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MEDICAL DEVICE REGULATION: THE FDA'S NEGLECTED CHILD

An Oversight Report on FDA Implementation of the Medical Device Amendments of 1976.

REPORT

OF THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS.

OF THE

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

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COMMITTEE ON ENERGY AND COMMERCE,
Washington, D.C., April 29, 1983.

LETTER OF TRANSMITTAL

TO MEMBERS, COMMITTEE ON ENERGY AND COMMERCE.

DEAR COLLEAGUE: The hearings of the Subcommittee on Oversight and Investigations on July 16, 1982, marked the first congressional review of the Food and Drug Administration's implementation of the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act. That hearing record, together with other information developed by the staff relating to the FDA's medical device regulatory performance, paint a picture of bureaucratic neglect for public health and safety that shocks the conscience.

The Medical Device Amendments of 1976 were, and indeed remain, unique in health and safety legislation. They address the need to assure public protection from improperly manufactured or dangerously used products covering the entire spectrum of imaginable complexity from Band-Aids and tongue depressors to dialysis machines and artificial hearts. The device amendments take a creative approach; they vest authority in FDA to treat medical devices as rigorously as their individual characteristics warrant. They rest on the simple philosophy that devices should be regulated only as intensively as necessary to protect public health. For some devices, this means the full panoply of premarket review in a process akin to that for a new drug. For some, this means a requirement to meet objective performance standards that assure safety and efficacy. And for the remainder, this means simply that their manufacturing adhere to well accepted principles of quality control.

Reflecting what the subcommittee can only regard as a cavalier disregard for the potential consequences, the FDA has barely begun to implement the provisions of the law. It has not even completed the process of classifying devices so that the staggered system of regulatory controls that lies at the heart of the law can take hold. And even as to those devices that have been finally classified, the agency virtually refuses to do what the law commands. Not a single performance standard for a class II medical device has been established—not a single proceeding even to develop such a standard has been commenced. The FDA has chosen to reserve rigorous premarketing regulatory controls only for recently developed—post 1976—class III devices, the most risk-laden, while it ignores the facts that scores of these class III devices, marketed before 1976, are now in widespread use and that their manufacturers have never been required to demonstrate their

safety or efficacy. The totally unacceptable result of these defaults is that the FDA is regulating many of the most risk-laden devices as if they were the least risky, that is, the agency is treating pacemakers virtually as if they were tongue depressors.

Perhaps the agency's most disturbing default of all—and the one that provokes the most anxiety about its consequences—is its failure to move forward with a requirement that manufacturers inform the FDA when their devices kill, injure, or lead to some other adverse experience. As a result, neither the FDA nor the public knows today how dangerous medical devices are, and we as legislators lack an adequate basis to decide whether the device amendments and their regulatory system are adequate to the task of protecting the public. It is the subcommittee's earnest hope that—after almost 7 years—the FDA and responsible officials in the executive branch will expedite the development and approval of an adequate mandatory adverse device experience reporting system.

The report also discusses the effects on device regulation of the Reagan administration's increased emphasis on cost-benefit analysis and cost-effectiveness. I believe the subcommittee's record demonstrates the risks to health and safety associated with this increased emphasis, which is embodied in this administration's regulatory relief program.

The FDA's derelictions in the device area have not been confined to the failure to implement the law. Included within the report are four case studies of regulatory timidity which make the distressing point that the agency lacks the fortitude to take strong, rapid action in the public interest. These examples include, most notably, the FDA's failure to recommend the criminal prosecution of Baxter-Travenol Laboratories, Inc., which submitted false information to the FDA about a device which it knew to be defective and which it, despite that knowledge, proceeded to mass market.

This will not be the last subcommittee review of medical device regulation. It is our intention to monitor closely the work of the new administration heading the Bureau of Medical Devices and to assure that they are called to account for their progress in reversing the dismal record of their predecessors. The American people, who rely upon their health officials for the protection to which the public are entitled, will not accept less.

Sincerely,

JOHN D. DINGELL, *Chairman,*
Subcommittee on Oversight and Investigations.

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MEDICAL DEVICE REGULATION: THE FDA'S NEGLECTED CHILD

I. Introduction

In this report, the Subcommittee on Oversight and Investigations reviews the implementation by the Food and Drug Administration [FDA] of the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act.[1] The subcommittee's July 16, 1982 hearing—the first congressional oversight inquiry since enactment of the device amendments—and the accompanying investigation have revealed that the agency, in numerous respects, has failed to enforce the new device law effectively and efficiently since its enactment in 1976.

The device amendments represent a complex, novel approach to regulation. They frequently specify in considerable detail steps to be taken by the agency in pursuit of regulation, and it can fairly be said that the FDA was entitled to a reasonable period of time to get its feet wet. But that time has passed. And a review of the agency's performance over the 6 years since passage of the device amendments compels the conclusion that it has not been diligent. The array of products involved here is far too broad, and congressional recognition of the risks to public health has been far too explicit, to countenance the agency's failure to implement central provisions of the device amendments. As a consequence of that failure, the public has been exposed to unnecessary risks with, as yet, unknown consequences.

From bedpans to brainscans, the medical device industry supplies the American health care system with a staggering variety of products. Entries cover the entire spectrum of imaginable complexity from Band-Aids and tongue depressers, to artificial limbs, joints, and other prosthetics, to diagnostic tests, to dialysis machines, pacemakers, and other life-support systems, and, soon, to artificial hearts. In all, the American public is blessed with over 1,700 different types of medical devices, produced in over 7,000 different establishments which turn out over 41,000 separate products.

Prior to enactment of the medical device amendments, both the regulators at FDA and the regulated community operated under a regulatory nightmare for all concerned. Companies could never be sure what their obligations were under existing laws. The public knew that the Government was unable to maintain control over the safety and efficacy of numerous health care products in daily use. And the FDA knew its authority to monitor and regulate the flow of medical devices was ambiguous and constantly subject to legal attack.

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[1] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq. (1938), as amended, Pub. L. 94-295 (May 28, 1976). Hereinafter referred to as the device amendments.

Until 1976, the FDA had no distinct authority to regulate the entry of medical devices into the stream of interstate commerce. The agency was authorized to enjoin the further sale of adulterated or misbranded devices and to remove them from the market through its seizure powers. But it could not take steps to ensure that devices were safe and effective before they were marketed except in those circumstances where the agency was prepared to convince a court that the device was a drug within the meaning of the Food, Drug, and Cosmetic Act.[2]

The increasing willingness of the courts to construe the Act broadly, thus permitting the agency to subject new medical devices to the full panoply of premarket clearance reserved for new drugs, coupled with reports of adverse experience with medical devices already on the market, created a climate for change. Throughout the early 1970's, legislation was introduced in both Houses of Congress to establish separate authority for the control of medical devices. This effort culiminated in 1976 with the enactment of the Medical Device Amendments.

The device amendments vested authority in the FDA to treat medical devices as rigorously as their individual characteristics warranted. A three-tiered classification scheme was designed to stratify the industry's output into a regulatory system of measured intensity: the least rigorous controls were reserved for the least risky devices, and so forth. The philosophy reflected in the device amendments' central provisions was simply that medical devices should be regulated only as intensively as necessary to protect public health. For some, this meant a full premarket review process akin to that applicable to new drugs. For others, this meant a requirement to meet standards of performance setting levels of device manufacture and functioning that would insure safe, effective use. For the remainder, this meant simply adherence to procedures in their manufacture that reflected widely accepted principles of quality control.

Six years have passed since the device amendments were enacted. For over 2 years—mid-1980 to mid-1982—FDA's Bureau of Medical Devices had no permanent Director and did not command the attention of the agency's management. The questionable quality of much of the Bureau's work led to a system where the ageny's chief counsel in advance had to review and approve virtually everything the Bureau produced for public dissemination. The number of substantive steps to implement the device amendments accomplished by the Bureau were extremely few. Until recently, the absence of congressional oversight permitted the agency to continue to drag its feet in, or to avoid altogether, implementing the basics of the regulatory system that lies at heart of the device amendments.

This is not to say that implementation of the device amendments should have been easy—or even that it necessarily should have been completed by now. But, the subcommittee does find major fault with the agency's failure to advise the Congress of the considerable difficulties it has apparently experienced in attempting to carry out its legislative mandate in a timely fashion. We cannot now ascertain

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[2] 21 U.S.C. 321(g). See, generally, *U.S.* v. *Bacto-Unidisk*, 394 U.S. 784 (1969); *AMP* v. *Gardner*, 389 F. 2d 825 (2d Cir. 1968), *cert. denied*, 383 U.S. 825 (1968).

the extent to which the agency's poor record has resulted from poor management or from a statutory scheme that has proved more difficult to administer than anticipated. But the conclusion is inescapable that, had the agency attached priority to the work of the Bureau of Medical Devices, that organization would not now find itself in the disrepair in which it lies.

On July 16, 1982, the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce held the first hearings since the passage of the 1976 device amendments to review their implementation and functioning. Testimony was received from the Commissioner of FDA, Arthur Hull Hayes, Jr., M.D.; the Acting Director of the Bureau of Medical Devices, Victor M. Zafra; and the Chief Counsel of FDA, Thomas Scarlett, Esq. Testimony was also received from Sidney M. Wolfe, director of the Health Research Group, a nonprofit health-oriented public interest organization.

In the month preceding the hearing, and with full knowledge of their imminence, the agency announced the appointment of the first permaent Bureau Director since early 1980. It also decided to merge the Bureaus of Medical Devices and Radiological Health, and it recommended to Congress, for the first time since 1976, changes in the device amendments to facilitate their implementation. Thus, even before it was held, the hearing produced results. But as Chairman Dingell stated at the opening of the hearing, and as the record of the subcommittee's investigation reveals about the past 6 years of medical device regulation, piecemeal legislative modifications and organizational shell games are not enough:

> [T]his committee will be less than impressed with a recent flurry of organizational restructuring and submission of legislative proposals in response to our inquiry. Such activity will not be accepted by this chairman or this Committee as a substitute for the full and faithful execution of the law.[3]

Based on the hearing record and other sources, this report reviews the work of the Bureau of Medical Devices in several important respects. It commences with a brief overview of the major provisions of the Device Amendments of 1976 and the agency's actions to date. Thereafter, report sections address (1) the agency's major failures regarding the treatment of class II and III devices and regarding the need for reliable data on adverse experiences with medical devices; (2) the regulatory issues raised by user-related, as opposed to manufacturer-related, device problems; (3) the 510(k) [4] process by which virtually all new medical devices are marketed; (4) a series of four specific case studies in regulatory timidity which assess the performance of the Bureau of Medical Devices and the agency in protecting the public; (5) the effect of the Reagan administration's program for regulatory relief on the regulation of medical devices; and (6) a review of the device industry's recent performance and its perceptions of Federal regulation as indicated by a recent FDA-sponsored national survey of medical device manufacturers.

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[3] "FDA Oversight: Medical Devices", hearings before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, 97th Congress, 2d Session, July 16, 1982, Serial No. 97-144 (hereinafter cited as Hearings) at p. 2.

[4] 21 U.S.C., sec. 360(k).

II. Summary of Findings, Conclusions, and Recommendations

1. Through negligence, or by intention, the FDA has failed to implement major provisions of the medical device amendments to the Food, Drug, and Cosmetic Act:

(a) The agency has lost control of the medical device classification process, failing to complete in 6 years major tasks for which Congress allocated 1 year.

(b) The agency has not even begun to develop standards to assure the safe, effective performance of class II devices.

(c) The agency has not required manufacturers of "old" class III devices to submit premarket approval applications.

(d) The agency has adopted no valid, reliable adverse experience reporting system to inform the agency of device-related deaths, injuries, or device defects.

(e) The agency has used its significant new authority to notify professionals and users of devices of risks of harm a mere three times in 6 years, and it has used its authority to order repair, replacement, or refund but once.

2. The FDA is relying almost exclusively on "General Controls" to regulate devices when it previously determined that such general controls were inadequate.

3. As a consequence, the FDA is not equipped and, therefore, is unable to assure the American public that many medical devices currently on the market—and relied upon to treat disease and to sustain life—are safe and effective.

4. By failing to "restrict" devices in order to address problems caused through their misuse by inappropriately trained persons or in poorly equipped facilities, the FDA has failed to deal with the most frequent source of device-related injuries.

5. The FDA seriously compromised the credibility of its law enforcement deterrent when, having found clear violations of law, it failed to recommend meaningful prosecutive action promptly and vigorously.

(a) In the case involving Baxter-Travenol, the agency failed to recommend prosecution for the intentional submission of false information in a report required to be submitted to the Government.

(b) In the cases involving Bausch & Lomb and Wesley-Jessen, the agency, after making repeated, unequivocal public announcements of its position, delayed recommending prosecution against two companies, which openly defied the agency's admonitions not to market certain bifocal soft contact lenses without prior FDA approval. The remainder of the industry sought such approval and was thereby greatly prejudiced by its adherence to governmental pronouncements that apparently did not represent a position the Government was prepared to enforce.

6. The FDA's delay in down-classifying certain soft contact lens materials out of class III has perpetuated the monopoly profits of the few firms that hold FDA approval to market these materials. It has prevented others from entering the market and competing on price.

And it has, therefore, allowed prices for these devices to remain artificially high.

7. Although the agency recognizes that tampon absorbency is related to the risk of toxic shock syndrome, the FDA has established no performance standards for tampons (a class II device). Consumers are therefore unable, except through their own experimentation, to compare tampon brands on the basis of absorbency.

LEGISLATIVE RECOMMENDATIONS

As Chairman Dingell made clear at the commencement of the July 16 oversight hearing, legislative modifications will not substitute for full and faithful execution of the law. Indeed, the subcommittee uncovered no evidence that calls into question the essential soundness of the measured regulatory system that lies at the core of the device amendments. What was revealed instead was an astounding lack of action on the part of the Federal agency charged with implementing that system and thereby protecting the public health. To say that the subcommittee recommends that the device amendments be implemented as written would be too mild. The subcommittee, as elected representatives of the American people, demands it.

This is not to say that specific, narrowly crafted legislative proposals aimed at streamlining certain aspects of the regulatory process would be inappropriate. But the subcommittee is concerned that any proposal to streamline a process that has not even begun may be misdirected. The system must be tried before areas for improvement can be identified. Despite these misgivings, the subcommittee does believe that congressional attention may legitimately be directed to the problem presented by the agency's classification of most medical devices into class II, requiring the promulgation of over 1,000 separate performance standards. Accomplishment of that task, according to any procedure no matter how streamlined, is a practical impossibility. The subcommittee, therefore, recommends that consideration be given to alternatives that recognize that although devices placed into class II may pose significant risks to health, with respect to some devices those risks may be addressed by a species of controls less comprehensive than the mandatory performance standards now required by section 514.[5]

III. The Device Amendments—an Overview

A. DEVICE CLASSIFICATION—SECTION 513

The amendments create a three-tiered classification system of ascending stringency into which all medical devices must fit. Class I is reserved for the least risk-laden devices. Regulatory controls for these devices are general in scope and do not, as a rule, involve device-specific requirements. Class II is reserved for devices to which the general controls apply, but which need more to assure their safety and efficacy. Performance standards establishing levels of device functioning, labeling and other features are necessary. Class III is reserved

[5] This recommendation is discussed more fully at pp. 17–18 infra.

for the most risk-laden devices, which are subject to the general controls and which are also required to undergo a review of safety and efficacy akin to that for new drugs prior to marketing.

This statutory scheme grew from a 1970 recommendation for a staggered regulatory system by the Cooper committee, the Study Group on Medical Devices convened by the Assistant Secretary for Health, Education, and Welfare.[6] Formation of the study group was announced in a message from President Nixon to the Congress on Oct. 30, 1969, in which the President affirmed his support for minimum standards for medical devices and premarket clearance in appropriate cases.

Classification is accomplished pursuant to section 513 of the act. Although final responsibility rests with the Secretary of Health and Human Services, the Secretary is required to obtain the classification recommendations of panels of experts constituted according to sections 513 (b) and (c).[7] Congress knew that the FDA had already begun to implement the Cooper committee recommendations regarding classification prior to enactment of the device amendments. It therefore provided that the panels were to submit within 1 year thereafter their recommendations respecting *all* devices on the market prior to the date of enactment of the device amendments.[8]

The 1 year time limit (with final agency action presumably soon thereafter) appeared reasonable in light of the fact that the FDA had begun classifying devices soon after issuance of the Cooper committee report. It surveyed the industry in 1970–71 and had a list of 1,100 manufacturers and over 8,000 products. It divided the devices into categories (similar to those extant today) and enlisted fourteen advisory panels to review the available evidence. The panels had completed their review and made classification recommendations on all known devices on the market prior to enactment of the device amendments.[9] Thereafter, all Congress envisioned was the reconvening of these panels and the review of their original classifications in light of the statutorily defined classification criteria that were compatible with, though not identical to, the criteria originally used.[10]

The significance of the 1 year timeframe for final recommendations was never grasped by the agency.[11] During testimony at the July 16, 1982 oversight hearing—over 5 years after the deadline had passed—Commissioner Hayes stated that he was pleased to report that we are

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[6] The Cooper committee report is titled "Medical Devices: A Legislative Plan". Study Group on Medical Devices, Department of Health, Education, and Welfare, September 1970. The findings of the Cooper Committee were considered by the drafters of the device amendments and reflected in the legislation to a significant degree. See, for example, Medical Device Amendments of 1976, Report by the Committee on Interstate and Foreign Commerce, House Rept. No. 94–853, 94th Cong., 2d Sess. 9–12, 34 (1976). The House Commerce Committee report will be referred to extensively throughout this document as House report.

[7] Pursuant to 21 CFR, sec. 5.10, the Secretary has delegated (through the Assistant Secretary for Health) his authority over all functions under the Food, Drug, and Cosmetic Act to the Commissioner of Food and Drugs. (21 CFR, sec. 5.10(a)(1)). The delegation, until recently, included blanket authority to issue all regulations of FDA. (21 CFR, sec. 5.10(a)(15)). Former HHS Secretary Schweiker reserved his authority to review certain regulations which establish procedural rules applicable to a general class of products subject to regulation or which present highly significant public issues involving the quality, availability, marketability or cost of products subject to regulation. (21 CFR, sec. 5.11(a)). 46 F.R. 26025, 26300. (May 1981)

[8] Section 513(c)(3).

[9] House report, supra, note 6, p. 11.

[10] Id., p. 39.

[11] It took the agency 2 years just to promulgate the regulations prescribing the classification process that were required by section 513(c)(1). See 21 CFR, part 860 (42 F.R. 32993, July 28, 1978).

about three-quarters of the way through classification.[12] He anticipated that the process would finally be completed during the first half of calendar 1983. Of the 1,700 categories of medical devices involved in the process, only about 800 have been finally classified to date. The remaining 900 classifications have been proposed for comment. The agency's sluggish approach has had far-reaching consequences. Unclassified devices cannot be regulated according to the device amendments' three-tiered system. The delay has no doubt also deflected significant resources from other important device regulation priorities which, in part, may explain why the agency has not even begun to implement the staggered regulatory controls for many of those 800 device categories that have been finally classified.[13]

B. GENERAL CONTROLS—CLASS I

The device amendments establish classifications of devices in terms of the level of regulatory control necessary to assure their safety and efficacy. "General Controls" are applicable to all marketed devices regardless of their classification. Where these controls, alone, are deemed sufficient to assure safety and efficacy of a device, it is to be placed into class I.[14] Of the actual 804 so far final device classifications, 238 (30 percent) are class I.[15] A summary of the various general controls follows:

1. Adulteration or misbranding (sections 501 and 502)

The general controls, first, include the act's pre-existing prohibitions against marketing adulterated or misbranded devices. These prohibitions have been enforced by seizure, injunction, or other prosecutive actions,[16] but these remedies have not been frequently used. A total of 102 seizure actions relating to devices were filed during the period beginning with fiscal year 1976 and ending at the first quarter of fiscal year 1982—an average of 17 actions per year. Thirteen (13) injunctions have been filed during the same period—an average of two per year—and two other unspecified prosecutions have been commenced.[17]

The device amendments added a provision (section 304(g)) which authorizes the agency to order a device detained for up to 20 days if an inspector has reason to believe that the device is adulterated or misbranded. The agency has promulgated regulations implementing this new authority, but it exercised it only nine times during the 1976–82

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[12] Hearings, supra, note 3, p. 6.

[13] See parts IV A and IV B infra, discussing regulation of class II and class III devices.

[14] Section 513(a)(1)(A). Class I devices also include those nonlife-sustaining or life-threatening devices as to which there is insufficient information to determine that the general controls are adequate, or to establish a performance standard (class II), section 513(a)(1)(A)(ii).

[15] Seven advisory committee reports are represented in these 804 final classifications: Neurology (21 CFR, part 882); cardiovascular (part 870); obstetrics/gynecology (part 884); hematology/pathology (part 864); general hospital use (part 880); anesthesiology (part 868); and immunology and microbiology (part 866). The immunology, general hospital, and hematology groups percentages of class I devices (at 57 percent, 56 percent, and 38 percent, respectively) were well above the overall average of 30 percent class I designations. The cardiovascular and OB/GYN groups' percentages of class I devices (at 2 percent and 6 percent, respectively) were well below the average.

[16] Sections 301(a), 302, and 304.

[17] Bureau of Medical Devices Summary of Regulatory Activities, submission retained in subcommittee files. These data should be contrasted with recalls by more than 850 firms of over 1,300 devices during the same period. Id.

period, and only once since the beginning of fiscal 1981.[18] The common shortcoming of all these remedies is that they react to problems with devices already on the market; they do not prevent the introduction of unsafe or ineffective devices. Indeed, throughout the judicial proceedings involved in pursuing them, manufacturers may continue to market their products. The inability of such reactive methods to provide adequate public protection contributed to Congress' decision to enact a preventive regulatory system to assure safe and effective performance before problems occur.[19]

2. Regulation and listing (section 510)

The general controls include new requirements for device manufacturers to register with the agency at least annually (Section 510(a) through (g)) and to list all services which they manufacture, together with information respecting applicability of performance standards or premarket approval for class II or III devices (Section 510(j)).

3. Premarket notification (section 510(k))

Although generally not discussed as a general control, the requirement in section 510(k) for a manufacturer to notify the FDA at least 90 days before first introducing a device into the market has proven to be one of the most important provisions in the device amendments. The section also requires that the manufacturer report a proposed device's classification and the actions it has taken to comply with the regulatory controls applicable to class II or III devices. Congress may well have anticipated a large volume of these premarket notifications, (given the vitality, diversity, and speed of technological advance in the medical device industry), but it probably did not envision the importance these submissions would play in resolving a high volume of significant regulatory decisions by the agency. This is because section 510(k)'s requirement that the manufacturer address the classification of a device not previously introduced into the market raises the critical regulatory issue of whether a device is "new." [20]

The regulatory controls applicable to a device depend on its classification, and the classification of a device depends both on the rigor needed to assure its safety and efficacy and, importantly here, on whether it is a new device. While the general rule is that, ultimately, all devices are to be classified according to the need for controls, an exception is created for devices not on the market when the device amendments were enacted. Some of these are new and will automatically be classified into class III—the category of most rigorous regulatory controls. They will undergo a premarket approval procedure akin to that applicable to new drugs before they may be marketed. This automatic class III designation does not apply to devices first marketed after enactment that are substantially equivalent to (1) a device that was marketed before enactment of the device amendments, or (2) to any other class I or II device (regardless of when it was first marketed).[21]

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[18] See 21 CFR, sec. 800.55 and BMD Summary of Regulatory Activities, supra, note 17.
[19] House report, supra, note 6, pp. 6–8, 13.
[20] The section 510(k) process is discussed in more detail, infra, at p. 32 et seq.
[21] Section 513(f). To put it another way, a device will be classified into class III either automatically—because it is a new device—or deliberately—because a classification panel or the agency decides that it belongs there.

Thousands of section 510(k) submissions, thus, convey manufacturers' contentions that their devices are substantially equivalent to other devices on the market and may therefore be marketed without undergoing premarket approval. The 510(k) process provides the agency with a direct opportunity to observe the entry of these new products onto the market and to decide whether any require a formal demonstration of safety and efficacy before they are first sold.

4. Banning (section 516)

The general controls include new authority to ban devices that are hazardous or that present a substantial deception. Banning is an extraordinary remedy to be reserved for instances where the risk or deception is significant and where labeling changes are insufficient to eliminate it. Section 516 requires the Secretary to confer with the appropriate classification panels and to proceed by regulation, providing the opportunity for an informal hearing to interested persons. The agency, in 1979, promulgated a set of regulations (21 CFR, part 895) to implement this statutory authority, but it has yet to ban its first device.

During the July hearing, Chairman Dingell questioned agency officials concerning the safety and efficacy of synthetic hair implants.[22] Acting Medical Device Bureau Director Zafra agreed that there is no evidence that such implants are safe and effective and that the agency had received numerous complaints of injury—infections, scarring, swelling—associated with this procedure, as well as evidence of mutagenicity in the hair dyes used in the implants. The expert panel involved had unanimously voted to recommend banning the procedure, but, because the agency believed there are no firms currently engaged in synthetic implanting, it did not propose a regulation to impose the ban. Acting Director Zafra testified that the banning regulation would enable the agency to attack firms that commenced implanting without initiating judicial proceedings and reproving each time that the process was unsafe. Without a ban, the agency lacks the mechanism to move rapidly to prevent the harm this process causes, whenever it occurs. The subcommittee expects that the agency will not persist in a case-by-case approach if synthetic hair implants reappear.

