

# Loops and Loopholes: Hazardous Device Regulation Under the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act

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As medical technology has advanced in the last two decades, there has been a substantial increase in the use of medical devices. The device industry is now a multi-billion dollar enterprise, producing not only simple items such as cotton swabs and stethoscopes but also chemically and mechanically complex devices such as plastic implants and electronic pace-makers. For the most part, new devices improve health and prolong life without untoward side effects. Some devices, however, especially those permanently implanted in the human body, present long-term or subtle risks of serious injury and death to their intended beneficiaries.

Until 1976, the federal government lacked adequate regulatory power to assure the safety of these products, referred to in this Article as hazardous or potentially hazardous medical devices. With the enactment of the Medical Device Amendments to the Food, Drug, and Cosmetic Act (FDCA),<sup>1</sup> the government obtained the authority to set standards for and require the testing of these devices and to survey and regulate their use in patients. The Amendments are a compromise. They are the result of seven years of lobbying by health advocates and the device industry. They provide the Food and Drug Administration (FDA) with broad substantive powers to exercise within complex administrative procedures.

This Article examines the adequacy of the Medical Device Amendments in protecting the user from potentially hazardous devices. To assess

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1. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539, *codified at* 21 U.S.C.A. §§ 360c-360k (West Supp. 1977). Citation will be made to the code sections. The preamble to the law states that it is an act:

To amend the Federal Food, Drug and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes.

the likelihood that FDA will use the Amendments to their greatest protective potential, the Article studies the history of FDA's regulation of devices under the previous law and reviews the first year of the agency's implementation of the new statute. The Article discusses the opportunities for input by consumer and health advocates in the decision-making process, suggesting strategies that health advocates can follow to make the most of the tools offered by the Amendments.

Part I discusses the scope of the hazardous device problem and the history of device regulation preceding the passage of the Amendments. Part II describes FDA's new authority to require pre-market testing of devices for safety and effectiveness in relation to the regulation of hazardous devices. Part III analyzes the provisions respecting post-market surveillance and provides a model for regulation of hazardous devices at the post-market level. Part IV discusses the potential role of consumer and health advocates in the decision-making process, suggesting tactics for the most efficient use of consumer advocates' limited resources.

## I

### BACKGROUND TO THE PASSAGE OF THE MEDICAL DEVICE AMENDMENTS

#### A. *The Scope of the Problem of Medical Devices*

##### 1. *Device Injuries*

*No one should be exposed to possible electrocution, unwarranted infection, or permanent disability by faultily manufactured or poorly designed devices.*<sup>2</sup>

In 1970, a federal survey of the preceding ten year period revealed 10,000 injuries from medical devices including 731 deaths. Several examples are instructive. 512 of the deaths were due to defective heart valves alone.<sup>3</sup> Failure of cardiac pacemakers also caused serious harm. Between 1972 and 1975, manufacturers recalled 22,310 potentially defective pacemakers.<sup>4</sup> Recent hearings have documented the serious hazards of the intrauterine

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2. 119 CONG. REC. 9125 (1973) (remarks of Sen. Nelson).

3. *Medical Device Amendments of 1975: Hearings on H.R. 5545, H.R. 974, and S. 510 Before the Subcomm. on Health and the Environment of the Committee on Interstate and Foreign Commerce, 94th Cong., 1st Sess. 199 (1975)* (statement of Rep. Fred B. Rooney) [hereinafter cited as *1975 Device Hearings*]. See also Cooper, *Device Legislation*, 26 FOOD DRUG COSM. L.J. 165, 170 (1971).

4. COMPTROLLER GENERAL OF THE UNITED STATES, FOOD AND DRUG ADMINISTRATION'S INVESTIGATION OF DEFECTIVE CARDIAC PACEMAKERS RECALLED BY THE GENERAL ELECTRIC COMPANY 21 (1975). There are currently 125,000 users of implanted cardiac pacemakers in the United States with an estimated annual increase of 30,000 users. *Id.* at 1. Since 1972, 22,310 pacemakers have been recalled, "many of which exhibited the same basic problem—shunting due to accumulation of moisture on the pacemakers' circuitry." *Id.* at 21. The Comptroller General's report is a detailed study of pacemaker failure in the United States.

device (IUD) in general,<sup>5</sup> and of the Dalkon shield in particular.<sup>6</sup> Approximately six million American women use the IUD and face potentially fatal risks including serious infections, spontaneous and septic abortions, tubal pregnancy, and possible death.<sup>7</sup> This catalogue of injuries does not tell the whole story. Device injury statistics underestimate the problem because no systematic records of the industry have been maintained.

The number of injuries and risks of injury are constantly increasing as the device industry expands. The development of the plastics, electronics, and metallurgical fields, and rapid advancements in biomedical engineering, have virtually revolutionized the device industry since World War II. There are now approximately 1,100 companies producing 12,000 different types of devices with total annual retail sales of five billion dollars.<sup>8</sup>

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5. For IUDs generally, see *Regulation of Medical Devices (Intrauterine Contraceptive Devices): Hearings Before a Subcomm. of the Committee on Government Operations, 93rd Cong., 1st Sess. (1973)* [hereinafter cited as *IUD Hearings*].

6. For debate on the Dalkon shield, see *Food and Drug Administration, Practice and Procedure, 1975: Joint Hearings Before the Subcomm. on Health of the Comm. on Labor and Public Welfare and the Subcomm. on Administrative Practice and Procedure of the Comm. on the Judiciary, 94th Cong., 1st Sess., at 1-273 (1975)* [hereinafter cited as *1975 Shield Hearings*].

7. For a detailed review of medical and legal issues concerning the IUD, see Note, *The Intrauterine Device: A Criticism of Governmental Complaisance and An Analysis of Manufacturer and Physician Liability*, 24 CLEV. ST. L. REV. 247 (1975). For recent medical studies of IUD related injuries, see Cates, Ory, Rochat & Tyler, *The Intrauterine Device and Deaths from Spontaneous Abortion*, 295 NEW ENGLAND J. MED. 1155 (1976); Levinson & Richardson, *The Dalkon Shield Story*, 11 ADVANCES PLANNED PARENTHOOD 53 (1976); Tatum, Schmidt, Phillips, McCarty & O'Leary, *The Dalkon Shield Controversy: Structural and Bacteriological Studies of IUD Tails*, 231 J. AM. MED. A. 711 (1975).

Some economic commentators have stated that costs of drug regulation, especially the efficacy requirements established in 1962 under the New Drug Amendments, outweigh the benefits of such regulation. See S. PELTZMAN, *REGULATION OF PHARMACEUTICAL INNOVATION: THE 1962 AMENDMENTS (1974)* Pre-market approval of drugs has been said to lead to heavy costs in delays and decreases in drug innovation as well as to increases in the cost of research and development and wasted research resources. See generally H. GRABOWSKI, *DRUG REGULATION AND INNOVATION: EMPIRICAL EVIDENCE AND POLICY OPTIONS (1976)*. This Article assumes that the risks posed by hazardous medical devices are significant and that regulation of those risks is essential. Costs, of course, will vary from device to device. But the decrease in social risks outweighs the economic cost borne by society.

8. The figures in the following table, although they are not strictly comparable, indicate the trend in value of products shipped by manufacturers of surgical, medical, and dental instruments and supplies.

Year	Number of Manufacturers	Value of Shipments
1937 <sup>a</sup>	463	\$100 million
1947 <sup>a</sup>	980	\$372 million
1963 <sup>a</sup>	1,300	\$ 1 billion
1967 <sup>a</sup>	1,500	\$ 1.5 billion
1971 <sup>b</sup>	1,100	\$ 3 billion
1975 <sup>c</sup>	1,000 <sup>c</sup>	\$ 6 billion
1976 <sup>d</sup>	1,500	\$3-5 billion (estimated)

<sup>a</sup>Cooper, *supra* note 3, at 166.

## 2. *Hazardous or Potentially Hazardous Medical Devices*

Some medical devices—those which this Article denominates “hazardous” or “potentially hazardous”—present risks of subtle or long-term harm to the human body. The effects of hazardous devices on the body are often difficult to foresee or discover. Yet the risks they pose can be both severe to the individual and widespread in the population.

Two examples illustrate some of these risks. First, vitallium, one of the most commonly used implant alloys, is a cobalt-based substance which has generally been regarded as inert. A recent study, however, found that vitallium discs implanted subcutaneously in rats induce cancer.<sup>9</sup> Second, the implanted plastic IUD is now known to cause pelvic inflammation, spontaneous abortions, and other injuries. Yet for years adverse reaction reports were so inadequate that the link between IUDs and their complications was obscured by the numerous other causes of the same effects.<sup>10</sup>

Most of the thousands of devices in use are not hazardous. Although they can cause injury, products such as cotton swabs and bed pans, which come into brief contact with the body in the course of appropriate use by medical professionals, do not present risks of the kind described above.<sup>11</sup> The same is true for more sophisticated diagnostic equipment, such as electroencephalograms, defibrillators, and electronic monitoring equipment. Injuries from defects and malfunctions of such machines, including shock and electrocution, can be serious and often fatal,<sup>12</sup> but are not of the latent or subtle variety considered here.

The medical devices which are hazardous or potentially hazardous are primarily those which are implanted. The implantation of foreign substances into the internal human environment offers great medical benefits, but its risks are generally not well known. Risks can arise from the type of substance implanted or the physical characteristics of the implanted device. The most frequently implanted substances are metal alloys and plastics. The known risks associated with such implants include alteration of basic body

<sup>b</sup>119 CONG. REC. 9125 (1973) (remarks of Sen. Nelson).

<sup>c</sup>1975 *Device Hearings*, *supra* note 3, at 199 (statement of Rep. Rooney).

<sup>d</sup>121 CONG. REC. 10693 (1975) (remarks of Sen. Ribicoff).

<sup>e</sup>The figure for 1975 includes at least 1000 medical device “industries” producing “some 12,000 medical devices.” 1975 *Device Hearings*, *supra* note 3, at 199.

9. *Implanted Devices That Have Posed Problems*, 121 CONG. REC. 10689, 10690 (1975) (placed in the record by Sen. Nelson).

10. *IUD Hearings*, *supra* note 5, at 6 (statement of John G. Madry, Jr., M.D.).

11. This does not mean that such simple medical devices can never be harmful. In 1967 and 1968 over two million unsterile swabs, one million unsterile tongue depressors, and several thousand ineffective and dangerous resuscitators were recalled from the market. Cooper, *supra* note 3, at 168.

12. *Accidental Electrocutions Claim 1,200 Patients a Year*, *Electronic News*, Jan. 27, 1969, reprinted in 115 CONG. REC. 4265 (1969). See also Randal, *Electric Risk in Hospitals is Held Rising*, *Washington [D.C.] Evening Star*, Feb. 17, 1969, reprinted in 115 CONG. REC. 4267 (1969).

chemistry, inflammation and damage to surrounding tissue, and corrosion, dissolution, and disintegration of the implants themselves, causing the infiltration of foreign substances into the body. There are likely to be many currently unknown risks as well.

