

# The Effectiveness of FDA Medical Device Regulation

## I. INTRODUCTION

In the last dozen years, attempts to increase the public's protection from deficient, unreliable, and ineffective medical devices have manifested themselves in some twenty-eight Congressional bills and six presidential messages.<sup>1</sup> Yet it is only within the last year that the nation's political ambience has begun to reveal a significant concern for protecting the public from these devices.

It is difficult to accurately assess the amount of suffering that deficient medical devices cause. This is because the Federal Food and Drug Administration (FDA), the principal governmental agency that oversees the medical device industry,<sup>2</sup> cannot require reports of medical device-related injuries or even the registration of medical device manufacturers. In addition, many or most of the injuries and deaths caused by defective and ineffective medical devices are not reported in the medical literature due to fears of malpractice suits.<sup>3</sup>

Nevertheless it is apparent from the discoveries of Congress, the Food and Drug Administration and the courts that all too many ineffective and dangerous devices are finding their way into the hands of medical practitioners and the public.

A study by the FDA, surveying medical literature published since 1963, hinted at the magnitude of the problem created by deficient medical devices. The problem is clearly significant with injuries and deaths in the thousands.<sup>4</sup> Because physicians fear malpractice litiga-

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<sup>1</sup>Address by Mrs. Virginia Knauer, Special Presidential Assistant for Consumer Affairs, before the National Conference on Medical Devices, September 6, 1969 [hereinafter cited as Knauer Address].

<sup>2</sup>Other sources of law regulating medical devices include CAL. HEALTH & SAFETY CODE § 6200 *et seq.* (West 1973); FTC powers, 15 U.S.C. § 55 (1973); ATOMIC ENERGY COMMISSION powers, 42 U.S.C. § 2051 (1973). FTC and AEC powers are, compared to FDA powers, seldom invoked to regulate medical devices. In addition, FTC powers are limited to advertising aspects of medical devices and AEC is limited to nuclear powered devices. The FDA has neither of these limitations. California provisions are seldom invoked and will be subject to federal pre-emption in light of proposed and pending federal legislation. (*Infra*, note 103).

<sup>3</sup>43 HOSPITALS 65 (1969).

<sup>4</sup>Christopher Dodge Analysis, Library of Congress Research Service, appearing at

tion and would thereby be reluctant to report many of these injuries in the medical literature, we can probably conclude that this FDA survey resulted in a very conservative estimation of the problem of deficient medical devices. In another study, for example, a downtown New York teaching hospital found that of several thousand pieces of incoming medical instruments, forty percent either did not meet the specifications of the manufacturers or were otherwise hazardous to patients.<sup>5</sup>

The scope of the medical device problem is broad and, in some cases, the resulting dangers plain and acute. Pacemakers, used to regulate heart beats, are inserted into the body without testings or examination.<sup>6</sup> Toilet valves, by comparison, are subject to several tests before use.<sup>7</sup> The problem extends to virtually every article used in medical treatment, ranging from the widely used interuterine contraceptive devices (IUD's) to post-natal incubators to tracheotomy tubes.<sup>8</sup>

In the initial portions of this article, the definition of medical devices will include only such items as pacemakers, IUD's, plastic tracheotomy tubes, and the like. However, it will become apparent that the statutory definition of device has been substantially enlarged by judicial attempts to expand existing FDA authority in the public

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877-8 of *Hearings on Medical Device Amendments before Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 93rd Cong., 1st Sess. (1973) [hereinafter cited as *Dodge Analysis*]. The study showed 512 deaths and 300 injuries connected with the implantation of heart valves, 89 deaths and 186 injuries associated with pacemakers, 47 deaths and several injuries associated with anesthesia machines, 28 deaths and 171 injuries arising from the use of catheters, over 8,000 injuries resulting from the use of IUD's, over 2,000 injuries associated with radiation equipment, and hundreds of other injuries related to the use of other miscellaneous devices ranging from hip prosthesis to contact lenses.

<sup>5</sup>THE ELECTRONIC ENGINEER, July 1969, at 3.

<sup>6</sup>Washington Post, February 20, 1969, § A, at 2.

<sup>7</sup>See Knauer Address, *supra* note 1.

<sup>8</sup>*E.g.*, defibrulators, devices employed by doctors to induce a normal pulse in a patient suffering cardiac arrest, are found to cause electrical hazards to both patients and physicians. See Statement of Charles Edwards, Assistant Secretary of Health, Dept. of HEW, during *Hearings on Medical Device Amendments before Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 93rd Cong., 1st Sess. 183 (1973).

Some plastic tracheotomy tubes are placed on the market with blockages that prohibit the passage of life sustaining air or gases. *Id.* Interuterine contraceptive devices (IUD's) which are designed to avoid the problem of accidental expulsion from the uterus, have a tendency to become so imbedded in the uterus lining that the device's removal necessitated the removal of the whole uterus. See *Hearings of Medical Device Amendments before Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 93rd Cong., 1st Sess. 182 (1973) [hereinafter cited as *Kennedy Hearings*]. Incubators, used for life maintenance of premature newborns, have been discovered with thermostats that allow incubation temperatures to rise to 145° F., *Id.*, while other incubators have been found with faulty electrical systems that lead to shorts and resulting flash fires in the oxygen rich environment of the incubator. *Id.* at 435.

interest. These same judicial attempts, however, have left the legal definition of "medical device" in a state of confusion.

This paper will investigate the deficiencies in the current FDA authority to regulate devices, deficiencies that allow faulty medical devices to threaten the health and safety of the public. The present FDA authority over medical devices is limited to hunting down, seizing, condemning, and obtaining a court injunction against shipments of such devices in interstate commerce. This catch-as-catch-can authority will be compared to the FDA's authority over drugs. The difficulties of regulating the medical device industry will then be examined. Finally, this article will examine pending proposals for change in medical device regulation and present suggestions for the evaluation of new regulatory schemes.