5. Good manufacturing practices (Section 520(f))

The device amendments authorize the agency to promulgate regulations requiring good manufacturing practices [GMP] to be used in the methods of manufacture, packing, storage, and installation of devices. The agency is required to establish a GMP advisory committee which will advise and make recommendations concerning the regulations and petitions by manufacturers for exemptions or variances from particular requirements.

In a commendable effort to incorporate the device amendments' theme of staggered regulatory controls necessary to assure safety and efficacy, the GMP regulations single out critical devices, components, and operations for special vigilance.[23] The term critical comprehends matters relating to surgical implants or life supporting or sustaining

[22] Hearings, supra, note 3, pp. 125–126.
[23] 21 CFR, secs. 820.3 (e)–(g), .81, .101, .116, .121, .151, .161, .182, .185, and .195.

devices, the failure of which can be reasonably expected to result in significant injury.

Commissioner Hayes testified that the GMP requirement is the most important general control.[24] FDA inspectors, pursuant to section 704 of the act, monitor compliance with the agency's GMP regulations. Where a facility is engaged in manufacturing class II or III devices, section 510(h) requires these inspections to occur at least once every 2 years. Inspections cover the entire range of quality control procedures adopted to comply with the GMP regulations including a review of records required to be kept. Section 704(a), conferring the inspectional authority, provides expanded authority where "restricted" devices are manufactured. There, a GMP inspection may extend to "all things therein—including records, files, papers, processes, controls, and facilities—bearing on whether * * * [such restricted] devices are adulterated or misbranded." In other facilities, the device GMP inspection is limited to records required to be kept by law.[25]

6. Restriction (section 520(e))

The Cooper Committee recommended that Congress address hazards that arose from faults in device design and manufacture, and it also expressed concern about hazards that were the result of the way medical devices were used. Section 520(e) of the device amendments responded to this concern by authorizing the agency to restrict the sale or distribution of a device to prescription by a practitioner, or upon other conditions, if the agency decides there cannot otherwise be reasonable assurance of its safety and effectiveness. The agency is authorized to restrict a type of device by regulation (section 520 (e)(1)), or it may include a restriction as a part of a mandatory performance standard for a class II device (section 514(a)(2)(B) (v)), or it may include a restriction as a condition to its approval of a premarket approval application for a class III device (section 515 (d)(1)(B)(ii)).[26]

Prior to adoption of the device amendments, FDA had very limited authority to address user-related device problems. The act recognized the concept of a prescription device, but not explicitly. Section 502(f) accomplished this by authorizing the agency to exempt a device from the act's labeling requirements if they are not necessary for the protection of the public health. Regulations promulgated before enactment of the device amendments implemented this authority, declaring that devices that are so hazardous that they cannot be used except under the supervision of a practitioner are exempt from the act's requirement to include adequate directions for use and warnings against unsafe use.[27]

It is clear, however, that status as a prescription device is not the same as status as a restricted device. Designation as a prescription device is made by the manufacturer itself—in deciding how to label—restriction is imposed by the agency.[28] The result of prescription status is that the device is not available over-the-counter and its label-

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[24] Hearings, supra, note 3, p. 6.
[25] This distinction in inspectional authority is a significant one. See pp. 28–30, infra.
[26] Restriction of devices is discussed more fully, infra, at p. 27 et seq.
[27] 21 CFR, sec. 801.109, (41 F.R. 6896, February 13, 1976).
[28] See 46 F.R. 57569, discussed at pp. 27–28, infra.

ing lacks certain essential information. The result of restricted status may include the aforementioned, but it may also extend to limitations on sale or distribution to hospitals or clinics, or to particular categories of health care professionals.[29] Restricted status also expands the agency's access to records that may be important when injuries have occurred. Unfortunately, the agency has not meaningfully implemented its authority to restrict devices.[30] Its failure to do so leaves unaddressed the widely shared, long-standing concerns with injuries resulting from improper use of devices.

7. Reporting requirements (section 519)

The device amendments establish a general rule that the agency may require manufacturers to establish and maintain records, make reports, and provide information necessary to assure that their devices comply with the law (section 519(a)). Congress was conscious of the potential for such requirements to become onerous. The agency may not make recordkeeping and reporting unduly burdensome—taking cost of compliance into account—and it is required to identify the information sought and explain why it is being sought. Moreover, the device amendments expressly provide that manufacturers of class I devices may not generally be required to maintain records, or submit reports or information, not in their possession.

While Congress was concerned that the agency evaluate carefully the need for establishing reporting and recordkeeping requirements, it was clear that the admonitions of section 519(a) were not limitations on the agency's authority to obtain information needed to insure that the public is protected from potentially hazardous devices.[31] In particular, the drafters recognized the central importance of information about product defects and recalls and the need for regulations to guarantee that such information would be available. The agency's continuing failure to respond to this need by instituting a reliable industrywide system to provide valid information to the FDA about adverse experience with medical devices is one of its major shortcomings in implementing its regulatory authority.[32]

8. New remedies: Notification, repair, replacement, or refund (Section 518)

When the agency determines that a device presents an unreasonable risk of substantial harm to the public, it may order notification of this fact to all appropriate persons (section 518(a)). But the agency must first conclude that no more practicable means are available to address the risk. This provision, as applied, has, therefore, meant that manufacturers have had the opportunity to disseminate such notices voluntarily. The agency has ordered notification only three times since the device amendments were enacted. On 21 other occasions firms were warned that section 518 was going to be used if they did not cooperate voluntarily.[33] This volume should be reviewed in light of the recalls

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[29] House report, supra, note 6, pp. 24–25.

[30] The agency has designed certain specific class III devices as restricted as a condition to its approval of premarket approval applications. However, as discussed infra, pp. —, it has done no more than incorporate the requirements of the prescription device regulations.

[31] House report, supra, note 6, p. 24.

[32] See discussion, infra, at pp. 21–27.

[33] Bureau of Medical Devices submission, retained in the subcommittee files, supra, note 17, p. 3.

by over 850 firms of over 1,500 different devices during the same period.[34] One particularly disquieting explanation for the disparity in these figures is that the FDA frequently obtains information establishing the existence of an unreasonable risk—if at all—only well after that information is available to and acted upon by the manufacturer.[35] It also appears that if the agency had in place a reliable system to provide it with adverse experience information, this disparity would be reduced.

When notification pursuant to section 518(a) is not sufficient to eliminate the unreasonable risk, and where that risk is the result of improper design or manufacture—as opposed to the failure of a third party to exercise care in the use of a device—the agency is authorized to require the manufacturer to submit a plan for repairing or replacing the device or for refunding the purchase price (section 518(b)). These redress provisions are to be made available without charge to those who avail themselves of the remedy (section 518(b)(3)), and the offending manufacturer may be required to reimburse others who incur expenses in connection with carrying out the redress program (section 518(c)). Yet, for all their promise, the redress provisions of sections 518 (b) and (c) have been used but once in 6 years, when the FDA ordered the manufacturer of a dephibrolator to repair a switch in August, 1978.[36]

C. PERFORMANCE STANDARDS—SECTION 514

The device amendments provide a highly detailed agenda to govern development of performance standards necessary to assure the safety and efficacy of class II devices. The standards are to include provisions respecting the components and construction of the device and its compatibility with power systems, and provisions for testing the device and measuring its performance to assure its conformity to the standard (section 514(a)(2)). Congress envisioned that manufacturers of class II devices would certify to purchasers that they conform to an applicable performance standard or periodically so certify to the agency.[37]

The process for promulgation of a performance standard is set forth in great detail. As many as five Federal Register notices appear to be involved, and a substantial time period would appear to be required to (1) initiate the process, (2) invite the submission of, or offers to develop, proposed standards, (3) accept an existing standard as, or an offer to develop, a proposed standard, (4) propose a standard, and (5) establish a standard (see Sections 514(b) through (g)).

The major problem with the agency's implementation of these class II regulatory controls is easy to frame: It has ignored them. While it expected the time necessary to develop and promulgate regulations specifying the procedure to promulgate performance standards (21 CFR, part 861), the agency has yet to commence its first proceeding. This record is inexplicable in view of the fact that about 61 percent—

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[34] Id., p. 4.
[35] See the statements of Acting Bureau Director Zafra and Dr. Sidney Wolfe, infra. at p. 22.
[36] Bureau submission, supra, note 17, p. 3.
[37] House report, supra, note 6, pp. 26–27.

493 out of the final 804—of all devices so far finally classified have been put by the agency into class II. These classification decisions represent findings by the agency that performance standards are necessary to assure the safety and efficacy of these devices, and, consequently, that the residual general controls are by themselves insufficient to protect the public.[38] Despite this, the general controls are the only applicable regulatory safeguards in effect to protect the public from the risk of injury from unsafe and ineffective class II devices. On top of this, the absence of an effective adverse experience reporting system magnifies the risks of the agency's inaction for it means that the consequences are unknown.

The agency's slack approach has upset the foundation on which the device amendments rest: Measured regulatory controls matched to the level of device-associated risks.[39]

D. PREMARKET APPROVAL—SECTION 515

Class III devices are required to undergo premarket approval, a process in which the agency reviews—prior to marketing—a detailed application containing extensive information about safety and efficacy, components, manufacture and quality control, and other product features (section 515(c)). The agency is required to act on a premarket approval application—frequently called a PMA—within 180 days after its receipt, and it is required to deny approval if there is inadequate assurance of safety, efficacy, good manufacturing practice, proper labeling, or conformity with a section 514 performance standard—where compliance with the standard is a condition to approval of the PMA (section 515(d)).

While premarket approval is supposed to apply to all class III devices, in practice it has only applied to new—post-Amendments—devices. An important exception was created in the device amendments for devices—or their substantial equivalents—on the market prior to their enactment. These pre-Amendments class III devices are required to submit PMA's only after the agency promulgates a regulation specifically calling for them (section 515(b)). The major problem here is not the statutory grace period; it is, again, agency inaction. The FDA has ignored the statute's requirement to promulgate these regulations and to obtain the necessary information to assure that these risk-laden class III devices are safe and effective. The agency's decision to forego this requirement has frightening implications. Over 70 different types of class III devices were marketed prior to enactment of the device amendments.[40] None of these devices has been required to demonstrate its safety or efficacy, and none of the substantially equivalent class III devices currently being allowed into the market—such as replacement heart valves and fetal electroencephalographic monitors—is being required to make such a showing.[41]

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[38] The cardiovascular, anesthesia, and OB/GYN groups of devices had 79 percent, 79 percent, and 71 percent class II designations, respectively (See 21 CFR, parts 870, 868, and 884), which were above the 61 percent overall average for all finally classified devices.

[39] The problems with class II device regulation are more fully discussed, infra, at pp. 14–18.

[40] The majority of these are devices in the cardiovascular and OB/GYN categories. (21 CFR, parts 870 and 884.)

[41] These problems are discussed more fully, infra, at pp. 18–21.

Again, as with class II devices, the agency's failure to adhere to the intended statutory scheme subverts the foundation of the device amendments. Significant numbers of class III devices, and all class II devices, are being regulated only by the general controls—as if they all were class I devices.[42] The agency's additional decision not to develop a meaningful adverse experience reporting system produces the nightmarish result that extremely complex, sometimes hazardous devices flow throughout the stream of commerce without the agency being in a position to assure their safety or their efficacy or to learn of deaths or injuries caused by these devices if they occur.

IV. FDA's Major Failures: Class II and III Devices and Adverse Experience Reporting

A. CLASS II DEVICES

A device must be classified into class II—performance standards—if the act's general controls are insufficient to provide a reasonable assurance of its safety and efficacy and if there is enough information available to establish a standard. Section 513(a)(1)(B) of the act plainly specifies that classification into the performance standards category represents a determination that it is necessary to establish for the device a performance standard under section 514 to provide reasonable assurance of its safety and effectiveness.

The process of classifying over 40,000 different device products on the market today—grouped into 1,733 different categories—is not yet completed; but, so far, the agency has determined, either finally or provisionally, that over 1,000 of these device types belong in class II.[43] That is, the agency has determined that the majority of medical devices currently available may be used safely and effectively only if they are subject to a performance standard. Despite this finding, the agency has not commenced a single standard-setting proceeding for any class II device. In the absence of such standards, the statute (and FDA) says, by implication, that the public cannot rely upon class II devices—such as cardiac monitors, ventilators, respirators, and neonatal incubators—to provide safe, effective, diagnosis and treatment.

There is no room to question Congress' intention that devices placed in class II meet applicable performance standards. The legislative history states that devices classified into class II will be required to conform to performance standards.[44] In the absence of such standards,

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[42] As previously stated, the subcommittee recognizes that the general controls include adherence to good manufacturing practices and that the law requires the agency to inspect manufacturing establishments for class II and class III devices at least every 2 years. It is also recognized that critical devices are subject to more stringent GMP requirements than noncritical ones.

[43] Medical device amendments, FDA compilation, retained in subcommittee files; 1,023 device types have been classed (or proposed for classification) into class II, 25 have been classed into classes I and II, 13 have been classed into classes II and III, and 1 had been classed into classes I, II, and III. This total of 1,062 is over 61 percent of all classifications. In interviews with subcommittee, the Acting Bureau Director stated that these device types probably represent about 2,000 different devices.

[44] House report, supra, note 6, p. 26. The report recognizes that the process of promulgating such standards will take time, but it is ineluctably clear that the Secretary was not vested with discretion to decide whether to regulate class II devices by means of performance standards. The point is belabored here because the language of section 514(a) might be read to suggest that the Secretary was given such discretion. It begins: "The Secretary may by regulation, promulgated in accordance with this section, establish a performance standard for (a) class II device. (Emphasis added.)

class II devices are subject only to the general controls of the act and thus are regulated in the same fashion as class I devices. This result sabotages the basic regulatory scheme of the act.

The agency has explained its disregard for Congress express intention by claiming that the general controls applicable to all devices are effective regulatory tools, that the adoption of voluntary standards and other steps by the industry are a substitute for section 514 mandatory standards, and that the complex procedure for promulgating standards prescribed by section 514 is cumbersome and, with so many devices in class II, will never be completed. Perhaps most troubling of all, the Acting Bureau Director further sought to justify to the subcommittee staff the failure to implement section 514 by claiming that the agency was aware of no problems with class II devices and that mandatory standards were therefore not necessary to protect the public against risks.[45] In fact, however, no conclusions can be drawn about the extent of problems with class II devices, or any other devices for that matter, because the agency lacks the information needed to assess it. To premise, even in part, a failure to act of such major dimension on the limited available data on device problems, which the agency knows to belie the true state of device-related adverse experience, is unconscionable.[46]

If Congress had intended that substitutes for mandatory performance standards be employed as alternatives, it would have said so. The agency's mandate was to promulgate performance standards or return to Congress and explain why it could not and seek assistance. In this regard, the submission of a legislative proposal to simplify the standard setting process of section 514 dated 2 days in advance of this subcommittee's oversight hearing can not be considered the faithful discharge of the agency's duty. Furthermore, even if this subcommittee were disposed to countenance statutorily unauthorized alternatives to mandatory section 514 performance standards, the agency's intention to rely upon the general controls and on industry voluntarism is unacceptable.

The list of general controls enacted by Congress to apply to all devices does indeed include effective regulatory tools. But the agency has failed to implement many of them. It has not developed a meaningful adverse experience reporting system. It has not restricted devices to reduce the risk of user-related injury. It has not banned a single device because of an unreasonable, substantial risk of illness or injury. It has used its significant new authority to notify professionals and users of devices of risks of harm a mere three times in 6 years, and it has used its authority to order repair, replacement, or refund but once.[47] In fact, even though Commissioner Hayes called the agency s GMP regulations its most important general control,[48] it should be obvious that a poorly conceived, poorly designed device may be manufactured according to perfectly sound quality control procedures with disastrous effects.

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[45] These explanations and justifications were communicated to the subcommittee staff in a Feb. 25, 1982 meeting with the Acting Bureau Director, Victor Zafra, and his Deputy, Robert Britain.

[46] The agency's failure to adopt a meaningful adverse device experience reporting system is discussed, infra, at pp. 21–27.

[47] Submission of Bureau of Medical Devices, supra, note 17.

[48] Hearings, supra, note 3, p. 6.

The second alternative to mandatory standards, voluntary solutions to medical device problems, is the cornerstone of a draft policy statement on class II devices recently issued by the agency.[49] The agency stated that it would use the most cost effective regulatory alternative to address class II medical device problems; that it would request manufacturers voluntarily to solve device problems; that it would publicize particular device problems; that it would participate in developing voluntary standards; and that it would develop guidelines. The agency stated that if these approaches begin to remedy a—Class II—medical device problem, FDA will defer development of a mandatory standard.

The subcommittee categorically rejects such a policy of reacting to problems after they occur as a meaningful alternative to performance standards because it runs directly contrary to the notion of risk prevention that is embodied in the letter and the philosophy of the entire Food, Drug, and Cosmetic Act. As a reflection of that philosophy, the device amendments were enacted not to enable the agency to respond to problems with medical devices but to prevent device problems from occurring. The whole notion of a performance standard is that it provides a circumstantial guarantee of reliably safe, effective device performance. To shift focus away from the preventive and back to the remedial, whether it be by voluntary or mandatory means, is to stand the device amendments on their head. It returns Government involvement in the medical device area to the pre-device amendments days when the agency's authority was limited to taking action against devices after they had caused illness or injury—after they became problems. It was the consensus of the Congress and the American people that such a reactive governmental presence in the device area was not adequate to protect public health.[50] This arose in part from the judgment that the costs of solving problems frequently outweigh the costs of preventing them.

On July 14, 1982, two days before this subcommittee's hearing, and over 6 years after enactment of the device amendments, the Department transmitted a proposal to amend the provisions governing the development of performance standards.[51] It is the only proposal that has been made by any administration to date to amend the device amendments. Viewed in terms of its substance rather than the reasons for its emergence, the proposal would simplify the process of promulgation by reducing the separate steps and Federal Register publications—with their attendant workload and delay—required to promulgate a standard. While any proposal to make section 514 standard setting more expeditious has a certain facial appeal, especially if it signals the agency's intention to begin carrying out its statutory man-

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[49] CCH Medical Device Reports, para. 17,582, p. 17,804, Jan. 26, 1982.

[50] House report, supra, note 6, pp. 6–10.

[51] The current promulgation process includes the following steps requiring notice published in the Federal Register: (1) Initiation of a proceeding for a performance standard, which provides an opportunity for manufacturers to request reclassification (section 514(b)(1)(A)); (2) an invitation to persons to submit existing performance standards or to offer to develop a proposed standard (section 514(c)(1)); (3) acceptance of an offer to develop a proposed performance standard (section 514(c)(2)) or rejection of an existing standard offered as a proposed standard (section 514(d)(2)); (4) notice of proposed rulemaking regarding a proposed performance standard (section 514(g)(1)(A)); and (5) promulgation of a regulation establishing a performance standard (section 514(g)(3)).

The proposal advanced by the Department would eliminate the second and third steps: the invitation to submit existing standards or to offer to develop a proposed standard, and the acceptance of such an offer.

date, it is hard for the subcommittee to embrace a proposal to truncate a carefully laid out regulatory process without a single example to support the need for change. Furthermore, the subcommittee concludes that proposals aimed at shortening and simplifying the process of promulgating performance standards for class II devices are largely superficial. They treat the symptoms and not the disease. Even assuming, arguendo, that the current departmental proposal would shorten the process from 5 years to 2 years, with more than a thousand separate performance standards to promulgate, our grandchildren might not see the end of standard setting for these devices. With such a tremendous time span involved, by the time these performance standards are completed, technological change will have undoubtedly created the need to amend them, and a second round of standard setting will inevitably ensue.

The problem appears to lie not so much in the process of setting standards but in the process of classification that led to over a thousand devices being placed in the standard setting category. While speculation might lead to the conclusion that the experts on the advisory classification panels most often chose class II simply because they wanted to avoid the extremes of too much (class III) or too little (class I) regulation, such speculation is pointless. Sections 513(c)(2) and 515(d)(1) provide that the panels only recommend classifications to the agency. It is for the agency to make the final decision on which classification shall be proposed for public comment and which shall be adopted as final in light of those comments. Thus, it can fairly be concluded that throughout the still-continuing classification process, the agency has known it was creating an impossible situation for itself—a regulatory Frankenstein that it has no hope of controlling. The agency's failure to advise the Congress of the steadily worsening predicament, and its decision instead to ignore congressional intent and to treat class II devices as if they were class I devices, is intolerable.

Attention must be focused on solving the dilemma posed by the number of class II devices and their need for performance standards. One condition must be accepted as given: If performance standards are to be expected to provide near-term public protection, there must be fewer devices subject to such standards. Not only are a thousand standard setting proceedings impracticable; they will be mooted by technological advances upon their completion. One solution that may profitably be considered is to create a new, fourth device classification between classes I and II. Performance standards would be retained for class II devices, while devices in this new class IIA would be subject to greater regulatory controls than class I devices, but would not be subject to mandatory section 514 performance standards. Controls for such a class IIA could include (a) restrictions (under section 520(e)) with highly specific requirements for labeling and with limitations on channels of distribution that would insure, where appropriate, that a health professional was involved in either the sale or use of the device;[52] (b) increased mandatory adverse experience reporting re-

[52] Restrictions may now be placed on a device as part of a performance standard setting process. (Section 514(a)(2)(B)(v).) This provision could be extended to the reclassification process and thereby avoid the need for a separate section 520(e) rulemaking proceeding.

quirements structured to insure that any data tending to show the emergence of ill effects from the class IIA device would be expeditiously reported; and (c) the adoption of objective performance specifications by the manufacturer of each class IIA device which must be submitted to FDA now, or when the device is first classified or introduced, and against which the device must be tested periodically with the certified results accessible to FDA during GMP inspections.[53]

The determination of which current class II devices would remain subject to mandatory performance standards and which would be moved to class IIA must not involve a complex, lengthy reclassification process. That would simply exacerbate the problem. Section 513(c)(2)(A) has required each classification advisory panel to include a recommendation for the assignment of a priority for the application of the requirements of section 514 * * * to a device recommended to be classified in class II * * *. The agency could use this expert prioritization as a basis for its own review and for a proposal to change a device's classification. It would be anticipated that those class II devices that had been assigned the highest priority by the expert panels would remain in class II and those with lower priority would be proposed for reclassification into class IIA.

The subcommittee recommends that the Subcommittee on Health and Environment consider this proposal to reduce the number of devices that would be subject to mandatory performance standards and take whatever further action is deemed appropriate.

B. Class III Devices

The amendments reserve their most restrictive regulatory controls—Class III Premarket Approval—for devices which support or sustain life, are of substantial importance in preventing the impairment of health, or present a potential unreasonable risk of illness or injury.[54] Neither general controls nor performance standards provide sufficient assurance of their safe, effective performance. All class III devices are required to have in effect an approved premarket approval application—pursuant to section 515—which establishes that the device is safe, effective, manufactured in accord with good manufacturing practices, and appropriately labeled.[55] Marketing a class III device without an approved PMA application renders the device adulterated and subject to the act's available remedies.[56]

Congress permitted different treatment for class III devices depending on whether they were marketed before or after enactment of the device amendments. A device marketed prior to the amendments (an old class III device) was provided with a grace period before it was required to obtain premarket approval. [57] A device not marketed prior to enactment, but substantially equivalent to a class III device marketed prior to enactment, was also provided this grace

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[53] The GMP regulations may now provide for such testing of critical devices. See 21 CFR, sec. 820.161.

[54] Section 513(a)(1)(c)(ii).

[55] The agency is directed to deny approval of a PMA application if it finds that any one of these elements is lacking, or if the device fails to conform to an applicable section 514 performance standard, compliance with which is a condition of approval of the application (section 515(d)(2)).

[56] Section 501(f)(1).

[57] Sections 510(f)(1); 515(b)(1)(A).

period.[58] A device not marketed prior to enactment, and not substantially equivalent to an old device, is a new device and may not be marketed at all until it meets premarket approval requirements.[59] The grace period for old devices provides 30 months from the date of final classification into class III or 90 days from the promulgation of a regulation calling for the submission of PMA's, whichever is later.[60] Thus, until FDA promulgates a regulation calling for submission of PMA's, manufacturers of old and substantially equivalent class III devices are not required to submit them. The agency has neither promulgated nor proposed such a regulation.

Manufacturers of new, unique class III devices have been submitting premarket approval applications since the device amendments were enacted. To date, the agency has approved 114 individual PMA applications.[61] These relatively few, truly new class III devices are unique in the universe of thousands of medical devices on the market because they represent the only devices as to which FDA has applied the full panoply of regulatory controls authorized by the device amendments.[62] Not only have premarket approval applications been required and submitted, but all approvals of these PMA's have been conditioned on the manufacturers' complying with a requirement to report adverse reactions and device defects.[63] Frequently, FDA's approval letters also restrict these devices, invoking the prescription device regulations in 21 CFR, sec. 801.109.[64]

In stark contrast stands the agency's treatment of the majority of class III devices on the market today—those old devices that were introduced prior to the device amendments or those that are substantially equivalent. These old class III devices pose no less of a risk than new ones, and the statute contains no difference in substantive treatment for pre-enactment as opposed to post-enactment class III devices. Yet, the agency has failed—without consultation with Congress, contrary to the explicit directions of the statute, and in disregard of its duty to protect public health—to call for submissions of PMA's. It, therefore, is treating pre-enactment class III devices virtually as if they were class I devices—as if they were ice bags or bed boards.