Metal implants are used most commonly for orthopedic repair. Examples include bands, screws, and pins implanted to correct fractures and fuse joints and internal prostheses such as moveable joint replacements for joints destroyed by bone disease or severe fractures. Metals commonly used for implantation include stainless steel, copper, vitallium, and other metal alloys. Metal implants in living tissue can corrode, releasing electrolytes which cause tissue inflammation.<sup>13</sup> Even the lowly dental filling is dangerous; mercury and beryllium contained in fillings have poisoned recipients.<sup>14</sup> As mentioned above, vitallium, once believed to be inert, may induce cancer.<sup>15</sup>

Implanted plastics also pose long-term or subtle hazards. There are 30 to 40 cases in the medical literature describing the leaching into the bloodstream of toxic substances, such as polyvinyl chloride, from plastic-covered bone pins.<sup>16</sup> The effects of such substances will not be known for many years. Silicone, used for breast augmentation and reconstructive plastic surgery, has led to severe chemical reactions, infections, and gangrene.<sup>17</sup> The incompatibility of some types of intraocular lenses (plastic lenses permanently implanted on the human eye) with living tissue has caused serious damage to many patients, including glaucoma, corneal disease, and infection.<sup>18</sup> Fragments of teflon catheters have broken off during surgery.<sup>19</sup> These fragments are not susceptible to X-ray visualization, and the complications of this type of involuntary "implant" include sepsis, perforation, thrombosis, and death.<sup>20</sup>

The physical characteristics of a device can also cause subtle harm. For example, the multifilament tails of the plastic Dalkon shield mentioned above permit bacteria to travel into the uterus. The multifilament tail is

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13. Davidson, *Preventive "Medicine" for Medical Devices: Is Further Regulation Required?*, 55 MARQ. L. REV. 405, 427 (1972).

14. *Implanted Devices That Have Posed Problems*, supra note 9, 121 CONG. REC. at 10690.

15. *Id.*

16. *Id.*

17. *Id.* A San Jose, California jury recently awarded \$1.95 million in damages to a woman in a medical malpractice case after complications arising from silicone injections necessitated removal of both of her breasts. *Jury Ups the Ante in Silicone Case*, S.F. Chronicle, Nov. 23, 1977, at 2, col. 1.

18. *1975 Device Hearings*, supra note 3, at 221 (testimony of Sidney Wolfe and Anita Johnson, Public Citizens Health Research Group).

19. *Implanted Devices That Have Posed Problems*, supra note 9, 121 CONG. REC. at 10690.

20. Information based on a study reported in Dotter, Rosch & Bilbao, *Transluminal Extraction of Catheter and Guide Fragments from the Heart and Great Vessels*; 29 *Collected Cases*, 111 AM. J. ROENTGENOLOGY, RADIUM THERAPY NUCLEAR MED. 467 (1971).

believed to be the cause of uterine infection, sterility, and death in affected women.<sup>21</sup>

In addition to these known dangers, much is unknown about the hazards associated with implantation of foreign matter into the human body. Enough knowledge is available to create an awareness of the existence of risk. However, until 1976 regulatory mechanisms to protect the consumer against known and suspected risks, as well as to discover unknown risks through tests, had not kept pace with the problems posed by the growing device industry.

### B. *The Development of Device Regulation*

To understand the characteristics of the Medical Device Amendments, it is necessary to trace the historical development of federal regulation of drugs and devices. From the date of the earliest food and drug legislation in 1906, Congress has always distinguished drugs and devices, and it has expanded the government's power to regulate devices less quickly than its power to regulate drugs.

#### 1. *The Development of Drug and Device Legislation from 1906 to 1976*

Federal drug regulation began at the turn of the century out of concern over the poisonous effects of many chemicals, compounds, elixirs, liniments, and other substances touted as means of curing or preventing illness. The 1906 Pure Food and Drug Act gave the government the authority to bring suits to remove such substances from the market.<sup>22</sup> This law did not apply to medical devices. At that time, medical devices were either simple objects or gross mechanical contraptions considered outside the scope of the drug law.

In 1938 came the first federal regulation of medical devices, as a step-child of increased control over drugs. Public outcry over 73 deaths in 1937 from ingestion of a drug called Elixir-Sulfanilimide,<sup>23</sup> which was untested for toxic effects, led Congress to reconsider the adequacy of existing regulatory protection. The 1938 Food, Drug, and Cosmetic Act increased control over drugs and subjected medical devices to regulation for the first time.<sup>24</sup>

Devices, however, were not subjected to controls as stringent as those for drugs. An early draft of the 1938 law proposed that the definition of drugs include "all substances, preparations and *devices* intended for use in

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21. *1975 Shield Hearings*, *supra* note 6, at 31.

22. Act of June 30, 1906, ch. 3915, 34 Stat. 768 (1906).

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

24. Act of June 25, 1938, ch. 675, 52 Stat. 1040 (1938). *See also* V. KLEINFELD & C. DUNN, FEDERAL FOOD DRUG AND COSMETIC ACT JUDICIAL & ADMINISTRATIVE RECORD 1938-1949 (1949), for a lengthy history of the 1938 Act.

the cure, mitigation, treatment or prevention of disease in man or other animals."<sup>25</sup> Thus, "drug" would have become a broad legal term of art which would include medical devices. Critics of this proposal considered it incongruous to label as drugs such gross devices as shoulder braces, radium belts, and crutches.<sup>26</sup> Most devices were still large mechanical objects applied externally. The 1938 law ultimately treated drugs and devices separately. Drugs were defined as "articles" and devices as "instruments, apparatus, and contrivances."<sup>27</sup>

The distinction was important because in the 1938 Act Congress significantly increased FDA's regulatory power over drugs. The Act empowered FDA to require pre-market testing of drugs. Manufacturers were required to substantiate claims that their products were safe. The Act also gave FDA post-marketing power over drugs, including the authority to require registration and recording by drug manufacturers, and to compel disclosure of complaints. Devices, however, were subject to lesser controls. FDA obtained authority to regulate devices only after they entered interstate commerce and only if the agency could show that the device was mislabeled or dangerous.<sup>28</sup>

The gap between drug and device regulation widened further in 1962. The European thalidomide tragedy in 1961 generated a movement for more thorough drug regulation. In 1962, the Drug Amendments of 1962 were enacted, considerably increasing FDA's authority to regulate drugs.<sup>29</sup> The Amendments required manufacturers to demonstrate the effectiveness of drugs, as well as their safety, before receiving permission to place the drugs

25. S. REP. NO. 493, 73rd Cong., 2d Sess. (1934) (emphasis added).

26. 79 CONG. REC. 4841, 4913 (1938). 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).

27. The definitions read in full as follows:

The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia 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.

21 U.S.C. § 321(g) (1970).

The term "device" . . . means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for the 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.

*Id.* § 321(h).

28. *Id.* §§ 331, 351. The latter section reads:

A drug or device shall be deemed to be adulterated—(a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; . . . .

29. *Id.* § 355.

on the market. Post-market controls over both prescription and non-prescription drugs were also expanded.<sup>30</sup>

During the debate preceding enactment, proposals were made to increase controls over devices as well. One bill called for establishing standards for medical devices and requiring proof of their safety and efficacy prior to marketing.<sup>31</sup> The Drug Amendments of 1962, however, did not increase the minimal controls over devices established in 1938.

The conceptual distinction between drugs and devices created by the 1938 Act remained a barrier in the minds of the legislators to generalizing the thalidomide lesson beyond the medical concept of drugs. By 1962, hazardous devices were in existence which posed risks as severe, long-term, and subtle as those of drugs. Congress, however, did not perceive, or chose not to acknowledge, the substantial similarity of drug and device hazards. Until the Medical Device Amendments were enacted in 1976, the growing need for more device regulation was met only by creative, though severely limited, administrative adaptation of the tools designed for drug control.

In the 1960s, FDA attempted to make do with the limited direct authority over devices conferred by the 1938 Act. The agency also attempted to expand the definition of "drug" so as to bring some devices under the provisions of the Drug Amendments of 1962.

## 2. *Direct Authority over Devices under the 1938 Provisions*

Under the 1938 law, FDA could not initiate regulatory action until a device had entered interstate commerce, and then only if it deemed the device improperly labeled ("misbranded") or dangerous ("adulterated").<sup>32</sup> Once FDA considered a product misbranded or adulterated, it could initiate a seizure action<sup>33</sup> and seek to enjoin the manufacturer from further production of the device.<sup>34</sup>

Seizure was the tactic most frequently employed against misbranded or adulterated devices. The agency filed a libel action in a district court, alleging the device to be misbranded or adulterated. FDA seized the device prior to trial. The seizure would be upheld if FDA could prove its charges at trial. This proceeding affected only the specific device seized.

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30. *Id.* § 351.

31. H.R. 1235, 94th Cong., 1st Sess. (1975). Representative Leonor Sullivan introduced this omnibus bill to amend the Food, Drug and Cosmetic Act in every Congress beginning with the 87th Congress down to the 94th Congress, each time under the same bill number. See *1975 Device Hearings, supra* note 3, at 205-10.

32. 21 U.S.C. § 331 (1970). See *id.* § 352 for the definition of "misbranded" drugs and devices and *id.* § 351 for the definition of "adulterated."

33. *Id.* § 334.

34. *Id.* § 332.

Only after the agency succeeded in the initial action could it make multiple seizures or move the court to enjoin further production.<sup>35</sup>

Multiple seizures were impractical because it was extremely difficult to trace the ultimate location of the condemned devices and virtually impossible to seize them all. Device manufacturers could evade injunction by making insignificant changes in their products and marketing them as "new" devices.<sup>36</sup> A classic case study of these unwieldy procedures is the attempt to condemn the Diapulse machine in 1965. The Diapulse machine was a quack device which purported to cure 121 separate ailments including arthritis, typhoid fever, tuberculosis, and syphilis.<sup>37</sup> Seven years elapsed from the initial seizure in 1965 until a federal court enjoined further production of the machine.<sup>38</sup>

FDA could supplement its formal regulatory powers with informal pressure on the industry. If it suspected a device hazard, the agency could request that the manufacturer voluntarily recall the device at its own expense.<sup>39</sup> FDA had no authority to order the recall of a device, but industry compliance could sometimes be coerced by the threat of adverse publicity.<sup>40</sup>

### 3. *Creative Use of the Drug Amendments of 1962 for Device Regulation*

Confronted with inadequate regulatory powers, FDA classified some devices as drugs under the 1962 law. Two important court decisions in the 1960's upheld FDA's approach, which narrowed the distinction between drugs and devices.

In 1968, in *AMP, Inc. v. Gardner*,<sup>41</sup> the Second Circuit upheld FDA's classification as a "new drug" a nylon ligature loop and nylon locking disc used to tie off severed blood vessels during surgery. The court stated that the purpose of drug regulation under the 1938 Act and its 1962 Amendments was to keep inadequately tested and potentially harmful medi-

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35. *Id.* §§ 332, 334.

36. See COMPTROLLER GENERAL OF THE UNITED STATES, LACK OF AUTHORITY LIMITS CONSUMER PROTECTION: PROBLEMS IN IDENTIFYING AND REMOVING FROM THE MARKET PRODUCTS WHICH VIOLATE THE LAW, B-164031(2), at 18-25 (1972).

37. Case Comment, *U.S. v. The Diapulse Corporation of America*, 8 NEW ENGLAND L. REV. 111, 113 (1972).

38. *Id.* at 119.

39. For a discussion of the voluntary recall process in the context of cardiac pacemakers, see COMPTROLLER GENERAL, *supra* note 4, at 2, 4-15.