## II. COMPARISON OF FDA AUTHORITY OVER DRUGS AND AUTHORITY OVER DEVICES

The Food and Drug Administration was established pursuant to authority granted by the 1906 Pure Food and Drug Act.<sup>9</sup> This Act gave the FDA power to regulate "all medicines and preparations . . . for internal or external use . . . intended for the cure, mitigation or prevention of diseases . . ." <sup>10</sup>

It is unclear whether this 1906 Act included authority over devices.<sup>11</sup> It was not until the 1938 Amendments to the 1906 Act that the word "device" actually appeared in the statutes.<sup>12</sup> And it was not until after the passage of these 1938 Amendments that the Federal Food and Drug Administration actually embarked upon the prosecution of defective medical devices moving in interstate commerce.<sup>13</sup>

Examination of the 1938 Amendments reveals several similarities between the statutory sanctions governing drugs and those governing devices. Both drugs and devices are subject to like prohibitions against adulteration<sup>14</sup> or misbranding.<sup>15</sup> Once the FDA is convinced that either a drug or device is misbranded or adulterated, it can seize the item.<sup>16</sup> After such a seizure, devices and drugs are subjected to

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<sup>9</sup>Pure Food and Drug Act, Act of June 30, 1906, ch. 3915 § 6, 34 Stat. 768.

<sup>10</sup>Pure Food and Drug Act, Act of June 30, 1906, ch. 3915 § 6, 34 Stat. 769.

<sup>11</sup>See SENATE REPORT NO. 646, 74th Cong., 1st Sess. (1935); and 79 CONG. REC. 4841 (1945).

<sup>12</sup>Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-392.

<sup>13</sup>Statement of Sherwin Gardner, Acting Commissioner, Food and Drug Administration, Dept. of HEW, *Hearings on Regulation of Medical Devices (Intra-uterine Contraceptive Devices) before Subcomm. on Intergovernmental Relations of the Comm. on Government Operations*, 93rd Cong., 1st Sess. 180 (1973) [hereinafter cited as Gardner Statement].

<sup>14</sup>21 U.S.C. § 351 (1972).

<sup>15</sup>21 U.S.C. § 352 (1972).

<sup>16</sup>21 U.S.C. § 334 (1972).

identical court proceedings with an injunction as the ultimate judicial remedy.<sup>17</sup>

However, the difference between the drug and device powers possessed by the FDA profoundly outweigh these similarities. Before drugs can be manufactured, the manufacturer must register with the Secretary of the Department of Health, Education and Welfare.<sup>18</sup> The manufacturer must then apply to the Secretary for approval of any drug it produces.<sup>19</sup> To get such approval, the manufacturer must show that the drug is safe and reliable for its purported use.<sup>20</sup> Since 1962,<sup>21</sup> the manufacturer of a new drug has also been required to show that the drug is effective.<sup>22</sup> Approval can be withdrawn at any time based upon a finding by the Secretary that the drug is unreliable or unsafe.<sup>23</sup> While a drug is on the market, the FDA is empowered to inspect all records, papers, processes and facilities bearing on whether that drug is adulterated or misbranded.<sup>24</sup>

The FDA's authority over the manufacturer of devices is very different. The device manufacturer does not have to register with the Secretary of HEW. He is free to produce and market his device without maintaining records or proving that his device is either safe, reliable, or effective. Thus, the Secretary has no power of approval or subsequent disapproval. Further, it would appear that the device manufacturer can refuse the Secretary permission to inspect records, files, papers, processes, production control procedures, and facilities in cases of suspected adulteration or misbranding.<sup>25</sup>

By requiring registration, inspection, and the regular production reports, the FDA can insure the continuing safety and effectiveness of drugs actually sold to the public. However, regarding devices, the FDA must rely on complaints or its own discoveries before regulatory authority can be invoked. Thus, the discovery of deficient devices is not insured by the regulatory scheme. And, once the Administration's authority is triggered, it is limited to the issues of misbranding and adulteration. The Administration is foreclosed from investigating the vital questions of safety, reliability, and effectiveness.

Once the FDA decides to act against a device, it can proceed in various ways. First, it can seize one device. This single seizure is

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<sup>17</sup>21 U.S.C. § 332 (1972).

<sup>18</sup>21 U.S.C. § 360(b) (1972).

<sup>19</sup>21 U.S.C. § 355 (1972).

<sup>20</sup>21 U.S.C. § 355 (1972).

<sup>21</sup>Drug Amendments of 1962, 21 U.S.C. §§ 301; 321; 351; 355; 357 (1972).

<sup>22</sup>21 U.S.C. § 355(b) (1972).

<sup>23</sup>21 U.S.C. § 355(e) (1972).

<sup>24</sup>21 U.S.C. § 374(a)(2) (1972).

<sup>25</sup>21 U.S.C. § 374(a)(2) (1972). It should be pointed out that this result is by implication since there is a statutory void on the subject of device manufacturing.

followed by an *in rem* proceeding during which the FDA seeks to have the device declared adulterated or misbranded.<sup>26</sup> Second, after a device has been declared adulterated or misbranded and after a further hearing the FDA can secure an injunction against shipments of the device in interstate commerce.<sup>27</sup> Third, if the device creates imminent danger to health, the Administration is empowered to make unlimited seizures.<sup>28</sup> The latter power is rarely used.<sup>29</sup>

In instances where the Food and Drug Administration has seized a single device, it is prohibited by statute from seizing others until an injunction is obtained.<sup>30</sup> This provision allows the manufacturer to continue to produce and market his device in the interim, which may be a considerable length of time.

In summary, the FDA's authority over drugs greatly exceeds its authority over devices. The need for more stringent regulation of devices is clearly demonstrated by both the number of deficient devices on the market and by the very nature of the FDA medical device authority. This comparison raises the question whether improved consumer protection might be achieved by simply extending the more stringent FDA drug authority to include devices. However, before exploring the desirability of expanding the FDA's statutory authority over devices, the basic nature and general trends of the medical device industry must be considered.

### III. CHANGES IN THE MEDICAL DEVICE FIELD SINCE 1938

The complexity of the average medical device has dramatically increased since the enactment of the 1938 Amendments to the 1906 Pure Food and Drug Act. This fact has compounded the difficulties of the FDA in providing effective public protection against faulty medical devices. During and after World War II, there was a rapid advancement in the relevant technologies of metallurgy, electronic miniaturization, plastics and nuclear power.<sup>31</sup> The result has been that neither the average physician nor the informed public can properly evaluate the complex mechanical and electronic wizardry employed in such modern medical devices as heart pacemakers, kid-

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<sup>26</sup> 21 U.S.C. § 344 (1972).