The agency has accomplished this result by failing to publish a regulation requiring manufacturers to submit applications for premarket approval of their old class III devices, even though the device amendments explicitly require that such "regulation be promulgated. Section 515(b)(1) states that the agency shall by regulation * * * require that such—old—device have an approval under this section of an application for premarket approval." A part of the problem undoubtedly is that the device amendments did not totally tie the agency's hands by explicitly stating by when this regulation must be promul-

[58] Sections 501(f)(1), 515(b)(1)(B).
[59] Section 515(a).
[60] Section 510(f)(2)(B).
[61] Hearings, supra, note 3, pp. 24–26.
[62] While all the applicable general controls apply to all class I devices, the agency has failed to require any manufacturer of such devices to report deaths, injuries, or other adverse experiences associated with their use.
[63] Hearings, supra, note 3, pp. 24, 27.
[64] A sample of approval letters is retained in the subcommittee's files. See also the statement of FDA, withdrawing its proposed restricted device regulation, that the agency would rely upon prescription device regulations to restrict new devices. Infra, pp. 30–31.

gated. The core of the problem is simply the agency's decision to ignore an explicit congressional directive. Dr. Sidney Wolfe of the Health Research Group testified that:

> FDA officials have . . . stated that they do not intend to ask for clinical data on Class III devices that are now on the market even though the law requires this. These devices have never been shown to be safe and effective.[65]

The device amendments afford manufacturers of preenactment class III devices a grace period, not an exemption, from the requirement to file a PMA. Congress intended that the safety and efficacy of these high-risk devices be reviewed and demonstrated, not that they merely be subject to the good manufacturing practice regulations or the other general controls reserved for class I devices that are now being applied to them. The legislative history makes this crystal clear:

> Classification into class III [serves] the important purpose of providing notice to manufacturers and importers of such ["old"] devices that they must begin preparation for submission of applications for premarket approval.[66]

The drafters expected that the 30-month grace period—after final classification into class III—would be "a sufficient time * * * to develop data and conduct the investigations necessary to support an application for premarket approval." [67] They expected manufacturers to begin the task at once of developing data upon final classification since:

> If manufacturers . . . initiate investigations only upon promulgation of the regulation requiring premarket approval, they risk having inadequate time [within ninety days thereafter] to submit an approvable application. . . . In such cases, their devices would be required to be removed from the market." [68]

The double faceted (30 months/90 day) grace period only makes sense if it is read to require the agency to promulgate the section 515(b) regulation within the 30-month period. If Congress intended the agency to be free to disregard the 30-month period, and to promulgate the regulation whenever it chose—with submissions due only 90 days thereafter—it would not have included the 30-month provision at all. Supporting this view, the legislative history states that it was because of the length of the 30-month period that Congress decided not to permit any extension of the 90-day deadline after promulgation of the section 515(b) regulation.[69] It is thus apparent that Congress intended 30 months plus 90 days after a device's final classification to be the outside time limit for the submission of data on its safety and efficacy.

Accordingly, the subcommittee finds appropriate the citizen petition, filed with FDA by the Health Research Group on May 5, 1982, calling for the agency to promulgate a regulation requiring submission of applications for premarket approval for the eleven class III neurology device types that were finally classified on Oct. 4, 1979.[70] Thirty months since that final classification have elapsed. The HRG petition was supplemented with information on the devices

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[65] Hearings, supra, note 3, p. 139. Dr. Wolfe's testimony corroborates identical statements made to the subcommittee staff in interviews with the Acting Bureau Director. Mr. Zafra's explanation for this approach was that the agency was aware of no problems with these class III devices and therefore did not see the need to call for submission of premarket approval applications.

[66] House report, supra, note 6, p. 42.

[67] Id.

[68] Id.

[69] Id.

involved and the documented problems experienced with many of them.[71] This supplemental information serves to reinforce the agency's original decision to place those devices into class III. But the agency should not consider the existence or nonexistence of any such problems with old class III devices to provide a basis for it to pick and choose which class III devices must have PMA submissions. The device amendments permit no such distinction.

Recently, the 30-month period also expired with respect to two additional groups of device classifications: Cardiovascular devices and obstetrical and gynecological devices.[72] Twenty-six of the 139 device types finally classified in the cardiovascular group are class III. Sixteen of the 69 device types classified in the OB/GYN group are class III. These include some of the most critical imaginable devices in terms of their importance for sustaining life and the attendant risks if they fail to perform. They include cardiopulmonary bypass oxygenerators—used in bypass surgery to oxygenate blood (21 CFR, sec. 870.4350) arterial embolization devices—intravascular implanted devices to control hemorrhaging or halt blood flow, (21 CFR, sec. 870.3300) vascular graft prostheses—used to replace sections of small arteries (21 CFR, sec. 870.3459), replacement heart valves (21 CFR, sec. 870.3925), contraceptive tubal occlusion devices—used to close fallopian tubes to prevent pregnancy (21 CFR, sec. 884.5380), and fetal electroencephalographic monitors (21 CFR, sec. 884.2620).

The agency placed these devices into class III because it determined that detailed submissions from manufacturers establishing their safety and efficacy were essential. The fact that these devices are on the market now should add to, not diminish, the agency's sense of urgency to obtain these submissions.

C. ADVERSE EXPERIENCE REPORTING

Responsible officials of the FDA have long recognized the need for an effective system to report on problems experienced with medical devices. During the Nixon administration, then FDA Commissioner Charles C. Edwards, testifying before the Senate Health Subcommittee on proposed medical device legislation, stated:

> A more important reason or our lack of data [on injuries caused by medical devices] is that unlike adverse reaction experience from new drugs, adverse reaction experience with medical devices is not ordinarily brought to the attention of the Food and Drug Administration because there is no legal requirement that this be done.[73]

Almost a decade later, and despite the intervening passage of authorizing legislation, there is still no requirement that manufacturers of medical devices advise the FDA when they learn that their products have caused death or injury. Instead, the agency has chosen to rely upon its own inspections of manufacturers' complaint files to uncover this information and upon a voluntary reporting system that,

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[70] Petition No. 82P-0151/CP printed in hearings, supra, note 3, pp. 170-71.
[71] Id. pp. 172-78.
[72] The cardiovascular classifications became final on March 5, 1980 and the OB/GYN classifications became final on March 26, 1980 (see 21 CFR, parts 870 and 884).
[73] Medical Device Amendments, 1973, hearings on S. 2368 before the Subcommittee on Health, Committee on Labor and Public Welfare, U.S. Senate (prepared statement).

by the agency's own admission, fails to reflect the true nature and extent of device-caused adverse reactions.[74]

Officials of the agency agree that it is not adequately informed on the nature and scope of problems with medical devices. Acting Bureau Director Zafra has stated that only 15 percent of—device manufacturers'—recalls come to FDA's attention.[75] Dr. Wolfe of the Health Research Group testified that his organization has estimated that, under the current system, in 1981 there was an average time lag of over 3 months between the time a recalling manufacturer notified its customers of the recall and publication of the recall in the FDA Enforcement Report.[76] While valid and reliable information about problems experienced with medical devices would seem to be a prerequisite to any comprehensive regulatory scheme, such information is particularly essential, now, because of FDA's failure to apply central portions of the device amendments to high risk devices currently on the market.

There is no issue over the FDA's authority to promulgate regulations requiring mandatory experience reporting [MER]. Section 519 of the Device Amendments authorized the FDA to require manufacturers, importers, and distributors of medical devices to establish and maintain records, make reports, and provide information to the FDA to insure that medical devices are not adulterated or misbranded.[77] Although the explicit language of section 519 is permissive, the legislative history of the device amendments reflects the intention that a defect/injury reporting regulation be promulgated. The agency, in recognition of this, stated that the legislative history expressly contemplates this type of reporting regulation.[78]

Pursuant to this authority, the agency proposed on November 18, 1980, a mandatory experience reporting scheme to require manufacturers and distributors of medical devices to submit reports concerning medical devices that may have caused death or injury, that may have a defect that could result in death or injury, or that are the subject of a remedial action.[79]

The MER proposal was broad and was subject to substantial criticism from industry. Much of this centered on the requirement to report problems that may have led to adverse experiences. This requirement, it was argued, would lead to the costly and frequent transmission of volumes of information based on rumor or surmise rather than on a confirmed causal connection between the device and the adverse experience.[80] Also criticized was the proposed requirement to report any

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[74] In proposing recently to reclassify certain devices, the agency stated: "FDA recognizes that the [Device Experience Network] is wholly voluntary and, as such, cannot reasonably be expected to receive reports of all adverse reactions or complications from [the devices]". 47 F.R. 53406, Nov. 26, 1982.

[75] Medical Devices and Diagnostic Industry, Dec. 22, 1980, p. 11.

[76] Hearings, supra, note 3, p. 142.

[77] Reports of device related death or injury may demonstrate the inadequacy of a device's labeling, and in this manner may show that the device is misbranded. See 45 F.R. 76184 (Nov. 18, 1980).

[78] House report, supra, note 6, pp. 23–24; 46 F.R. 57568 (Nov. 24, 1981).

[79] 45 F.R. 76183, Nov. 18, 1980. Ninety days for public comment were provided, and a public hearing was held on Feb. 2, 1981.

[80] The agency had anticipated this criticism in the preamble to the proposed regulation. It stated that it recognized it would be less costly to limit reports to confirmed device problems; but it believed that manufacturers would characterize few problems as confirmed deficiencies. This, in turn, would lead to the transmission of few reports. The agency was also concerned about the length of time necessary for manufacturers and distributors to confirm that a device deficiency actually existed. 45 F.R. at 76185.

remedial action taken by a manufacturer to correct any suspected or confirmed device deficiency without regard to whether any adverse experience had occurred. As worded, this aspect of the proposal might have required routine modifications resulting from a manufacturer's maintenance or quality control program to be reported to the Government. Other perceived deficiencies in the proposed regulation included the short timeframes allowed to submit required reports and the consequent effects on the quality and completeness of the information submitted; the requirement for the same kinds of reports to be filed for class I device problems as for class II and III devices; and the reporting and paperwork burdens placed upon distributors—as opposed to manufacturers—of devices.[81]

Pursuant to the Federal Reports Act, 44 U.S.C., chapter 35, the agency, during the 90-day comment period, submitted the proposed reporting regulation to the Office of Management and Budget for clearance.[82] It did not fare well. On February 10, 1981, OMB returned the proposal to the agency, unapproved, stating that a thorough reassessment was required.[83] The letter of disapproval from OMB cited the large volume of information required to be reported, some of which—such as that relating to remedial actions—would be extremely burdensome and not clearly useful. The letter called for a thorough reassessment of the proposal and a reevaluation of its costs and benefits as well as the burden estimate of all proposed information requirements.

Taken alone, this admonition from OMB would seem to fall from the same mold of boilerplate criticism currently raised to much current and proposed governmental regulation. However, the OMB letter took pains to make clear that it felt that the concept underlying the reporting proposal had considerable merit:

> We believe that some kind of *mandatory* reporting system is warranted, particularly as relates to deaths and injuries, and believe that certain recordkeeping requirements are also justified.[84]

Viewed from this perspective, the agency's decision, nine months later, to forego its effort and hold the proposed regulation in abeyance in light of the comments received and Executive Order 12291 cannot be justified as fully protecting the public.[85] Even OMB believed that some mandatory reporting was required.

The agency's reasons for sitting still were articulated by Commissioner Hayes, who testified during the hearings that the agency had been "grappling with * * * the best way to assure that we have the pertinent information" to act upon; that FDA had been attempting "to discern * * * what is the information that we really need."[86] The Commissioner focused concern on requiring too much information that would lead to a paperwork nightmare without real improvement

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[81] Distributor was defined broadly to include any person or firm that furthers the marketing of a device from the original place of manufacture to the ultimate consumer.

[82] 44 U.S.C., sec. 3509 prohibits a Federal agency from collecting information from 10 or more persons unless, in advance, the agency submits the plan to the director of OMB, and the Director states that he does not disapprove the plan.

[83] Letter from Jim J. Tozzi, Deputy Administrator, Office of Information and Regulatory Affairs, OMB, to Dr. Mark Novitch, Acting Commissioner, FDA, Feb. 18, 1981, printed in Hearings, supra, note 2, p. 14.

[84] Id., emphasis added.

[85] 46 F.R. 57568 (Nov. 24, 1981).

[86] Hearings, supra, note 3, pp. 28, 40.

in the agency's ability to react to protect the public. However, this concern with the overbreadth and consequent burdensomeness in the originally proposed MER regulation appears misdirected.

To begin with, FDA's indecision over the kind of data it needs to protect the public from dangerously defective devices stands in contrast to existing requirements of other Federal agencies to report on defects and injuries to consumers resulting from products that are far more numerous and innocuous than medical devices. Pursuant to the provisions in its act, the Consumer Product Safety Commission [CPSC] has promulgated regulations requiring a manufacturer of any consumer product to report a defect which could create a substantial risk of injury to the public.[87] The CPSC statute and regulations contemplate an obligation to report even before an adverse experience occurs.[88] Where a death or injury does occur, the CPSC regulations require that it be reported to the agency unless the firm has investigated and determined that the information is not reportable. The regulations allow up to 10 days for such an investigation.[89] CPSC's regulations apply to any consumer product and have led to reports by manufacturers of defects associated with waffle irons, deck chairs, coffee pots, and squeeze toys, to name but a few.[90]

Furthermore, Commissioner Hayes' explanation for holding the MER rulemaking in abeyance—that the agency has yet to discern what kind of adverse experience information it really needs—is belied by FDA's current practice of conditioning approval of PMA's for new class III devices on the manufacturers submitting adverse experience information to the agency. Commissioner Hayes and Acting Director Zafra testified that every PMA approved since passage of the device amendments—approximately 100—has included, as a condition to that approval, a requirement to report information on adverse reactions and device defects within 10 days.[91] It is hard to reconcile this consistent practice with the Comissioner's expressed justification for holding the rulemaking in abeyance. In fact, the agency has been able, since 1976, to discern the kind of information it really needs from manufacturers and to condition the approval to market a new device on the manufacturer's providing that information to the agency. Why should these mandatory requirements be limited only to those who manufacture new medical devices? Old ones may pose just as great a threat as new ones; to the extent they do not, manufacturers will not be required to report anything. If the form and language of these requirements are adequate to advise manufacturers of new

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[87] Pursuant to 15 U.S.C., sec. 2064 (a) and (b), the CPSC has created a regulatory scheme whereby manufacturers' obligations to report on substantial product hazards are clearly delineated. The regulations define such hazards by example as well as by explanation, specify the information which must be reported, and the time within which it must be reported. (16 CFR, part 1115).

[88] Similarly, the National Traffic and Motor Vehicle Safety Act requires a manufacturer, who learns that any motor vehicle or item of replacement equipment manufactured by him contains a defect and determines in good faith that the defect relates to safety, to notify the Secretary of Transportation and owners, purchasers, and dealers and to remedy the defect. 15 U.S.C., secs. 1411, 1413. Regulations of the National Highway Traffic Safety Administration implement the statutory requirements, specifying in detail the information to be provided to owners in order to inform them of the defect and motivate them to have their vehicles inspected and repaired. (49 CFR, part 577.) See also 49 CFR, parts 573, 576.

[89] 21 CFR, secs. 1115.12(c) and 1115.14(d).

[90] Telephone communication between subcommittee staff and staff of the Consumer Product Safety Commission, March 19, 1982.

devices of their obligations, then they will serve equally well to advise those who already market devices.

Much of the FDA's excuse for not moving forward with the MER proposal relates to the alternatives which agency officials claim have served adequately to protect the public and to keep the agency abreast of device-related problems. These alternatives consist of: one, the FDA's access to manufacturers' complaint files during periodic GMP inspections and two, the DEN program [Device Experience Network], which includes the voluntary problem reporting program. In interviews with subcommittee staff, officials of the Bureau of Medical Devices relied on the existence of these alternative sources of information as their basis for concluding that no widespread device-related problems were occurring. This, it was stated, contributed to their decisions not be promulgate class II performance standards and not to call for safety and efficacy data for any preenactment class III devices.

Despite the importation that these alternative sources of adverse experience information had for important BMD regulatory decisions, the Bureau's previously expressed satisfaction with complaint files and the voluntary reporting program was not repeated during the July 16 hearing. In fact, Acting Director Zafra testified that there was general agreement in the agency that death and injury reporting should be required and that agency did not intend to rely on the voluntary reporting system indefinitely.[92] And for good reason. Manufacturers' complaint files, by and large, are a very poor substitute for a mandatory experience reporting system. Complaint files are reviewed during periodic GMP inspections, but those inspections may occur only every 2 years.[93] Furthermore, in 1982, the Bureau—seeking alternatives to the MER proposal after it had been held in abeyance—embarked on a survey of manufacturers' complaint files in order to ascertain their usefulness. In the first phase of the survey, 40 device firms' complaint files were inspected; 60 percent—24 firms—were rated as having either poor or unusable complaint files. A total of 7,831 complaints—for 171 products—were noted in the files including reports of 3 deaths, 20 injuries, and 48 hazards none of which had been reported to FDA under the voluntary reporting program.[94]

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[91] Hearings, supra, note 3, pp. 24, 27–28. The boilerplate approval letter now in use states that FDA approval is "subject to full compliance with the conditions described in the enclosure * * *" and that "Failure to comply with conditions of approval invalidates this approval order." With respect to adverse reaction and device defect reporting, the current conditions are:

"You shall submit a written report to the FDA, BMD (address above) within 10 days after you receive or have knowledge of information about:

(1) a mixup of the device or its labeling with another article;

(2) any significant chemical, physical, or other change or deterioration in the device, or any failure of one or more of the devices to meet the specifications established in the application;

(3) any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and has not been addressed in the device's labeling; and

(4) any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and has been addressed by the device's labeling, but is occurring with unexpected severity or frequency."

[92] Hearings, supra, note 3, pp. 24, 27.

[93] See section 510(h), which requires such inpsection at least once every 2 years for establishments manufacturing class II or III devices. There is no statutory timeframe for inspections of establishments manufacturing class I devices.

[94] Memo from Ann B. Holt, Associate Director for Compliance, to Acting Director of Bureau of Medical Devices, Feb. 16, 1982, p. 5, printed in Hearings, supra, note 3, p. 207.

While one can speculate over the reasons for nonreporting, the survey revealed that some firms had:

> Interesting definitions of complaints, that is, one firm considers a report a complaint only when the complainant asks for a response. Another firm defines complaints as items sent to headquarters; everything received by manufacturing sites are "service requests." [95]

Likewise, the agency's voluntary defect reporting program cannot be relied upon to supply complete, reliable information on device-related deaths and injuries. The program is called the device experience network. It encourages potential sources of information—hospitals, professionals, et cetera—to report observations to FDA through the medical device and laboratory product problem reporting program, a system funded by FDA and coordinated by the U.S. Pharmacopeia. USP has a toll-free telephone number, and it mails postage-paid preaddressed reporting forms to aid sources in reporting adverse experiences. Upon receipt, USP forwards the reports to FDA and to the manufacturer.

Manufacturers simply cannot be expected voluntarily to submit reports to the Government that acknowledge and detail lapses in design, engineering, or performance of their products. For the same reasons, hospitals or other facilities and practitioners will be reticent to make a Federal case and call attention to a mishap with a device. FDA recognized these inherent conflicts, and the inadequacy of voluntary reporting, in 1980 when it proposed making experience reporting mandatory:

> The current atmosphere of medical malpractice and product liability makes it very difficult to establish or expect a voluntary flow of device problem data from the health care community and the device industry.[96]

The agency also recognized that the voluntary DEN program primarily taps information from health care professionals, not from the device industry itself:

> The voluntary system will continue to relate useful information concerning device problems, but it cannot provide the same level of data that manufacturers and distributors possess. For example, manufacturers probably receive more reports concerning deaths and serious injuries than FDA since malpractice has made practitioners very cautious about reporting these events to anyone without a 'need to know.' FDA believes that manufacturers receive these reports because practitioners (and their attorneys) want to determine the cause of deaths and injuries and also want to avoid any additional occurrences. Devices manufacturers and distributors are also in the best position to know the design, characteristics, and limitations associated with their devices. In addition, they also have access to records concerning product specifications, quality assurance, prior product changes, etc. FDA's current surveillance activities cannot provide all the information that would be related by MER reports because this type of information is usually unknown or unavailable to our voluntary reporters.[97]

Ultimately, the agency admitted to OMB that it was totally at sea regarding the true magnitude of device-related problems. In attempting to estimate the reporting burden that the MER proposal would impose on the device industry, the agency stated that it had no information concerning the actual number and types of device problem reports that manufacturers and distributors receive. In fact, this lack

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[95] Id.
[96] OMB clearance request from FDA to OMB, printed in Hearings, supra, note 3, pp. 16–17.
[97] Id.

of information is one of the reasons for promulgating the MER regulations.[98]

The agency appears to agree that a mandatory reporting scheme is essential if it is ever to gain an understanding of device problem areas. Its current practice of conditioning individual new class III device approvals on the submission of information on adverse experiences has established this. Despite this recognition, however, the agency has tied its own hands. It seems to want a mandatory scheme, but it claims an inability to decide precisely what information it needs. This problem seems perfectly amenable to solution through the normal process of public participation in agency rulemaking. The notice and comment procedure attendant to a further proposal for a reporting scheme will undoubtedly supply the agency—as it has in the past—with every conceivable refinement to limit the paper flow to the essentials. The FDA may include with publication of a new proposal a series of questions to avoid the risk that commenters might overlook key issues in the proposal.

It is a sorry fact that now, over 6 years since passage of the device amendments, the FDA, the Congress, and the public are in the dark over whether medical devices are safer today than they were prior to the device amendments. It is essential that the FDA move rapidly to remedy this condition.

V. Restricted Devices

As part of the general controls available to the agency to regulate devices, Congress included authority to restrict the sale, distribution, or use of a device only upon the authorization of a licensed practitioner, or upon other conditions, if the Secretary determines that because of a device's risk there is no other way to assure its safety and efficacy (section 520(e)). The legislative history explains that Congress sought to supersede and add to the existing authority used by the FDA to limit sale or use of certain devices except by prescription.[99] Authority beyond prescription was necessary because many—including the Cooper committee—believed that major problems arose from misuse of devices by practitioners, and not just from manufacturing or design defects. Establishing conditions under which devices could be used, or limiting or describing the facilities where they could be used, or the training or qualification of those who use them in treatment, was envisioned as a way to address user-related problems. Controls such as these were not contemplated by the lone previously existing authority to limit devices to a practitioner's prescription.

FDA's prescription authority over devices derives from section 502 (f)(2) of the act, which permits the Secretary to exempt certain devices from the requirement that all devices bear adequate directions for use. The prescription device regulations which implement this authority condition this labeling exemption on the device being sold

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[98] Id. Since first proposing the mandatory scheme, and while holding the proposal in abeyance, the agency has obtained the preliminary results of the survey of manufacturers' complaint files, referred to in note 94, supra, which shows the majority (60 percent) to be in poor or unusable condition.

[99] House report, supra, note 3, p. 24.

only to or on the prescription or other order of—a licensed—practitioner (21 CFR. sec. 801.109(A)(1)(2)). These regulations, by their terms, speak to the fact—not the nature or extent—of professional involvement and to labeling requirements for such devices. They do not address the kinds of restrictions on sale or use that need to be imposed to protect the public from harm due to their misuse. The authority to restrict a device, added by section 520(e) of the device amendments, supplies the necessary additional capacity to restrict channels of distribution or conditions of use of any device where this is necessary to protect the public. Section 520(e) requires that the agency proceed by regulation and therefore presupposes action to restrict a class or type of device. The device amendments also permit the agency to restrict sale or distribution (1) as a condition to approval of a new class III device, and (2) as an element in performance standards for class II devices.[100]

Beyond control over channels of distribution and conditions of use, the designation of a device as restricted improves the agency's capacity to protect public health by expanding its authority to inspect device-manufacturing facilities pursuant to section 704(a) of the act.[101] The weak provisions of the 1938 Food, Drug, and Cosmetic Act—that were equally applicable to devices, food, and drugs—had required FDA to obtain permission from the owner before inspecting factories, warehouses, or other establishments. Equal treatment of food-, drug-, and device-plant inspections continued when, in 1953, Congress strengthened the act by eliminating the need to obtain permission prior to inspection. However, when section 704 was strengthened again in the 1962 amendments to the act, the additional authority to inspect all things in the establishment bearing on possible violations of the act, including records, files, papers, processes, controls, and facilities was extended only to inspections dealing with prescription drugs. The 1976 device amendments extended this expanded inspection authority to restricted devices.[102] This meant that, for the first time, FDA inspectors could obtain documents as well as inspect facilities where devices were manufactured.

The key to the implementation of all this new-found inspection authority, of course, was an administrative determination that a device was to be restricted in order to assure its safety and efficacy. The FDA sought to implement all this authority in one fell swoop, through what the Second Circuit Court of Appeals termed a feat of procedural brinksmanship.[103] It published a final regulation—without notice or opportunity to comment—one week after enactment of the device amendments declaring that restricted devices include all prescription devices as now defined in 21 CFR 801.109 * * *.[104] The industry opposed the agency's declaration-by-fiat. Interestingly, the lawsuits in which

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[100] Id. at pp. 26, 32. Sections 515(d)(1)(B)(ii) and 514(1)(2)(B)(v).