40. Morey, *FDA Publicity Against Consumer Products—Time for Statutory Revitalization?*, 30 BUS. LAW. 165, 167 (1974). See also Gellhorn, *Adverse Publicity by Administrative Agencies*, 86 HARV. L. REV. 1380 (1973). Under an amendment to the Federal Trade Commission Act, the FTC was directed to monitor the honesty of medical device advertising. 15 U.S.C. §§ 45-52 (1970). While there was some regulation of devices advertised to consumers, there was virtually no regulation of advertising of prescription devices. *IUD Hearings*, *supra* note 5, at 388-91. For a general discussion of the problems of interagency cooperation, see Schwartz, *Protecting Consumer Health and Safety: The Need for Coordinated Regulation Among Federal Agencies*, 43 GEO. WASH. L. REV. 1031 (1975).

41. 389 F.2d 825 (2d Cir. 1968).

cal products out of interstate commerce.<sup>42</sup> By emphasizing the protective purposes of the law, and by broadly construing the term "drug," the court held that a medical product not generally recognized as safe and effective by experts could be termed a "drug" and be regulated as such.<sup>43</sup>

The following year, the Supreme Court also liberally construed the term "drug" in *United States v. An Article of Drug . . . Bacto-Unidisk*.<sup>44</sup> The Court upheld FDA's classification of an antibiotic disc as a drug.<sup>45</sup> The disc, which never came into contact with the body, was used as a screening test to determine the proper antibiotic to administer to the patient. The Court concluded that the term "drug" was a legal term of art which could be "given a liberal construction consistent with the [FDCA's] overriding purpose to protect public health . . . ."<sup>46</sup>

The *AMP* and *Bacto-Unidisk* cases demonstrate the agency's and the courts' willingness to expand the meaning of "drug" for regulatory purposes. The Second Circuit in the *AMP* case defined a drug as any medical product whose safety and effectiveness was not generally recognized.<sup>47</sup> Potentially hazardous medical devices thus could be treated as "drugs" and regulated under the 1962 Amendments.

Reliance on FDA's drug regulation authority was not a permanent solution to device regulation. FDA did not have express legislative authority to regulate devices as drugs. From FDA's point of view, the prospect of challenges from manufacturers may have deterred widespread use of the approach. On the other hand, manufacturers were uncertain as to how FDA would treat a particular device.<sup>48</sup>

#### 4. *The Genesis of the Medical Device Amendments*

Recognizing the problem of inadequate regulatory power over devices, in 1969 the Department of Health, Education, and Welfare, of which FDA is a part, convened a study group chaired by Dr. Theodore Cooper to investigate the need for additional device legislation.<sup>49</sup> The Cooper Committee recommended a new law covering all medical devices, from thermometers to heart valves. It recommended a classification system whereby only

42. *Id.* at 829.

43. *Id.*

44. 394 U.S. 784 (1969).

45. *Id.* at 793.

46. *Id.* at 798.

47. 389 F.2d at 826-27. See *Orthopedic Equipment Co. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960) (holding that a surgically implanted nail is a device, not a drug).

48. See Radzius, *The Federal Food, Drug and Cosmetic Act, Drug or Device?*, 8 WAKE FOREST L. REV. 527, 533-34 (1972).

49. COOPER COMMITTEE, U.S. DEP'T OF HEALTH, EDUCATION, AND WELFARE, MEDICAL DEVICES: A LEGISLATIVE PLAN, STUDY GROUP ON MEDICAL DEVICES (1970) [hereinafter cited as COOPER REPORT]. Dr. Cooper at the time of this report was Director of the National Heart and Lung Institute, and now is Assistant Secretary for Health.

certain devices would be subject to a pre-market review of their safety and effectiveness.

In the seven years between the Cooper Committee report and the passage of the Medical Device Amendments in 1976, numerous bills for device regulation were proposed and debated.<sup>50</sup> The IUD controversy and the extensive pacemaker recalls in the mid-seventies stimulated public concern and legislative interest, much as had the Elixir-Sulfanilimide disaster in 1937 and the thalidomide tragedy in 1962.<sup>51</sup> The result was the Medical Device Amendments, which finally elevate some devices to a status "separate but equal" to that of drugs. How this legislation affects the control of hazardous medical devices is the subject of Part II and Part III of this Article.

## II

### PRE-MARKET CONTROLS

To provide the public with adequate protection from hazardous and potentially hazardous medical devices, control must be exercised at two stages. First, before such a device is marketed, it must be tested for possible long-term and subtle harmful effects. Pre-market controls are the subject of this Part. Second, because even the most thorough pre-market screening will fail to detect some dangers, there must be post-market surveillance for such harms to the device's users, and adequate powers to ameliorate them. Part III will discuss post-market issues. At both stages, in deciding whether to permit initial or continued use of a device, FDA must give serious weight to the risks of long-term and subtle dangers revealed by such pre-market and post-market investigations.

The Amendments seek to provide "reasonable assurance of safety and effectiveness" for all devices.<sup>52</sup> FDA is to determine if such assurance exists by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use."<sup>53</sup> But

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50. Some of the bills introduced in the preceding years include: H.R. 9984, 93d Cong., 1st Sess. (1973); S. 2368, 93d Cong., 1st Sess. (1973); H.R. 5545, 94th Cong., 1st Sess. (1975); S. 510, 94th Cong., 1st Sess. (1975); H.R. 11124, 94th Cong., 2d Sess. (1976).

The Senate and the House of Representatives were in disagreement in the 94th Congress' effort. After the Senate passed S. 510, the House amendment struck out all of the Senate bill and inserted a substitute text, H.R. 11124. The Conference Committee agreed to use the House amendment as the basis for the conference substitute with changes made to reflect certain policies of the Senate bill. For a comparison of the Senate bill, the House Amendment, and the Conference substitute, which became the Medical Device Amendments, see HOUSE COMMITTEE OF CONFERENCE, JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE, [MEDICAL DEVICE AMENDMENTS OF 1976], H.R. REP. NO. 1090, 94th Cong., 2d Sess. 51-66, *reprinted in* [1976] U.S. CODE CONG. & AD. NEWS 1103 [hereinafter cited as 1976 MDA CONF. REP.].

51. See notes 5 (pacemakers) and 6 (IUDs) *supra*.

52. 21 U.S.C.A. §§ 360c(a)(1)-(3) (West Supp. 1977).

53. *Id.* § 360c(a)(2)(C). Subsections (A) and (B) of § 360c acknowledge special characteristics of devices as compared with drugs. Subsection (A) states that safety and effectiveness are

not all devices present similar risks or benefits, and the risks of some are better known than the risks of others. To organize FDA's evaluation of device safety and effectiveness, the Amendments instruct the agency to divide all devices into three classes. Class I consists of those generally considered to present no serious risks.<sup>54</sup> Class II consists of those devices whose characteristics are well known enough so that safety and efficacy can be guaranteed through performance standards set on the basis of available knowledge.<sup>55</sup> Class III consists of those whose safety and effectiveness are sufficiently uncertain that they cannot be determined without additional testing.<sup>56</sup> Most hazardous or potentially hazardous devices should be in

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to be determined with respect to the persons for whose use the device is represented or intended. *Id.* § 360c(a)(2)(A).

Unlike drugs, some devices, such as surgical instruments, defibrillators, and diagnostic equipment, will be controlled primarily by health professionals. The House Report makes clear that evaluation of safety and effectiveness information of these devices should be with reference to their suitability for use by professionals rather than laypersons. HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, MEDICAL DEVICE AMENDMENTS OF 1976, H.R. REP. NO. 853, 94th Cong., 2nd Sess., at 17 (1976) [hereinafter cited as 1976 HOUSE DEVICE REP.]. This report includes a section by section analysis of the House Amendment to S. 510. This amendment was the basis of the conference substitute which became law. Under 21 U.S.C.A. § 360c(a)(2)(B) (West Supp. 1977), safety and effectiveness are to be determined with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device.

Drug regulations have a similar provision. A drug is not considered unsafe, for example, if it can injure a patient who purposefully exceeds the prescribed dosage. Devices present further conditions of use. The House Committee noted that panels should consider the environment in which a device is to be used. The evaluation must consider whether the device will be used primarily in hospitals or solely in the home. 1976 HOUSE DEVICE REP., *supra*, at 17.

54. 21 U.S.C.A. § 360c(a)(1)(A) (West Supp. 1977). This section reads:

**Class I, General Controls.—**

(i) A device for which the controls authorized by or under section 351, 352, 360, 360f, 360h, 360i, or 360j of this title or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury, is to be regulated by the controls referred to in clause (i).

55. 21 U.S.C.A. § 360c(a)(1)(B) (West Supp. 1977). This section reads:

**Class II, Performance Standards.—**A device which cannot be classified as a class I device because the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, for which there is sufficient information to establish a performance standard to provide such assurance, and for which it is therefore necessary to establish for the device a performance standard under section 360d of this title to provide reasonable assurance of its safety and effectiveness.

56. 21 U.S.C.A. § 360c(a)(1)(C) (West Supp. 1977). This section reads:

**Class III, Premarket Approval.—**A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the controls authorized by or under sections 351, 352, 360,

Class III and subjected to investigation of their long-term and subtle effects or those of their constituents. There is, however, enough leeway in the classification system that many potentially hazardous implantables have been placed in Class I and Class II.<sup>57</sup> Class I provides no pre-market regulation either in the form of testing or standard-setting. And, because Class II performance standards are based only on what is already known about a device and its materials, standards will not assure the public of the absence of long-term and subtle risks from these misclassified devices.<sup>58</sup>

The adequate regulation of potentially hazardous devices properly placed in Class III depends on FDA's requiring tests which can resolve doubts about the existence of long-term or subtle risks, and on FDA's according evidence of risk a high value in the balancing of risks and benefits. The proper regulation of implantables misplaced in Class II depends on their reclassification or on giving serious weight to existing information on dangers in the design of performance standards.

#### A. Classification Procedures

Only devices placed in Class III receive pre-market review by the agency of the safety and effectiveness data. Classification panels, selected by FDA and guided by congressional and administrative criteria, will make all preliminary classification decisions subject to approval by FDA.<sup>59</sup> The following sections will discuss the structure of the panels, the congressional guidelines set forth in the Amendments, and the administrative implementation of congressional intent. The analysis reveals that FDA has virtually unlimited discretion to decide the substantive issues of classification.

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360f, 360h, 360i, and 360j of this title are sufficient to provide reasonable assurance of the safety and effectiveness of the device and (II) cannot be classified as a class II device because insufficient information exists for the establishment of a performance standard to provide reasonable assurance of its safety and effectiveness, and

(ii) (I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury, is to be subject, in accordance with section 360e of this title to premarket approval to provide reasonable assurance of its safety and effectiveness.

57. See text accompanying notes 78-80 *infra*. Classification information is based on computer printouts of the work of the panels obtained from FDA. FDA claims to have no figures on the total number of devices on the market. Letter from Joseph N. Gaydoes, Division of Compliance, Bureau of Medical Devices and Diagnostic Products, Food and Drug Administration, to the author, Sept. 15, 1976 (on file in the offices of the *Ecology Law Quarterly*). The author was able to obtain printouts listing by panel the classification of devices as of June, 1976 and January, 1977. These were received from FDA in September, 1976 and May, 1977, respectively. In January, 1978, the only readily available compilation was a statistical summary, current as of November, 1977, of the total number of devices classified into each class by each panel. The printouts and the summary are available in the offices of the *Ecology Law Quarterly*.