<sup>27</sup> 21 U.S.C. § 332 (1972). There appears to be a conflict in the assessment of how easy it is to get this subsequent injunction after a device has been condemned. For an article pointing out the difficulty of obtaining a permanent injunction see 25 FOOD DRUG COSM. L.J. 238 (1970); for cases applying *res judicata*, see *U.S. v. 216*, more or less, of Sudden Change, 318 F.2d 817 (2d Cir. 1963); and *U.S. v. Nysco Laboratories*, 300 F.2d 550 (7th Cir. 1962).

<sup>28</sup> 21 U.S.C. § 334(a)(1)(B) (1972).

<sup>29</sup> 35 CONSUMER REP. 257 (April 1970).

<sup>30</sup> Gardner Statement, *supra* note 13, at 180-1.

<sup>31</sup> 21 U.S.C. § 334(a)(1) (1972).

ney dialysis units, surgical implants, intensive care monitoring units and other diagnostic and therapeutic instrumentation.

The materials and technology presently employed in manufacturing medical devices were not, for the most part, developed for the medical device industry but rather for defense, aerospace, and general industry. This technology, in its early stages of development, had little if any concern for biological and medical suitability.<sup>32</sup> For example, polyvinyl chloride plasticizers are in widespread use in the manufacturing of plastics. When these same plasticizers are used in the production of plastic blood bags there is a danger of introduction of toxic substances into the bloodstream.<sup>33</sup>

Because of this new technology and the resulting increase in the complexity of medical devices, the FDA cannot, as it once did, rely upon the professional opinion of the average medical practitioner as to whether or not a device works. Regarding many of these complex devices, such testimony is beyond the average physician's competency.<sup>34</sup> As a result, factual assertions that a device is misbranded or adulterated are much harder to support.

Since the 1950's the FDA has met this problem by hiring experts, sponsoring research, and assembling comprehensive factual backgrounds before prosecuting each case of misbranding or adulteration of a device.<sup>35</sup> The process is expensive and time consuming. From a policy viewpoint, it is relevant to note that the cost of protecting the consumer in this way is borne by the public rather than by the device manufacturer.

The case of the interuterine device (the IUD) highlights several of the problems lurking in the medical device field. Since there is no legal requirement for pre-market testing of devices, no conclusive studies of the effects of IUD use were carried out prior to its widespread use. Thus, although the IUD was one of the most commonly used medical devices, it was only after extensive marketing that some of its many hazards were exposed. During recent House hearings on IUD's, one physician testified:

Because of the prodigious flow of prominent distributions to physicians of reports by population planners, as well as the occurrence of friendly news articles in the lay publications American physicians in private practice appear to have unwittingly become participants in a great experiment . . . utilizing as experimental subjects patients for whom the IUD was not even the prime target for usage. Yet neither the physician nor patients have been provided sufficient facts by researchers or manufacturers to allow for any IUD to have been

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<sup>32</sup>Link, 7 MED. INSTRUMENTATION 151 (1973).

<sup>33</sup>*Id.* at 152.

<sup>34</sup>Gardner Statement, *supra* note 13, at 180-1.

<sup>35</sup>*Id.* at 181.

inserted on the basis of informed advice by the physician or informed consent by the patient.<sup>36</sup>

The hearing committee found support for the conclusion that the IUD user subjects herself to hazards ranging from hemorrhaging to cancer to fetal injury.<sup>37</sup>

The FDA responded to the problem by making widespread inquiries within the medical community. However, it was unable to issue warnings based on this investigation until 1967.<sup>38</sup> This was five years after the IUD had come into extensive use — and after some two million insertions.<sup>39</sup> This can hardly be regarded as a satisfactory means of protecting the public from unsafe medical devices.

#### IV. CASE STUDIES ON SEIZURE ACTIONS

Despite the fact that early medical devices were relatively simple and their deficiencies relatively easy to prove, the FDA began its regulation of medical devices at a very slow pace.<sup>40</sup> Statistics show, however, that the Administration has since significantly expanded its activities in regulating devices.<sup>41</sup>

However, the statistics of FDA enforcement activity cannot tell the whole story: an analysis of two judicial seizure actions also provides a basis for appraising the effectiveness of these activities in protecting the public. In the case of *United States v. Relaxacizor, Inc.*,<sup>42</sup> the defendant manufacturer sold a device that he advertised as a “girth reducer” which could be safely used without medical supervision. The device worked to “reduce girth” by means of small electric shocks that cause muscle contractions. In so activating these

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<sup>36</sup>*Hearings on Regulation of Medical Devices, (Intrauterine Contraceptive Devices) before Subcomm. on Intergovernmental Relations of the Comm. on Government Operations, 93rd Cong., 1st Sess. 11 (1973).* These hearings were not conducted in conjunction with any proposed medical device legislation but were conducted solely for the purpose of ascertaining the dangers of IUD's and looking at the present regulatory inadequacies that permit the availability of unsafe IUD's.

<sup>37</sup>*Id.* at 10. The House Committee holding these hearings pointed out studies which indicated that the hazards of IUD's include: (1) severe hemorrhaging necessitating blood transfusions or causing anemia, (2) increased incidence of ovarian or tubal pregnancies among those patients becoming pregnant while using an IUD, (3) perforations of the uterus by the IUD requiring surgical removal from the abdominal cavity, or other abnormal location, (4) infection, (5) cancer, or (6) injury to a fetus.

<sup>38</sup>Gardner Statement, *supra* note 13, at 199.

<sup>39</sup>*Id.*

<sup>40</sup>*Id.* at 198. During its first three years of policing the field (1939-41) the Administration executed only 100 seizures. During World War II, device seizures dropped to fewer than half a dozen per year. *Id.* at 180-1.

<sup>41</sup>*Id.* at 198. During the first three months of 1973, the Administration seized over 300 devices, was instrumental in the recall of more than 35 kinds of devices, and issued over 1,800 advisory opinions.