[101] See generally, *Becton Dickinson* v. *FDA*, 589 F. 2d 1175 (2d Cir. 1978), where the court of appeals reviewed the history of the statutory expansion of inspectional authority for restricted medical devices.

[102] The device amendments also created requirements for the advertising of restricted devices, exempting such advertising from scrutiny under the Federal Trade Commission Act (section 502(r), and the amendments added additional registration/listing requirements for establishments manufacturing restricted devices (section 510(j)(1)(B)(ii)).

[103] Becton Dickinson, supra, 589 F. 2d at 1182.

[104] 41 F.R. 22620, 22621, June 4, 1976. Within a few weeks, (on June 21, 1976, Representative Paul Rogers, the primary sponsor of the Device Amendments in the House, took the unusual step of writing to the agency and telling the Commissioner that it was illegal to declare prescription devices to be restricted devices without a rulemaking proceeding that afforded the opportunity for public participation. (589 F.2d at 1182).

the issue of the procedural irregularity in adopting the regulation arose did not result from the FDA attempts to impose limitations on the sale or distribution of such newly restricted devices. Rather, it was over inspections. FDA investigators began to arrive at establishments where restricted—that is, prescription—devices were manufactured seeking access to, among other things, complaint files.[105] In numerous cases, manufacturers resisted on the grounds that the FDA's designation of their devices as restricted was flawed procedurally and therefore unlawful.[106] After two Federal circuit courts of appeal agreed with the manufacturers' contentions, the FDA decided to stop litigating cases premised on the lawfulness of its original designation.[107]

Of course, the agency need not have litigated at all to establish its authority over restricted devices. As both courts of appeal noted in supporting the manufacturers, a 5 U.S.C., sec. 553 rulemaking proceeding was what Congress had intended in section 520(e), and the second circuit in Becton, Dickinson opined that had the agency commenced such a proceeding in June 1976, it probably would have completed it by the end of that year. Without a valid regulation, the agency after 3 years of litigation was back at square one. No devices were lawfully "restricted".[108]

Fortunately for the public, FDA access to important documents pertaining to devices was not totally erased by the invalidation of the June 1976 restricted device regulation. In 1978, the agency promulgated its Good Manufacturing Practice Regulations—pursuant to section 520(f) of the device amendments—which included a series of requirements to prepare and retain various records pertaining to device manufacturing and complaints.[109] Under section 704(e) of the act—also added by the device amendments—all manufacturers required to maintain any records by certain sections of the new amendments—or regulations promulgated pursuant thereto—are required to make them available to FDA's inspectors, irrespective of whether the device to which they relate is designated as restricted.[110] Therefore, even in the absence of restriction, the FDA can obtain access to documents which the agency describes, in advance, in a regulation of general applicability. To date, the GMP regulations are the ones which specify the maintenance of such documents. However, in the individual case where an inspector might need materials other than those specific ones required to be maintained by the agency's generically worded GMP regulations, FDA lacks the authority to obtain them. This is not a purely hypothetical worry; at least one manufacturer of high risk devices—

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[105] For example, FDA Inspectors at the Becton Dickinson plant were initially provided access to these files by the company volunntarily. They found that the complaint files disclosed "deficiencies of some seriousness" and, when they returned the following day to continue their inspection, further access was refused. Becton, Dickinson, supra, 589 F.2d at 1178.

[106] In re Establishment Inspection of Portex, Inc., 595 F.2d 84 (1st Cir. 1979) : *Becton, Dickinson* v. *FDA, supra;* In re Establishment Inspection of American Technology (No. CV-78-1727—LEN C.D. Cal. 1978) ; In re Establishment Inspection of Portex, Inc. (No. MED-78-272 ; D. Mass. 1978) ; *U.S.* v. *Sherwood Medical Industries, Inc.* (No. 77-0890-CV-N-Z ; W.D. Mo. 1977) ; In re Establishment Inspection of Sherwood Medical Industries, Inc. (No. 77-0265-CV-W-Z ; W.D. Mo. 1977).

[107] See 45 F.R. 65619, 65620 ; October 3, 1980.

[108] The agency would argue that an individual new class III device whose PMA was approved on condition that the device be restricted in prescribed respects would be considered a restricted device for purposes of section 704(a). There are about 100 such devices, out of the total of 40,000 devices on the market today.

[109] 21 CFR, part 820. See sec. 820.180 et seq.

[110] The requirement is limited to records required by sections 519 or 520(g). The GMP regulations derive from section 519's general requirements as well as those of section 520(f).

a pacemaker—convinced a court that the agency could be denied access to important records relating to reported failures of its device because the GMP regulations did not cover them.[111]

The concern that a need would arise to obtain such otherwise unobtainable materials relating to high risk devices was real enough for the agency to take steps to avoid it. In October 1980, the agency proposed a regulation to designate as a restricted device any one of six categories of devices.[112] The preamble to the proposal explained FDA's unsuccessful attempt in 1976 to designate all prescription devices as restricted and reviewed the history of litigation referenced above. Clearly, this new proposed regulation was put forward primarily as a remedy for denial of access to records during inspections. A review of its provisions reveals that the agency did not at all propose to address problems associated with the misuse of medical devices in any direct way. The proposed regulation simply expanded the labeling requirements of the current prescription devices regulation, and it changed the name of these devices to restricted devices. But the proposal created no restrictions on the sale, distribution, or use of such devices beyond those already a part of the prescription device regulations.[113]

A year after its was proposed, the restricted devices regulations was withdrawn. Citing Executive Order 12291—the Reagan administration's directive on regulatory relief—and the comments received, the agency stated, in effect, that it could not justify the proposal. It stated that it would content itself with inspection authority under section 704(e)—thereby limiting its access to only those records required by the GMP regulations—and that it would use the current labeling and dispensing requirements of the prescription device regulations.[114] This result is undesireable for two reasons. First, the agency will be forced to litigate over its right of access to particular documents in manufacturers' files, and these cases will turn on whether a court believes the materials in question are required to be maintained by section 519. Second, and more importantly, the agency lost the opportunity to begin to address pervasive user-related device problems which are not

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[111] In May 1980, FDA inspectors sought access to various classes of documents relating to performance failure and consumer complaint about the Medtronic battery powered implanted cardiac pacemaker. The inspection arose from reports of a significant number of sudden failures of the device. The inspectors sought access to, among other things, (1) failure investigation reports, (2) a computerized printout of failures (including all code or legend information needed to interpret the failure data), (3) complaint files, and (4) complaint file handling procedures, failure analysis procedures, and returned product handling procedures. When the manufacturer refused to produce any of these, FDA obtained a warrant from a U.S. magistrate. The manufacturer moved to quash the warrant, arguing that access to the documents was outside FDA's statutory authority. The motion to quash was denied by the magistrate, but, on appeal, the U.S. district court reversed in part. The court ruled that the computerized printout of failures and the written complaint files handling procedures, failure analysis procedures, and returned product handling procedures were not records required to be maintained by the statute or the implementing GMP regulations. Therefore, despite their obvious importance, the FDA could not lawfully obtain them pursuant to section 704(e) of the act. In the Matter of Establishment Inspection of Medtronic, Inc., Civ 3–80–504. (D. Minn. Oct. 15, 1980).

[112] 45 F.R. 65619, Oct. 3, 1980. The six categories of devices proposed for restriction were: (1) devices intended to penetrate or pierce the skin; (2) devices intended to be implanted in the body or for correcting or replacing a body part; (3) devices intended to introduce energy on or into the body; (4) devices intended to deliver medicinal gas to the body; (5) devices, other than in vitro diagnostics, intended for use in diagnosis of diseases or to monitor body functions; and (6) in vitro diagnostic devices intended to be used by a health professional.

[113] Compare proposed sections 801.109 and 801.110 (reprinted in CCH Medical Device Reports, para. 11,621, p. 7759–60, 1981) with 21 CFR, secs. 801.109, 801.110. The common restrictions upon sale or distribution are simply that, if a manufacturer wants to be exempt from the misbranding provision in section 502(f) of the Act, it must limit distribution to "qualified health professions" in the course of their professional practice.

[114] 46 F.R. 57569, Nov. 24, 1981.

at all confronted by the existing prescription device regulations and which present a significant risk to public health.

Conditioning the use of, or limiting channels of distribution for, a type of device by way of a regulation under section 520(e), or for an individual newly approved class II or class III device provides the agency with a unique tool to address risks markedly different from the manufacturing-related defficiencies on which the remainder of the device amendments primarily focus. That is, most of the general controls, and the major thrust of the provisions in the performance standards and premarket approval sections, are geared toward ensuring that finished devices, when ready for use, will be free from defects, safe and effective. Restriction, on the other hand, can address problems with a device once it is in use. It deals with the risks that practitioners, technicians, or others who employ the device are doing so improperly due to inadequate training, experience, facilities, or instructions.[115]

Unfortunately, the risks from improper use are all too real. During the hearings, Congressman Gore revealed the preliminary results of a study being undertaken by the General Accounting Office to assess the incidence of and risks from device-related injuries. The GAO had completed three-quarters of its review and had found tentatively:

> That operator or user error is the predominant cause of both medical device failures to perform as well as device-related patient injury. Operator error was listed as the predominant cause in over 60 percent of the cases with other causes, including faulty design, defective components, improper labeling, inadequate instruction, and inadequate maintenance and repair following.[116]

Moreover, the risks posed by user-related error have been recognized for a substantial period—beginning long before GAO commenced its current study and long before the device amendments were enacted.

In 1970, the Cooper committee concluded that:

> Many hazards associated with medical devices arise not from their design and manufacture, but rather from the way in which they are used. The study group is distressed by the lack of data in many areas related to the interaction of medical devices with the human body, and by the seeming unquestioning acceptance of claims for medical device safety and performance unsubstantiated or inadequately supported by scientific fact. It seems likely that such acceptance, 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 usage particularly of more complicated or sophisticated instrumentation. Electrical hazards arising from improper installation and interconnection of devices with one another is a case in point. Greater knowledge on the part of professional and technical health personnel no doubt would contribute to resolution of an important part of the total hazards problem. Greater knowledge on the part of physician users is needed about the mechanisms of action, the limitations of usefulness, the precautions that must be observed, and the instructions needed to assure proper operation of devices.[117]

In 1974, the Congressional Research Service stated:

> It is concluded by opponents of proposed stringent [medical device] legislation that major needs in the medical device field are not in areas of design or defects to which present legislation is directed. It is felt that the major priority is improving the knowledge and understanding of medical device technology. Improving the knowledge of the purchaser and the user might significanly increase the

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[115] See comment of Commissioner Hayes, Hearings, supra, note 3, p. 129, quoted infra.
[116] Hearings, supra, note 3, p. 128. Emphasis added.
[117] Cooper committee report, p. 6.

benefits of medical devices and materially reduce the types of mishaps which have resulted from the use of devices up to the present time.[118]

The agency apparently has yet to recognize these risks. Current regulations are not adequate to address user-related device problems. They say nothing about the training or experience of the practitioner or the conditions under which a device must be used to ensure safe, effective treatment. As Commissioner Hayes acknowledged during the hearings, the agency needs to address these issues directly in order to combat user-related problems:

> One of the interesting things from the data that you quote from GAO would suggest that perhaps the biggest problem that we have appears not to be in the manufacturing of the medical devices but rather with user and practitioner error. This suggests we must talk about such things as restriction of devices as well as education, information, and the like.[119]

The GAO's preliminary findings thus do not raise new issues, and they should be no surprise. The fact is that user- and practioner-related error have been major problems in the medical device industry for a long time. The preliminary findings of the GAO are not a revelation but a confirmation of this fact. Had the agency been sensitive to problems long associated with the use of medical devices, it could have acted appropriately by implementing its significant new authority in section 520(e) to restrict devices to address these problems. The agency's failure to act in this area must be added to its failure to promulgate performance standards for class II devices, its failure to call for data establishing the safety and efficacy of preamendments class III devices, and its failure to establish an adequate reporting system as still another significant example of a lost opportunity to protect the public.

Furthermore, the agency need not resort to formal regulatory measures to begin to achieve a meaningful increase in public protection from use-related device problems. The subcommittee recommends that the agency inaugurate educational programs, and develop explanatory materials, to improve the knowledge of patients, technicians, and professionals regarding the safe use of devices and the hazards associated with improper use. Of course, the ability to target educational efforts effectively requires information about where such efforts are most needed. So, again, the agency's failure to install a valid adverse experience reporting system prevents it from taking meaningful steps to protect the public.

VI. Premarketing Control by Default: Section 510(k)

New devices are automatically classified into class III.[120] This automatic classification rule imposes the full requirements of the class III premarket approval process upon all new devices regardless of their potential hazard to health or safety. The drafters of the device amendments afforded manufacturers of such automatically classified devices the opportunity to petition the agency for reclassification into class I or II and thereby avoid the burden of the premarket approval

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[118] Dodge, "Medical Devices: A Brief Review of Legislation and Issues Related to Regulation." Congressional Research Service, Nov. 4, 1974.
[119] Hearings, supra, note 3, p. 129.
[120] Section 513(f)(1).

process. The device amendments require approval or denial of such a petition within 210 days from its filing.[121]

The device amendments contain a provision designed to prevent manufacturers from circumventing the automatic class III designation of new devices. Section 510(k) requires manufacturers to notify the agency 90 days before introducing a device into commerce for the first time and to specify whether the device has been classified and the actions taken to comply with any applicable requirements for performance standards or premarket approval. This provision enables the agency to assure that new devices are not marketed until they comply with applicable requirements or are reclassified into class I or II.[122]

The 510(k) process allows the agency to prevent circumvention of the automatic classification of new devices into class III by considering the issue of whether a device is substantially equivalent to another device already on the market. If the agency agrees that a device for which a 510(k) notification is submitted is substantially equivalent, it is not new and need not undergo premarket approval. If the agency does not agree, a manufacturer may immediately file a premarket approval application for its new device, or commence gathering the necesessary data on safety and efficacy before submitting a PMA, or petition the agency to reclassify the device into class I or II.[123]

Some have suggested that Congress original intent in section 510(k) merely was to provide a simple system for notifying FDA that a classified or unclassified device was to be marketed, and that the process has now become overly complicated by its focus on substantial equivalence.[124] Indeed, section 510(k) itself contains no reference to substantial equivalence, or to significant changes from other devices, or to data pertaining to safety and efficacy. Yet, all of these have, to varying degrees, become part of the 510(k) process. And properly so. The agency is justified by the terms of the statute in calling for such materials. It is charged with reviewing a device's classification, prior to marketing, and determinations about classification are inextricably connected to whether a device is either substantially equivalent to another or new.

Congress original intention was to create a regulatory system of both pre- and post-marketing controls to assure safety and efficacy. As already discussed, the agency has ignored the basics of that system by failing to set performance standards for class II devices and by failing to call for safety and efficacy data covering numerous class III devices. If these controls were in place—with their direct and indirect assurances of safety and efficacy—discussion of the agency's implementation of section 510(k)'s premarket notification require-

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[121] Section 513(f)(2). The agency is required to notify the petitioner within 30 days of any deficiencies in the petition (section 513(f)(2)(A)); to refer the petition to an appropriate classification panel which must make its recommendation to approve or deny reclassification within 90 days (section 513(f)(2)(B)); and to approve or deny the petition within 90 days of receipt of the panel's recommendation (section 513(f)(2)(C)).

[122] House report, supra, note 6, p. 37. See Hearings, supra, note 3, p. 8. The FDA's implementing regulations (21 CFR, part 807, subpart E) clarify the circumstances under which manufacturers must file a 510(k) notification. Submission is required when a device is being significantly modified, or when the device is being introduced for the first time by a firm required to register under the act, regardless of whether the device is unique or substantially equivalent to another device. (21 CFR, sec. 807.81(a).)

[123] Hearings, supra, note 3, p. 8.

[124] See, e.g., L. Pilot, "The 510(k) Process—a Candidate for Reform." Medical Device and Diagnostic Industry, Vol. 3, No. 4, April 1981, at p. 24.

ments—in terms of the data sought and the complexity of the submissions needed to resolve the issue of substantial equivalence—might take a different turn. But, by defaulting in its obligation to establish safeguards for classes II and III devices, the agency has forced itself to rely heavily upon the 510(k) process as a weak surrogate mechanism to provide some modicum of assurance of the safety and efficacy of devices that, contrary to congressional intent, are subject only to the general controls.

The volume of 510(k) submissions is immense. Nothing in the legislative history of the device amendments suggests that Congress expected the flood of devices introduced after passage of the device amendments that have not been new and, therefore, have not required premarket approval. That is, Congress probably did not anticipate manufacturers' decisions to introduce substantially equivalent—as opposed to new—devices in the proportion that has obtained in the past 6 years. Of the over 17,000 510(k) submissions made since enactment of the device amendments, all but 1 or 2 percent—about 16,700 devices—have been found to be substantially equivalent to another pre- or post-amendments device and have, therefore, avoided premarket approval.[125] This figure is to be contrasted with the mere 114 new, unique class III devices that have been approved through the premarket approval process.

The almost 17,000 devices allowed onto the market via the 510(k) process include 4,100 found substantially equivalent to class I devices, 9,800 found substantially equivalent to class II devices, and 1,000 found substantially equivalent to class III devices.[126] There are no performance standards backing up these 510(k) decisions to assure the safety and efficacy of almost 10,000 class II devices. And there are no regulations calling for premarket approval of the preamendments—and 1,000 substantially equivalent—class III devices now on the market. The reality of current device regulation is that many manufacturers need not expect to meet performance standards or demonstrate safety and efficacy in a PMA; all they need do is demonstrate substantial equivalence and the barriers to begin and continue marketing are down.[127] Once such equivalence is shown, devices are marketed in a regulatory system that treats all of them the same. They are subjected to general controls and no more. The three-tiered regulatory system created by Congress has been collapsed by FDA inaction into a system that treats the most hazardous device virtually as if it were the least hazardous—that virtually treats coronary bypass blood oxygenators as if they were no more hazardous than tongue depressors. While Congress may not have anticipated the immense number of 510(k)'s for substantially equivalent devices—as compared to PMA's for new devices—it clearly did not intend all devices to be subject to the same set of regulatory controls—and the minimum controls at that.

A 510(k) finding of substantial equivalence is not an acceptable substitute for the regulatory system at the heart of the device amendments. Although relevant, a finding of substantial equivalence to an

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[125] Hearings, supra, note 3, p. 9. Indeed, the agency has estimated that 47 percent of these are not only substantially equivalent but virtually identical to preamendments devices. Id.

[126] BMD submission in subcommittee files. Approximately 2,000 of the total of 17,000 devices were found substantially equivalent prior to 1977 during which period the agency did not list the classification of the devices to which they were substantially equivalent.

[127] The sole exception to this rule is the manufacturer of a new, unique class III device who must file a PMA.

already marketed device is not an assurance of safety and efficacy. It is simply a recognition that a newly introduced device poses risks and benefits not materially different from an already marketed device, and that it may, therefore, be regulated in the same fashion to assure its safety and efficacy. To the extent the device to which the newly introduced device is equivalent poses risks, or lacks efficacy, so also will the new device pose risks or lack efficacy. It is regrettable that this crude mechanism—never intended as a substitute for measured, direct regulatory requirements—has come to be relied upon for so much in the regulatory system.

Given that the 510(k) process—by default—has become a more important regulatory tool than Congress envisioned, two conclusions are apparent. First, until the agency has taken serious steps to implement the statutorily mandated three-tiered regulatory system created to assure that marketed devices are safe and effective, any attempt to weaken the 510(k) process—especially to facilitate entry of class II and class III substantially equivalent devices into the market—should be resisted. This would include attempts to reduce the burden in terms of the amount of information now called for in the agency's regulations governing the premarket notification process.[128] This conclusion is by no means an endorsement of the use of the 510(k) process as a substitute for class II and III regulatory controls. It simply recognizes that no matter how desirable or necessary, these controls cannot be fully implemented to provide protection immediately. Something must continue to fill the gap while the agency begins to put the mandated controls in place.

Second, the agency must insist, through all available means, that the information provided in 510(k) submissions is accurate and complete. When manufacturers supply inaccurate or false information, and the agency learns of this, it must take pains to assure that its response reinforces the integrity of the 510(k) process. Unfortunately, this has not always occurred. In the matter involving Baxter Travenol Laboratories, discussed immediately following, the agency's limp response to the intentional submission of false information jeopardized the integrity of the 510(k) process by signaling the industry that the agency lacks the backbone to attack abusers vigorously.

VII. Four Case Studies of Regulatory Timidity

A. VOLUMETRIC PUMP CASSETTE

The IMED Corp. is a relatively small device manufacturing firm that has profitably marketed a medical device since 1974 which regulates the flow of intravenous fluid from its source to the patient. Called a volumetric infusion pump, this device represents a substatnial improvement in the precision of intravenous administration. The pump

[128] Although the statute allows 90 days for the agency to review 510(k) submissions, the agency has been processing submission in a time frame averaging 40 day. (BMD Submission retained in the Subcommittee files). The Harris Survey, referred to in section IX, infra, asked respondents about their experience with, and to rate the reasonableness of, the 510(k) process. 44 percent of respondents had never filed a 510(k); 52 percent had filed (table 5–9). Despite the fact that many had no experience, all respondents were asked to rate the reasonableness of the 510(k) requirement. 45 percent felt it was either very or somewhat reasonable; 41 percent felt it was very or somewhat unreasonable (table 6–6). This relationship—a slight plurality believing it to be more than less reasonable—was carried over into the two subsamples of those that had and had not filed a 510(k).

accommodates a disposable plastic cassette, engineered to fit into a hollow receptacle, that connects to the line of flow and regulates it by means of a rotating valve that opens and closes. The cassette must be changed at least every 24 hours.

A good-sized hospital—with 375 beds—has about 35 infusion pumps and it uses approximately 10,000 disposable volumetric pump cassettes each year. The annual national sales of the cassettes are about $50 million.[129] IMED Corp. manufactures the most widely used infusion pump. It, naturally, also sells a large number of volumetric pump cassettes to fit its pump. Another infusion pump is manufactured by Baxter Travenol Laboratories, Inc., but it does not use a disposable cassette.

IMED's pump cassette business proved exceedingly attractive to Baxter Travenol—the world's largest manufacturer of intravenous solutions with assets over $800 million, and 1980 sales over $1.3 billion. It decided that the disposable volumetric pump cassette business was lucrative enough to justify duplicating IMED's cassette, notifying the FDA of its intention to market this substantially equivalent device, and marketing it under Travenol's name to fit the IMED pump. Travenol's cassette is now on the market competing with IMED's; IMED is suing Travenol for patent infringement.[130]

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[129] Recent press accounts report that IMED is being bought by Warner-Lambert for $405 million. Remarks attributed to Warner-Lambert's president forecast that, by 1990, the disposable cassette market may approach $700 million. MDDI Reports, Vol. 8, No. 29, July 19, 1982, p. 9.

[130] *IMED Corporation* v. *Travenol Laboratories*, Civ. Action No. 81-C-3155, N.D. Ill. The effect of a finding of substantial equivalence upon the rights and liabilities of parties under the patent laws presents intriguing questions: To what extent can an FDA finding of substantial equivalence be used as evidence of patent infringement? Might such a finding be prima facie evidence of infringement? Under the patent laws the courts have developed a doctrine of equivalents which prevents a party from making only insignificant changes to another's patented device and thereby avoiding liability for infringement. The Supreme Court has ruled that:

"One thing is substantially the same as another if it performs substantially the same function in substantially the same way to obtain substantially the same result. . . . Authorities concur that the substantial equivalent of a thing, in the sense of the patent law, is the same as the thing itself; so that if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form or shape [citation omitted]." *Machine Co.* v. *Murphy*, 97 U.S. 120, 125 (1877). See *Graver Tank & Mfg. Co.* v. *Linde Air Products*, 339 U.S. 605 (1950).

This superficial congruence in legal standards, however, may not withstand analysis. The substantial equivalent of a thing, for purposes of the patent laws, may well not be the same as its substantial equivalent for purposes of the medical device law. What makes this distinction in standards with similar-sounding names plausible is the wide discretion vested by Congress in the FDA to employ a flexible interpretation of substantial equivalence in administering sections 513(f)(1) and 510(k) of the device amendments: "The term substantially equivalent is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purpose as marketed products. The committee believes the term should be construed narrowly where necessary to assure the safety and effectiveness of the device but not so narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness. Thus, differences between new and marketed devices in materials, design, or energy source, for example, would have a bearing on the adequacy of information as to a new device's safety and effectiveness, and such devices should be automatically classified into class III. On the other hand, copies of devices marketed prior to enactment, or devices whose variations are immaterial to safety and effectiveness would not necessarily fall under the automatic classification scheme." House Report, supra, note 3, pp. 36–37.

Given this legislative history, which indicates that where differences relate to the safety or efficacy of a device, substantial equivalence should be construed narrowly (and vice versa), it would, therefore, appear that in any given case, the concept of substantial equivalence for medical devices may be more or less expansive than for purposes of patent infringement.