58. See the discussion of performance standards at text accompanying notes 93-103 *infra*.

59. 21 U.S.C.A. § 360c(c) (West Supp. 1977).

### 1. *The Panels*

FDA appoints and supervises the panels which make the classification decisions. In May, 1975, a full year before passage of the legislation, the agency established fourteen classification panels based on medical specialties.<sup>60</sup> The panels were staffed by experts in the respective fields. The panels began classifying devices before being authorized by the new law. By the time the Amendments were enacted, 2,500 devices had already been classified.<sup>61</sup> While all preliminarily classified devices were to be reviewed in light of the statute, FDA did not expect the panels to make significant changes.<sup>62</sup>

The explanation for this action prior to the legislation was that it would provide notice to the industry of what would be expected of them when the legislation was passed.<sup>63</sup> While the contours of a classification system were being hotly debated in Congress, the agency was confident that regardless of the outcome their preliminary classifications generally would not need to be changed. This uncharacteristically aggressive action on the part of FDA may have been motivated by a desire to influence the outcome of the legislation.

### 2. *Statutory Guidance for Classification Decisions*

A panel must place a device in Class III if there is not enough information about the device to permit the panel to determine with "reasonable assurance" that the device is safe and effective.<sup>64</sup> In other words, to place a device in Classes I or II, the panel must be reasonably sure that there is no unknown information which, if known, would alter the panel's judg-

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60. The fourteen specialty panels were: Anesthesiology, Cardiovascular, Dental, Dialysis Subcommittee, Ear Nose and Throat (ENT), Neurology, Ophthalmology, Radiology, General Hospital and Personal Use, Pulmonary, Orthopedic, Gastroenterology and Urology, Obstetrical and Gynecological, and General and Plastic Surgery. Food and Drug Administration, *Medical Device Classification Procedures: Notice to Manufacturers*, 40 Fed. Reg. 21,848-49 (1975). Subsequently, several panels were added and others dropped, reflecting the difficulty of classifying devices by user specialty when several specialties may use a particular device. The statistical information available to the author on classification decisions by the panels, see notes 57 *supra* and 79 *infra*, covers only 15 of the panels, with the exception that the November, 1977, print-out covers all 19 panels currently authorized in 21 C.F.R. § 14.100(d) (1977), *as amended*, 42 Fed. Reg. 41,852 (1977).

The law defines "experts" as persons qualified by training and experience to evaluate safety and effectiveness of devices referred to the panel. 21 U.S.C.A. § 360c(b)(2) (West Supp. 1977). Experts must "to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices." *Id.* Each panel was to contain a diversified group of experts from the fields of clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. Each panel also includes, as nonvoting members, one representative of consumer interests and one representative of manufacturing interests. *Id.* See generally Note, 50 TEMPLE L.Q. 1105, 1114-18 (1977).

61. See note 57 *supra*.

62. Food and Drug Administration, *Medical Device Classification Procedures: Notice to Manufacturers*, 40 Fed. Reg. 21,849 (1975).

63. *Id.*

64. 21 U.S.C.A. § 360c(a)(1)(C) (West Supp. 1977).

ment as to whether the device's benefits outweigh its risks. For devices placed in Class III, manufacturers must perform studies to supply the absent information. Only when the safety and effectiveness of such a device has been researched adequately will the panels weigh its benefits and risks to determine if it should be approved for marketing.

The Amendments provide little guidance about what constitutes "reasonable assurance." The provisions on effectiveness indicate in more detail than those on safety the amount and character of information which must be available, but as to both safety and effectiveness, the panels and FDA have substantial discretion to set criteria for classification.

The effectiveness provisions indicate generally the kind of evidence which must be present. Effectiveness is to be determined "on the basis of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device . . . ." <sup>65</sup> In general, if such studies of a device's effectiveness have not been performed, the device must be placed in Class III, and the studies will be required prior to any further consideration of whether to approve the device. The House Committee contemplated the use of reliable clinical test methods, similar to existing provisions relating to drugs. <sup>66</sup>

There are devices, however, for which such tests cannot be designed; there is no equivalent of a sugar pill placebo for such devices as heart valves. Thus the Device Amendments require clinical testing only when it is "appropriate," and other forms of well-controlled investigations may suffice to show effectiveness. <sup>67</sup>

In certain circumstances, however, anecdotal evidence and information from uncontrolled sources may be used to establish a device's effectiveness. If FDA determines that there is "valid scientific evidence" other than well-controlled investigations which is "sufficient to determine the effectiveness of a device" and "from which it can fairly and responsibly be concluded by qualified experts" that the device will have its purported effect under intended conditions of use, then FDA may find the device effective. <sup>68</sup> The House Committee expected that the use of evidence other than well-con-

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65. *Id.* § 360c(a)(3)(A). See note 60 *supra*.

66. 1976 HOUSE DEVICE REP., *supra* note 53, at 17. See 21 U.S.C. § 351 (1970). See also 21 C.F.R. § 314.111(a)(5)(ii)(a) (1977), which describes the principles of a "well-controlled" drug study as including: (1) A clear statement of objectives; (2) adequate methods for selection of subjects; (3) an explanation of methods of observation and recording of results; (4) comparison of results to permit quantitative evaluation; and (5) summary of the methods of analysis. The Supreme Court discussed the problem of acquiring substantial evidence of efficacy of new drugs in *Weinberger v. Hynson, Wescott & Dunning*, 412 U.S. 609, 619 (1972). For a discussion of the problems of transferring the "well-controlled" investigation standards for drugs to devices, see Hoffman, *Well-Controlled Investigations and Medical Devices*, 31 FOOD DRUG COSM. L. J. 86 (1976).

67. 1976 HOUSE DEVICE REP., *supra* note 53, at 17.

68. 21 U.S.C.A. §360c(a)(3)(B) (West Supp. 1977).

trolled studies would be permitted only when such studies would pose undue risks to experimental subjects or if existing case histories of the device in use assure its effectiveness.<sup>69</sup> The provisions for anecdotal proof of effectiveness were not intended to be a loophole through which the requirement for scientifically reliable proof could be evaded.<sup>70</sup>

The Amendments do not contain an equivalent specification of what evidence must be available to provide "reasonable assurance" of safety. Neither the statute nor the legislative history indicates directly the kinds of risks which must be tested for before a device's risks and benefits may be weighed. In another context, however, the legislative history indicates some of the kinds of harms which would justify taking a device off the market. The House Committee stated that a device could be banned if it seriously endangered the health of exposed persons. The Committee continued: "the danger need not be imminent, and may involve serious long-term risks such as a significant likelihood of carcinogenicity."<sup>71</sup> It would seem that if such risks justified removing a device from the market, testing to establish whether such risks exist should be required prior to allowing new devices on the market. Where such testing has not been done, the device must be placed in Class III.

The statute establishes some presumptions about classification which are intended to place certain kinds of devices in Class III, so that further inquiry into their safety and effectiveness will be made. An "old" device—one on the market when the Amendments were enacted, or one within the type of, or "substantially equivalent" to, a device then on the market—is presumptively placed in Class III either if it is to be implanted in the human body or if it is purported to be life-sustaining or life-supporting.<sup>72</sup> If the classification panel determines that pre-market testing of the device is not needed, the panel must give its reasons for a less restrictive classification.<sup>73</sup>

All "new" devices—those not on the market on the date of enactment and not "substantially equivalent" to one then on the market—are placed automatically in Class III.<sup>74</sup> A manufacturer can petition the panel to reclassify the device downward. The panel then evaluates whether pre-

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69. 1976 HOUSE DEVICE REP., *supra* note 53, at 17.

70. *Id.*

71. *Id.* at 20. See also note 50 *supra*. For a discussion of FDA's power to ban hazardous medical devices, see text accompanying notes 128-131 *infra*.

72. 21 U.S.C.A. § 360c(c)(2)(C) (West Supp. 1977). The Joint Explanatory Statement of the Committee of Conference of the House and Senate states that while they recognize that many considerations must be taken into account in determining whether a device is purported or represented to be for a use in supporting or sustaining human life, the conferees expect the panels and the Secretary to consider devices which are essential to the restoration or continuation of a bodily function important to life to be life supporting or life sustaining.

1976 MDA CONF. REP., *supra* note 50, at 58.

73. 21 U.S.C.A. § 360c(c)(2)(C) (West Supp. 1977).

74. *Id.* § 360c(f)(1).

market testing is necessary to provide reasonable assurance of the device's safety and effectiveness.<sup>75</sup>

The Amendments do not require that any device remain in Class III. FDA has broad discretion in determining what suffices to rebut these presumptions of Class III status. Nonetheless, the panels must present some affirmative explanation of why further study of safety and effectiveness is unnecessary, and the burden of showing the existence of adequate information to determine such a device's safety and effectiveness with "reasonable assurance" falls on the manufacturer.

### 3. *Administrative Guidelines for Classification Decisions*

To implement the broad statutory language, FDA has a system for classifying devices, sometimes called a "classification logic system." Like the classification panels, this system was drawn up prior to the passage of the Amendments.<sup>76</sup> The system consists of 18 questions relating to the safety and effectiveness of a device.<sup>77</sup> The classification of each device is a result of a panel's answers to the 18 questions.

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75. *Id.* § 360c(f)(1)(B)(i). There is a curious lack of symmetry between the definition of Class III, see note 56 *supra*, and the classification presumptions. Class III is designed for all life-supporting or life-sustaining devices for which safety and effectiveness information is not known and for devices which present a potential unreasonable risk of illness or injury. In the presumption section, 21 U.S.C.A. § 360c(f)(i)(B) (West Supp. 1977), all new devices which are purported to be life-sustaining or life-supporting or *are to be implanted* in the human body cannot be reclassified out of Class III unless the agency determines that a Class III designation is not necessary to provide a reasonable assurance of safety and effectiveness. Since the requirement of reasonable assurance of safety and effectiveness is the general standard for granting or denying a petition to reclassify, the singling out of implantables may not be meaningful. Thus, an implantable device which is not considered to create a potentially unreasonable risk of harm or is not life-sustaining or life-supporting, see note 72 *supra*, could fall into Class I, the least protective classification. This lack of symmetry, or failure to denote implantables as equals to life-sustaining or life-supporting devices, could lead to a serious loophole in the device law.

76. Food and Drug Administration, Medical Device Classification System, BMDDP/DCSE (HRK-400) (Revision 6, June 21, 1974).

77. Food and Drug Administration, *Medical Device Classification Procedures: Notice to Manufacturers*, 40 Fed. Reg. 21,849-50 (1975). The eighteen questions are:

- (1) Is the device custom made?
- (2) Although the device is custom made, can standards be applied?
- (3) Is the device life-sustaining or life-supporting?
- (4) Is the device or diagnostic information derived from use of the device potentially hazardous to life or good health when properly used?
- (5) Is the device of such a nature that: (a) sufficient scientific and medical data exist from which adequate standards governing the device safety and efficacy could now be established; and (b) development and application of such a standard would be adequate to control the device?
- (6) Is the device currently in use and marketed in the U.S.?
- (7) When the device is used, is it remote from the body?
- (8) Is the device powered by a nonmanual external or internal source (such as electrical, pneumatic, nuclear, etc.)?
- (9) Will the use of device or failure of power or device power source present a potential hazard to the patient?
- (10) Does the device emit and/or inject any form of energy to or into the body?