<sup>42</sup>340 Fed. Supp. 943 (C.D. Cal. 1970).

muscles, the device bypassed body pain sensation mechanisms that normally protect muscles against stress and fatigue. A federal district court, finding that the device had over sixty medically aggravating properties,<sup>43</sup> concluded:

The labeling of the Relaxacizor fails to bear adequate directions for safe use by a layman and such directions cannot be written because there are so many contraindications for its use in conditions which the user cannot evaluate and may not even be aware that he has.<sup>44</sup>

The court held that the Administration was entitled to a permanent injunction because a set of instructions could not be formulated which would adequately convey the dangers of this device to the public.<sup>45</sup>

Despite complete legal success in the prosecution of this case, other aspects of the controversy demonstrate less than effective control of defective devices. The Administration was compelled during its five year prosecution to expend over one half million dollars to effect the removal of the Relaxacizor from the market.<sup>46</sup> It is especially disturbing to note that before the injunction was finally obtained, over 400,000 of these Relaxacizors were distributed to an unsuspecting public. The number of these devices remaining in the hands of users is unknown. Some three and a half years after the judicial decision a young man in Texas was electrocuted by a Relaxacizor.<sup>47</sup>

*United States v. Diapulse Corp.*<sup>48</sup> further illustrates the cumbersome nature of the present regulatory scheme. The defendant manufacturer boasted that its machine was capable of curing 121 specific human ailments. The device was originally seized in 1966 when a Connecticut jury found that 49 of these claims were misleading or false and hence the device was misbranded. The FDA, rather than seeking an injunction, sought to have the defendant relabel the device. The FDA and the defendant failed to reach an agreement, and it was not until 1971 that the injunction was finally issued.<sup>49</sup> The efforts to get this device off the market spanned ten years; the FDA is still making seizures of the device.<sup>50</sup>

These device seizure cases indicate that even a greatly expanded

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<sup>43</sup>*Id.* at 945. These included a propensity towards creating cardiovascular complications, abnormal muscle strains, emotional effects, and skin and vascular abnormalities, to name a few.

<sup>44</sup>*Id.* at 947.

<sup>45</sup>*Id.*

<sup>46</sup>Kennedy Hearings, *supra* note 8, at 184.

<sup>47</sup>*Id.*

<sup>48</sup>457 F.2d 25 (2d Cir. 1972). See also: Helmanis, *Case Comment on U.S. v. Diapulse Corporation of America*, 8 N. ENG. L. REV. 111 (1972-3) [hereinafter cited as Helmanis].

<sup>49</sup>457 F.2d 25 (2d Cir. 1972).

<sup>50</sup>Kennedy Hearings, *supra* note 8, at 184.



enforcement program under present FDA statutory authority would not ensure public safety. High litigation costs created by expensive expert testimony, piecemeal seizures caused by incomplete regulatory authority, and the length of time involved in obtaining an injunction against defective devices all work to effect unnecessary public exposure to dangerous and ineffective devices. These deficiencies show a desperate need for change in existing Food and Drug Administration authority. A brief examination of the medical device industry is useful to an understanding of the manner in which regulation can best be tailored to the field of medical devices.

## V. THE MEDICAL DEVICE INDUSTRY

Two things become evident from surveying the medical device industry. First, there are enormous numbers of medical devices available. Second, the medical device industry is very different from the drug industry. These two factors are the dominant considerations in tailoring expansion of FDA authority over devices. They also militate against wholesale transplantation of FDA drug authority to the medical device field.

The medical device industry is now undergoing tremendous growth,<sup>51</sup> and predictions of even greater future growth have been made.<sup>52</sup> Further, medical devices profoundly affect the lives of hundreds of thousands of people. For example, an estimated 100,000 persons in this country currently have pacemakers.<sup>53</sup> In this setting, it would appear that the public welfare might best be served by strong regulation permitting removal of unsafe and ineffective de-

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<sup>51</sup>Statements by Sens. Kennedy and Nelson, Kennedy Hearings, *supra* note 8, at 3. See EXCERPTA MEDICA, § 27 for a survey of the nature and growth in the number of medical devices. (Internat. Med. Abstracting Serv., Amsterdam, Neth., pub.).

<sup>52</sup>Joseph Radzius, *The Current Status of Medical Device Legislation*, a prepared speech [unpublished] presented at the annual meeting of American College of Legal Medicine, San Francisco, California, May 5, 1973, at 2. Mr. Radzius is Food and Drug Counsel for Dow Chemical Corp.

Despite these predictions, it remains clear that few people are adequately able to speak for the entire medical industry. This is true because of the industry's variety and the lack of information on the actual extent as to the number of devices and device manufacturers. Estimations on the number of different medical devices currently on the market vary from 5,000 (Kennedy Hearings, *supra* note 8, at 2) to 100,000 (3 MED. INSTRUMENTATION 6, 193 (1969)). The estimates of the number of companies manufacturing these devices vary from 1,100 (Kennedy Hearings, *supra* note 8, at 3) to 3,000 (3 MED. INSTRUMENTATION 6, 193 (1969)). In 1971, it was estimated that medical device sales were about half those of the pharmaceutical industry with retail sales for devices totaling more than three billion dollars. (Kennedy Hearings, *supra* note 8, at 3). In 1973, a representative of the industry estimated that the annual sales of the medical device industry had increased to about six billion dollars (*Id.* at 710).

<sup>53</sup>Kennedy Hearings, *supra* note 8, at 183. Further, in the past one and a half decades, over 200,000 heart valves have been implanted (*Id.* at 710). Approximately 1.5 million artificial kidney dialyses were performed during 1973 (*Id.*).

vices from the market. However, a strong argument can be made that the public interest is better served by an opposite approach. Little or no regulation of the medical device field would permit rapid expansion, effecting a greater number of treatments and cures than might be possible under more stringent regulation.

In attempting to choose between these conflicting philosophies of regulation, a comparison of the device industry to the drug industry is again instructive. Such a comparison is summarized in the following chart.<sup>54</sup>

	<i>Drug Industry</i>	<i>Device Industry</i>
<i>Developer</i>	large	small
<i>Cost to Produce</i>	low	low to very high
<i>User</i>	patient	professional (implants or applies device to patient)
<i>Usual Life</i>	metabolized on use	long
<i>Effect</i>	subtle	apparent
<i>Technical Change</i>	rapid	very rapid
<i>Number of Users</i>	many	few

Though somewhat simplified, this comparison points out a number of factors which distinguish the drug and device industries. For example, regarding change, one problem in device development which is unknown in the drug industry is the utilization of electronics. Electronic medical devices are subject to rapid technical change and hence to rapid obsolescence.<sup>55</sup> This fact leads to problems in regulation. If these electronic devices were regulated by pre-market testing, a development lag could occur before a device is finally approved for use. The end result might be the use of outmoded medical devices when more sophisticated and effective alternatives are available.<sup>56</sup>

Another distinguishing factor is the size of the product developers. Often life saving devices are developed by an individual physician or medical technician working to save the life or improve the health of a single patient.<sup>57</sup> Such a process of development is economically difficult. Even after the idea is conceived by a health professional<sup>58</sup> and a pilot model is produced by a willing manufacturer, further testing is often conducted. Once marketed, many new devices

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<sup>54</sup> 21 J.A.M.A. 1749 (1969).