The flexibility of the substantial equivalence standard for purposes of medical devices is confirmed by the fact that the FDA has not specified any meaning for the term in its regulations [see 21 CFR, secs. 807.81(a), 807.87(h)], it has not clearly indicated the kind of data needed to support a manufacturer's assertion of substantial equivalence, and it has reserved the discretion to request any additional information regarding the device that it deems necessary to decide whether or not a device is substantially equivalent to another [sec. 807.87 (f) and (h)]. Finally, when the agency determines that a device is substantially equivalent to another, the reasons for its finding are not revealed to the public. (Under certain circumstances the manufacturer's submission will be made public, section 807.95.) This, it would seem, would make it difficult to argue that the agency's determination has any particular relevance in an infringement action.

Depositions taken in the *IMED* v. *Travenol* patent suit revealed many of Travenol's activities in developing and marketing its look-alike disposable cassette. Of special significance is the fact that Travenol lied to the Food and Drug Administration in submitting its 510(k) prior to marketing the cassette. Investigation also revealed that FDA was aware that the Travenol cassette had been tested by two independent university hospital laboratories and had been found to be defective. The agency dismissed this evidence as inconsequential and was unable at the July hearings to assure the public that the device was safe.

The depositions in the patent infringement suit establish that Travenol wanted to commence marketing its disposable cassette by July 1, 1980,[131] and its engineers and marketing personnel knew that one of the required premarketing steps was to get the necessary clearance from FDA. Accordingly, on March 27, 1980, Travenol sent FDA a formal 510(k) notification stating that it was providing 90 days prior notice of its intention to market the cassette. Travenol stated that its cassette was substantially equivalent to the cassette marketed by IMED. Travenol also stated that the equivalency of the products was supported by:

1. Photograph of IMED C–924 Accusett.
2. Photograph of Travenol 2C1020 Volumetric Pump Cassette.
3. Labeling accompanying IMED C–924 Accusett.
4. Draft labeling for Travenol 2C1020 Volumetric Pump Cassette.[132]

In fact, at the time of this 510(k) notification, no Travenol cassette existed. The second photograph submitted with the 510(k), which was labeled as the Travenol device, was actually a second photo of the IMED cassette. One of Travenol's employees was instructed to shave off a strip of its plastic body, and the company's regulatory affairs administrator knowingly and falsely labeled the device as the Travenol 2C1020 Volumetric Pump Cassette.[133] FDA duly reviewed the March 27, 1980 Travenol 510(k) submission, noted nothing extraordinary, made a telephone request for clarifying information on the materials used, and approved it on May 8, 1980.

Travenol was not ready to market the cassette by July 1, as originally planned. Significantly, in November/December 1980, when Travenol started biding on various hospitals' invitations to supply cassettes, it learned that the hospital biomedical director at the University of Arkansas had tested Travenol's cassettes and found that they leaked fluid into the intravenous line when the valve was supposedly closed.[134] This finding was corroborated by the results of a similar test at the University of Nebraska.[135] The leaking was substantial; the range of uncontrollable flow of 56–103 ml. per hour equalled normal dosage flow ranges depending on the drug used.[136]

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[131] Deposition of Michael P. DeFrank, June 29, 1981, at p. 20. Mr. DeFrank was program manager of Travenol, responsible for development of all of Travenol's disposable devices for intravenous administration (Dep. at p. 10).

[132] Hearings, supra, note 3, pp. 234–243.

[133] DeFrank deposition at pp. 203–11.

[134] Letter, Nov. 5, 1980, from Lawrence A. Robinson, M.S., Pharm. D., University of Arkansas for Medical Sciences, to Thomas Nickel, Product Manager, Infusion Pumps, Travenol Laboratories, Inc. Hearings, supra, note 3, pp. 224–26.

[135] Memorandum, Dec. 17, 1980, from Larry Fennigkoh, CCE, Director, Biomedical Instrumentation, University of Nebraska Medical Center. Hearings, supra, note 3, pp. 219–23.

[136] Id., pp. 99–100.

FDA first learned that Travenol had lied in its March 1980 510(k) notification on August 6, 1981, when IMED's lawyer presented FDA's Chicago field office with the incriminating deposition of one of Travenol's responsible officials and the two hospital clinical evaluations. Just 9 work days later, Travenol sent FDA a supplement to 510(k) notification in which it stated that it wanted to update our file by supplying a photo of a currently marketed Travenol cassette. Travenol also stated: "Attachment 2 of the original * * * submission dated March 27, 1980, included a photograph of a prototype 2C1020 set which was an IMED cassette modified to reflect Travenol design."

Based on IMED's allegations, and on Travenol's virtually contemporaneous confirmation, FDA launched an investigation to determine what action was appropriate. The agency addressed two issues: First, did Travenol violate the Food, Drug, and Cosmetic Act (21 U.S.C. 331(q)(2)), or 18 U.S.C. 1001, by filing a false 510(k) in 1980; and second, had Travenol's cassette been further modified from IMED's design, after the filing of the 510(k), to such an extent that FDA's substantially equivalent determination of May 8, 1980 no longer applied.

FDA disposed of the first issue in short order. Various Bureau of Medical Devices officials decided that Travenol's March 1980 510(k) was misleading, at least unethical, and at best deceptive.[137] Yet, they decided Travenol's false statements were immaterial, and therefore not illegal, because the 510(k) depicted the device Travenol intended to market and because FDA's regulations do not require a device to be in existence before a 510(k) notification can be submitted.[138] In interviews with the subcommittee staff, the responsible FDA officials, including the chief counsel's office, explained that if Travenol had correctly stated the facts—that is was intending to market a yet-to-be-developed device and that a photo of a prototype of the device was enclosed—the Bureau of Medical Devices would have approved the 510(k) anyway.[139] Because the falsehood did not affect the Bureau's decision, the argument goes, Travenol's false submission did not violate section 301(q)(2) of the act that prohibits the submission of a required report regarding a device that is false or misleading in any material respect, 21 U.S.C. 331(q)(2). A similar analysis led FDA not to recommend prosecution of Travenol under 18 U.S.C. 1001.

The Bureau's second area of inquiry took more time. If Travenol's currently marketed cassette had been modified since the time of the original 510(k) submission, so that it was no longer substantially equivalent to IMED's, then the Bureau would have grounds to revoke its original 510(k) approval. Throughout October/November 1981, the Bureau attempted to learn whether the Travenol cassette then in use differed from the one the company described in March 1980. The documents obtained, together with staff interviews with the responsible Bureau personnel, reveal that: One, the Bureau contacted Travenol and asked for the changes made in the device since 1980,[140] and two, evaluated the changes and decided that they had not affected either the

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[137] Id., at pp. 244–45.
[138] Id., p. 97, where Commissioner Hayes reiterated this analysis in his testimony.
[139] See letter to Hon. John P. East, U.S. Senator, Dec. 11, 1981. Id., at pp. 227–28.
[140] Memorandum of telephone conversation between Robert S. Kennedy, Ph. D., BMD Associate Director for Device Evaluation, FDA, and Maynard Youngs, assistant general counsel, Travenol Laboratories, Inc., Nov. 9, 1981. Hearings, supra, note 3, p. 229.

safety and efficacy of the device or its substantial equivalence to the IMED device.[141]

FDA completed its investigation in late November 1981. It decided that no enforcement action of any kind was warranted. The Associate Director of the Bureau of Medical Devices on November 25 wrote to Travenol expressing serious concern that Travenol did not advise FDA of its false statements in its original 510(k) until a year and a half after the fact:

> Additionally, we have learned that at the time of your original submission, a "Travenol" device did not exist other than as an IMED device modified to reflect Travenol's design changes. We believe such omission of information serves to defeat the spirit if not the letter of the law and regulations. Future submissions are to be complete and contain the full and factual information about the status of the device for which the 510(k) notification is being submitted.
>
> In the future, ensure that representation [sic] made to FDA, including photographs of the device, are factual and complete, and contain no ambiguity.[142]

The subcommittee has focused on three issues: First, did an FDA employee improperly contact Travenol in August 1981 and advise it of FDA's discovery of the falsity of Travenol's March 1980 510(k) submission; second, was FDA's decision not to recommend prosecution under 21 U.S.C., 331(q)(2) or 18 U.S.C., 1001 a wise exercise of its enforcement discretion; and third, did the agency's actions adequately protect the public health.

1. Regarding improper contact

The fact that Travenol chose to "update" its 510(k) submission 9 working days after IMED's attorney first called the irregularities to FDA's attention—especially after an 18-month silence—suggests that more than mere coincidence might have been at work. Travenol is headquartered near Chicago, and IMED's attorney had presented the incriminating deposition, as well as the clinical studies, to FDA's Chicago field office.

Subcommittee staff interviewed every current FDA employee involved in FDA's investigation of the Travenol 510(k) and discovered no evidence that any employee improperly contacted Travenol.[143] This conclusion coincides with that arrived at by those in the agency who also sought to ascertain whether any improper contacts occurred. The most likely source of Travenol's August 19, 1981, supplemental submission appears to be the fact that its lawyers attended the Michael DeFrank deposition in late June that, for the first time, revealed Travenol's conduct and the falsity of the submission. Lawyers for both sides advised their clients of the revelations, and both clients apparently decided to contact FDA with the pertinent information in the

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[141] Letter from Maynard, Youngs to Robert S. Kennedy, Nov. 16, 1981, and memorandum from Fernando Villaroel, Ph. D., Director, BMD Divilon of Gastroenterology-Urology and General Use Devices, FDA, to Robert S. Kennedy, Nov. 25, 1981. Id. at pp. 230–31.

[142] Letter to Thomas D. Nickel, Travenol Laboratories from Robert S. Kennedy, Nov. 25, 1981. Id. at p. 233.

[143] The 12 FDA employees interviewed (in alphabetical order) were: (1) Harry Butts, Director, BMD Division of Compliance Operations; (2) Robert Gatling, Chief, Hospital Devices Unit, BMD Division of Gastroenterology-Urology and General Use Devices; (3) Ann Holt, BMD Associate Director for Compliance; (4) Linda Horton, FDA Deputy Chief Counsel; (5) Robert S. Kennedy, BMD Associate Director for Device Evaluation; (6) Michael Landa, FDA Associate Chief Counsel for Medical Devices; (7) Edward McDonnel, Director, BMD Division of Compliance Practices; (8) Steven Nedelman, Consumer Safety Officer, BMD Compliance Division; (9) Robert Sauer, BMD Executive Officer; (10) Thomas Scarlett, FDA Chief Counsel; (11) Mervin Shumate, FDA Director of Enforcement Policy; and (12) Fernando Villaroel, Director BMD Division of Gastroenterology-Urology and General Use Devices.

same timeframe.[144] The subcommittee, therefore, finds no factual basis to conclude that any improper contacts occurred.

2. Regarding the FDA's enforcement response

As previously indicated, FDA officials concluded that although Travenol's March 27, 1980, submission was misleading, at least unethical, and at best deceptive, no recommendation to prosecute Travenol was forwarded to the Justice Department. Both available statutory remedies for submission of false statements, 21 U.S.C., sec. 331(q)(2), and 18 U.S.C., sec. 1001, contain materiality elements that must be proved to make out a violation. Attorneys for the agency concluded that Travenol's misconduct was an immaterial falsehood, and therefore, not a violation, first, because officials in BMD stated that their initial decision on substantial equivalence would have been the same if they had known the truth, and, second, because they concluded that the statute and pertinent regulations do not require a device actually to exist before the agency can conclude it is substantially equivalent to a preamendments device. These decisions need to be reviewed in light of the pertinent authorities and, importantly, in light of their effect on the integrity of the entire 510(k) process.

The courts have yet had no opportunity to construe the materiality element in 21 U.S.C., sec. 331(q)(2) which was added to the act by the 1976 device amendments; however, the substantial case law developed in connection with 18 U.S.C., sec. 1001 and its materiality element would undoubtedly be persuasive in construing the former statute. The courts appear to have made clear that it is not necessary that the government actually rely upon or be deceived by a false statement in order for it to be material within the meaning of 18 U.S.C., sec. 1001.[145] The critical issue is whether the false statement is capable of influencing the decision the agency or department must make.[146]

Viewed against these standards, the agency's decision that Travenol's false submission was legally immaterial is excessively timid. FDA's regulations governing the required elements in a 510(k) notification specify that a manufacturer must submit data to support the assertion that the proffered device is substantially equivalent to another device. 21 CFR, sec. 807.87(f). In Travenol's case, misrepresentations to the agency were made to satisfy this requirement. Actually, when its 510(k) notification is fully parsed, Travenol made four false representations to the agency, rather than the single misrepresentation to which the agency's chief counsel referred in testimony.[147] First, the company represented that its volumetric pump cassette (model 2C1020) existed when in fact it did not.[148] Second, the

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[144] Maynard Youngs, assistant general counsel to Travenol, stated to subcommittee staff in an interview on Feb. 23, 1982, that the reason for his company's Aug. 19, 1981 submission was the discovery, by its patent lawyers during the DeFrank deposition, of company employees' misguided conduct in filing the original 510(k).

[145] See *U.S.* v. *Lichenstein*, 610 F.2d 1272 (5th Cir. 1980), cert. denied, 100 C. Ct. 2991 (1980); *U.S.* v. *Jones*, 464 F.2d 1118 (8th Cir. 1972), cert. denied, 409 U.S. 111 (1973); *U.S.* v. *Valdez*, 594 F.2d 725 (9th Cir. 1979); *U.S.* v. *Talkington*, 589 F.2d (9th Cir. 1978); *U.S.* v. *Goldfine*, 538 F.2d 815 (9th Cir. 1976).

[146] *U.S.* v. *Lichenstein*, supra; U.S. Voorhees, 593 F.2d 346 (8th Cir. 1979), cert. denied, 441 U.S. 936 (1979); *Tzantarmus* v. *U.S.*, 402 F.2d 163 (9th Cir. 1968), cert. denied, 394 U.S. 966 (1969); *U.S.* v. *Carrier*, 654 F.2d 559 (9th Cir. 1981); *U.S.* v. *Goldfine*, supra.

[147] Scarlett, hearings, supra, note 3, p. 103. The chief counsel referred only to the submission of the falsely labeled photograph.

[148] Travenol's Mar. 27, 1980 510(k) notification stated, "This pump cassette is substantially equivalent to those marketed by both the IMED Corporation and McGaw Laboratories. * * * The equivalency of the three products is supported by * * *." Id. at p. 234.

company submitted a photograph, which is represented to be a picture of its cassette, to demonstrate its equivalence to the IMED device. In fact the photographed device was an IMED device with a strip of its plastic body shaved off.[149] Third, the company represented that a list of materials attached to the submission had been used to build its cassette, when in fact the materials had not been used because the cassette had not been built.[150] Finally, when the FDA employee reviewing the Travenol 510(k) submission called the company's Regulatory Affairs Administrator and asked for more information comparing the materials used in the Travenol and IMED devices, the Travenol official stated that "the materials were generally the same" when, again, the device did not exist.[151]

From the face of the Travenol 510(k) submission it is clear the company believed that its representations were responsive to regulatory requirements and were material to FDA's deliberations on substantial equivalency. The submission explicitly stated that the photograph and the other statements representing both that the device existed and had been manufactured from the specified materials were being offered to support the equivalency of the Travenol and IMED devices. When given the chance to correct the misrepresentations 10 days after the submission in a telephone conversation, the responsible company official reiterated the falsehood. The company's assumptions about the importance of its misstatements to FDA's decisionmaking are not surprising; it seems reasonable to believe that FDA's deliberations over the substantial equivalence of a device would be influenced by the data supporting the application and by whether the proffered device was only an engineering concept or was developed, tested to support the instructions for use on its label, in production, and ready for distribution.

What is surprising is how wrong Travenol was in believing that it must adduce evidence to support its assertion that its disposable cassette was substantially equivalent to IMED's. The thrust of Commissioner Hayes' testimony at the hearings was that a simple statement of what it is, what it does is quite sufficient for FDA to decide on substantial equivalence.[152] The Commissioner and others at the agency were particularly concerned that to move against Travenol here would establish the precedent that a device must actually exist before the agency could decide on its equivalence to another device. The Commissioner testified that to require a device actually to exist before making the equivalency decision would be extremely anticompetitive. It would prevent companies from developing prototypes or starting production, presumably because companies would be unwilling to risk the expenditure of capital to develop a new device without knowing in advance whether FDA will stand in the way of its marketing by requiring a full dress demonstration (in a PMA) of its safety and efficacy.[153] The

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[149] DeFrank deposition, pp. 203–11.

[150] Hearings, supra, note 3, p. 238. Due to difficulties encountered in manufacturing the cassette—after the 510(k) had been submitted—Travenol had to make changes in certain items on the list provided to FDA with the 510(k) notification. See letter cited in note 132, supra.

[151] Memorandum of Telephone Conversation between Edward Estrin, biomedical engineer, BMD division of gastroenterology-urology, and general use devices, and Dennis A. Ocwieja, regulatory affairs administrator, Travenol Laboratories, Apr. 7, 1980. Hearings, supra, note 3, p. 232.

[152] Id., p. 97.

[153] Id. If FDA decides that the proffered device is not substantially equivalent, then it is a new device automatically placed in class III and subject to premarket approval.

FDA wants to retain discretion to deliver a decision on equivalence based, not on what a manufacturer has developed, but on what a manufacturer intends to develop. Based upon its view that a device need not exist before it can be found substantially equivalent, the agency rested its decision that Travenol's misrepresentations were immaterial.[154]

This analysis seems to miss the point, however. Even if the agency may not require it, even if a device's existence is not necessary, statements representing that a device does, in fact, exist are capable of influencing an equivalency decision. As indicated, the four misrepresentations outlined above were directly responsive to FDA regulations covering 510(k) submissions that require the manufacturer to supply data for the agency to consider in deciding whether the proffered device is similar to others. The supportive data required by regulation and supplied by Travenol were false. For the agency to state that it did not rely upon Travenol's assertions because it was immaterial whether the device actually existed injects an element into the pertinent criminal statute that is not there.[155] Even if—unknown to Travenol—FDA was prepared to accept much less by way of support than Travenol had offered, FDA's decision was, at a bare minimum, made easier by the false information Travenol supplied. The subcommittee believes that this information was therefore material within the meaning of 18 U.S.C. 1001, and 21 U.S.C. 331(q)(2), and that if the agency were concerned with the ramifications of its actions—beyond this individual case—it would have recommended prosecution.

Those ramifications are indeed far reaching. As discussed earlier, the 510(k) process is the vehicle by which the vast majority of devices have been allowed onto the market since enactment of the device amendments. Over 17,000 510(k) submissions have been made since 1976, virtually all of which have led to findings of substantial equivalence. This makes it particularly important for 510(k) submissions to be scrupulously accurate and for the agency to take the steps necessary to let manufacturers know the importance the agency attaches to the accuracy of the submissions. FDA's disposition of the Travenol matter sends the opposite signal. In what was, hopefully, a rare opportunity to deal with a manufacturer deliberately falsifying a 510(k) submission and to use this occurrence as an example to let the industry know the importance the agency attaches to the integrity of the 510(k) system, the agency sent a signal of indifference lacking any legal effect. This is an invitation to other firms to follow in Travenol's footsteps.

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[154] A case can be made in support of the agency's flexible policy. Judgments about substantial equivalence are supposed to take account of whether differences between a proffered device and its marketed referent relate to safety and efficacy. See note 130, supra. For some devices, the differences, whether existing or planned, would not relate to safety or efficacy. In these circumstances, there would appear to be no necessity for the device to exist before a 510(k) is filed. In others, where differences could affect safety or efficacy, the existence of a device in final form should be required. The agency can achieve this result by requiring the manufacturer to submit results of tests on the device. However, this flexible policy rests on no explicit foundation in the language of the Device Amendment or FDA's regulations. Section 513(f)(1) of the Device Amendments states that any device not introduced for commercial distribution before enactment of the Amendments "is" a class III device unless, inter alia, it "is" substantially equivalent to a class I or class II device. "Is" was the term used, not "will be." FDA regulations, if anything, speak as if the proffered device must exist. They call for a statement indicating the device is similar to * * * other products of comparable type * * * accompanied by data to support the statement. 21 CFR, part 807.

[155] See cases cited in notes 145–146, supra.

3. Regarding the risk to public health

Equally troubling to the subcommittee was FDA's response to evidence that the Travenol cassette was so defective in design or manufacture that it leaked fluid when its valve was supposedly closed. This evidence, in the form of reports of laboratory tests from the University of Arkansas and the University of Nebraska, was presented to FDA officials at the same time as the incriminating deposition of Travenol's employee. Under questioning, Commissioner Hayes agreed that the level of leakage found to flow through in the studies was within the range of normal dosage—56 to 103 ml. per hour—for certain drugs and that, depending on the drug, the consequences of such an uncontrolled flow through could obviously be serious.[156]

Despite the unambiguous hazard documented by this evidence, prior to the subcommittee's July 1982 hearing the agency ignored it. No other conclusion is possible. FDA was in direct contact with Travenol during this period to inquire about any changes made in the cassette since the original March 1980 510(k) submission, yet no one at the agency asked the company about the defects in the device. In fact, the documents obtained show that the studies were not even mentioned to Travenol.[157] Nor did FDA contact the hospitals where the studies were conducted, or conduct, on its own, any test of the Travenol device then on the market to see if it was defective.[158]

The agency's sole response to this evidence was to conduct a GMP inspection of Travenol's facility and to check the company's complaint files. Because only 21 complaints concerning the device were found, and because the DEN program only had four complaints, the agency assumed the problem was not significant.[159] It made this decision despite the fact that, in general, 60 percent of companies' complaint files are poor or unusable,[160] and that the DEN program, relying totally on voluntary reporting of device problems, vastly understated their incidence.[161]

As a consequence of the agency's failure to follow up on this data—the only evidence of any kind then available to it relating to the safety or efficacy of the Travenol cassette—Victor Zafra, then the agency's Acting Director of the Bureau of Medical Devices, was forced to make a discomforting admission:

> Congressman GORE. Wait a second now. You have got two university hospitals, both of which have tested this device, hooked it up, run fluid through it, and tested it. Both of them say it is life-threatening. Then you come here and tell us in response that you want to reassure us that FDA has looked at it and it doesn't think it is life-threatening.
>
> Do you want to make that statement, Mr. Zafra? Do you want to tell us that you can reassure us that it is not life-threatening?
>
> Mr. ZAFRA. That wasn't the statement I was trying to make.
>
> Congressman GORE. You cannot make that statement, can you? Can you make that statement?
>
> Mr. ZAFRA. No, I don't think we can.[162]

4. Post-hearing developments

As a result of the hearings, FDA decided to test the Travenol and IMED cassettes. The agency, first, found no flowthrough characteris-

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[156] Hearings, supra, note 3, pp. 99–100.
[157] See memorandum and letter at Id., pp. 229–31. See testimony at pp. 98–102.
[158] Id., pp. 101–102.
[159] Id., p. 99.
[160] Id., p. 98.
[161] See pp. 26–27, supra.
[162] Hearings, supra, note 3, p. 101.

tics with the IMED cassette. It next discovered that the Travenol cassette had evolved beyond the model tested and found defective at the Universities of Arkansas and Nebraska, and that two subsequent generations of Travenol cassettes had been developed and marketed. By mid-September 1982 the agency obtained samples of both later generations, both of which were then still in use, and tested them for flow-through characteristics. It found that the second generation model exhibited the defect while the third generation did not. It also learned from Travenol that about 72,000 of the defective original cassettes—tested at the universities—had been marketed and 800,000 of the defective second generation cassettes had been marketed before giving way to the currently marketed third generation. The agency estimated that about 225,000 defective cassettes remained available for use.

The agency thereafter conducted an evaluation of the health hazard presented by the defective cassettes, presumably because it was a product being recalled or considered for recall.[163] The Health Evaluation Committee considered the evidence developed in the FDA laboratory tests and concluded that the use of this device may cause temporary or medically reversible adverse health consequences. The probability of serious adverse health consequences is remote.[164] The committee's choice of this language was not fortuitous; it tracks, verbatim, the agency's definition of the risks warranting designation of a class II recall.[165]

The Evaluation Committee reached its conclusion after consideration of the following: Reports of adverse effects, the likelihood that flow-through would occur in any given situation, and the population at risk if flow-through did occur.[166] First, there had been no reports of complaints or injuries resulting from the defect. Second, the laboratory tests had revealed that uncontrolled flow-through occurs with a defective cassette only when certain conditions are met. The pump governing the intravenous flow must be switched off while the valve in the cassette is rotating. The valve rotates to allow fluid to be sucked into the cassette's chamber, and it rotates again to a different position to allow the fluid to be expelled through the intravenous tubing and into the patient. During each fill/expel cycle of the pump, the valve is actually rotating for only about 1.2 seconds. A typical fill/expel cycle lasts about 20 seconds; so a first approximation of the danger zone during which a flow-through condition could be produced in about 6 percent—1.2 seconds divided by 20 seconds—of the time the pump is in operation. A further condition that must be met before flow-through will occur relates to the actual position of the valve when the pump is switched off during that short danger period—1.2 seconds—when the valve is rotating. The laboratory tests showed that the valve rotates through a total arc of 53 degrees in those 1.2 seconds, but that flow-through occurred only when the rotating valve happened to be within a 7 degree sub-arc when the pump was switched off. This represents about 13 percent of the total space through which the valve rotates in its active 1.2 seconds.

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[163] 21 CFR Part 7.41(a).
[164] The report of the Health Hazard Evaluation Committee is attached hereto at pp. 69–70.
[165] 21 CFR, part 7.3(m)(2).
[166] The step-by-step analysis of the Evaluation Committee, discussed in the text, was communicated to the subcommittee staff at an interview on Nov. 18, 1982.