The questions themselves are very general. For example, Question 4 asks if the device is "potentially hazardous to life or good health" when used properly. Question 13 asks if the device material is "generally acceptable" for contact with the body. The questions call for simple conclusions; they are answered "yes" or "no" with no explanation. Panel members can insert their own value judgments as to what constitute acceptable hazards. The logic system in itself does not control classification results much better than the statutory language. Its virtue, however, is that it requires answers to somewhat focused questions. Challenges to a classification decision can be based on disagreements with a particular answer, and the discretionary nature of the decision is somewhat narrowed thereby.

#### 4. Preliminary Classification Results

The classification results, as of November, 1977, indicate that potentially hazardous devices will not consistently receive the highest standard of protection available.<sup>78</sup> At the time of passage of the Amendments, the panels had classified 2,500 devices, of which only 3.3 percent fell into Class III. By November, 1977, 3,453 devices had been classified, but the percentage placed in Class III had dropped to 3.0.<sup>79</sup>

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- (11) Have the energy levels used been shown to be acceptable?
  - (12) Will malfunction of the device result in safe energy levels?
  - (13) Does the device use material for contact with the body which is generally acceptable or has known and acceptable properties which can be provided with no additional control requirements?
  - (14) Does the device have any known hazards, limitations, or shortcomings which can be avoided by promulgation of Federal regulations applicable to the device in question?
  - (15) If the device performs some measurement function, should the accuracy, reproducibility or limitations of the information supplied be clearly indicated to the user by appropriate labeling, instructions, or precautions?
  - (16) Does the device have performance characteristics which should be maintained at a satisfactory level, such level having general agreement among the user groups?
  - (17) Is the device used with other devices in such a way that the system in which it is used can be hazardous if the system is not assembled, used or maintained in a satisfactory fashion?
  - (18) Is the device potentially hazardous to the fetus or the gonads when properly used?

Question 18 was added by the Ob/Gyn advisory panel. It originally demanded the addition of three questions relating to potential fetal and genetic damage. The question adopted was resisted by the agency and finally added only after a threatened revolt of panel members. *1975 Shield Hearings*, *supra* note 6, at 10 (statement of Richard Dickey, M.D., Ph.D.).

78. A partial list of implantable devices in Class II includes arterial graft prostheses, chin, ear, eye, larynx, mammary, maxillofacial, nasal, tendon, penile, and testicular prostheses, absorbable sutures, penile implants, testicular implants, urethral splints, implantable drainage catheters, metal methacrylate, implanted neurostimulators, and implants for diaphyseal substitute. Information from computer print-outs discussed in note 57 *supra*.

79. Author's calculations based on computer print-outs received from the FDA, *supra* note 57. The following table is a breakdown of the classifications panel by panel (see note 60 *supra* for full names of panels):

A comparison of classifications as of June, 1976 and January, 1977 indicates the flexibility of the classification scheme. For example, in 1977 the Obstetrics/Gynecology Panel moved ten devices previously in Class II into Class III. In contrast, the Orthopedic Panel changed the response to Question 4—is the device “potentially hazardous”?—from “yes” to “no” for all joint and osteosynthesis implants. All of these implants, previously in Class II, are now provisionally in Class I.<sup>80</sup>

Several conclusions can be drawn from these statistics. The classification panels are not wholly committed to their tentative classification decisions. Many hazardous devices, especially orthopedic implants, are not in Class III. While there were some reclassifications into Class III, there were also reclassifications of potentially hazardous implants into Class I, the lowest level of protection. Thus, there is no clear indication that the potentially hazardous devices misclassified in Class II or Class I will ever be placed, by the panels, in Class III.

### B. Pre-market Screening—Approval of Devices Properly Placed in Class III

After a device has been placed in Class III, it must be approved for use before it may be marketed. Whether subtle or long-term hazards are detected at this point depends on the quantity and quality of testing that the agency requires. When such hazards are detected, whether the device will be approved depends on the standards for balancing benefits and risks that the agency applies.

Panel	Class I		Class II		Class III	
	1976	1977	1976	1977	1976	1977
Anes.	12	21	149	136	10	9
C.V.	0	0	132	149	15	15
Dental	158	206	156	118	5	6
Dial.	28	28	48	48	0	0
ENT	168	173	25	22	3	3
Neur.	66	74	86	89	5	5
Oph.	107	118	98	93	10	5
Rad.	116	104	152	117	0	0
G.H.	115	109	60	59	1	1
Pul.	12	12	32	32	0	0
Ortho.	32	53	39	7	2	2
G.U.	30	31	218	216	17	18
Ob/Gyn.	3	20	108	97	11	21
Gen/Plas Surg.	172	173	99	99	0	0
Physiatry	—	154	—	67	—	3
TOTAL	1015	1276	1406	1350	79	88

By November, 1977, the total number of devices classified had increased to 3,453, but only 104 were placed in Class III. Most of the increase was in Class II; Class I devices dropped to 1,244 while Class II increased to 2,105. The panel alignment has also changed. See note 60 *supra*.

80. The print-outs, *supra* note 57, give the panel's response to each of the 18 questions, but not the reasons for the response. The author assumes that the devices are provisionally placed in class I because the print-outs list the classification as I(II).

There are two basic procedures for securing pre-market approval. A manufacturer can file an application for the approval of a device ready to be marketed.<sup>81</sup> A manufacturer can also invoke regulatory action earlier; he can apply for the approval of a "product development protocol" guiding the development of a device from the early design stages to its introduction to the market.<sup>82</sup>

The applicant for the approval of a fully developed device must report all information which is known or should reasonably be known about its safety and effectiveness.<sup>83</sup> There must be full disclosure of the device's components, properties, principles of operation, manufacturing and processing information, and other data. Samples and proposed labeling also must be submitted.<sup>84</sup> The appropriate classification panel studies the information and submits a report and a recommendation to FDA. The agency has 180 days from the receipt of this report to approve or deny the application.<sup>85</sup> If FDA finds that there remains insufficient evidence of the device's safety or effectiveness or that the application does not conform to general controls on labeling and on processing or manufacturing methods, the agency must deny the application.<sup>86</sup> A statement suggesting any measures which could be taken to make the application approvable must accompany a denial.<sup>87</sup> This statement could include requirements that certain tests be performed to establish whether particular hazards exist. Whenever new information warrants, FDA can withdraw a previously granted approval.<sup>88</sup>

The manufacturer who wishes to develop a new device from the design stage may submit a product development protocol. The protocol is a plan for research and testing. If FDA approves the protocol and if the manufacturer completes it satisfactorily, the agency will approve the marketing of the device. An approved protocol can be revoked or declared not properly completed on any of the grounds for rejecting an application for approval of an already developed device.<sup>89</sup>

As noted above, once adequate information is available, the decision whether to approve a device for marketing depends on whether FDA judges its "probable benefits" to outweigh its "probable risks."<sup>90</sup> The statute and the legislative history do not provide FDA much guidance on how to make this evaluation. First, one must determine the meaning of the term "probable." The use of the term implies that Congress did not want FDA to

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81. 21 U.S.C.A. § 360e(c) (West Supp. 1977).

82. *Id.* § 360e(f).

83. *Id.* § 360e(c)(1)(A).

84. *Id.* §§ 360e(c)(1)(B)-(G).

85. *Id.* § 360e(d)(1)(A).

86. *Id.* §§ 360e(d)(2)(A)-(E).

87. *Id.* § 360e(d)(2).

88. *Id.* § 360e(e).

89. *Id.* § 360e(f)(7).

90. *Id.* § 360c(a)(2)(C).

consider purely speculative benefits or risks. The probable benefits of a device are relatively easy to foresee; presumably, benefits are apparent in the purpose of the device and its effectiveness in accomplishing that purpose. However, risks are generally less apparent than benefits. If "probable" were construed to permit FDA to consider only risks that are quite well established, the real hazards of devices may be seriously understated. FDA should be required to take seriously risks suggested, but not yet proven, by safety studies. Consistent with the protective purpose of the Amendments, the phrase "probable risks" should be liberally construed to take cognizance of such suspected dangers.

Second, the statute and legislative history do not comment directly on what constitutes an unreasonable balance of risks and benefits justifying denial of approval to market a device. Looking at comments on other provisions of the Amendments, one can find some discussion of what is an unreasonable risk. Discussing the power to ban, the House Report states that an unreasonable risk exists where there are dangers of serious injury or serious damage to the health of exposed individuals. As noted above, the House Committee viewed as unreasonable a "significant likelihood" that a device would cause cancer or other serious long-term effects.<sup>91</sup> In another discussion of reasonableness, the Committee stated that FDA must consider such factors as the severity of the harm which might be caused, the source of the risk, the size of the risk to any individual, and the number of people subject to it.<sup>92</sup>

It is apparent that Congress intended FDA to consider long-term and subtle risks of harm. The statute and the legislative history, however, do not state precisely what weight these dangers should be given in the balancing of risks and benefits. Ultimately, what constitutes an unreasonable risk is left largely to FDA's discretion.

### C. Performance Standards—Regulation of Devices Misplaced in Class II

The Amendments require that for devices placed in Class II, performance standards be set which provide "reasonable assurance" of safe and effective performance.<sup>93</sup> The same weighing of probable risks and benefits must be made in designing these standards as is made in evaluating a Class III device.<sup>94</sup> A standard can include provisions respecting construction, components, properties, testing, performance characteristics, labeling, installation, maintenance, and operation and use of a device.<sup>95</sup> Beyond the phrase "reasonable assurance" and the list of permitted features of a

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91. See text accompanying note 71 *supra*.

92. 1976 HOUSE DEVICE REP., *supra* note 53, at 21.

93. 21 U.S.C.A. § 360d(a) (West Supp. 1977).

94. *Id.* § 360c(a)(2).

95. *Id.* §§ 360d(a)(2)(B)-(C).

standard, the statute and the legislative history do not provide guidance to the agency guaranteeing the adoption of highly protective standards.

Performance standards, however, are generally inappropriate for potentially hazardous devices because in setting such standards FDA and the panels are instructed to presume that all significant risks are already known and that no additional testing to uncover subtle or long-term risks is needed.<sup>96</sup> The classification statistics show that numerous implantables suitable for Class III have been placed in Class II.<sup>97</sup> There are two options for dealing with these misclassified devices. First, one can petition FDA to move the devices into Class III so that they will receive adequate testing and evaluation prior to marketing. As a practical matter, petitions to reclassify probably will not often succeed, since FDA's classification decisions are so highly discretionary. If the reclassification of a device is not possible, one must attempt to ensure that a protective performance standard is set.

There are several opportunities for the reclassification of a device misplaced in Class II. Before the drafting of a performance standard begins, one can petition FDA to shift the device into Class III. The Amendments also permit FDA, on its own initiative or in response to the petition of an interested party, to reclassify a device against a panel's recommendation.<sup>98</sup>

If reclassification is not possible, there are opportunities to affect the content of the performance standard developed for the device. The Amendments establish four ways to establish a standard: FDA can accept an existing standard, it can allow a qualified private "offeror" to write a standard, it can allow another federal agency to develop a standard, or it can do so itself.<sup>99</sup>

There are several ways in which an interested party can see that highly protective requirements are embodied in performance standards. The most effective way would be to develop standards as a private offeror. To do so, however, requires extensive technical expertise and a great investment of time and money.<sup>100</sup> The Amendments also provide less burdensome, al-

96. *1975 Device Hearings*, *supra* note 3, at 252. The testimony of Dr. Joel Nobel, Director of the Emergency Care Research Institute, is quoted there:

[Standards] institutionalize last year's technologic state of the art, and the last decade's belief about pathophysiology. They thus inhibit improvement and innovation and reduce the inclination to take fresh looks at old problems.