<sup>55</sup> Kennedy Hearings, *supra* note 8, at 438.

<sup>56</sup> *Id.*

<sup>57</sup> For example, hydrocephalus is a disease involving excessive pressure of cerebral spinal fluid, the fluid that circulates in and around the brain. As the disease progresses and the pressure of the fluid increases, mental retardation, and ultimately, death results. See F. NETTER, THE NERVOUS SYSTEM, CIBA COLLECTION OF MEDICAL ILLUSTRATION 102 (1968). A mechanical engineer named Holter developed a shunt to relieve this pressure and saved the life of his son. Since then, 300,000 such shunts have been used. (7 MED. INSTRUMENTATION 2, 145 (1973)).

<sup>58</sup> Kennedy Hearings, *supra* note 8, at 469 and 488.

have very small annual sales.<sup>59</sup> Arguably, stringent requirements that compel individual inventors and their manufacturers to expend great sums of money proving the safety and effectiveness of new devices may curtail the development of those medical devices with predictably small markets.

Money for research and testing is not the only hurdle that a device inventor or manufacturer might encounter. There is presently an acute shortage of experts in the medical and engineering field.<sup>60</sup> This shortage raises the question whether trained personnel would be available to test the devices, and if so, at what price.

Since smaller companies might not have the economic resources to support extensive pre-market testing or participation in a standard setting process,<sup>61</sup> one can predict that many smaller firms might be forced out of business.<sup>62</sup> The larger companies which would then remain in the medical device field might, given the higher business entry costs involved in testing and standard setting, tend to produce only those devices which could be widely marketed. Thus, devices with a small market might become unavailable. Competition might also be reduced, adversely affecting the price of surviving medical devices and supplies.<sup>63</sup>

This examination of the variety of medical devices and of the industry's methods of development thus frames a dilemma. Regulation is apt to discourage innovation and development of new and valuable medical devices. However, the price of continuous innovation is the exposure of patients and device users to the risks of defective and unreliable devices.

Possible responses to this dilemma cover a broad spectrum, ranging from no regulation to an expansion of FDA power to a level equivalent to its authority over drugs. One alternative deserving examination is the possibility of leaving device regulation in the hands of the medical profession.

## VI. THE PHYSICIAN AS THE PUBLIC PROTECTOR

Not all medical devices are used under a physician's supervision. Additionally there is some question as to the ability of physicians to supervise the use of certain medical devices and evaluate device safety.

As fellow professionals, doctors tend to resent lawyers and legal regulation.<sup>64</sup> As a result one might predict that many doctors would

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<sup>59</sup> 7 MED. INSTRUMENTATION 2, 145. For similar comments see 10 MED. WORLD NEWS 11 (1969).

<sup>60</sup> Kennedy Hearings, *supra* note 8, at 461.

<sup>61</sup> *Id.* at 441.

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> For an entertaining case on intolerance see *Rutherford v. American Medical*

resist attempts to regulate their professional judgment on the use of medical devices. A spokesman for the American Medical Association has pointed out that the application of many devices is unique to a particular individual. He urged, therefore, that the judgment on the use of devices continue to remain with the practicing physician.<sup>65</sup> An eminent Harvard Medical School professor implicitly emphasized the need for supervision of medical devices by the individual physician when he defined a "safe device" as one which ". . . is safer than the disease process for which it is used and is the best available for that purpose."<sup>66</sup>

In short, many physicians see it as their duty to make their own assessment of a patient's need and to evaluate the device's effect rather than to simply defer to strict regulatory standards. The question then becomes, can the physician be entrusted to safely carry out such a function. A study group<sup>67</sup> set up under the auspices of the Food and Drug Administration concluded in its report:

It seems likely that such acceptance [of medical devices] and much of the improper usage of devices stems largely from a lack of information on the part of many health professionals, unprepared by their training and experience to understand the principles of operation and safe usages particularly of more complicated or sophisticated instrumentation.<sup>68</sup>

This lack of training in supervising the use of more sophisticated medical devices was emphasized during recent Senate hearings when it was revealed that some doctors staunchly defend the value of devices which others regard as quack devices.<sup>69</sup>

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*Assoc., et al.*, 379 F.2d 641 (7th Cir. 1967). In a mammoth 243 page complaint, a physician charged the AMA, the FDA, and others with conspiracy to suppress innovations in medical therapy. The physician was denied an injunction.

<sup>65</sup>Statement of Richard Palmer, M.D., Board of Trustees, AMA, Kennedy Hearings, *supra* note 8, at 728.

<sup>66</sup>8 AAMI NEWS 7 (Sept.-Oct. 1973). (Official Newsletter of the Assoc. for the Advancement of Medical Instrumentation).

<sup>67</sup>THE REPORT OF THE STUDY GROUP ON MEDICAL DEVICES [COOPER REPORT] was released on September 19, 1970. The committee consisted of FDA and other federal officials, and was set up by the FDA to study the regulation of medical devices. Most of the committee's recommendations are incorporated into current proposed legislation. Therefore, the Cooper Report constitutes a very authoritative influence in the area. The most salient characteristic of the Group's recommendation is the establishment of three classes of devices: those that can be exempt from standards or pre-clearance; those that should comply with safety and performance standards; those that should be subject to pre-market testings. For definitions and discussion of these recommendations, see *infra* notes 89-98 and accompanying text.

The FDA did not respond to the author's requests for a copy of the COOPER REPORT. A copy was obtained through a special AAMI NEWSLETTER published shortly after the release of the REPORT. Cites are by necessity made to this NEWSLETTER copy.

<sup>68</sup>Special AAMI NEWSLETTER on the COOPER REPORT (Sept. 1970) at 6 [hereinafter cited as SPECIAL NEWSLETTER].

<sup>69</sup>Kennedy Hearings, *supra* note 8, at 513.