Thus, for flowthrough to occur, not only must the valve be rotating—which happens about 6 percent of the time a pump is turned on—but it must be within a particular position range—which represents about 13 percent of the total movement—when the pump is switched off. These conditions combine to produce a risk condition during less than 1 percent of the time (6 percent × 13 percent = .78 percent) that a pump and defective cassette are in use.

That is not the whole calculation of the level of risk involved. The Evaluation Committee also considered the fact that infusion pumps, which are pre-set to administer an entire bottle's worth of fluid at a given flow rate automatically, are rarely turned off by the attending nurse at any time. Pumps are typically switched off only when the bottle is empty and must be changed—but there then is no risk from a flowthrough defect because there is no solution left to flow through. The only other time when pumps may be switched off while fluid remains in the bottle is when the patient needs some supplemental infusion which is to be administered through the same intravenous line that is already plugged into the patient's system—the tubing is designed with a γ-joint to permit this. The Evaluation Committee's judgment was that this supplemental infusion occurred only about 1 percent of all the times that intravenous fluids are administered by automatic pumps. This further diminished the incidence of risk from uncontrolled flowthrough to 1 percent of 1 percent of the time, or to 1 in 10,000.

The third and final risk assessment factor woven into the equation by the Health Hazard Evaluation Committee was the population that would be at risk if an uncontrolled flowthrough occurred. It concluded that that group would principally be critically ill newborn children who were obtaining their sustenance or medication via intravenous administration. Although the consequences here would be alarming indeed, this group of patients only represent, in the Evaluation Committee's judgment, about 1 percent of all patients who might need an I.V. Therefore, the Evaluation Committee's final rough quantitation of the risk of health hazard from uncontrolled flowthrough from a defective Travenol cassette was 1 percent of 1 percent of 1 percent—or one in a million times.

It is instructive that, while small quantitatively, the quality of the hazard was such that the Evaluation Committee chose not to describe it in other terms such as those which would define a class III recall, that is, a situation not likely to cause adverse health consequences. While the risk was remote, it was still significant. This considered decision was a product of the evidence developed in FDA's laboratory tests and the Evaluation Committee's expert clinical judgment as to its significance. Nothing in the Evaluation Committee's analysis suggests it was conducted in other than the routine fashion in which such assessments are frequently made and communicated to the agency's enforcement officials.

Coupled with this assessment of health risk, the agency also obtained documents and information from Travenol that, for the first time, established that the company knew in October 1980—prior to the conduct of the laboratory tests at the Universities of Arkansas and Nebraska—that its cassette then in production was defective. The FDA obtained from Travenol a copy of the laboratory notebook of a

Travenol employee who, on October 9, 1980, conducted two laboratory tests comparing Travenol and IMED cassettes. All of the tested Travenol cassettes allowed air to flow through; none of the IMED cassettes did. Additionally, four of the five tested Travenol cassettes allowed fluid to flow through; none of the IMED cassettes did.[167]

Despite these findings, Travenol released for sale over 2,700 of these defective units on October 27, 1980. Furthermore, the company was not influenced by the reports from Arkansas and Nebraska that it received in November/December 1980 and that confirmed the presence of the flow-through defect. Travenol released an additional 70,000 units for sale between January 1981 and December 1981. The company revised its valve design in an attempt to correct the defect in late 1980—the "second generation" cassette. But it apparently was unwilling to absorb the costs of scrapping or repairing 70,000 defective first generation cassettes—so it sold them knowing that they had problems.

An FDA engineer who reviewed these newly obtained inculpatory documents from Travenol asked the company's general counsel "why Travenol continued to ship cassettes with valves that could exhibit flow-through so long after the valve was redesigned." [168] The company official responded that "theoretical analysis and testing had shown that flow-through would not occur in normal valve positions and that no flow-through complaints had been received from the field." [169] But this was not convincing. In the same conversation, the FDA engineer also asked the Travenol official:

> Why Travenol only pressure tests production cassettes to 8 psig if they are intended for use with pumps which exceed this pressure (some older IMED pumps can generate up to 45 psig opm occlusion). Mr. Youngs said that he did not know. I stated that this is one are [sic] he should explore, since I felt the testing does not make any sense." [170]

Thus, Travenol lied to the FDA; it manufactured a defective cassette; it sold that cassette knowing of its defect; and, apparently, it employed invalid in-house testing procedures that did not assess the cassette's performance under actual operating conditions. The entire record of Travenol's conduct engenders in this subcommittee a sense of affront that is not tempered by the decision of the FDA Hazard Evaluation Committee that the actual chance of serious risk to critically ill newborn children was remote.

It appears, however, that the FDA did not, and does not, share the subcommittee's sentiment. It did not recommend to the Justice Department that the company be prosecuted because the original misstatement in the 510(k) submission was not material. It did not ask the company to recall the 225,000 defective cassettes that the FDA believes still remain available for use. Instead, the agency wrote the company on October 6, 1982, to advise it that the FDA's tests showed what Travenol already knew: That flow-through and valve leakage can occur in these devices.[171] The agency did not ask the company to replace the defective

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[167] The range of flow-through was 15 ml./hr. to 110 ml./hr. This is the same level of magnitude as reported by the two university hospitals.

[168] Memorandum of telephone conversation between George C. Brolick, BMD, FDA and Maynard Youngs, general counsel, Travenol Laboratories, Aug. 31, 1982.

[169] Id.

[170] Id.

[171] Letter to Vernon Loucks, Jr., president, Travenol Laboratories from Ann B. Holt, DVM, Associate Director for Compliance, BMD, Oct. 6, 1982.

cassettes with the other defect-free ones that Travenol currently sells. Instead:

> In order to preclude the possibility of harm to patients, we request that your firm promptly alert users not to turn off the pumps while the valve is rotating, because to do so may result in flow-through.[172]

The FDA thus permitted Travenol to shift the responsibility for remedying its defective product onto the shoulders of the hospital personnel and individual consumers who use them in their homes.[173]

The agency's October 6 letter invoked section 518 of the device amendments which authorizes the agency to notify health professionals and the public at risk when a device poses an unreasonable risk of substantial harm to the public health and where no more practical means is available * * * to eliminate such risk * * *. In response to FDA's request, on October 20, 1982, Travenol sent letters to its customers stating that it had recently learned there is a remote possibility that a slow rate of solution flow-through may occur when using certain Travenol Volumetric Pump Cassettes. The company stated it was alerting users not to turn off the pump while the valve is rotating. As an alternate procedure, clamp the administration tubing when the power switch is in the off position.[174]

The FDA is now in the process of evaluating how effective Travenol's notification has been. It is not a recall, and, therefore, was not reported in the agency's weekly enforcement report.[175] This undoubtedly saved Travenol a measure of adverse publicity. The agency maintains that although Travenol's action was not termed by FDA a recall, that the FDA's field personnel who are auditing the effectiveness of the company's actions are treating it as if it were a class II recall and as if it were subject to the agency's existing guidelines covering that kind of corrective action.[176] No guidelines or regulations exist which specify manufacturer or agency responsibilities in a section 518 notification program. If the recall guidelines ought to apply, the subcommittee recommends that the agency make them applicable. If different guidelines are necessary, they should be promulgated. Neither the agency nor manufacturers are well served by the resort to remedies that lack a mechanism to govern their operation.

The subcommittee will continue its review of the FDA's activity in this matter.

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[172] Id.

[173] The company advised FDA that 10,751 cassettes had been shipped to home users as of Oct. 25, 1982. Not all of those were defective, however, because some percentage of these were third generation cassettes.

[174] Letter to hospital administrators, from H. J. Nichols, group product manager, Travenol Laboratories, Oct. 20, 1982.

[175] The agency's failure to term this action a recall instead of, or in addition to, a section 518 notification seems inconsistent with other reported actions taken by the FDA in similar situations. The agency's Apr. 7, 1982, enforcement report (p. 4) describes a class II recall of a stationary exercise bicycle with labeling that does not contain adequate directions for use or warnings about the potential risk if the seat attachment bolt and nut are not assembled and secured properly. The June 23, 1982 report (p. 2) lists a class II recall of an infusion pump for anticoagulants where a possibility existed that a primer switch might stick and cause over-infusion if the device is disinfected with certain chemical solutions. The Aug. 11, 1982 report (p. 2) lists a class II recall of a cardioresuscitation system that would not display data on a monitor if the monitor is not properly seated. Each of the three above matters designated as class II recalls involves a problem that could be addressed by a correction in the field. Each was publicized in the enforcement report. It is not clear whether the agency regards the Travenol matter as less or more serious than these recalls, but it clearly treated it differently for reasons that are not as yet clear.

[176] 21 CFR, part 7, subpart B.

B. TAMPON WARNINGS

During 1980, the Centers for Disease Control and the FDA revealed evidence linking tampon use with toxic shock syndrome [TSS], a recently recognized disease that occurs most often in menstruating women under 30. The disease is serious and can result in death. It is believed to be caused by a bacterium, staphylococcus aureus, and its symptoms include a rapid drop in blood pressure and shock.

Data concerning this disease were first published in May 1980. The Centers for Disease Control [CDC] found that 95 percent of the reported cases occurred in women, and that TSS almost uniformly occurred during the menstrual period. Evidence developed later in the year by the State Health Departments of Utah, Wisconsin, and Minnesota, as well as by CDC, demonstrated a relationship between Toxic Shock Syndrome and the use of tampons during menstruation. While the evidence revealed at least some association between TSS and all the brands of tampons then on the market, Procter & Gamble's RELY brand was most clearly associated with the incidence of TSS.[177] In response to public and governmental pressure, Procter & Gamble entered into a consent agreement with FDA which provided for the recall and removal of RELY from the market. Numerous product liability suits are currently pending against Procter & Gamble alleging defects and negligence in the design, manufacture, and testing of RELY.

On October 21, 1980, FDA published for comment a proposed regulation that would require manufacturers to label tampon packages with a warning that would alert users to the risk of TSS and encourage them to obtain prompt medical attention when the early symptoms of the disease are observed.[178] The agency stated that the public health problem raised by the relationship between tampons and TSS needed to be dealt with rapidly, so it reduced the comment period on its proposal from 60 to 30 days, and it proposed to make the regulation effective quickly, that is, 60 days after final publication.[179]

During this period of extreme interest in 1980, manufacturers of tampons began to take actions voluntarily to protect the public health and their own legal positions. For example, International Playtex began labeling its tampons using the warning language proposed by FDA in October 1980. Johnson & Johnson and Kimberly-Clark also began labeling. Tampax began including a patient package insert addressing the TSS/tampon issue.

Despite FDA's statements in its October 1980 labeling proposal that is was shortening the comment period to 30 days because the association of tampons with TSS is a public health problem that needs to be dealt with promptly, the agency failed to act on the proposal until June 22, 1982—a delay of 1 year and 8 months.[180] During this period. TSS has remained a threat to the lives of many young women. The CDC stated that 867 cases of TSS were reported in 1980 and 492 cases in 1981.[181] The figures for 1981 are particularly disquieting because they occurred during the period of FDA inaction

[177] 45 F.R. 69840, Oct. 21, 1980.
[178] Id.
[179] Id., proposed section 801.430(e).
[180] 47 F.R. 26982, June 22, 1981.
[181] Hearings, supra, note 3, p. 121.

on the proposed warning. The CDC also advises that although TSS incidence figures are now remaining constant, they are the product of a surveillance system that does not detect all cases. In fact, CDC has assumed that the reported incidence figures reflect 15 percent of the cases which actually occur. This leads CDC to estimate the true rate of severe cases of TSS to be 300 to 400 per month, and, if milder cases of TSS are as common as severe cases, the actual rate of the disease to be in the vicinity of 600 to 800 cases per month.[182] Based on these and other estimates, FDA took pains in its Federal Register proposal to refute comments that the incidence of TSS is now decreasing and that the incidence of TSS was related solely to the use of one tampon brand, Procter & Gamble's RELY that was removed from the market in 1980.

FDA justified the 20-month delay in finalizing the warning requirement, in part, by citing industry's voluntary efforts to supply information to consumers on TSS.[183] Yet, a review of those voluntary efforts discloses a less than satisfactory performance. Initially, after the revelations of 1980 concerning TSS, many firms (excluding Tampax) began to include permanent warning information on their labels. However, apparently due to the passage of time without final FDA action, the firms, perceiving their interests to be better served through less open communication with consumers, bowed to the forces of the free market and removed the warnings from their labels.[184] Tampax, the industry leader with a reported 58 percent market share of the $410 million tampon market,[185] has never put warnings on its labels, and it has included information on its package inserts describing TSS that has created the impression that the disease posed little risk to women:

> TSS is a very rare illness that affects mainly women during menstrual periods. U.S. Government reports show about 750 cases of TSS among 52,000,000 menstruating women in 1980, with a sharp drop in new cases since September 1980.[186]

In fact, the FDA has agreed with estimates based upon reported studies that the incidence of TSS is between 6 and 17 cases per 100,000 menstruating women.[187] This rate extrapolates to between 3,100 and 8,800 cases among the 52 million menstruating women used in the Tampax insert as a base. Not only is the incidence of risk therefore substantially understated in the insert, but the wording of the notice suggests that the incidence is decreasing. This later statement is also a misrepresentation. In the June 22 Federal Register notice, the agency engaged in a substantial refutation of industry arguments that the incidence of TSS is decreasing. Referring to the CDC estimates and to data developed by State health departments, the agency stated that it was "concerned that many people seem to believe that the incidence of TSS is decreasing." The agency stated that it "disagrees . . . that there is a basis for concluding that the incidence of TSS is now decreasing or that the incidence of TSS is related solely to the use of RELY brand tampons." [188]

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[182] 47 F.R. at 26982.
[183] Hearings, supra, note 3, pp. 109–10.
[184] Id., pp.119–20. The firms moved the information to inserts included within the box.
[185] Chicago Tribune, May 6, 1981, p. 3.
[186] Hearings, supra, note 3, p. 112.
[187] 47 F.R. at 26985. The Centers for Disease Control have developed incidence estimates of 600 to 800 new TSS cases per month that corroborate this projection.
[188] 47 F.R. at 26982.

In the face of this diminishing, and even deceptive, provision of information to consumers, the agency's decision to permit 6 months of continued marketing by the tampon industry before the final warning regulation published in June 1982 took effect appears to be a needlessly dangerous outcome.

Tampons are a class II device, placed in that category because the agency accepted the opinion of its expert advisory panel that mandatory performance standards are necessary in order for the device to be safe and effective.[189] The agency's failure here—as with every other class II device—to promulgate any performance standard to regulate tampon design or manufacture provides a concrete illustration of the consequences of its approach to class II devices. FDA explicitly recognized the importance of tampon absorbency to the risk of TSS, and it included in the final regulation a requirement to advise consumers to use tampons "with the miminal absorbency needed to control menstrual flow." [190] This requirement arose from the agency recognition that at least one study had found a statistically significant relationship between TSS and tampon absorbency.[191] The importance of absorbency to the risk of TSS was recently confirmed by a joint panel of the National Institute of Medicine and the National Academy of Sciences which issued a report advising women, among other things, to avoid the use of "super plus" or highly absorbent tampons because of their increased risk.[192] Furthermore, FDA reported that there is now no common understanding of the terms ("regular," "super," "super-plus") manufacturers use to describe the absorbency of their products. It concluded, therefore, that "consumers could not identify those lower-risk tampons from product labeling." [193] Thus, a woman seeking to purchase a low absorbency product might buy a "regular" tampon manufactured by one company and end up with a product that is more absorbent—and riskier—than another manufacturer's that is labeled as "super" absorbent.

Even in a circumstance as clear as this, where the agency has recognized the importance of a particular performance attribute to public safety and where current marketing is providing information that will mislead consumers who are seeking to protect themselves, the agency steadfastly has refused to break its perfect record and commence a standard setting proceeding. It prefers, instead, to rely upon the development of a voluntary standard by the tampon industry with no timetable specified for its completion and no guarantee that companies will adhere to it.[194] In the meantime, women are left on their own to experiment with these products in the hope that they will find one that suits their needs before they find one that injures them.

C. RECLASSIFICATION OF CONTACT LENS MATERIAL

Obtaining premarket approval from FDA to market a class III medical device is an expensive and lengthy process, the exigencies of which

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[189] 45 F.R. 12715, 12717 (1980).
[190] 21 CFR, sec. 801.430(d)(3).
[191] 47 F.R. at 26987.
[192] Toxic Shock Syndrome: Assessment of Current Information and Future Research Needs, National Institute of Medicine (released June 4, 1982). Science, Vol. 216, June 18, 1982, p. 1300.
[193] 47 F.R. at 26987.
[194] Hearings, supra, note 3, pp. 121–22.

make it very difficult for small firms to obtain approval.[195] Where premarket approval is necessary to protect the health and safety of the public, these requirements are unquestionably justified. But where experience demonstrates that rigorous premarket review is no longer necessary, its continuation becomes onerous, and it can cause substantial economic dislocation.

In January and March 1981, the Contact Lens Manufacturers Association petitioned the agency, pursuant to section 513(e), to reclassify the materials from which certain contact lenses are made from class III into class II.[196] The January 1981 petition covered lenses made principally of hydroxyethyl methacrylate [HEMA], and the March 1981 petition covered lenses consisting principally of rigid gas permeable plastic materials. The HEMA petition centered on CLMA's argument that FDA had substantial experience with these devices over their 12 years of marketing and that there is no evidence of any significant health problems relating to their use. The gas permeable materials petition argued that compliance with a revised standard of the American National Standards Institute would provide adequate protection for the public health. The association amended its two petitions in March 1981, and in April the FDA expert advisory panel charged with responsibility for ophthalmic devices reviewed them. The panel was satisfied that the petitions should be approved. It asked for some modifications which CLMA submitted satisfactorily in June 1981.[197]

FDA was silent for 5 months. It then published on November 18, 1981 a statement in the "Federal Register" that the petitions were deficient—that "they are not adequate to satisfy all the requirements" of 21 CFR section 860.123 of the regulations governing reclassification of devices pursuant to section 513(e).[198] Inexplicably, FDA did not specify to CLMA or to other interested parties what the precise problems with the petitions were. The notice opaquely stated that while the petitions could not pass muster, their intent was "meritorious." Rather than return the petitions to CLMA for correction or supplementation, the agency summarily classified the petitions as "moot," apparently because it decided to undertake, on its own, to do whatever work it believed necessary to cure the deficiencies it perceived in the petitions. This failure to accept or reject left the matter in limbo, totally within the discretion of the agency. As Congressman Whittaker aptly noted.

> Mr. WHITTAKER. On what basis was the provider of this information supposed to act if they had given you a battery of material, and you declared it inadequate but did not tell them in which way it was inadequate? Were they supposed to mindread just what the information was you really desired before you would consider it adequate?[199]

As justification for this approach, the acting Bureau Director testified that the agency believed it could conduct a literature review to gather "new information" about the safety and efficacy of these devices—as required by section 513(e)—faster than CLMA could.[200] The

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[195] See the Harris Survey, pp. 61–68, infra.
[196] Section 513(e) provides that, "based on new information respecting a device, the Secretary may upon his own initiative or upon petition of an interested person, by regulation, (1) change such device's classification. . . ."
[197] Hearings, supra, note 3, p. 29.
[198] 46 F.R. 57648, Nov. 24, 1981.
[199] Hearings, supra, note 3, p. 30.
[200] Id.

agency shouldered this responsibility, apparently, in part to make amends for its slow pace of dealing with the petitions and also because the agency believed that these devices should no longer be subject to the rigors of premarket review. Unfortunately, with a friend like FDA, CLMA needed no enemies. As of the date of hearing on this matter, 8 months after the agency moved ahead on its own, no formal action had been commenced to reclassify these devices.[201]

The agency's decision to freeze CLMA out of the process of gathering evidence to support the reclassification was ill--advised. First, the agency was understaffed. The people who were called upon to repair the deficiencies in the petitions were employed in the ophthalmic devices section, the busiest part of the Bureau of Medical Devices.[202] In fact, the agency had to add staff from another bureau organization who were not experienced in the eye care area to aid in the conduct of the literature search.[203] Second, the agency was hamstrung by section 520(c) of the act which prevents it from using information obtained from other parties in their premarket approval applications to reclassify a device. It thus put the agency on precisely the same footing as any outside party seeking to adduce evidence adequate to justify a reclassification. Third, it is hard to believe that agency employees taken away from their normal duties would be motivated to move rapidly to cure deficiencies in the submission of a trade association presumably capable of representing the best interests of its members and able to gather evidence of the safety and efficacy of the products they manufacture.

What makes the agency's sluggish performance in this matter more troublesome is that there was virtually uniform support for reclassification in the industry and within the agency, as Congressman Whittaker established at the hearings, and there are deleterious effects that the delay has had upon the smaller firms in this industry and upon the public:

> Mr. WHITTAKER. Would not the reclassification of the hema and gas-permeable lens materials to a class II device encourage a greater variety of small manufacturers to enter the field, thus potentially reducing the cost to consumers and providing a greater variety of the products?
>
> Mr. HAYES. Well, I don't know the industry well enough to be able to give you a definitive answer, but it would certainly seem to make sense from what I do know of it, and from the facts of the case, that if you reclassify—and therefore—improve the ability for more small manufacturers to engage in this in a successfully competitive way, then clearly there would be more competition.
>
> Whether that would lower prices I don't know. I would presume and hope so.[204]

Unfortunately, small firms restricted to marketing their less competitive, less desirable lens materials will not be able to survive FDA's delay much longer. Comments filed in support of the reclassification petition make clear that these firms have been forced to reduce their employment and that they are suffering operating loses while waiting for the reclassification which the entire industry saves for those companies which have previously obtained premarket approvals.[205]

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[201] Section 513(e) prescribes reclassification by a regulatory process that requires the Secretary to publish the recommendation of the expert panel to which a petition was referred and to engage in a notice and comment process prior to promulgatio

[202] Hearings, supra, note 3, p. 30.

[203] Id., p. 34.

[204] Id., pp. 95–96.

[205] Id., pp. 36–94.

One year after the agency "mooted" CLMA's petitions, and undertook on its own to develop support for reclassification, it published a proposal in the Federal Register to reclassify these materials from class III to class I.[206] CLMA had petitioned to move the devices into class II, but the FDA has tentatively decided "there is no need to establish a performance standard" to provide adequate assurance of safety and efficacy for these contact lens materials. There are three primary reasons articulated for its decision. First, since the mid- to late-1970's, contact lenses made from these materials have been marketed and have been shown to be safe and effective. The absence of reports of significant adverse side effects reported to the Device Experience Network during this period apparently weighed heavily in arriving at this conclusion. Second, the FDA states that the 510(k) premarket notification requirement, and its regulations implementing the requirement, "will enable FDA to insure that only . . . contact lenses that are safe and effective will be marketed." [207] Third, the FDA states that application of the GMP regulations "will enable FDA to insure that only . . . contact lenses of uniform quality will be marketed." [208]

One aspect of the FDA's proposal, in particular, raises questions: The agency may intend to rely too heavily—or improperly—upon the 510(k) process for assurances of safety and efficacy. Although, on its face, the proposal is to move the devices from class III to class I, it seems that the agency may intend in the substantial equivalence review in the 510(k) process to treat the devices as if they were moved to class II and were subject to a performance standard. The FDA's intentions in this regard are suggested by its statements listing the numerous parameters along which substantial equivalence decisions will be made, and by its statements that its substantial equivalence decisions will enable it to assure that the lenses possess the desired properties and characteristics to a clinically significant degree.[209]

These statements signal an intention to use the 510(k) process to achieve adherence to a de facto performance standard. That is, the agency's strict insistence on a high level of similarity between new products and reclassified contact lenses will ultimately become the de facto application of a performance standard where the characteristics of the reclassified materials, to which new products must be substantially equivalent, have become the "standard."

Of course, all substantial equivalence judgments in the section 510(k) process can be said to involve assessing a new device against the "standard" represented by another device to which it is claimed to be substantially equivalent. But distortion of this process occurs if it is taken to an extreme, where equivalence is construed so narrowly that no differences between devices will be tolerated. At that point, the FDA will be using the characteristics of the reclassified devices as a performance standard which all new devices must meet. While this regulatory approach may not directly contravene any explicit provision of the device amendments, it certainly contravenes Congress' intention that when manufacturers of devices are to be required to adhere to a performance standard they be informed in advance of the

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[206] 47 F.R. 53402 (Nov. 26, 1981). 47 F.R. 53411 (Nov. 26, 1982).
[207] 47 F.R. at 53405, 53406, 53414, and 53415.
[208] Id.
[209] Id.

elements of that standard so that they may structure their engineering and manufacturing processes accordingly. Creating a de facto performance standard through the 510(k) process leaves manufacturers in the dark over the manufacturing criteria they will be held to, and vests the FDA with a level of discretion that Congress did not intend.[210] If the agency believes that adherence to a performance standard is necessary to assure that contact lenses are safe and effective, it should reclassify them into class II and commence the necessary standard setting proceeding.

