to one which would revise the entire administrative framework for regulation of food, drugs, devices, and cosmetics.[210]

Other proposed legislation ranges somewhere in between these two extremes. These intermediate measures generally would authorize either the Secretary of the Department of Health, Education and Welfare,[211] or a proposed new entity, the Federal Medical Evaluations Board,[212] to establish standards for medical devices, under varying circumstances, with interested parties being allowed to participate. These bills also provide for premarket clearance of certain medical devices, such as devices intended to be used within the human body or intended to subject the human body to atomic or electrical energy not generally recognized by qualified experts as safe, reliable or effective for use as prescribed and devices found to be unreasonably hazardous when used, as intended, in life-

required pretesting of new cosmetics, new devices, or both, see Weitzman, *supra* note 34, at 249. Three bills introduced in the 91st Congress would have authorized the Secretary of HEW to establish device standards and would have required premarket clearance of certain types of medical devices if not generally recognized by qualified experts as safe, reliable and effective for their intended use. S. 2107, 91st Cong., 1st Sess. (1969); H.R. 7315, 91st Cong., 1st Sess. (1969); and H.R. 16190, 91st Cong., 2d Sess. (1970). The devices these bills would have subjected to preclearance were those (1) intended to be placed within the body or in contract with mucous membrane indefinitely or for a long period of time, (2) intended to be used to subject the body to radiation, electricity, or other types of energy, or (3) found by the Secretary to present probable cause to believe that such devices were not safe, reliable, or effective for their intended use.

207. 92d Cong., 1st Sess. (1971).

208. Styn, *supra* note 34, at 538.

209. H.R. 3122, 92d Cong., 1st Sess. (1971).

210. S. 3419, 92d Cong., 2d Sess. (1972).

211. S. 1824, 92d Cong., 1st Sess. (1971) (introduced by Senator Gaylord Nelson of Wisconsin); S. 3028, 92d Cong., 1st Sess. (1971); H.R. 12,316, 92d Cong., 1st Sess. (1971); H.R. 13,793, 92d Cong., 2d Sess. (1972); H.R. 14,230, 92d Cong., 2d Sess. (1972).

212. H.R. 925, 92d Cong., 1st Sess. (1971); H.R. 2567, 92d Cong., 1st Sess. (1971); H.R. 3843, 92d Cong., 1st Sess. (1971); H.R. 11, 983, 92d Cong., 1st Sess. (1971).

threatening situations. Generally proposed by these bills is an application-for-premarket-approval procedure similar to that for "new drugs," as well as recordkeeping requirements, registration of manufacturers, and specification of good manufacturing practice.

Although most of the bills already mentioned have differing provisions, and some are tougher than others, one current bill stands apart from and takes a somewhat different approach than the rest. House Bill 1545[213] provides for a one-year study and inventory of all medical devices by experts in the respective fields, with the purpose of classifying devices into three categories. The first category would consist of those devices generally recognized as currently safe, reliable and effective for their intended uses and would, therefore, be exempt from regulation. Devices which are found to require reasonable standards to assure their safety, reliability and effectiveness would comprise the second category. The only devices subject to premarket clearance would be those in the third category, consisting of devices either not generally recognized as safe, reliable and effective or generally accepted but undergoing continual change because of developing technology.

Various approaches for eliminating the present inconsistency between the regulation of drugs and devices are suggested by the pending bills. At least some of theseupproaches should afford some basis for realistic regulation. In view of the past history of food and drug legislation, where tragic events have resulted in overwhelming public demand for immediwe remedial legislative action, the possibility of such an event involving a medical device occurring in the future and resulting in very restrictive regulation would seem to indicate that medical device manufacturers might be wise to support reasonable legislation now, rather than have unduly burdensome regulation forced upon them in a time of crisis.[214]

## CONCLUSION

The present dichotomy between the regulation of drugs and

213. 92d Cong., 2d Sess. (1971).

214. As of this writing, none of the bills mentioned herein, with one exception, have been reported out of committee. The exception is S. 3419 (note 210 *supra*), which was passed by the Senate, as amended, on June 21, 1972. Depending on the fate of this measure in the House, medical devices may yet become subject to further regulation during the present Congress. However, because this bill is such a broad measure, it would be very difficult to predict what additional regulation of medical devices, if any, might be included in the final version, should it become law.

devices appears to have been inadvertently created by Congress. The courts, when faced with this dichotomy, have been compelled to resort to making public policy decisions in trying to resolve the statutory ambiguities. The administrative agency presently responsible for the regulation of drugs and medical devices has been continually frustrated by its impotence to deal with the problems posed by medical devices. The general public mistakenly believes it is being afforded protection, and conscientious, legitimate manufacturers are put at a competitive disadvantage vis-à-vis manufacturers who do not voluntarily follow private standards and perform adequate premarket testing of their products.

It appears that an eventual change in the federal law with respect to regulation of medical devices is inevitable. When this change will occur and what form it will take remains to be determined. However, it would seem to be in the best interests of all concerned for such a change to occur before it is precipitated by another national tragedy or near tragedy. Hurried, piecemeal legislation seems to have caused the present confused statutory framework; the confusion and inconsistency might better be corrected by carefully considered comprehensive legislation now, with the device manufacturers participating in its formulation, than by legislation in the future, which might be enacted without full consideration of its ramifications and consequences.