Recently, the Association for the Advancement of Medical Instrumentation surveyed medical schools to determine whether they offer courses on medical devices. It found that only twenty-seven percent of the schools offer any instruction in this area; and with few exceptions, such courses are offered solely on an elective basis.<sup>70</sup>

In light of this inadequate education<sup>71</sup> and training, it seems likely that doctors and medical personnel will remain ill-equipped to protect their patients from dangerous and ineffective devices. It would seem, therefore, that medical device regulation cannot be abandoned, even as to those devices that are utilized under a physician's care.

## VII. JUDICIAL EXPANSION OF FDA AUTHORITY OVER DEVICES

The courts have recognized both the critical importance medical devices have in this country's health care system and the deficiencies of the present regulatory scheme. The result has been a tendency toward liberal interpretation of FDA statutory authority over devices.<sup>72</sup> The most daring judicial attempts at expansion have involved the conclusion that some devices, by their nature, can be regulated under the more comprehensive<sup>73</sup> FDA drug authority.

The central question in such cases hinges on whether an article will be classified as a device or as a drug. A drug is defined statutorily as follows:

The term 'drug' means (A) articles recognized in the Official United States Pharmacopia, Official Homeopathic Pharmacopia of the United States, or Official National Formulary or any supplements to them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases in man or other animals; and (C) articles (other than food) intended to affect the structure or function of the body of man or other animals and 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.<sup>74</sup>

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<sup>70</sup> 8 AAMI NEWS 7 (Sept.-Oct. 1973).

<sup>71</sup> This is a recommendation of the COOPER REPORT, SPECIAL NEWSLETTER, *supra* note 68, at 5.

<sup>72</sup> *E.g.*, in *United States v. Diapulse Corp.*, 457 F.2d 25 (2d Cir. 1972), the court held that mislabeling or adulteration did not have to be harmful to the public in order that there be a violation of the Act. In *Diapulse*, the court predicated the lifting of an injunction upon FDA approval of Diapulse's labeling. This was tantamount to pre-clearance — which Diapulse pointed out was not provided for under the statutes. The court overruled Diapulse's objection, and held that FDA approval prior to the marketing of the device was authorized under the court's broad equitable powers of injunction. In *United States v. Ellis Research Laboratories*, 300 F.2d 550 (7th Cir. 1962), the court held that a device had to be properly labeled even if it was to be used solely by a licensed practitioner.

<sup>73</sup> See note 8-32 *supra* and accompanying text.

<sup>74</sup> 21 U.S.C. § 321(g) (1972).

A device is statutorily defined as follows:

The term 'device' . . . means instruments, apparatus, and contrivances, including their components, parts and accessories intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure of any function of the body of man or other animals.<sup>75</sup>

Thus the definition of drugs is mutually exclusive of that of devices. Further, the meaning of the statutory definition of "device" seems plain. However, this plain meaning has been rejected in cases where the judiciary desired to subject devices to the more rigorous regulation applying to drugs.

Such was the result in the case of *AMP, Inc. v. John Gardener*<sup>76</sup> where the court was asked to classify a nylon ligature loop and nylon locking disk, used in permanently tying off blood vessels severed during surgery.<sup>77</sup> The Second Circuit affirmed the district court's<sup>78</sup> holding as the basis that concern for the toxicity and carcinogenic effect of the nylon left in the patient's body brought the article within the statutory ambit of drug regulation. Therefore, as prescribed by the drug statutes, the article would have to be shown safe and effective before marketing.<sup>79</sup> Hence, the summary judgment of the district court was affirmed on the grounds that the "drug" was not generally recognized among experts as safe and effective under the conditions of intended use, as required by drug regulations.

The distinction between drug and device arose again in the 1968 United States Supreme Court decision of *United States v. An Article of Drug \*\*\*\*\* Backto-Unidisk*.<sup>80</sup> There, the product consisted of a sensitized disk upon which a blood sample was placed. The purpose of this procedure was to determine which of several antibiotics would be best suited to a patient's needs. The Sixth Circuit Court of

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<sup>75</sup> 21 U.S.C. § 321(h) (1972). For a more comprehensive treatment of what constitutes a device, see H. TOULMIN, A TREATISE ON LAW OF FOODS, DRUGS AND COSMETICS, 617 (2d ed. 1963). Toulmin generally points out that articles not intended for therapeutic use, such as athletic supporters, rubber nipples, shaving brushes, and materials used in taking dental impressions, are exempt from device classifications. Examples of court determinations of device classifications include: *United States v. 23, more or less, Articles*, 192 F.2d 308 (2d Cir. 1951) (Sleep inducing records classified as devices); *Gelman v. United States*, 159 F.2d 881 (8th Cir. 1947) (Prophylactics classified as devices); *Orthopedic Equipment Co., Inc. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960) (Surgical nails held to be devices); *United States v. One Device Intended for Use as a Colonic Irrigator*, 160 F.2d 194 (10th Cir. 1947) (Colonic irrigators held to be devices).

<sup>76</sup> 389 F.2d 825 (2d Cir. 1968).

<sup>77</sup> In practice, the nylon loop is placed around the severed vessel, the locking disk is attached, and the excess nylon is cut off. The nylon suture and disk remain in the patient's body.

<sup>78</sup> 275 F. Supp. 410 (S.D.N.Y. 1967).

<sup>79</sup> 389 F.2d at 827 (2d Cir. 1968).

<sup>80</sup> 394 U.S. 784, *reh. denied*, 395 U.S. 954 (1969).

Appeals concluded that it would be "ridiculous and contrary to common sense" to conclude that this article is a drug.<sup>81</sup> The United States Supreme Court reversed.