D. BIFOCAL SOFT CONTACT LENSES

In the early 1970's, firms began to obtain FDA approval to market soft contact lenses. Later in the decade, research and development led to the emergence of a bifocal soft lens, a portion of which is of a different power, in order to provide both distance and near vision correction. FDA monitored the development of the bifocal soft lens, and on several occasions it made the industry aware that no bifocal soft lens could be marketed without prior approval by FDA. As early as June 1980, the agency issued guidelines stating that if a manufacturer changes either the configuration or the indications for use of a previously approved soft contact lens, it is required to conduct clinical testing on the lens to establish its safety and efficacy and to submit a PMA and obtain prior FDA approval to market the modified lens.[211] In July 1981, during on open meeting of the Ophthalmic Device Section Advisory Committee, the committee members (all highly qualified experts in this field) repeated the need for clinical testing and FDA approval prior to the marketing of a bifocal soft lens.[212]

In August 1981, Bausch and Lomb notified the agency that it was adding a bifocal soft lens to its line of previously approved soft contact lenses. FDA also learned in September that the Wesley-Jessen division of Schering Plough was marketing bifocal lenses. Both companies were on notice that FDA required a submission of clinical evidence prior to marketing, yet neither company undertook to supply data establishing the safety or efficacy of these new devices.[213] Over the next 3 months, the agency and the companies pressed their respective views regarding the need for premaret approval in correspondence and meetings. Yet, while the parties were posturing, the companies were commercially distributing the lenses.

There was never any room for question about FDA's position in regard to the legality of these firms' behavior either prior to or after it learned they had commenced marketing these bifocal soft contacts. On October 7 the agency reiterated its consistent position in a letter to Bausch and Lomb and Wesley-Jessen and to all other manufacturers of soft contact lenses stating:

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[210] See discussion of the 510(k) process at pp. 32–35, supra. The Subcommittee recognizes that Congress did invest the agency with a measure of discretion by providing for a flexible interpretation of the term "substantial equivalence". It is also recognized that the legislative history reflects Congressional intention for the term to be construed narrowly where differences between "new" and marketed devices have a bearing on safety and effectiveness. House Report, supra, note 6, pp. 36–37.

[211] Hearings, supra, note 3, p. 115.

[212] Id.

[213] See, e.g., Letter from Michael Fitzpatrick, Regulatory Affairs Administrator, Bausch and Lomb to Jean McDowell, Chief, Document Control Center, FDA, Aug. 21, 1981, printed at id., p. 110.

Modification of such lenses in design and indications for use constitute substantial changes which require FDA approval prior to marketing. Until such approval, these lenses may only be distributed as investigational devices for investigational use.[214]

Nevertheless, the agency—despite its numerous, unequivocal statements regarding the illegality of commercial distribution—waited until December 29 before asking the appropriate U.S. attorneys to commence seizure actions against Bausch and Lomb and Wesley-Jessen. During the 3½ months while the companies were sparring with FDA, they were gaining substantial economic benefits from being the first on the market with this new product.[215] The reason they were first was not necessarily because their devices were developed first; it was because competing firms (like Ciba-Geigy and Salvatori Ophthalmics) respected FDA's statements regarding the need for prior approval and clinical data.[216] These and other firms' reward for complying with FDA's expression of the requirements of the law was to lose significant competitive advantage to firms that defied FDA.

In addressing the length of time it took the agency to move formally against the offending firms, FDA's chief counsel testified that "three and a half months from identification of a problem to transmitting an enforcement action to the U.S. attorney's office is pretty prompt for the FDA in this area." [217] Yet, as Mr. Scarlett agreed, a seizure pursuant to 21 U.S.C. section 334 of these companies' devices would have been neither a complex nor a difficult proceeding to undertake from the Government's standpoint. In fact, preparing a seizure case is one of the simplest actions that a lawyer in food and drug practice can prepare, and it did not take 3 months to prepare these cases.[218] The reason for the delay appears to have been the time necessary for the agency internally to debate its substantive position in the matter even though it had informed the companies directly in regulatory letters that it was unlawful to market the lenses without submitting data,[219] and even though it had previously made the clear, industry-wide announcements of its position in June 1980 and in July 1980.

Chairman DINGELL. Didn't you tell Bausch & Lomb this was a violation of law?
Mr. SCARLETT. Yes, we did.
Chairman DINGELL. And you told them well before the three months, did you not?
Mr. SCARLETT. Yes, we did. But when we go into court we want to be certain what we are saying is correct.[220]

What is disturbing about this colloquy is not the agency's desire to be certain before commencing judicial proceedings, but the implicit statement that the agency actually considered *not* commencing an action because its position might not have been "correct." This point was made explicit in Mr. Scarlett's February 15, 1983 letter to the subcommittee staff where he states that the November 23, 1981 meeting "was no pro forma meeting serving only as a checkpoint before an inevitable decision to refer the cases . . . the important point is that

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[214] Letter from Ann Holt, Associate Director for Compliance, Bureau of Medical Devices, to various contact lens manufacturers, Oct. 7, 1981, printed at id., pp. 108–109.
[215] Id., p. 112.
[216] Id., p. 115.
[217] Id., p. 114.
[218] Id., pp. 112–13. In a subsequent letter to subcommittee staff, Mr. Scarlett stated that the decision to go forward with the cases was no made until Nov. 23—5 weeks prior to his transmission of the matter to the U.S. attorneys.
[219] Id., pp. 107, 114–15.
[220] Id., pp. 113–14.

even as late as November 23, the agency had not decided that the companies' legal position could be defeated in court."

When the agency intends for an entire industry to be governed by a statement of policy, it seems essential that those within the agency who will bear responsibility for enforcing that policy be involved in its formulation and satisfied with that policy. Otherwise the agency runs the risk of failing to back itself up by taking prompt, appropriate enforcement action against firms that disregard that policy in an effort to gain economic advantage. Such failures will compromise the agency's credibility and makes it far less able to secure voluntary compliance with agency pronouncements in the future.

Also troublesome is the fact that the offending parties here were large firms in an industry where small firms proliferate. The leisurely pace of law enforcement actions against Bausch and Lomb and Wesley-Jessen had the effect of benefiting those who needed it least and prejudicing those who would suffer the most.

The seizure complaint against Wesley-Jessen—alleging that the lenses were adulterated because they were not covered by an approved PMA—was filed by the U.S. Attorney with the U.S. District Court for the Northern District of Illinois on January 4, 1982.[221] On February 2, 1982, the U.S. Marshal seized lenses within the judicial district, but Wesley-Jessen continued to market the bifocal soft contacts elsewhere. On February 16, the agency sought and was granted a temporary restraining order against further marketing of the devices by the company, and on March 18, the agency obtained a preliminary injunction.[222]

The seizure complaint against Bausch and Lomb, finally forwarded for filing to the U.S. Attorney in Buffalo, N.Y. on December 29, was never filed. Instead, the parties negotiated a consent agreement that was finalized on January 22, 1982. As part of the negotiations, Bausch and Lomb agreed, on January 12, to cease further commerical distribution of the lenses. The consent agreement prohibited further sale or promotion of the device by Bausch and Lomb until FDA approved it. It also required the company to notify its customers, primarily wholesalers and distributors, of FDA's position regarding the lenses, and to ask its customers to certify that they will not sell their lenses already in their inventory.

The agreement also reflected the fact that Bausch and Lomb—at the same time it was unlawfully marketing its lenses—was conducting a clinical trial to determine whether the devices were safe and effective. Hedging its bet in this manner, the company had engaged in a parallel marketing scheme whereby it gathered evidence of safety and efficacy while commerically distributing its product. Then, if the agency prevailed, the company apparently expected to reconstitute the data as an application for premarket approval. The consent agreement contained FDA's agreement to accept this post-marketing data as a supplemental PMA application, to review it to determine its sufficiency, to forward it to the appropriate panel for review, and to issue an order approving or denying the supplemental application.[223] This agreement to evaluate

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[221] *U.S. v. Article of Device . . .* "One Sterile Lens Durasoft 2 . . . ," No. 82C0013 (N.D. Ill., filed Jan. 4, 1982).

[222] *U.S. v. Wesley-Jessen, Inc.*, No. 82C874 (N.D. Ill., injunction issued Mar. 18, 1982).

[223] Consent Agreement, p. 6, annexed hereto at p. 71 et seq.

Bausch and Lomb's clinical data raises further questions about FDA's handling of this matter.[224]

Foremost among these questions is the fact that the research appeared to violate FDA's regulations governing these investigations. The statement of informed consent provided to subjects in the study stated that the bifocal soft contact lenses were "already approved by FDA and already on the market" and that the study was being conducted "to confirm" their efficacy.[225] These assertions to subjects appear to violate regulations which forbid a sponsor from representing that an investigational device "is safe or effective for the purposes for which it is being investigated" (21 CFR section 812.7(d)).

It is also arguable that use of the informed consent form containing the false characterizations violated FDA's general informed consent regulations which require consent to be sought "only under circumstances that provide the prospective subject . . . sufficient opportunity to consider whether or not to participate . . ." (21 CFR sec. 50.25). It appears reasonable that prospective study subjects might have altered their decision whether to participate in the study based on the knowledge that the bifocal lens they would be wearing had not been approved by FDA and that the study was to determine whether the device was safe and effective. Finally, the assertion that the bifocal soft lenses were already "approved by FDA" appears to contravene section 301(1) of the act, which prohibits:

> The using, on the labeling of any drug or device, or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under section 505, 515 or 520(g), as the case may be, or that such drug or device complies with the provisions of such section.

The act defines "labeling" to mean "all labels and other written, printed, or graphic matter (1) upon any article . . . or (2) accompanying such article". (21 U.S.C. sec. 201(m)). The statement of informed consent certainly accompanied the devices and provided information about their properties, safety, and efficacy. If this information is considered labeling, then it is in violation of law because it clearly stated that the lenses were "approved by FDA" when, in fact, they were not.

The agency was aware of these deficiencies in the conduct of Bausch and Lomb's research.[226] It was faced with a choice. On the one hand, it could permit Bausch and Lomb to rely upon research premised upon "FDA-approved" status of the devices being investigated, which was conducted after the product was in commercial distribution, and in which subjects were told (and presumably influenced by the fact) that the devices were "approved." On the other hand, the agency could insist the research meet the generally applicable standards for investigational devices under which every other manufacturer was attempting to get bifocal lenses onto the market. The agency, of course, had consistently maintained since the beginning of its direct

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[224] Staff was advised in a July 8, 1982 telephone interview with Dr. George Murray of the FDA that the agency had tentatively found Bausch and Lomb's data to be acceptable, that it had been referred to the expert panel for study, that the panel had reviewed the data and had recommended acceptance of the application and that the agency was preparing to approve the application within the next 4 to 6 weeks. Utilimately, the application was approved on Nov. 16, 1982.

[225] Hearings, supra, note 3, p. 132.

[226] Id., pp. 131–35.

dealings with Bausch and Lomb and, indeed, since 1980, that bifocal soft contact lenses were investigational devices.

The agency adopted the former course. Pursuant to the consent agreement, it tentatively evaluated the research, forwarded it to the appropriate advisory panel for review, and in turn, received the panel's recommendation to approve the lenses, and took final action approving them in November 1982.[227] Both Commissioner Hayes and Chief Counsel Scarlett testified that the agency concluded it would not be "in the public interest" to force this company to perform duplicate tests that met the requirements of its investigational research regulations.[228] Such a course would have "penalized" the company, while all the agency sought to do was to get the offending device off the market.[229]

From the perspective of Bausch and Lomb's honest competitors, who chose to abide by FDA's dictates on the requirements of the law, the agency's decision adds insult to injury. Not only were they prejudiced by Bausch & Lomb's early, unlawful entry into the market, but they saw the company permitted to rely upon research data gathered after the unlawful marketing commenced which failed to comply with FDA regulations. The agency's failure to follow through with internal policy decisions that support its public policy pronouncements has taught the regulated industry a lesson: voluntary compliance with agency policy is fraught with the risk that those who fail to comply will gain an advantage.

It could be argued, in justifying the agency's disposition of this matter, that its statutory mandate relates solely to protecting the health and safety of the public and that this does not always mesh with protecting the competitive health of industry. But to protect public health, the agency must be able to secure the cooperation of industry without the need, on all occasions, to resort to judicial proceedings. Industry's willingness to cooperate is tied, understandably, to companies' assessments of the consequences of a failure to comply voluntarily with agency statements of policy. When, as here, companies see a failure to cooperate that results, at worst, in leaving the offender in status quo ante with no "penalty" imposed, and, in actuality, with a "leg up" on competitors, the incentive for future cooperation is jeopardized.

The subcommittee finds that if the FDA is to be able effectively to call upon manufacturers to take action voluntarily to comply with its pronouncements on the requirements of the law, then it must be prepared to act promptly and convincingly against companies who see their economic self interest to lie in pursuing contrary individual courses of action. To do less compromises the agency's credibility and its ability to deter unlawful conduct that potentially threatens the public health and safety.

VIII. The Role of Cost Benefit Analysis in Medical Device Regulation

Since 1981, there has been a recurrent regulatory approach contributing to FDA's failures to adopt an adverse experience reporting

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[227] See n. 224, supra.
[228] Hearings, supra, note 3, p. 132.
[229] Id.

system, to adopt a regulation restricting the sale or conditions of use of devices, and to begin setting performance standards for class II devices. Contributing to each has been the nonstatutory change in decisionmaking standards made by the current administration as evidenced by Executive Order 12291, issued by President Reagan on February 17, 1981. Whether it was cited explicitly or relied upon implicitly (as in the search for the "most cost-effective" alternative) the Executive order, or the increased emphasis placed upon cost/benefit in decisionmaking, clearly was a factor in each of these decisions to delay, defer, or default from FDA's statutorily-mandated responsibilities.

Commissioner Hayes was questioned at length by Chairman Dingell and Congressman Gore on the reasons the agency held in abeyance its proposed regulation requiring adverse experience reporting. The Commissioner testified that his "chief reason" was that he is "really not certain about the best way to do it." [230] He acknowledged at the same time that the agency was able to decide on a reporting requirement for all unique, new high technology devices approved since 1976 but claimed the agency was unable to resolve how to gather such information for the remaining products on the market.[231] This makes the "chief" explanation hard to swallow. Six years of experience in gathering reports from many manufacturers, together with the information gathered in the nowsuspended rulemaking proceeding, is a more than sufficient basis to draft a regulation governing the remainder of devices on the market.

In fact, this extensive experience has not been sufficient. The Federal Register notice announcing suspension stated that "FDA has become subject to requirements more extensive than those in effect at the time of publication." [232] Those requirements included not only Executive Order 12291, in light of which the proposed rule had to be reviewed, but also the inevitability that any proposed rulemaking would be subject to the scrutiny of ranking executive branch officials within the Department of Health and Human Services and the Office of Management and Budget. Commissioner Hayes' testimony confirms that, whether or not he suspended the rule in deference to OMB's specific direction, he was keenly aware of, and his reasons were premised on, the philosophy central to the Executive order:

> There is no question that one of the reasons that I and I alone made the decision that this rule should be put in abeyance was because I felt cost-benefits, appropriateness, and efficiency of reporting were important. Cost effectiveness and the like are terribly important.[233]

When Chairman Dingell inquired into the legal basis supporting the suspension decision, the following colloquy ensued:

> Chairman DINGELL. Where, Mr. Scarlett or Dr. Hayes, in the basic statute under which you labor on this particular point is there a statutory exemption to allow you to respond to the administration's demand that the regulations be cost-effective? Where is there the authority for the OMB to tell you to withhold action, particular action, with regard to medical devices experience reporting?
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> Chief Counsel SCARLETT. [after quoting the language of Section 519 which authorizes reporting regulations] I don't think you could point to any specific legal requirement for which OMB is responsible.

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[230] Id., p. 11.
[231] The agency uniformly conditions approval of all new class III devices to require manufacturers to report adverse experience and other essential information. Id., pp. 27–28.
[232] 46 F.R. 57568 (Nov. 24, 1981).
[233] Hearings, supra, note 3, pp. 22–23.

Chairman DINGELL. First of all [section 519] doesn't give OMB the power to tell you about regulation, does it?

Mr. SCARLETT. That is correct. This is my understanding.

Chairman DINGELL. The second point is that nowhere in that language does it require that the regulation be found to be cost effective, does it, or that it be precleared with OMB?

Mr. SCARLETT. It doesn't use the words cost effective.

Chairman DINGELL. It does not. Now, I have asked you to tell me specifically where in the statute as regards to cost-effectiveness, or as regards to the OMB's oversight is authorized.

Mr. SCARLETT. There is nothing in the Act specifically authorizing that.[234]

Reliance upon the vagaries of cost-effectiveness also contributed to the agency's decision to withdraw the proposed regulation restricting various categories of devices and behind its program to rely on alternatives to performance standards for class II devices. The restricted device proposal, developed by the Carter administration 4½ years after enactment of the device amendments, was withdrawn on the same day that the mandatory experience reporting proposal was suspended. Again, the Federal Register notice referred explicitly to the more extensive requirements imposed by the Executive order.[235] The agency noted, however, that it retained authority under the existing prescription devices regulation (21 CFR section 801.109) to restrict the sale and distribution of certain devices (see discussion at pp. 30–31 supra). The draft policy statement on class II devices opened with the statement: "The FDA will use the most cost-effective regulatory alternative to address class II medical device problems." [236] This left the congressionally mandated system of mandatory performance standards relegated to the status of a last resort, to be resorted to only when all other voluntary means failed.

The increased emphasis on cost effectiveness in these instances appears to have created an impediment to effective public protection. Three of the major provisions in the device amendments now lie in limbo as result of the application of cost benefit analyses. The following colloquy between Chairman Dingell, Commissioner Hayes, and Congressman Gore eloquently conveys the subcommittee's reason for concern:

Chairman DINGELL. Doctor, I think it is becoming quite plain to you from our discussion today, mine, Mr. Gore's comments, Mr. Whittaker's comments, that this subcommittee is very, very much troubled with the idea that we passed statutes which impose clear duties, responsibilities, guidelines for behavior on agencies. We are troubled that those guidelines are not carried out, and that the agency does not do that which the law mandates the agency to do. We are also troubled, perhaps more so, that OMB comes forward and says that you are supposed to act—you and the other regulators inside of Government—are supposed to act on the basis of a cost-benefit ratio. We find no evidence of a congressional intent to that effect, yet we read here in your pronouncements, as referred to by Mr. Gore and by the Chair, that you have acted in certain matters with regard to a finding of cost-benefit. You say, of course, this is your judgment, and that you were not responding to OMB's instructions; yet you cite OMB's instructions, and you use almost in haec verba the language of OMB.

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Commissioner HAYES. I do think, as just a matter of principle, that some of the things embodied in that executive order—that is, that before one writes a regulation or mandates anything, or, in fact, takes any action—that one asks: is it needed, what is it going to cost, not just in dollars, but the total costs, what

[234] Id., p. 28.
[235] 46 F.R. 57569 (Nov. 24, 1981).
[236] CCH Medical Device Reports, par. 17,582, p. 17,804. Jan. 26, 1982.

are you going to get for what you do? To me, it is irrational to write Government regulations or impossible rules and regulations on a medical center or anywhere else unless there is a reason for doing it, and you know how much it is going to cost you immediately or in the future, and you know your ability to implement the rule. These are questions that I would ask of anything that we do at the Food and Drug Administration as long as I am Commissioner, with or without any such executive order.

Congressman GORE. But it says more than that. It says undertake regulatory actions only when the benefits outweigh the costs. If that is the standard, if there is a requirement not to act until the calculated benefits outweigh the calculated costs, that is a burden that prevents—that will often prevent the public from receiving the protection that it needs. There are specific devices that are held up and now regulated just like tongue depressors. They include—let me read you this list-cardiac monitors, neonatal incubators, ventilators, respirators, anesthesia machines, implanted spinal cord stimulators for pain relief. These are all devices that, because of a holdup, are being looked upon in the same manner as tongue depressors. The public, I think, is entitled to the kind of protection that this law gave them. It is a perfectly reasonable law.

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Chairman DINGELL. Doctor, I just want to observe that much of what is in the executive order I regard as good sense. It would probably be done by a good regulator, but I don't regard the good sense mandates of that as being a substitution for the clear intention of the Congress unless in some way the OMB has risen, through some bootstrap operation of its own, to a level which is above the law.[237]

The subcommittee's experience with FDA's implementation of the medical device amendments presents important public policy questions regarding the risks of cost benefit analysis when applied to rules promulgated with intent to protect public health and safety. These cases are neither isolated nor unique. Executive Order 12291 is the cornerstone of the current administration's regulatory relief program. Many of its principles were embodied in regulatory reform legislation considered by the 97th Congress and not enacted. While the subcommittee may concede that the regulatory relief efforts during the past 2 years may have resulted in fewer regulations being promulgated, we are concerned by the potential for adverse consequences of those efforts. The examples of the medical device experience reporting regulations and the restricted device regulations provide clear evidence that, in the name of cost effectiveness, the protection of the health and safety of the American people may be compromised or even sacrificed.

Further, the example of the reclassification of contact lens materials presents striking evidence of the real problem associated with the current regulatory process: The problem of delay and its consequences on the ability of business to compete fairly and successfully. The subcommittee observes that nothing in the administration's current "regulatory relief" activities, nor in proposed regulatory reform legislation, addresses the major problem of delay in the regulatory process.

IX. A SURVEY OF THE MEDICAL DEVICE INDUSTRY'S PERCEPTION OF THE DEVICE AMENDMENTS AND FDA REGULATIONS

In 1980, the Bureau of Medical Devices' Office of Small Manufacturers Assistance commissioned a survey of device manufacturers to assess the impact of FDA regulations on the medical device industry and the reactions of manufacturers to the regulations.[238] The survey

[237] Hearings, supra, note 3, pp. 129–131.

[238] A Survey of Medical Device Manufacturers. Louis Harris and Associates, July 1982, Study No. 802005. NTIS No. —. Hereafter referred to as the "Survey."

sample was randomly drawn from the list of approximately 4,300 device manufacturing establishments registered with FDA in 1980 and was stratified to ensure that a sufficient number of small, medium, and large establishments were represented.[239] The survey was conducted and the results analyzed by Louis Harris and Associates, who report that the effort "provides the first systematic assessment of the regulated manufacturers' experiences with and attitudes toward the medical device regulations."

Before considering the survey, some issues must be addressed that cut across many of its findings. An important portion of the survey is devoted to questioning respondents concerning their reactions to particular regulations. However, unfortunately, Harris did not analyze these reactions taking due account of respondents' understanding of the regulatory scheme. This becomes an issue because other data make clear that many—sometimes as many as 32 percent—of the respondents understood FDA's regulations "only a little" or "hardly at all." It is, therefore, not possible to tell from the data presented whether an expressed reaction to a particular regulation is the product of informed experience or total ignorance. Since conclusions about the impact of, and industry's attitudes towards, specific regulations were a stated objective of this research, an effort should have been made to ascertain whether the respondent expressing the opinion was speaking from understanding or the lack of it.

Second, the magnitude of, and differences between, percentages reported in the survey must be interpreted with caution. As in any survey, the reported data are subject to a degree of statistical sampling error. The data from the sample vary from the true population data to a degree that may render an observed difference insignificant, statistically. That is, an observed difference in the sample may arise not from an actual difference in the population, but, rather, may arise as an artifact of the sampling process. The report does not contain estimates of this sampling error, so the statistical reliability of differences between reported percentages cannot be assessed. When the necessary allowances for sampling error are made, it is conceivable that apparent differences between responses might disappear.[240]

The survey provides insight into the characteristics of the device industry, its performance over the last decade, and some notion of its intentions for the future A particularly significant apparent conclusion to be draw from the data is that the industry's understanding and perceived problems with federal involvement vary significantly with the characteristics of its members, particularly with their size.

About one-third of device manufacturing establishments employ 9 or fewer employees, and almost two-thirds (64 percent) employ fewer than 50. Most of these small firms are relatively new. Roughly 40 percent have been manufacturing for 6 years or less; 70 percent for 12 years or less. By contrast, the large firms (with 500 or more employees) comprise only about 6 percent of all manufacturing

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[239] Survey, pp. 8–12. Four strata were selected to structure the sample: establishments with 1–9 employees, with 10–49 employees, with 50–499 employees, and over 500 employees. The sampling universe was limited to manufacturing establishments, as opposed to those that exclusively repackage, relabel, or distribute devices.

[240] Information submitted to the Subcommittee staff by Louis Harris and Associates reveals that, depending upon the size of the subsample represented, and the magnitude of the particular percentage reported, the true population percentage will (at the 95 percent confidence level) be between plus or minus 4 percent and 10 percent of the observed percentage reported.

establishments and are far more entrenched. Most of them (60 percent have been manufacturing for 13 years or longer (30 percent for longer than 20 years). Harris concludes from these data that entry into the device field remained relatively easy and attractive, particularly for small firms, after the passage of the 1976 amendments and FDA's adoption of implementing regulations.[241]

This salutary conclusion is complemented by data reflecting other important industry economic characteristics. There has been nearly constant growth in the size of all device manufacturing establishments during the past decade. The number of employees within each size stratum of firm has steadily increased.[242] Capital investment for growth and expansion, as well as annual sales, reflect a steady increase, although the Harris data were gathered in ranges rather than precise mounts, and they do not allow a comparison in growth rates based upon the size of firms.[243] Other data, independently generated by the Pharmaceutical Manufacturers Association, do supply some specificity, at least as to the growth in sales over the past decade. The association estimates that the industry's 1972 sales were approximately $3.97 billion, its 1977 sales were $8.09 billion, and its 1981 sales were $13.14 billion.[244]

In general, the responses to the survey questions suggest that the industry believes it has been making good economic progress. Taking inflation into account, 41 percent of the respondents state they are "more profitable" now (in late 1981) than 5 years ago. The remainder split about evenly into believing they are "as profitable" or "less profitable" than 5 years ago (27 percent each). Large corporations have done slightly better than the industry average: 45 percent state they are more profitable now.[245] Harris, assuming that 1981 was a particularly difficult year in terms of inflation and interest rates, concludes that the large number of firms reporting increased profitability, as against decidedly easier times 5 years earlier, confirms "an extremely postive pattern of economic growth in the medical device industry."[246]

Harris also concludes that his survey "documents an extraordinary level of innovative activity" in the device industry; that "innovation is the norm rather than the exception." Nearly half of all survey respondents (45 percent) said they had introduced a "really new" product at some time since 1972, and this development was just as common in small companies (53 percent) as in large ones (50 percent). The majority of all respondents (51 percent) report that new product introduction has increased over the past 5 years since the passage of the device amendments, although the larger firms were more likely (79 percent) to have experienced a substantial increase in new device introduction. A majority of all firms (57 percent) say they are "very"

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[241] Id., pp. 9, 28; tables 2–1 through 2–3.