For a discussion of the failure of industry-controlled consensus standards, see Brodsky & Cohen, "Uncle Sam", *the Product Safety Man: Consumer Product Safety Standards in the Marketplace and in the Courts*, 2 HOFSTRA L. REV. 619 (1974). See also *Joint Hearings Before the Subcomm. on Health of the Comm. on Labor and Public Welfare and the Subcomm. on Administrative Practice and Procedure of the Comm. on the Judiciary (Food and Drug Administrative Practice and Procedure)*, 94th Cong., 1st Sess. (1975); NATIONAL CONFERENCE ON PRODUCT SAFETY, NCPS FINAL REPORT 6, 48-62 (1970).

97. See text accompanying notes 79-80 *supra*.

98. 21 U.S.C.A. § 360c(e) (West Supp. 1977).

99. *Id.* §§ 360d(c)-(f).

100. See *id.* § 360d(e)(1). Technical competence of offerors has been defined under the Consumer Product Safety Act Regulations in 16 C.F.R. § 1105.6 (1977).

though less effective, means of influencing the content of performance standards. There is an opportunity for comment before FDA may accept an offer to develop a standard.<sup>101</sup> At this point an interested party could oppose the selection of offerors who might not advocate strong standards. There is another opportunity for comment before FDA may adopt a standard proposed by an offeror, or before it may adopt a pre-existing standard or one that it or another agency had developed.<sup>102</sup> FDA also has the power to amend previously adopted standards;<sup>103</sup> petitions for amendment may sometimes be successful.

#### D. Summary

The Amendments authorize, for the first time, regulation of medical devices before they enter interstate commerce. Adequate use of these important new powers could substantially reduce the risks associated with hazardous devices. Vigorous protection depends on the placement of devices in Class III and application of a high standard of safety and effectiveness before approval is granted. At the very least, FDA must promulgate performance standards for devices in Class II which reflect a sufficient appreciation of potential hazards. The highly discretionary nature of FDA's classification decisions and decisions as to the requirements for pre-market approval and for performance standards makes necessary constant participation by advocates of protective regulation of devices.

### III

#### POST-MARKET SURVEILLANCE

After a potentially hazardous device has gone into use, there must be close surveillance of its effects. As already noted, even the most thorough pre-clinical and clinical testing may not uncover all long-term or subtle hazards. This has been true of drugs, food additives, and pesticides, which are all subject to pre-market screening.<sup>104</sup> In order to assure the continued safety and effectiveness of approved devices, FDA must compile and analyze statistics on problems encountered by device users. When problems

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101. One of the problems in this process is potential domination of the standard setting process by industry. The Consumer Product Safety Act has no conflict of interest safeguards. 21 U.S.C.A. § 360(c)(3) (West Supp. 1977) requires offerors to state any potential conflict of interest, including financial interest in the device and affiliations with affected industry:

In instances in which more than one offer is submitted by technically competent persons, the Committee would expect the Secretary to afford priority to an offeror who has no proprietary interest in devices for which the standard is to be developed.

1976 HOUSE DEVICE REP., *supra*, note 53, at 28.

102. 21 U.S.C.A. § 360d(e)(4)(C) (West Supp. 1977).

103. *Id.* §§ 360d(g)(4)-(5).

104. See Spector, *Regulation of Pesticides by the Environmental Protection Agency*, 5 *ECOLOGY L.Q.* 233, 260-63 (1976); Freedman, *Reasonable Certainty of No Harm: Reviving the Safety Standard for Food Additives, Color Additives, and Animal Drugs*, 7 *ECOLOGY L.Q.* — (to appear).

are discovered, the agency must also be able to trace the device's users, give them appropriate notification, and provide them with effective remedies.

The General Controls provisions of the Amendments provide FDA with a broad mandate to establish regulations for surveillance, tracing, notification, and remedies.<sup>105</sup> To date, no regulations have been promulgated, and regulations have been proposed for the implementation only of the power to ban.<sup>106</sup> Following a discussion of FDA's post-market powers under the Amendments, Part III presents California's proposed regulations on IUDs as a model for post-market controls.

### A. General Controls Under The Medical Device Amendments

#### 1. Reports and Recordkeeping

Accumulation of accurate data on the safety and effectiveness of devices on the market is essential. The broadly drawn recordkeeping provisions in the Medical Device Amendments provide a valuable tool for the agency to obtain updated information on device hazards.

Under the law, the agency can require that manufacturers, importers, and distributors establish and maintain records and prepare such reports as may be reasonably necessary to assure the safety and effectiveness of a device.<sup>107</sup> Each request for a report must state the reason for the request.<sup>108</sup> There are some statutory limitations on the agency's power to require reports. No regulations can be "unduly burdensome."<sup>109</sup> To determine whether a regulation is "unduly burdensome," the agency balances the cost of compliance against the need to obtain information to protect public

105. 21 U.S.C.A. § 360c(a)(1)(A) (West Supp. 1977). General Controls powers are enumerated below:

- § 351 Adulterated drugs and devices
- § 352 Misbranded drugs and devices
- § 360 Registration of producers of drugs and devices
- § 360f Banned devices
- § 360h Notification—Repair, Recall, Reimburse
- § 306i Records and Reports on Devices
- § 306j General provisions respecting control of devices:
  - (b) Custom devices
  - (c) Trade secrets
  - (e) Restricted devices
  - (f) Good manufacturing practices
  - (g) Exemptions for investigational use
  - (h) Release of information respecting safety and effectiveness
  - (j) Traceability
  - (k) Research and development
  - (l) Transitional provisions for devices regulated as drugs.

106. Food and Drug Administration, *Establishment of Procedures to Make a Device a Banned Device*, 42 Fed. Reg. 42,000 (1977).

107. 21 U.S.C.A. § 360i (West Supp. 1977).

108. *Id.* § 360i(a)(3). The identity of the patients must be protected in these reports. *Id.* § 360i(a)(4).

109. *Id.* § 360i(a)(1).

health.<sup>110</sup> The agency may not require manufacturers, distributors or importers of devices placed in Class I—devices generally agreed to present no serious risks—to maintain records respecting information not in their possession or to submit reports on a periodic basis unless the information is necessary in order to reclassify the device or to show that it is adulterated or misbranded.<sup>111</sup> The purpose of this limitation is to assure that only necessary records and reports are required. There was no congressional intent to limit FDA's "authority to obtain information needed to insure that the public is protected from potentially hazardous devices."<sup>112</sup> With appropriate implementing regulations, FDA can obtain all information necessary to keep itself, manufacturers, and consumers well informed on device hazards.

## 2. Tracing

Amelioration of the hazards of a device currently in use can be effective only if the manufacturer or the agency knows how to find its users. The ability to trace a device through the distributive channels is an important regulatory tool. The House Committee commented that individual or batch numbering or coding would have greatly facilitated the recall of hazardous cardiac pacemakers.<sup>113</sup> The Amendments authorize tracing, but only in very general language.<sup>114</sup> The House Report anticipated the establishment of categories of products based on the degree to which the ability to trace was needed to protect public health.<sup>115</sup>

## 3. Notification Provisions

The power to notify users of defective products exists in many contexts other than device control. Notification procedures vary according to the characteristics of the regulated products.<sup>116</sup> Notifying users of medical devices of possible hazards presents three special problems: medical devices are more private than other consumer products, the doctor-patient relation-

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110. *Id.* See also 1976 HOUSE DEVICE REP., *supra* note 53, at 23-24.

111. 21 U.S.C.A. §§ 360i(a)(5)(A)-(B) (West Supp. 1977).

112. 1976 HOUSE DEVICE REP., *supra* note 53, at 24.

113. *Id.* at 52.

114. 21 U.S.C.A. § 360(j) (West Supp. 1977). The House Report states:

No regulation under this Act may impose on a type or class of device requirements for the traceability of such type or class of device unless such requirements are necessary to assure the protection of the public health.

1976 HOUSE DEVICE REP., *supra* note 53, at 52.

115. *Id.*

116. For example, under the National Motor Vehicles and Traffic Safety Act, the automobile manufacturer must keep records of all original purchasers and therefore has the means to notify them directly of any discovered defects. 15 U.S.C. § 1402(f) (Supp. V 1975). Other consumer products cannot be traced directly to their ultimate destination. Under the Consumer Product Safety Act the manufacturer may be ordered to take one or more of the following actions: (1) give public notice (presumably through a media campaign); (2) mail notice to other manufacturers, distributors or retailers; and (3) mail notice to every person to whom it knows such product was delivered or sold. *Id.* § 2064(c).

ship is sensitive to outside interference, and the discovery of a device hazard may have a large emotional and physical impact on the user.

The drafters of the Amendments attempted to allow for the special conditions of device use without undermining the effectiveness of notification. The law provides that if a device "presents an unreasonable risk of a substantial harm to public health" and if "notification . . . is necessary to eliminate the unreasonable risk . . . and no more practicable means is available . . .," the agency can require notification.<sup>117</sup> To determine whether a risk is unreasonable, the House Committee intended the agency to consider such factors as the severity of the harm presented by the risk, the cause of the risk, and the extent of the risk.<sup>118</sup> To decide whether harm is "substantial," the Committee considered inclusion of widespread nonserious harm to a large number of people as well as serious harm to a few individuals.<sup>119</sup>

Notification is to be made to all professionals who prescribe or use the device, and to any other persons, including manufacturers, distributors, and device users, who should "properly receive" such notification.<sup>120</sup> The special problems of medical devices affected decisions on who should "properly receive" notice.<sup>121</sup> The Amendments provide that all persons "subject to the risk" must be notified unless the agency determines that the impact of notice would imperil the health of an individual more than the lack of notice.<sup>122</sup> The persons "subject to the risk" are only those who may incur future damage which could be at least partly avoided by current action; persons subjected to risks but for whom no helpful action can be taken need not be notified.<sup>123</sup> The Amendments do not require that the manufacturer always notify such a person directly. In certain circumstances, greater danger may be created by notification than by the lack of it; a device user's apprehension may be more harmful than the actual hazard of the device. In such circumstances the manufacturer must notify the user's doctor, who must "provide for" more appropriate notice, such as by a close family member.<sup>124</sup>

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117. 21 U.S.C.A. §§ 360h(a)(1)-(2) (West Supp. 1977).

118. 1976 HOUSE DEVICE REP., *supra* note 53, at 21.

119. *Id.*

120. 21 U.S.C.A. § 360h(a)(2) (West Supp. 1977).

121. There was considerable debate over the question of who should properly receive notice. The fear was that notice in some instances might present a greater danger to the health of such individuals than lack of notice. One early bill excused notice if the agency determined that notification might create a greater danger than lack of it. H.R. 5545, 94th Cong., 1st Sess., § 518(a)(2) (1975). Consumer groups objected to this exemption, which permitted FDA arbitrarily to withhold important health information. 1975 *Device Hearings*, *supra* note 3, at 272. Another bill contained a provision allowing delay of notice if the agency determined that notice would endanger public health. S. 510, 94th Cong., 1st Sess., § 515(b)(2) (1975).

122. 21 U.S.C.A. § 360h(a)(1) (West Supp. 1977).

123. 1976 MDA CONF. REP., *supra* note 50, at 60.