The Supreme Court declined to inquire whether the classification of these discs as drugs was medically wise. Instead it inquired whether the characterization was legally allowable under the act's definition of drugs.<sup>82</sup> The framing of the question in this fashion indicates a policy disposition of the Court in favor of regulation. However, the Court went further and extended regulation by examining the Congressional intent underlying the definitions of drug and device. The court "found" this intent in Congressional discussion dating from the early 1930's, well before the 1938 Amendments first mentioned the word "device." The Court concluded:

Thus, it is clear that two parallel definitions were provided for semantic reasons only; for the purposes of the Act, the two definitions had the same effect of subjecting both drugs and devices to the adulteration and misbranding provisions. No practical significance to this distinction arose until the pre-market clearance provisions . . . were added after a drug tragedy in the fall of 1937.<sup>83</sup>

The Supreme Court further concluded that the language of the statute was of little assistance in determining the precise difference between a drug and device. Regarding the discs, the court said:

. . . Since the patient will tend to derive less benefit from a particular antibiotic if, though the antibiotic itself was properly batch tested, it was not the proper antibiotic to use, it was entirely reasonable for the Secretary to determine that the discs, like the antibiotics they serve, are drugs and similarly subject to pre-clearance certification . . . An opposite conclusion might undercut the value of testing the antibiotics themselves, for such testing would be a useless exercise if the wrong drug were ultimately administered even partially as the result of an unreliable disc.<sup>84</sup>

Clearly the Supreme Court was looking beyond the plain meaning of the statute defining devices and drugs to the consequences of classifying the disks as devices. While this concern with assuring safety in antibiotic treatments is entirely defensible, the *Backto-Unidisk* decision has created confusion as to whether an article is to be considered a device or a drug. This uncertainty is particularly unnecessary and unjustified in the case of articles which have a less critical effect on health.

Both of the above cases have been criticized by medical device industry spokesmen who are now uncertain as to whether their prod-

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<sup>81</sup> 392 F.2d 21 (6th Cir. 1968).

<sup>82</sup> 394 U.S. at 793-4 (1969).

<sup>83</sup> 394 U.S. at 797-8 (1969).

<sup>84</sup> 394 U.S. at 799 (1969).

ucts are devices or drugs.<sup>85</sup> No longer can manufacturers merely determine whether their article is an "instrument, apparatus, or contrivance" and thereby be assured by the language of the statute that the product will be exempt from the strict drug regulatory authority of the FDA. Now, the manufacturer must try to guess whether the instrument, apparatus, or contrivance might be appropriately dealt with under the drug classification.

The Acting Commissioner of the Food and Drug Administration has stated, however, that the administrative burden of handling all devices under the new drug provisions of the act would be overwhelming. This burden is attributable to two factors: first, many devices are not amenable to drug regulation; second, much more legislative authority and funding would have to be made available.<sup>86</sup>

In summary, the policy underlying these decisions is beneficial in that it protects the public from deficient and harmful devices. Further, the decisions are logical on a purely pragmatic level: articles implanted in the human body which are apt to have toxic or carcinogenic effects bear many similarities to drugs. Therefore, testings and regulation of such articles as drugs would seem appropriate. Finally, articles that determine which drug is to be used share many of the dangers of deficient, unreliable, or unsafe drugs.

However, as noted above, the price has been a profound confusion in the regulated industry. Therefore, though these cases express a laudable policy judgment, they also emphasize the need for Congress to revise its statutes on device regulation in order to eliminate unproductive and unnecessary uncertainty.

### VIII. ALTERNATIVES IN THE REGULATION OF MEDICAL DEVICES

Because the medical device industry is far from uniform in many respects, it is improbable that any one alternative in the regulation of medical devices can effectively and uniformly regulate the whole industry. The size of manufacturers varies from large corporations to individual physicians. Devices vary from simple non-mechanical contrivances to extremely complex electronic machines. While some devices are critical to life, others have little effect on a person's health.

These problems are compounded by the fact that adequate information on the exact nature of the medical device industry is not

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<sup>85</sup>Radzius, *The Federal Food, Drug and Cosmetic Act — Drug or Device?* 8 WAKE FOR. L. REV. 527 (1971-2); more generally see: Weitzman, *Drug, Device, Cosmetic?* FOOD, DRUG & COSM. L.J. 226 (1969); Styn, *A Dichotomy in Consumer Protection . . . The Drug Device Definition Dilemma*, 44 IND. L.J. 503 (1968-9)

<sup>86</sup>See Gardner Statement, *supra* note 13, at 200. A major FDA expansion has been in the promulgation of new regulations on "In Vitro Diagnostic Products for Human Use." See 37 FED. REG. 16613 (1972).



available. Not until late in 1973 were the first Congressional hearings directed to the subject of medical device regulation, and only two days of testimony were held.<sup>87</sup> Nevertheless, many suggestions for the regulation of the medical device industry have been proposed, and several deserve examination.

The first legislative proposal would defer the problem for five years while a commission studies manufacturing procedures for medical devices and determines the extent of necessary federal regulation. A bill to this effect has been introduced during each recent Session of Congress. However, each Session, the bill has died in committee.<sup>88</sup>

Another alternative would impose mandatory pre-clearance procedures. These pre-clearance procedures would require a showing of safety and reliability of all devices not generally recognized by qualified medical experts as safe and reliable.<sup>89</sup> The terms of this proposal are similar to current drug pre-clearance provisions discussed above.<sup>90</sup>

A third proposal would allow some devices to be sold only by prescription and to be used only under the direct supervision of a physician.<sup>91</sup> This would encourage unencumbered innovation in the medical device field by making custom devices, tailored to an individual patient's need, more readily available.<sup>92</sup> However, this proposal would limit the availability of devices to those persons who seek a physician's care. Since there would be no additional FDA regulation of these devices, the patient's primary protection would be the deterrent effect of negligence actions.<sup>93</sup>

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<sup>87</sup>Reference is to Kennedy Hearings, *supra* note 8. House hearings were held subsequently on October 23 and 24, 1973. These hearings were for four bills then before the House of Representatives. There is a noticeable lack of testimony, however. See *Hearings on Medical Devices, Before the Subcomm. on Public Health and Environment of the House Comm. on Interstate and Foreign Commerce*, 93rd Cong., 1st Sess. (1973) [hereinafter cited as *House Hearings*].

<sup>88</sup>See H.R. 539, 93rd Cong., 1st Sess. (1973); H.R. 539 was one of the four bills investigated in the *House Hearings*, *supra* note 87, but it has not at the date of this writing been reported out of committee. In view of passage of S. 2368 on February 1, 1974, the likelihood of this bill again dying in committee seems great.

<sup>89</sup>See H.R. 6073, 93rd Cong., 1st Sess. (1973).

<sup>90</sup>See *supra* notes 18-31 and accompanying text. It also has to be pointed out that it is uncertain what effect this would have on the growth of the medical device industry, particularly on the small medical device manufacturer who cannot finance pre-market testings. See *supra* notes 58-64 and accompanying text.