[242] For example, within very small firms (with 1–9 employees) the median number of employees rose from 4.1 to 7.8. Within larger firms (with 50–499 employees) the median rose from 119.2 to 212.5 employees (table 2–4).

[243] Id., pp. 29–32; tables 2–4 through 2–6. Also, data on sales and capital expenditures are not presented in constant dollars, so the effects of inflation on these numbers cannot be parsed.

[244] "Medical Devices and Diagnostic Products Industry, A Profile." Pharmaceutical Manufacturers Association, March 1982, pp. 11–12.

[245] Survey, table 2–10. A telling exception to the general positive response was expressed by industry members manufacturing ophthalmic devices. They split almost evenly with 41 percent stating they were less profitable than 5 years ago. Two of the case studies examined by the subcommittee in the July hearings may shed light on the reasons for this, see pp. 50–58, supra.

[246] Id., p. 25.

or "somewhat" likely to submit a PMA for a new product in the next 2 years.[247]

However, the prospects for future important innovation appear to depend significantly on manufacturers' size. Eighty-three percent of the corporate sample reports its intention to submit PMA's for new devices in the future; only 56 percent of small companies with 50 or fewer employees do. Similarly, about one-third (between 32 percent and 34 percent) of small companies say they are unlikely to consider developing and marketing new medical devices; only 10 percent of the corporate sample so state.[248] Harris probed for reasons for this reticence to develop new devices by asking whether the decision not to develop new products was made "as a result of FDA regulations." Thus, small companies, which had decided not to innovate in the future, were about as likely as not to blame FDA. About half (46 percent) attributed their decision directly to the agency's regulations. Of the large firms which decided not to innovate, only 20 percent (20 percent) blamed the agency.[249]

The disparity in plans for the future innovation between small and large firms is also clearly reflected in their intentions to market new class III devices. Some 69 percent of the corporate sample stated they will consider development of new class III devices; only 30 percent of small companies do. In fact, small companies most frequently said they would consider developing "new" devices only if they were not in class III. This is mildly confusing since one of the device amendments' fundamental provisions is that every truly new device is automatically a class III device. (Section 513(f)(1)). It is, therefore, likely that these manufacturers interpreted "new device" here as an advance over a preamendments device that is not so innovative that it loses its status as "substantially equivalent" to the preamendments device. Otherwise, the response is inconsistent and inexplicable.

From the pattern of responses. it appears that as the size of a firm diminishes, the more likely it will be to content itself with limited advances in its own product line—to the extent it intends to advance technologically at all. A minority of small firms will brave the uncertainties and burdens of developing important advances, but, at least in terms of the expressed intentions in this survey, more members of the large, corporate segment of the device industry appear willing to break new ground in the future.

While the passage and implementation of the device amendments appears not to have materially weakened the performance of the industry—at least as assessed in terms of the limited available economic data—nor to have stifled its creativity. many device manufacturers perceive Federal regulation of their products as "the single most serious problem" facing them today. More manufacturers picked "Federal regulation" (21 percent) from a prepared list of obstacles they currently face than picked "cost of supplies" (20 percent) or "raising capital for growth and expansion" (17 percent).[250] When

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[247] Id., pp. 106–110; tables 5–1, 5–6, 5–10.
[248] Id.
[249] Id., table 5–15. Alternative reasons for deciding not to innovate were not explored.
[250] Id., pp. 52–53; table 3–2. It is important to remember that manufacturers did not volunteer these responses. A list of eight "problems" was read to each respondent who then picked the "most serious." Harris elsewhere cautioned that data generated in this manner are inflated over what a free (open-ended) response would have produced. Not only are these data inflated to an unknown degree; it is also possible that the rank order of respondents' "most serious problems" elicted without prompting might have been different.

probed for the reasons for their dissatisfaction with Federal intervention, the industry, as a whole, most often referred to "paperwork" as a major problem (55 percent). This was followed by references to a lack of understanding of the regulations and their application (45 percent), to the amount of executive time spent on regulatory matters (42 percent), and to the costs of compliance (42 percent).[251]

As in other areas, the pattern of manufacturers' "single most serious" problems with the Federal presence differs markedly based on their size. In particular, the impact of "cost" is viewed quite differently. Only 7 percent of the smallest manufacturers view costs as their major problem, as opposed to 48 percent of the large corporate firms. In fact, for the large corporations, "cost" stands out alone—far outstripping "paperwork"—as their most serious problem. As corporate size diminishes, so does the mention of "cost" as the worst consequence of regulation. It is replaced by "paperwork" and by the significant problem of smaller firms in understanding the regulations and in knowing whether they apply (these problems were picked as the "most serious" over twice more frequently than "cost").[252]

The deemphasis on the cost of regulation as a major problem by smaller firms is particularly noteworthy in light of the fact that the estimated costs, when considered in relation to the size of establishments, might well be greater for smaller than for larger firms. Harris provides an estimate of major components in this regulatory cost, concentrating on increases in quality control expenses due to the GMP regulations. From survey responses, he calculates that roughly 6,400 employees have been added industry-wide as a direct result of device regulations, at a unit cost of $22,275 per year. This figure projects to about $142,500,000 as a best estimate for the industry as a whole—roughly 1.1 percent of the industry's $13 billion annual 1981 sales as estimated by the Pharmaceutical Manufacturers Association.[253] Harris also estimates that additional equipment with a one-time cost of $131,056,000 has been added as a result of the regulations.[254] Beyond variance due to sampling error, these estimates probably overrepresent regulatory costs to an unknown degree because employees and equipment are used for other than exclusively regulatory purposes. The estimates may also underrepresent the industry-wide totals, however, because they are based on a projection to establishments with on-site manufacturing. This is less than all firms listed with FDA.[255]

The Harris Survey provides no quantitative estimate of the benefits of FDA's regulations either to the industry or to the public. The industry itself is virtually unanimous (94 percent) in reporting that no cost savings to them have resulted from the regulations. While a few see regulations as "helpful" to them, the only real example of this is the 17 percent of industry that see FDA's Good Manufacturing Practice regulations in this light; an additional 9 percent see them as both a help and a burden.[256] In terms of benefits to the public, the industry's

[251] Id., pp. 54–55; tables 3–3, 3–4.
[252] Id., pp. 54–55; tables 3–3, 3–4.
[253] Id., pp. 58–60; table 3–7; PMA Industry Profile, n. 244, supra. The Harris personnel cost estimate is premised upon an average annual salary of $16,500 for quality control staff and an overhead rate of 35 percent. Because the best estimate is based on a survey with an attendant sampling error, the actual annual personnel cost attributed to the regulations, at a 95 percent confidence level, could be as low as $88,300,000 or as high as $196,700,000.
[254] Id., p. 59; table 3–8. The 95 percent confidence interval is $37,613,000 to $224,499,000.
[255] Id., p. 60. This survey did not cover establishments that merely repackage, relabel or distribute devices.
[256] Id., table 6–14.

view is that the regulations are, to some extent, effective. Seventeen percent see them as "very" and 44 percent as "somewhat" effective. But most in industry view their own production procedures, the incentives created by existing products liability laws, and even buyer awareness, that is, caveat emptor, as superior to FDA regulations in terms of public protection.[257] Harris cautions that the industry's perception of the benefits of regulation cannot be viewed as particularly objective and that the true benefit of the Federal intervention cannot be assessed by the survey. The nature of industry's qualitative response to this benefit issue appears to support his contention.

The data on costs at least suggests that they are material, and when viewed as a function of establishment size, impinge on the industry differentially. Harris estimates the regulations have required the smallest firms to increase staff by 3.5 percent, but the largest by only 1.2 percent.[258] On top of this, smaller firms claim they have less ability to pass the increased cost of regulation on to consumers. Some 28 percent state they can pass on "little" or "none" of the increase; only 10 percent of the large firms so state.[259]

In light of this, to find smaller firms still voicing greater concern over the lack of clarity in the Federal presence than over its cost is telling. Explanations of this prominent uncertainty about the rules among smaller firms could include the fact that the device amendments and the implementing regulations are still relatively new. Uncertainty among smaller manufacturers is probably also attributable to the fact that they are far less likely than larger firms to employ a regulatory affairs specialist full time. In fact, it is only when a firm reaches 1,000 or more employees that it is more likely than not to employ someone in that capacity.[260] Survey responses also reveal that most small firms do not use the Federal Register, they say they do not understand the mechanics of how to influence agency regulatory decisions, they have not participated through the comment process in agency rulemaking proceedings, and they give FDA low marks on encouraging manufacturers to participate in decisions concerning device regulation.[261]

For whatever reasons, the survey makes abundantly clear that a sizable proportion of the industry admits it does not understand the regulation of medical devices, and that this lack of understanding is related significantly to industry's general perception of the agency's performance.[262] The survey shows that the less these firms understand the regulatory scheme the less likely they are to rate the Government presence generally as effective in protecting the public, and the less likely they are to rate the agency as doing a good job in insuring that

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[257] Id., table 3-15. Fifty-three percent view their own "production procedures" as "very" effective; 37 percent so viewed the "products liability laws;" 29 percent so viewed "buyer awareness." Only 17 percent so viewed "FDA regulations."

[258] Id., table 4-10.

[259] Id., table 4-11.

[260] Id., table 3-9.

[261] Only 9 percent of the smallest firms use the Federal Register regularly; 93 percent of corporations do (tables 8-11, 8-12). Seventy-six percent of the smallest firms say they understand "only a little" or "hardly at all" how to influence a decision; 86 percent of corporations say they understand how to influence "mostly" or "fully" (table 8-5). Twenty-seven percent of the smallest firms have commented on a regulation; 86 percent of corporations have done so (table 8-6). Seventy-four percent of the smallest firms say FDA has been "only fair" or "poor" in encouraging their participation; 62 percent of corporations agree (table 8-7).

[262] Id., tables 8-1, 8-2, 8-3.

devices are safe and effective.[263] Unfortunately, the precise effects of ignorance or understanding on industry's perception of particular Federal requirements (such as product listing, premarket notification, and good manufacturing practices) cannot be assessed because Harris did not ascertain whether (or the extent to which) a respondent understood a regulation before asking for a reaction to its "reasonableness." Thus, all the survey results assessing the reasonableness of particular regulations in chapter 6 of the Harris Survey Report are infected, to some unknown degree, by responses based on ignorance. To the extent that decisions about changes in any regulation based on this survey are contemplated by the agency, this fact should be born in mind.

Level of understanding and particular regulations aside, FDA gets an overall negative rating from the industry on its job in insuring safe, effective, medical devices. Roughly 43 percent of all firms feel positively about the agency's performance ("excellent" or "pretty good"); 47 percent feel negatively (only "fair" or "poor"). Smaller firms feel more negative.[264] The negative perception is even more pronounced when considering FDA's provision of technical assistance and compliance information: 29 percent of all firms give the agency a positive rating; 64 percent rate it negatively. This ill feeling regarding technical assistance is fairly consistent across all firms; only the responses of the separate corporate sample moderate to a near balance at 45 percent positive/48 percent negative.[265]

There appears to be one reasonably bright spot amid this generally negative feeling about the agency's performance: The Bureau of Medical Device's Office of Small Manufacturer Assistance. Established as a result of section 10 of the amendments, the office received high marks from the manufacturers who had dealt with it.[266] Seventy-six percent of all manufacturers have heard of OSMA; however, only half of all manufacturers (48 percent) have called upon it for assistance (slightly more than half of the smaller manufacturers have used OSMA). These manufacturers were apparently satisfied; over 75 percent of those who used OSMA found it very or somewhat helpful.[267]

Manufacturers', and especially small manufacturers', positive regard for OSMA seems inconsistent with their generally negative opinion of FDA as a whole—particularly because the area where OSMA is supposed to provide assistance (understanding and application of the law and regulations to particular establishments) is perceived as a major problem by small firms. Perhaps those smaller manufacturers who admit to not understanding the regulatory scheme are

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[263] Id., where 71 percent of firms who claim they understand the regulations rate FDA as "effective" or "somewhat effective" at protecting the public, only 43 percent of firms who understand "only a little" or "not at all" so rate the agency (table 8-2). Similarly, 50 percent of firms that understand say the agency is doing a good or excellent job; only 33 percent of the firms that do not understand so rate the agency (table 8-2).

[264] Table 3-14.

[265] Table 8-4. The "corporate sample" was defined to include firms with three or more establishments.

[266] Section 10 of the device amendments requires the Secretary to establish within the Department "an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices to assist them in complying with the requirements of the . . . act."

[267] Survey, tables 8-8 through 8-10.

among the many who have not used OSMA. If so, it is incumbent on the agency to market this service more effectively than it has. Only half of the firms that know of OSMA have used it; about one-fourth of the firms with 50 or fewer employees have never even heard of OSMA.[268] FDA can ill afford to let so many in the industry remain in the dark when a fuller understanding of its mission and its requirements has been shown likely to promote the belief that the system can work, that the agency can do its job effectively, and that compliance need not be burdensome to smaller companies.

Summary of the survey findings

Despite its limitations, the Harris Survey provides useful insights into industry perceptions in three areas. First, as a whole, the device industry claims to be economically healthy. New, small firms have been able to enter, industry sales recently have been increasing at a higher rate, firms claim to have been more profitable recently than in the past, and innovation is occurring to a substantial degree. Second, the industry perceives the Federal regulatory presence to be a major problem which creates a paperwork burden, lacks clarity, and increases costs. The industry claims that its own production procedures, products liability laws, and even buyer self-protection are superior to Federal regulation in protecting the public. Third, there appear to be meaningful differences between the intentions and perceptions of large and small firms on a number of issues. Small firms frequently state that they will not venture into developing truly unique new devices; large firms far more frequently say they intend to market new class III devices. Small firms suffer more frequently from a lack of understanding of regulatory requirements than large firms, and this appears to contribute to a more negative impression of the agency than is held by large ones. Finally, smaller firms appear to feel more negatively about FDA than do larger ones, both in terms of the quality of the agency's performance and in terms of its encouraging industry participation in its decisionmaking.

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[268] Id., table 8–8.

EXHIBIT 1

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DATE: 09/22/82

1. PRODUCT: Travenol Volumetric Pump Cassette

2. MANUFACTURER OR FIRM: Travenol Laboratories Deerfield, Illinois 60015

3. PRODUCT DESCRIPTION AND USAGE: Volumetric pump cassette with administration tubing used with IMED Model 922, and 960 series pumps. Product used for infusing fluid/drug admixtures.

4. REPORTED PROBLEM, INCIDENT, DEFECT, DEFICIENCY, MALFUNCTION OR FAILURE: Flow-through problem with the volumetric pump cassette. Uncontrolled continuous flow from the bottle to the patient when and if pump valve stops in the flow-through position.

5. REPORTED ADVERSE EFFECTS, DISEASE, INJURIES OR DEATHS THAT HAVE OCCURRED FROM USE OF THE PRODUCT: No reported complaints or injuries.

6. EXISTING CONDITIONS THAT COULD CONTRIBUTE TO A CLINICAL SITUATION THAT WOULD EXPOSE HUMANS TO A HEALTH HAZARD: (1) Type of valve in the cassette, (2) height of the fluid container above the patient, (3) turning the pump off when valve is in the flow-through position, (4) drug being infused, (5) patient's condi (6) leaving the pump turned off but connected for a significant time period, and (7) leaving the pump turned off but connected with a needle or catheter having infiltrated.

7. ASSESSMENT OF THE HAZARD TO VARIOUS SEGMENTS OF THE POPULATION. WHAT SEGMENT IS AT HIGH RISK? Neonates and patients in danger of fluid overload.

8. DEGREE OF SERIOUSNESS OF HEALTH HAZARD TO WHICH THE POPULATION AT RISK WOULD BE EXPOSED: The use of this device may cause temporary or medically reversible adverse health consequences. The probability of serious adverse health consequences is remote.

9. ASSESSMENT OF THE LIKELIHOOD OF OCCURRENCE OF THE HAZARD: Likelihood of occurrence in a clinical situation is remote.

10. WHAT ARE THE IMMEDIATE AND/OR LONG TERM CONSEQUENCES OF OCCURRENCE OF THE HAZARD: (1) Possible fluid overload of critically ill neonates, and (2) skin slough with prolonged infiltration of drug.

11. SUMMARY OF HEALTH HAZARD EVALUATION: Flow-through occurs only when the pump is turned off with the valve in an intermediate position, which is a remote possibility. The most likely reasons to turn off a pump are to change the administration set or bottle, or to run a supplemental infusion via piggyback through the pump line. In the former situation the infusion is typically resumed within a few minutes, so the only clinical problem is a very slight overinfusion of a drug or fluid. In the latter situation, the pump may be turned off for a significant time period, so the most likely hazard would be fluid overloading of a critically ill neonate. The chance of the pump being turned off at a random moment when the valve is in the flow-through position is lowest at low pump flow rate settings, which are used for neonates. Therefore, the likelihood of creating this hazardous situation is remote.

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EXHIBIT 2

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION

In the matter of BAUSCH & LOMB, INC., a corporation	)))	CONSENT AGREEMENT

1. Bausch & Lomb, Inc. ("B&L") is a corporation organized, existing, and doing business under and by virtue of the laws of the State of New York, with its offices and principal place of business located at 1400 Goodman Street, Rochester, New York.

2. The P.A.1 series lenses are bifocal soft contact lenses in glass vials, each containing one clear, colorless plastic disc lens and labeled in part: "*** Power *** P.A.1 One Soflens *** Caution: Federal Law *** Bausch & Lomb, Inc., Rochester, New York 14602 ***." The P.A.1 series lens is a device within the meaning of the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. 321(h), and is intended for human use within the meaning of 21 U.S.C. 360j(1).

3. The P.A.1 series lens is a transitional device, which was classified under 21 U.S.C. 360(j)(1)(1)(E) into class III. In 1971, B&L obtained from the Food and Drug Administration ("FDA") approval of NDA 16-895 for the marketing of B&L's soft contact lens. B&L maintains that the application approved in 1971 covers the P.A.1 series lens and so notified FDA in August 1981 prior to marketing. In FDA's judgment, however, B&L does not have in effect for the P.A.1 series lens either an approved

application under 21 U.S.C. 360e or an exemption for investigational use under 21 U.S.C. 360j(g), which application or exemption is required by 21 U.S.C. 360j(1)(3)(D)(iii). FDA maintains, therefore, that P.A.1 series lenses are adulterated within the meaning of 21 U.S.C. 351(f)(1)(C) and thus prohibited from interstate commerce by 21 U.S.C. 331. B&L disputes FDA's judgment that the P.A.1 series lens does not have in effect an apprcved application under 21 U.S.C. 360e, and therefore B&L believes that their shipment in interstate commerce is lawful.

4. In September, October, and November 1981, FDA advised B&L that the P.A.1 series lens requires FDA approval prior to marketing. In late December 1981, FDA recommended the institution of enforcement proceedings against the P.A.1 series lens. On January 12, 1982, before any such action was instituted, B&L voluntarily suspended distribution of the P.A.1 series lens in the United States pending resolution of the device's regulatory status.

5. In settlement of enforcement proceedings recommended by FDA under the Act, B&L and FDA enter into this Agreement, any substantial breach of which by B&L shall be deemed to cause the adulteration of the P.A.1 series lens within the meaning of 21 U.S.C. 351(f)(1)(C). Any substantial breach of this Agreement by FDA shall cause this Agreement to be null and void. This Agreement applies to the P.A.1 series lens as described in paragraph 2 and to any identical product manufactured or distributed by B&L under any name.

6. B&L denies that the distribution of the P.A.1 series lens violated the Act or any other law. This Agreement does not constitute an admission by B&L of any such violation.

THEREFORE, IT IS AGREED that B&L shall:

7. Discontinue all sale and commercial distribution of, and not introduce or reintroduce for sale or commercial distribution, the P.A.1 series lens until the lens has been approved for marketing by FDA in accordance with 21 U.S.C. 360e.

8. Discontinue all promotion and advertising for the P.A.1 series lens and make every reasonable effort to withdraw from all media any advertisement for the P.A.1 series lens already placed.

9. Notify each person within the meaning of 21 U.S.C. 321(e) to whom P.A.1 series lenses have been distributed that FDA considers the lens to be an investigational device, request each such person to discontinue the fitting, dispensing, sale, and shipment of the lenses, and request each such person to sign and return to B&L a statement (a) acknowledging that such person understands that FDA considers the P.A.1 series lens to be an investigational device, (b) certifying that such person will not use for fitting or dispensing, and will not sell or ship, any lenses received by such person as part of a fitting set or otherwise, and (c) reporting the number of lenses in such person's possession, custody, or control. B&L shall include with the notification and statement required by this paragraph an envelope, addressed to B&L, bearing the address of the person

requested to return the statement and sufficient postage to ensure its prompt return once it is posted. The notification and statement required by this paragraph shall be submitted to and approved by FDA prior to their issuance by B&L.

10. Provide FDA, in writing, a detailed account of the number and location of all P.A.1 series lenses manufactured by B&L. Such accounting shall include but not be limited to the number and location of such lenses in inventory; the number and location of such lenses in the possession, custody, or control of distributors, the number of such lenses in fitting sets shipped to health care professionals, the number and location of such lenses shipped to investigators, and the number of such lenses that have been fitted. B&L also shall provide FDA's Buffalo District Office, upon request, periodic status reports concerning the following information:

(a) the number and location of all P.A.1 series lenses manufactured by B&L;

(b) the number of persons to whom the notification and statement required by paragraph 9 has been sent and the time frame in which such notifications were made;

(c) the number of persons who have returned the statement required by paragraph 9;

(d) the number and results of checks on the effectiveness of the actions required under paragraph 9;

(e) the estimated time frames for completing the notification required by paragraph 9; and

(f) any difficulties in carrying out the notification required by paragraph 9.

11. Retain and make available to FDA on request for review and copying all documents concerning the P.A.1 series lens B&L has made available to health care professionals and distributors since beginning distribution of the P.A.1 series lens including but not limited to: (a) communications to direct accounts and sub accounts; (b) instructions to the B&L sales force or others; (c) complete distribution records to distributors, eye care practitioners, and investigators; (d) response documents; and (e) records covering the effectiveness of the actions specified in paragraph 9. Records responsive to this paragraph shall be retained by B&L until FDA notifies B&L that such retention is no longer necessary. FDA agrees to treat as confidential all information provided by B&L under this paragraph which is of the type defined in section 20.61 of FDA's regulations governing public information, 21 CFR 20.61.

12. Remove from commerce all P.A.1 series lenses that have not been fitted to patients if the actions required by paragraph 9 do not result in the discontinuance of the fitting, dispensing, sale, and shipment of the lenses.

13. Not introduce or reintroduce after the date hereof the P.A.1 series lens for investigational use except in accordance with 21 U.S.C. 360j(g) and 21 CFR Part 812.

14. Not export the P.A.1 lens except in accordance with 21 U.S.C. 381(d)(2).

IT IS UNDERSTOOD that B&L has undertaken certain of these obligations before entering into this Agreement.

IT IS FURTHER AGREED that FDA shall review for valid scientific evidence of the safety and effectiveness of the P.A.1 series lens the data submitted to FDA by B&L on August 21, 1981, October 16, 1981, November 19, 1981, and December 15, 1981; provided, however, that before FDA may complete any such review, B&L shall notify FDA, in writing, that such data constitute a supplement to B&L's approved application for B&L's soft contact lens. If FDA tentatively concludes that the supplemental application meets the requirements of 21 U.S.C. 360e(c)(1), FDA shall refer the supplemental application to the appropriate panel for study and recommendation respecting approval, as required by 21 U.S.C. 360e(c)(2). After receipt of such panel's recommendation, FDA shall issue an order approving or denying the supplemental application in accordance with 21 U.S.C. 360e(d).

Entered this 22nd day of January, 1982.

The Food and Drug Administration

By: _____
Joseph P. Hile
Associate Commissioner 1/26/82
for Regulatory Affairs

By: _____
Victor Zafra 25.1.82
Acting Director
Bureau of Medical Devices

By: _____ 1/2 82
Thomas Scarlett
Chief Counsel

Bausch & Lomb, Inc.

By: _____
Daniel E. Gill
Chief Executive Officer

By: _____
Jay T. Holmes
Vice President, General
Counsel and Secretary

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