124. *Id.* at 59-60.

#### 4. *Repair, Replacement, or Refund*

As a corollary to the notification provisions, the Amendments provide statutory remedies of repair, replacement, or refund.<sup>125</sup> The remedies are available if a device presents an "unreasonable risk of substantial harm" and "there are reasonable grounds to believe that the device was not properly designed and manufactured with reference to the state of the art as it existed at the time" and if notification alone is inadequate.<sup>126</sup> The remedies are modeled on similar provisions for "substantial product hazard" under the Consumer Product Safety Act.<sup>127</sup>

These statutory remedies may be useless when hazardous devices are involved. Many hazardous devices, especially those permanently implanted in the body, can be repaired or replaced only with enormous medical risk. For example, a manufacturer may discover that an artificial heart valve it markets has a potentially defective strut that may cause the valve to fail. Repair or replacement would involve open heart surgery which might pose a greater medical risk than the potential failure of the device. Replacement may not be feasible at all for other types of hazardous devices. For example, it is medically impossible to remove certain orthopedic reconstructive devices. An individual with a total hip prosthesis cannot have it replaced even if the plastic of which it is composed is leaching toxic substances into his bloodstream.

#### 5. *Power to Ban*

FDA may ban a device from the market if the agency finds that it "presents substantial deception or an unreasonable and substantial risk of illness or injury" which cannot be corrected by labeling changes.<sup>128</sup> The ban is an emergency procedure. For certain hazardous devices, the ban may be made effective immediately upon publication in the Federal Register.<sup>129</sup> The legislative history indicates that while the danger posed by the device must be serious, it need not manifest itself immediately and may involve serious long-term risks such as carcinogenetic potential.<sup>130</sup> In the summer of 1977, FDA proposed regulations to implement the power to ban devices. The proposed regulations generally track the language in the Amendments, outlining the expedited procedures to remove hazardous devices from the market.<sup>131</sup>

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125. 21 U.S.C.A. §§ 360h(b)(2)(A)-(C) (West Supp. 1977).

126. *Id.* §§ 360h(b)(1)(A)(i)-(iv).

127. *See* 15 U.S.C. § 2064 (Supp. V 1975).

128. 21 U.S.C.A. § 360f(a) (West Supp. 1977).

129. *Id.* § 360f(b).

130. 1976 HOUSE DEVICE REP., *supra* note 53, at 20.

131. Food and Drug Administration, *Establishment of Procedures to Make a Device A Banned Device*, 42 Fed. Reg. 42,000 (1977).

The Medical Device Amendments provide broad authority for FDA to regulate information on hazards through the recordkeeping, tracing, notification, and banning provisions. However, all of these powers depend upon perceptively drafted implementing regulations. Such regulations have yet to be established. The California post-market regulations of one hazardous device, the IUD, provide a model for hazardous device control.

*B. California's Proposed IUD Regulations:  
A Model for Federal General Controls*

The California State Department of Health (DOH) has authority to impose marketing controls on new devices and drugs under the Sherman Food, Drug, and Cosmetic Act.<sup>132</sup> In 1975, DOH drafted proposed regulations for IUDs in response to a petition by a group of health advocates.<sup>133</sup> Due to DOH's uncertainty over whether state regulation of medical devices has been preempted by the Medical Device Amendments, these regulations have not yet been implemented.<sup>134</sup> The proposed provisions on recordkeep-

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132. CAL. HEALTH & SAFETY CODE §§ 26000-26851 (West Supp. 1977). The Act was passed in 1970. The IUD was considered a "new device" within the meaning of the code because substantial evidence was not available to determine its safety and effectiveness. In order for a new device to be marketed in California, it must have an NDA (new drug approval) clearance from the FDA or approval from the State Department of Health. An NDA was impossible because the FDA had refused to classify IUDs as drugs under the old law. Thus, the IUD manufacturers will have to submit new device applications to the State. These applications must disclose full reports of safety and efficacy, *id.* § 26670(b)(1), components, *id.* § 26670(b)(2), composition, *id.* 26670(b)(3), manufacturing practices, properties, and principles of operation, *id.* § 26670(b)(4), samples, *id.* § 26670(b)(5), and specimens of labels and advertising, *id.* § 26670(b)(6). There are also requirements for the maintenance of records and reports which will be governed by regulations issued by the Department, *id.* § 26674.

133. The petitioners included the Coalition for the Medical Rights of Women, the National Organization for Women, the National Organization of Women (California), and Black Women Organized for Action. They filed an administrative petition to DOH in November, 1974, requesting adoption of a regulation under the California Administrative Procedure Act, CAL. GOV'T CODE § 11426 (West 1966), which provides for such requests by private parties.

134. Carl Nelson, Drug and Medical Device Division of the Department of Health, telephone interview, March 14, 1978. The question of preemption has led DOH, perhaps unnecessarily, to postpone all action on the 1975 proposed regulations pending an FDA determination of the status of state and local laws regulating medical devices. State "requirements" are preempted by the Amendments if they are different from or in addition to requirements applicable under the Amendments. 21 U.S.C.A. § 360k(a) (West Supp. 1977). FDA believes that Congress intended to preempt state and local regulations which differ from federal requirements only if the state or local requirements "relate to matters already governed by specific, established Federal requirements applicable to a specific device." Food and Drug Administration, *Proposed Action on State of California Application for Exemption from Preemption of Requirements*, 42 Fed. Reg. 9,186 (1977). Since no final IUD regulations were promulgated by FDA until May, 1977, DOH could have implemented its own regulations pending FDA action, because they were not yet preempted.

However, DOH sought to obtain assurance from FDA that the California IUD regulations would be exempted from preemption pursuant to the authority to grant such exemptions vested in FDA under the Amendments. 21 U.S.C.A. § 360k(b) (West Supp. 1977). These exemptions can be granted by FDA for state and local regulations which are preempted by the Amendments but which: (1) are more stringent than Federal requirements applicable to the device; or (2) are

ing, notice, reporting, and tracing all reflect an understanding of the problems associated with potentially hazardous devices, however, and could serve as a model for federal regulation of all types of medical devices.

The recordkeeping proposals address several important aspects of hazardous device control. First, the manufacturer must submit a plan to DOH assuring that detailed records will be maintained.<sup>135</sup> Second, there is recognition of the need for continually updating the records, so that accurate reports are always available.<sup>136</sup> Third, and most important, records must be kept of all unusual failures or unexpected reactions even if the complications are not clearly attributable to the IUD.<sup>137</sup> "Unexpected" reactions include harms undetected during pre-market trials as well as suspected risks which are occurring at a higher rate than previously supposed.<sup>138</sup> Unexpected hazards must be reported, both to DOH and FDA, within fifteen days after they occur.<sup>139</sup> These provisions recognize the possibility of long-term or subtle harms which, while undetected in clinical trials, may emerge with widespread use.

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necessitated by compelling local conditions, so long as compliance with local regulations will not cause the device to be in violation of Federal requirements. *Id.* Since the only Federal action on IUDs thus far is one that requires labeling, Food and Drug Administration, *Intrauterine Contraceptive Devices; Professional and Patient Labelling*, 42 Fed. Reg. 23,772, corrected 42 Fed. Reg. 35,155 (1977), to be codified in 21 C.F.R. §§ 310.502, 801.427, California's regulations on advertising, labeling, experience data reporting, patient informed consent, and enforcement remedies would almost certainly meet the "more stringent" requirement for exemption from preemption.

FDA's proposed response of February 15, 1977 to DOH's petition for exemption was "Catch-22." The agency stated:

The Commissioner finds that these draft regulations do not have the force and effect of law in California, are therefore not a "requirement" within the meaning of, and are not preempted by, section 521(a) of the act. The Commissioner recommends that California review the final Federal regulation on IUD labeling requirements that will be published in the *Federal Register* in the near future before publishing its draft regulations in final form and before applying for an exemption from Federal preemption.

42 Fed. Reg. at 9,188. The regulations referred to were published in May, 1977, but DOH has yet to take any action on its own IUD regulations, pending a final FDA response.

The California experience during the implementation phase of the Medical Device Amendments demonstrates the capacity of important federal regulatory legislation to discourage states from implementing needed regulations, even when it is unlikely that the state regulations ultimately will be preempted by the federal law. Since promulgation of regulations for the large number of devices regulated by the Amendments will not be completed for years to come, some devices may remain unregulated even after both the state and the federal government have made the policy decision that regulation is needed.

135. Draft Regulations on Intrauterine Devices § 10439.5 (December 15, 1975). The plan must assure that information on the number of insertions, the status of those insertions, and all reported IUD failures will be maintained.

136. *Id.* § 10439.5(a)(2). All reports must be updated every three months during the first year the device is on the market, every six months during the second year, and annually thereafter.

137. *Id.* § 10439.5(a)(4).

138. *Id.*

139. *Id.*

The health care provider would also have affirmative reporting obligations. The provider must complete an insertion report card for each IUD insertion and return it to the manufacturer.<sup>140</sup>

The regulations would require that the patient receive information to facilitate notice and tracing. The patient must be informed of the known risks and benefits of the device and those of alternative forms of contraception.<sup>141</sup> The patient also must receive a card containing the lot and control number of the device. The card also advises the patient to contact the provider if adverse reactions occur.<sup>142</sup>

### C. Summary

Reporting, recordkeeping, and tracing are all critical to adequate post-market surveillance. The proposed California regulations for a specific hazardous device are a good model for the federal regulators. With proper implementation of the General Control provisions of the Amendments, post-market surveillance will substantially reduce the risks associated with beneficial, but potentially hazardous, medical devices. The inadequacy of remedies developed for conventional defective products, however, emphasizes the importance of extensive pre-market testing to reduce risks as much as possible before these remedies are needed.

## IV

### MAXIMIZING THE PROTECTIVE POTENTIAL OF THE MEDICAL DEVICE AMENDMENTS

#### A. Consumer Objectives

This Article has demonstrated four major goals for the achievement of maximum protection from the Medical Device Amendments. One objective is reclassification of hazardous and potentially hazardous devices from Class II to Class III. Second, for all Class III devices, there must be serious review of the safety and efficacy data before marketing. For all Class II devices, there must be well-drafted, rigorous performance standards. Finally, there must be adequate post-market surveillance of devices on the market.

Several formidable hurdles could prevent attainment of those goals. The most significant barrier could well be FDA. The agency is already burdened with enormous regulatory responsibilities. FDA has been the target of more than 100 congressional investigations, 50 highly critical reports by the General Accounting Office, and a series of self-initiated inquiries.<sup>143</sup> While it is beyond the scope of this paper to verify or refute

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140. *Id.* § 10439.3(b)(3)(A)(2)(iii).

141. *Id.* § 10439.3(b)(4).

142. *Id.* § 10439.3(b)(1)(C).

143. Lyons, *Demoralization Plaguing F.D.A.: Some Top Jobs Remain Unfilled*, N.Y. Times, March 14, 1977, at 1, col. 1. For examples of criticism of FDA procedures, see HOUSE

recent charges against the agency, these attacks cast doubt on FDA's incentive to regulate medical devices effectively.

The task of prodding the agency into action will likely fall to consumer groups. This responsibility presents additional hurdles. The most obvious problem is that these groups have limited resources. Numerous other health policy issues may deplete the resources of consumer groups and lead to serious under-representation of consumers in agency decision-making.<sup>144</sup> Furthermore, with the exception of the IUD, which has become a feminist issue, there is no identifiable "device" constituency from which to draw assets and support. Given these significant difficulties, it is important that interested consumers understand the structure of the device law in order to improve the likelihood that the goals will be attained.