<sup>91</sup>See S. 2368, 93rd Cong., 1st Sess. § 513(1) (1973).

<sup>92</sup>In the analogous drug field, a physician is free to prescribe a drug for any purpose that he wishes. However, this fact has been assailed as giving physicians too much control over the safety of their patients. See 120 CONG. REC. 1050 (daily ed. Feb. 1, 1974).

<sup>93</sup>Swartz, *Product Liability: Manufacturer's Responsibility for Defective or Neg-*

A fourth alternative calls for the FDA to promulgate standards for devices, either on its own or in cooperation with industry representatives. "Performance standards"<sup>94</sup> would be limited to characteristics of the device effecting safety and effectiveness. More stringent standards would relate to composition, construction, properties, and uniform identification of medical devices.<sup>95</sup> This scheme raises the problem of the time necessary to promulgate relevant standards. Further, standards, if set merely for the sake of regulation, have the potential of stifling innovation. Standards might be especially harmful to new devices susceptible to rapid obsolescence since the device could be obsolete by the time applicable standards are developed.

Other suggestions for the regulation of medical devices include FDA regulations requiring the repair or replacement of devices that fail to meet performance standards,<sup>96</sup> requirements for official names,<sup>97</sup> and administratively prescribed good manufacturing practices that would regulate not the device but the process of manufacture.<sup>98</sup>

### IX. THE FUTURE OF MEDICAL DEVICE LEGISLATION

It is often true that legislation can be compelled only by tragedy. This has certainly been the history of the legislative authority of the Federal Food and Drug Administration. The original 1906 Pure Food and Drug Act<sup>99</sup> was motivated by Upton Sinclair's *The Jungle*, dealing with the shocking conditions in the meat packing industry. It was not until 1938, after 107 persons were killed by the synergistic poisonous effects of the drug Elixir of Sulfanilamide<sup>100</sup> that the Administration's authority was again increased. Before the 1962 Kefauver-Harris Drug Amendments,<sup>101</sup> public interest in drug regulation was aroused by the malformation of thousands of babies in Western Europe as the result of the maternal use of the drug Thalidomide.<sup>102</sup>

In the field of medical devices, there is no perceptible dramatic

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*lightly Designed Medical and Surgical Instruments*, 18 DE PAUL L. REV. 348 (1968-69); see also *South Highlands Infirmary v. Camp*, 279 Ala. 1, 180 So. 2d 904 (1965).

<sup>94</sup>120 CONG. REC. 1047-8 (daily ed. Feb. 1, 1974) (Comments by Committee on § 513).

<sup>95</sup>Statement by President of Medical Surgical Manufacturers Assn., Kennedy Hearings, *supra* note 8, at 483.

<sup>96</sup>120 CONG. REC. 1042-3 (daily ed. Feb. 1, 1973) (Provisions of § 515 of S. 2368).

<sup>97</sup>120 CONG. REC. 1043 (daily ed. Feb. 1, 1973) (Provisions of § 502 of S. 2369).

<sup>98</sup>*Id.* (Provisions of § 501(g) of S.2368).

<sup>99</sup>Pure Food and Drug Act, *supra* note 9.

<sup>100</sup>C. Dunn, FEDERAL FOOD, DRUG AND COSMETIC ACT, 1316-27 (1938) (Reprint of Report of the Secretary of Agriculture on Deaths Due to Elixir of Sulfanilamide).

<sup>101</sup>Drug Amendments of 1962, *supra* note 21.

<sup>102</sup>Helmanis, *supra* note 48, at 528.

crisis at hand. However, this article has attempted to show that a definite problem exists.

It must be concluded that the medical device industry, because of its variety and its rapid growth, is very difficult to regulate. But that fact cannot justify the lack of registration procedures for device manufacturers; nor can it justify the absence of any requirement of device registration; nor can it justify the absence of FDA power to inspect the records of device manufacturers and to require reports from these same manufacturers. Such measures, even under the present limited authority of misbranding and adulteration, would do much to insure public safety.

Congress, in 1974, has come a record distance in approaching the job of revising legislation on medical devices.<sup>103</sup> Revision is past due. But because of the complexity of the medical device industry and the prospect for rapid change in the future, periodic re-evaluation of the problem will be necessary in order that we might have new and innovative medical devices without sacrificing public safety.

The following inquiries could serve as relevant guides to the evaluation of future medical device legislation: (1) Does the legislation effectively distinguish between drugs and devices? Inherent differences in the drug and device industries lead to the conclusion that they must be regulated differently; (2) How has medical device legislation affected the growth of the medical device industry? Has innovation been stifled? The public welfare is as much benefited by the introduction of new devices as by the elimination of unsafe, unreliable, and ineffective devices; (3) What is the impact of new legislation on the amount of information that appears on labeling and directions? A maximum disclosure of this information, insuring the intelligent use of devices, should be required before marketing; (4) Does the legislation encourage the training of doctors and health personnel in the use and understanding of medical devices? This training is the only way that the public can be protected from dangers that might be found in custom or prescription devices.

Medical devices figure in a vital portion of this country's health care and it is necessary that the deficiencies of the Food and Drug

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<sup>103</sup> On February 1, 1973, the Senate passed S. 2368. This bill by any account was very substantial in its increase in FDA authority over medical devices. Some of the provisions include medical device pre-clearance, standards, custom device exceptions, strengthening of report requirements to government of defective devices, regulation of medical device advertisements, and provisions for agreed-upon labels for medical devices. For passage of S. 2368, *see* 120 CONG. REC. 1035 (daily ed. Feb. 1, 1974). As of the date of this article, the House has not reported a medical device bill. For bills before the House, *see* STAFF OF SUBCOMM. ON PUBLIC HEALTH AND ENVIRONMENT OF THE HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, 93rd Cong., 1st Sess., MEDICAL DEVICE LEGISLATION INTRODUCED IN THE 93RD CONG. This document has a section by section comparison of some of the House bills.

Administration's authority over these devices be immediately remedied. At present, the FDA represents the most practical way to protect the public and guide the physician in the use of medical devices. However, in the long run the complexities of the medical device industry will require complex solutions. It is unrealistic to hope for a faultless regulatory scheme from the outset. To optimize the quality of health care it will be necessary to continually evaluate existing medical device legislation. Hopefully, there will be sufficient residual public interest to encourage continuing re-evaluation without the historic catalyst of tragedy.

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