### B. Consumer Participation in Device Regulation

The Amendments provide opportunities both for actual participation in decision-making and for comment in various forms on proposed agency decisions. Effective consumer participation requires a clear understanding of the complicated procedures established by the Amendments.

Consumers can participate in the decision-making process as members of classification panels or as offerors of performance standards. Each classification panel must include, as nonvoting participants, one representative from a consumer group and one from industry.<sup>145</sup> If a consumer group can demonstrate the requisite technical competence, the group may be an offeror and may develop a performance standard.<sup>146</sup>

Interested parties may comment on proposed decisions under four different procedures, each available as prescribed by the Amendments. Two of these formats, notice and comment<sup>147</sup> and hybrid hearing (called an "informal hearing" in the Act),<sup>148</sup> are relatively simple, informal, and

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SUBCOMM. ON OVERSIGHT AND INVESTIGATION OF THE COMM. ON INTERSTATE AND FOREIGN COMMERCE, 94TH CONG., 2D SESS., FEDERAL REGULATION AND REGULATORY REFORM (Comm. Print 1976). See also *Preclinical and Clinical Testing by the Pharmaceutical Industry Part II: Joint Hearings Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare and the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary*, 94th Cong., 2d Sess. (1976) (especially remarks of Sen. Kennedy, at 334, and of Gregory J. Ahart, at 325).

144. HOUSE COMMITTEE ON GOVERNMENT OPERATIONS, CONSUMER PROTECTION ACT OF 1977, H.R. REP. NO. 347, 95th Cong., 1st Sess. 10 (1977) (statement of Esther Peterson, President's Special Assistant for Consumer Affairs).

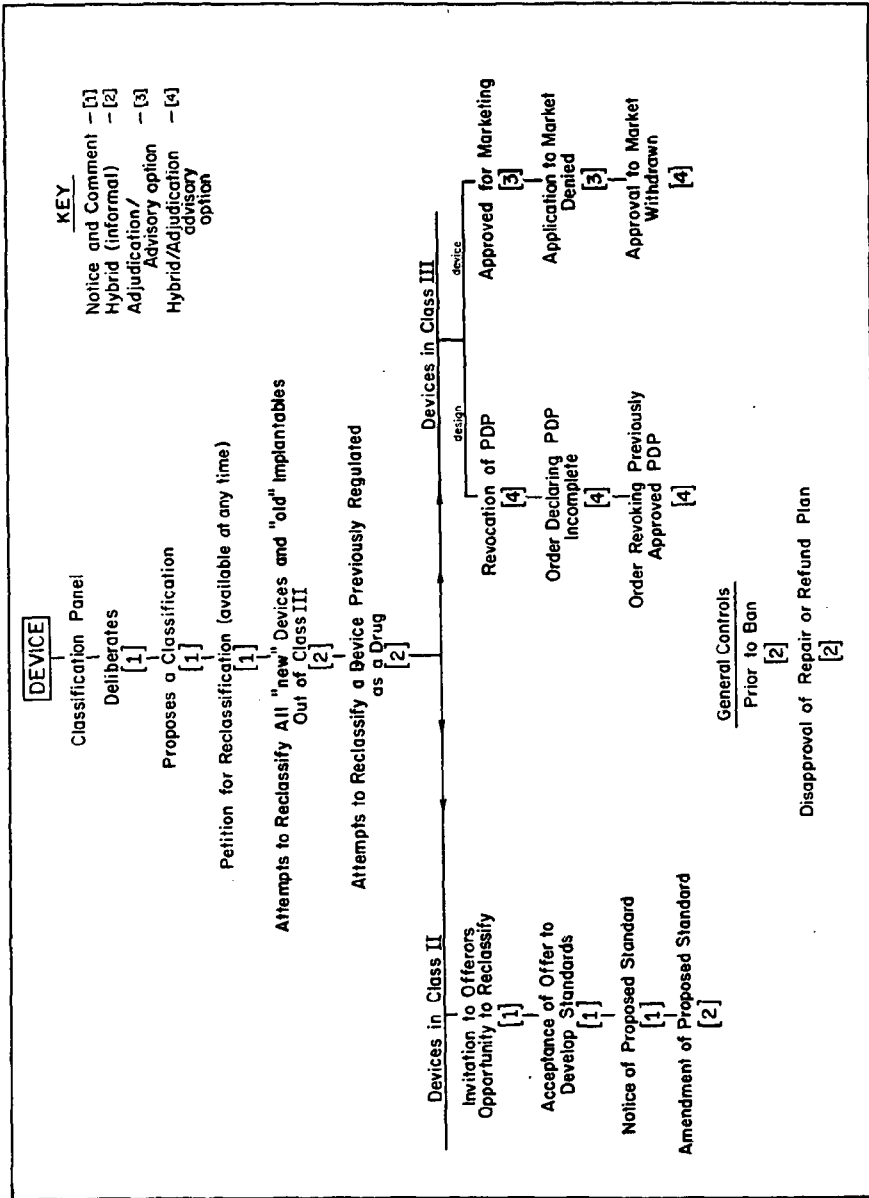
145. 21 U.S.C.A. § 360c(b)(2) (West Supp. 1977).

146. See *id.* § 360d(c). The experience of the Consumer Product Safety Commission has shown that participation of consumer groups in the expensive and time-consuming drafting of performance standards is likely to be limited. See Note, *Inside the Proposed Standard for Architectural Glass: An Outward Look at Consumer Participation in the CPSC's Offeror Process*, 43 GEO. WASH. L. REV. 1173, 1207 (1975).

147. 21 U.S.C.A. § 360d(b)-(c) (West Supp. 1977).

148. *Id.* § 321(y). The Amendments amended § 321 by the addition of subsection (y), which sets out the provisions of the new informal hearing. Each party to the hearing must have the

Procedure for Classification of a Medical Device



inexpensive. The two others are considerably more complex. One provides for a formal adjudication with participation by the classification panel for the device.<sup>149</sup> There is also a procedure allowing for an informal hearing prior to a ruling followed by a formal adjudication or advisory committee report after the agency decision.<sup>150</sup> Adjudications, with formal procedure and formal record-keeping,<sup>151</sup> are lengthy and expensive.<sup>152</sup> Consumer groups, with limited resources, will probably find that the commitment required for adjudications is prohibitive.

The chart on the opposite page illustrates which procedures must be followed at each stage of the regulatory process. The two simpler forms are available exclusively prior to the classification of a device and, once a device is placed in Class II, until an offeror drafts performance standards. After a device has been placed in Class III, however, only the formal and expensive procedures are available to the consumer who attempts comment on a decision.

Following a Class III designation, a manufacturer must invest considerable time and expense, either developing a protocol or preparing premarket review data. Agency action adverse to a manufacturer's interest at this stage could significantly affect the regulated business entity. In

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right to counsel, *id.* § 321(y)(2), and must be given a comprehensive statement of the basis of the action and a summary of the information to be presented in support of the action. *Id.* § 321(y)(3). Each party must be allowed to conduct reasonable questioning and to present any oral or written information relevant to the subject of the hearing. *Id.* § 321(y)(4). A written report of the hearing along with all submitted written material must be prepared by the presiding officer at the hearing so that each participant can review the report and correct or supplement the record. *Id.* § 321(y)(5). The agency can authorize the hearing to be transcribed, and a party has the right to transcription at his own expense. *Id.* § 321(y)(6).

For a discussion of the problems of "notice and comment" rulemaking and of the procedures of the CPSA, see Scalia & Goodman, *Procedural Aspects of the Consumer Product Safety Act*, 20 U.C.L.A. L. REV. 899, 911-913 (1973). For a discussion of innovation in rulemaking, see Hamilton, *Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking*, 60 CALIF. L. REV. 1276, 1323-1326 (1972).

149. 21 U.S.C.A. § 360e(g)(1) (West Supp. 1977). This section provides for review, under 5 U.S.C. § 554 (1970), of the following orders:

- (a) Approving or denying approval of an application for premarket approval;
- (b) Withdrawal of approval of an application for premarket approval;
- (c) Revocation of an approved PDP;
- (d) Declaration that an approved protocol has not been completed; or
- (e) Withdrawal of approval of an approved PDP.

150. 21 U.S.C.A. § 360e(g)(2) (West Supp. 1977). This procedure applies, at the option of the petitioner, for review of the same types of orders as are listed in note 149, *supra*. *Id.* §§ 360e(d)(3), (e)(2), (f)(8), 360(g)(1).

151. See 5 U.S.C. §§ 556, 557 (1970).

152. The FDCA is one of the few statutes requiring formal rulemaking in some instances. See 21 U.S.C. § 355(c)(2) (1970). Formal rulemaking can be extremely time-consuming. For example, the FDA hearing to fix standards for vitamin and mineral additives involved 110 parties; each had a right to present evidence and cross-examination. Formal rulemaking under the FDCA was modified by *Weinberger v. Hinson*, 412 U.S. 609, 622 (1973), where the Court upheld a summary judgment procedure for "new drug" applications.

several instances, the agency can revoke a previously conferred benefit.<sup>153</sup> The requirement of formal adjudicative procedures thus protects significant individual economic interests.

In order to strengthen consumer input, the consumer advocate must participate in the early stages of decision-making, when the channels through which he communicates are simple, informal and inexpensive. The problem, of course, is that risks may not be identified until the product is developed, tested, or even in widespread use. However, where the risks are known, or even suspected, the efficient advocate should expose those risks as early in the regulatory process as possible.

### *C. Other Tactical Considerations*

To battle FDA device by device to prevent marketing or to force reclassification would soon deplete the resources of the most well-financed consumer groups. If a battle is to be waged, it is crucial that the device at issue be a carefully chosen target device. That is, the target device should be made from a material or utilize a method of operation that is not unique to that device. For example, recognition by the agency that the components of the target device are hazardous would induce re-evaluation of a class of devices made from such components.

The consumer group should choose devices which will receive maximum publicity. In public health matters the effect of publicity is enormous. The publicity surrounding the hazards of two widely used devices, the IUD and the cardiac pacemaker, spurred the passage of the Amendments. Advocates should consider which demographic groups use a device, how widely it is used, and the severity of the suspected hazards.

### CONCLUSION

The story of medical device development (rapid growth of a "high technology" industry) characterizes a conflict present in modern technological society. While many medical devices have dramatically improved the quality of life, many others have created new and often unforeseen risks of injury and death. The real challenge is to minimize these risks without hampering the benefits which the advancing technology provides.

Our tools for the achievement of this goal are primitive. Left unregulated, the device industry has been irresponsible. Congress has produced a regulatory scheme that is cumbersome, confusing, and at times byzantine. The agency called upon to administer the scheme is overworked, underfinanced, and often indifferent. Improperly administered, this regulatory scheme may sacrifice the benefits of medical technology without reducing risk. Consumers are represented by advocates who may overstate their case in response to the powerful interests which oppose them.

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153. See text accompanying notes 98-103 *supra*.

There are no easy answers to this social problem. The Medical Device Amendments are a "solution" to device hazards delivered by Congress to FDA. This Article has provided illumination of the background, language, and possibilities of this admittedly limited "solution." Reasoned advocacy of public health must utilize this imperfect law in the interests of improving the quality of the internal human environment.

